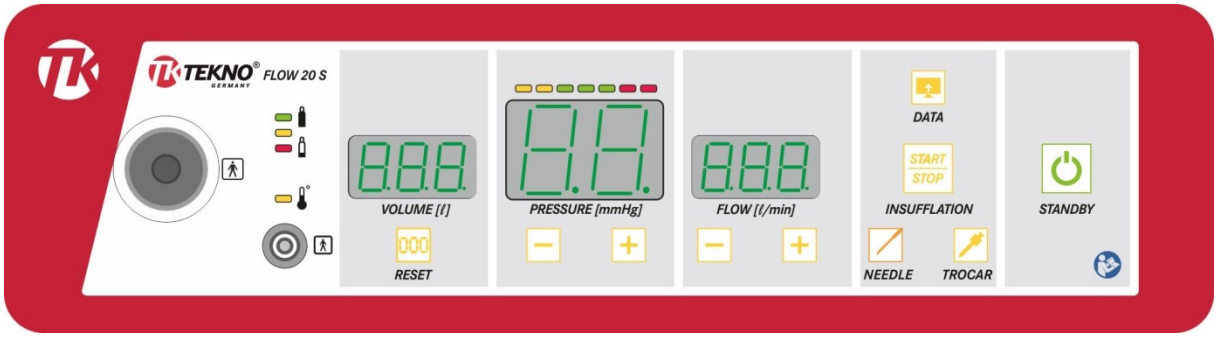
TeknoFlow S

CO_2-insufflator for laparoscopy



Operating manual

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Contents

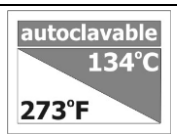
Symbols & signs

Signs

	Warning! Attention! Important information!
	Service

Symbols

	Follow the instructions!
	Symbol/sign "Pull mains plug"
	Medical device
	Dealer / Distributer
	Manufacturer
	Manufacturing date
	Reference/SKU
	Serial number
	Lot number/batch
	Applied part type: BF (connection)
	Connection for equipotential bonding
	Earthing

	Autoclavable
	Article, unsterile
	Disposable/non-reusable articles
	Consume by/use by
	Free of DEHP (diethylhexyl phthalate)
	Free of LATEX
	Free of BPA (Bisphenol A)
	Pay attention to the accompanying documents
Medical CO_2 **max. 80 bar**	Gas type identification: Medical carbon dioxide *(med. CO_2)*! Max.80bar
Ceramic fuses **2x T 3,15 AH 250V**	Marking device fuse: 2 pcs. ceramic fuses T 3.15AH (T=**T**räge [inert], A=**A**mpere [amp], H=**H**ohes Schaltvermögen [high switching capacity])
	ESD-sensitive components/devices
	Complies with the EC Directive "Medical Devices" 93/42/EEC
	Conforms to the EC directive “Waste Electrical and Electronic Equipment" WEEE 2002/96/EC

General information

Thank you for choosing a product from our company and therefore placing your trust in a modern and high-quality device.

Our name stands for many years of experience and diligence in the development and production of CO_2 insufflators, suction/irrigation pumps, light sources and camera systems.

This operating manual is intended to help you understand the function and operation of the device you have purchased.

The INSUFFLATOR is intended for use in professional healthcare facilities (classification according to CISPR 11: Group 1 class A, e.g. medical practices, clinics, operation rooms, intensive care units, hospital rooms, rooms for emergency rooms and accident clinics).

Local regulations

Some of the regulations and laws mentioned in this manual refer only to Germany! In other countries, the regulations and laws valid there must be adhered to! Inquire in advance about the local regulations in your country!

Device specifications

The rating plate *(rear of the device)* contains the technical specifications that must always be stated when ordering spare parts or other questions.

Warranty

The warranty period is one year, according to our warranty conditions.

Unauthorised opening of the device and repairs or changes by persons not authorised by the manufacturer release us from any liability for the operational safety of the device. Due to this, during the warranty period, any warranty claim expires.

The liability for the operational safety of the device by the manufacturer expires in the event that service work is carried out by unauthorised specialists, the prescribed intervals for checking and safety inspection (STK) are not complied with, as well as unauthorised opening of the device and intervention in the device by unauthorised persons and when using unauthorised spare parts.

Wear parts are excluded from the warranty.

Unpacking/basic equipment

Carefully remove the device and the supplied accessories from the packaging.
Check the delivery for completeness and possible damage during transport.

Should the delivery present a reason for complaint, please contact the manufacturer or supplier immediately.

Keep the original packaging, as it can be reused for any later transportation.

Service, repairs, changes

All services, such as regular inspections, repairs, modifications, calibrations, etc., may only be carried out in consideration of the special safety regulations for medical-technical devices and either by the manufacturer or by persons expressly authorised by it.

Performed services are to be entered in the table "Maintenance log".
An annual maintenance check with the electrical safety (STK) is a prerequisite for maintaining the basic safety and the performance characteristics of the device over the entire product life!

Returns to services and repairs

The customer (or operator) is required to clean and disinfect the equipment and accessories before returning to the manufacturer, following the instructions in this document (or the instructions supplied with them separately)! The return must be accompanied by proof of this reprocessing!
Please use the "Return shipment form"!
If there is insufficient proof, the repair or service may be rejected by the manufacturer!

Backup device

In the event of an error/failure of a device or a necessary check/repair, we (as the manufacturer) recommend keeping a replacement device ("backup" device) ready!
This recommendation applies especially to the "active" period of surgery on the patient in order to avoid interrupting an operation!

Responsibility

As the manufacturer of the device, we only consider ourselves responsible for the effects on the safety, reliability and performance of the device if:

- All assembly, expansion, readjustment, changes or repairs are carried out by persons authorised by us.
- The electrical installation of the room in question complies with the requirements of each country and is not inconsistent with the information in this manual.
- The used/combined devices comply with IEC 60601-1 and have been tested afterwards.
- The device is used in accordance with the instructions for use.

Rights

The information contained in this manual is subject to change without notice and may not be construed as a commitment by the manufacturer.
Subject to errors and technical changes.

Disposal

In accordance with the provisions of the European Directive on Waste Electrical and Electronic Equipment *(WEEE)* 2002/96/EC, this symbol indicates that the product must not be disposed of as unsorted municipal waste, but must be collected separately.
Contact your dealer for returns and/or collection systems available in your country.

User instructions

Intended use

Insufflation of gas for endoscopic diagnosis and therapy in the area of laparoscopy in the range of 1-30 mmHg (max. 65 mmHg as essential performance characteristic)!

Only use the device with accessories, wear parts and disposable articles that are advertised as accessories by the manufacturer or that have been proven to be technically and biologically safe.

The device is suitable for continuous operation!

In addition, it is essential to observe the "*Safety instructions*" starting on page 11

Intended purpose

The device is intended exclusively for the insufflation of medical CO_2 gas (other gases excluded) for endoscopic diagnosis and therapy in the field of **laparoscopy**.

The use of a device intended for laparoscopy is not permitted in the field of hysteroscopy or arthroscopy due to differing pressure conditions!

Only the accessories specified in the operating instructions may be used in compliance with the described application and safety instructions!

All regulations governing the operation of medical equipment and equipment in the operating theatre apply.

The function of laparoscopy is described in detail in the literature and underlines the purpose of this device.

The operation of the device is only allowed in professional healthcare facilities!
"Professional Healthcare Facility"

Qualification of the user/operator

The device may only be used by persons who have the appropriate professional qualifications and have been instructed in operating this device.
Before using the device, the user must be sure of the functional safety and the proper condition of the device.

Before using the device for the first time, please read the operating instructions carefully in order to avoid endangering the user and the patient.

Always keep the operating instructions within easy reach of the device!

Attention! These instructions should be available to the users of this device at all times!

Storage and operating conditions

Temperature:	Storage	- 20°C to + 70°C
	Operation	+ 10°C to + 40°C
Rel. humidity:	Storage	10% to 90%
	Operation	20% to 80%
Barometer:	Storage	350 mbar to 1020 mbar
	Operation	700 mbar to 1020 mbar

Indication/contraindication

Indication

Expansion of the abdominal cavity with CO_2 gas during laparoscopy, diagnostics or therapy.

Contraindication

The use of intra-abdominal insufflation is contraindicated whenever a laparoscopic procedure is contraindicated.

The responsible physician must decide on the basis of the general condition of the patient whether the intended use can take place.

Absolute contraindications are: an uncooperative patient; any surgical or therapeutic intervention where a laparoscopy is contraindicated!

Relative contraindications are: High-risk patients and inexperienced users!

Also observe the instructions in the manual of your laparoscope for absolute and relative contraindications.

Examples include:

- Higher-grade cardiopulmonary insufficiency
- Anaesthetic risk
- Adhesion situs in patients who have received multiple prior operations
- Peritonitis
- Ileus
- Coagulopathy
- Portal hypertension
- Caput medusae
- General inoperability

Other contraindications and side effects

In addition to the above, further contraindications and side effects have been described during a laparoscopic procedure.

You are therefore obliged to study the relevant literature prior to using the gas insufflator. By way of example, further known side effects may be mentioned here:

- Influences on the foetus during pregnancy
- Cardiovascular arrest
- Asystole
- Arrhythmias
- Gas embolism
- Shoulder pain
- Predisposition to the development of deep vein thrombosis
- Subcutaneous emphysema

Carbon dioxide partial pressure pCO2

The monitoring of the carbon dioxide partial pressure is absolutely necessary!

Side effects

Metabolic hyperacidity and resulting irregularities of the cardiovascular system.

Long-lasting intra-abdominal pressures above 20 mmHg must be avoided. This can result in the following side effects:

- Reduced ventilation with dangerous overstretching of the diaphragm
- Reduced venous reflux
- Reduced workload of the cardiovascular system
- Acidosis

Hypercapnia/hypercarbia Excessive absorption of CO_2 gas

Excessive absorption of CO_2 gas is due to excessive flow and/or unnecessarily high intraabdominal pressures.

Adequate distension of the abdomen can be achieved with pressures of between 15 and 20 mmHg. Pressure over 20 mmHg is rarely required. A slight intravasation can occur at these levels. Pressure values above 20 mmHg are not needed and only increase the amount and speed of intravasation. Proper ventilation helps to avoid problems with the CO_2 gas.

The use of additional sources of insufflation increases the intra-abdominal pressure. In this case, always observe the intra-abdominal pressure during the entire insufflation process.
The self-insufflation of CO_2-cooled lasers and argon beamers can lead to the target pressure being exceeded *(note also: "Automatic overpressure release function" p. 20)*.

Idiosyncratic reactions

In patients with sickle-cell anaemia or pulmonary insufficiency, use of this device may increase the risk of metabolic imbalance with increased CO_2 absorption.

Attention! Hypothermia

In the area of laparoscopy, the use of a heating element for heating the insufflation gas is recommended for permanent flow values above 10 litres per minute in order to avoid hypothermia in the patient.

Please note that patients under anaesthesia generally experience considerable heat loss.

Heating the insufflation gas can only compensate for part of this heat loss.

Safety instructions

General

Please read these safety instructions carefully before using the device!

These operating instructions contain detailed information on commissioning the device and its intended use.

Attention! ***Please be sure to familiarise yourself with the operation and functioning of the insufflator before using the device!***

In order to avoid the risk of electric shock, this device may only be connected to a supply network with a protective conductor!

Set up the device so that you can switch it off by pulling the mains plug! This process must be easy to handle!

The device is not explosion-proof! It must not be operated near explosive gases (e.g. anaesthetic gases)!

As the manufacturer, we guarantee that the device has been carefully checked before leaving the factory. However, we assume no liability for damage caused by unauthorised personnel or improper use of the device.

Changes to the device may not be made without the manufacturer's permission *(see also: "Service, Repairs, Changes" p. 6)*

Safety measures at the site

- Only place the device on even surfaces that have been secured against tipping. The ambient temperature and the relative humidity must correspond to the specified values *(see "Storage and operating conditions" p. 8)*.
- If the device has been exposed to extreme temperatures during transport, it must be acclimatised to room temperature before initial operation.
- Use only the supplied power cable to connect to the mains.
- The plug-in device for equipotential bonding should be connected accordingly.

  Note: *Basically, the device is earthed via the 3-pin earthed plug when connected to an earthed power line as specified.*
  When operating the device in rooms of group 2 according to DIN VDE 0100 , it is essential that the device is connected with a suitable cable to the stationary equipotential bonding of the room or the equipment cart. For this purpose, the device has a corresponding plug-in device (according to DIN 42801).
- Special precautions regarding electromagnetic compatibility must be made for electro-medical devices (see also: "Electromagnetic compatibility (EMC)" from page 35. Observe the following instructions before operating the insufflator:

  Mobile communication devices may affect the function of other electrical or electronic devices. Mobile phones or similar devices should therefore be switched off near medical devices or equipment.

  Use only the supplied cables or original spare parts. The use of other cables or spare parts can lead to a reduction of the interference resistance and to an increase of the emitted interference radiation.

  When the unit is placed near other electrical or electronic equipment or in combination with other equipment, the correct operation of the insufflator must be checked.
- The connection of two or more devices can lead to higher leakage currents.
- Before commissioning the device, check whether the local, available mains voltage corresponds to the voltage range of the insufflator indicated on the rating plate.
- The safe operation of the device is guaranteed up to a height of 3000m.

Professional competence

The field of endoscopy is not described in this instruction. Therefore, the device and its accessories may only be operated by doctors and medical assistants who have the professional qualifications.

Original accessories

For your own safety and that of the patient, please use only original accessories.

Note: *Please use* ***Highflow instruments*** *with LuerLock connection for maximum device performance! Only the use of instruments with large nominal widths enables the maximum system performance with the highest patient safety.*

The use of instruments without LuerLock connection with a direct hose connection ("hose olive") or large bore connections can endanger the patient and is prohibited!

The new accessory should be treated as if it were used!
The parts must be prepared before first use!

Damaged accessories

Check the accessories for functionality and integrity before each use of the device. Damaged parts must not be used.

Product life

With proper use and compliance with the intervals for carrying out the prescribed checks, the service life of the device ends after 10 years!

The service life of the supplied, reusable silicone tubing is limited to 2 years or 50 applications and must be replaced afterwards.

The service life of the electric heating part is limited to 2 years or 100 applications and must be replaced afterwards.

Cross-contamination

Attention! The use of a sterile filter is mandatory!

Use a new and sterile filter for each patient. Please insert a sterile filter with a minimum retention rate of 99.99% between the patient and the device. The filter prevents bodily fluids from entering the device or potential contaminants from the device entering the patient. Note that the filter can reduce the maximum gas flow.

Only use sterile media, sterile liquid and sterile accessories.
To avoid cross-contamination, the filter must be changed after each operation!

Disposable accessories must be disposed of according to current regulations!
Reusable accessories must be prepared according to the manufacturer's recommendations!
(See also: Chapter "Reprocessing"! from p.30)

Insufflation medium

Medical carbon dioxide *(CO_2)*, according to the European Pharmacopoeia EAB/EuAB and the German Pharmacopoeia *(DAB 10)*, is the prescribed insufflation gas.

Use medical CO_2 at full concentration. Mixtures of gases, compressed gases and contaminated gases must not be used!

Attention! ***When connecting the device to the gas supply, make absolutely sure of the correct gas type (CO_2) and the maximum permissible pressure (see note on the gas connection)! After all connections have been made, they must be checked for leaks (leakage test)!***

After maintenance work or repairs to the gas supply, a gas type check should always be carried out!

Use of a gas cylinder

The gas cylinder must be affixed vertically. This prevents the penetration of liquid CO_2 into the device.

Attention! ***Never affix the gas cylinder in a horizontal position.***

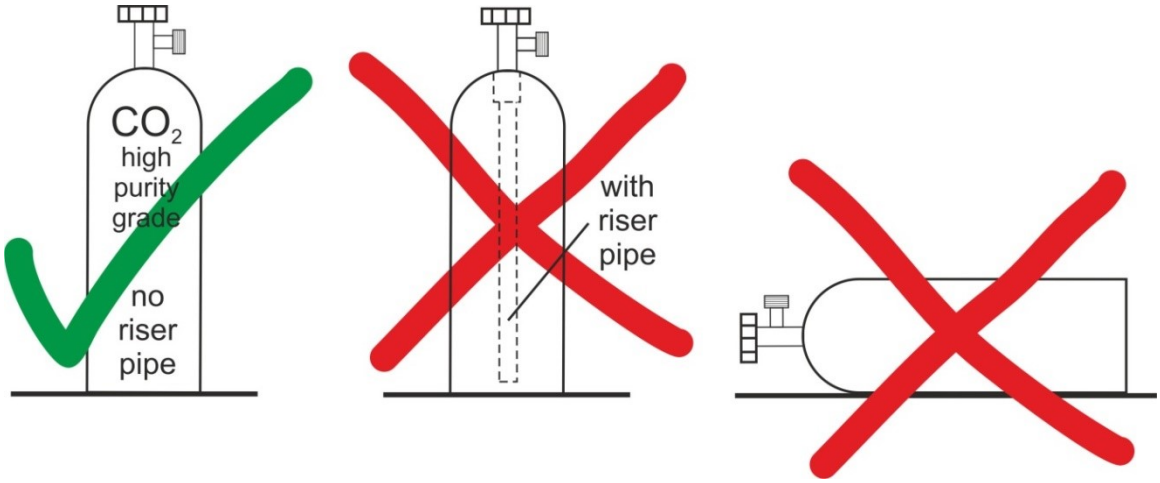
Please note that the carbon dioxide *(CO_2)* used is stored under high pressure in the gas storage tank.

When using a gas cylinder to supply the device with CO_2 gas, it is essential to observe the relevant industrial safety guidelines, the safety data sheet and the instructions of the gas supplier.

Since the CO_2 is in a liquid phase in the gas cylinder, the bottle must be vertical with the gas cylinder valve facing upwards. For the same reason, no bottles with immersion tubes may be connected! Make sure the gas cylinder is securely fastened.
Before connecting the gas cylinder and the existing high-pressure hose, the connections must be checked for cleanliness and damage! There must be no contamination!

Slowly open the valve of the gas cylinder to prevent the escape of liquid CO_2. Contact with liquid gas can lead to "cold burns".
Never completely empty the gas cylinder to prevent the ingress of contaminants into the container.

Mark the empty gas cylinder as "EMPTY" before transport.



Use with a central gas supply

The Insufflator is also designed for operation with a central gas supply.
The minimum pressure at the gas inlet must be 5 bar *(= 72.5 PSI)*. The insufflator must be changed in the device setup *(see chapter "Central Gas Supply" p. 23)*.

Control elements and displays

Front

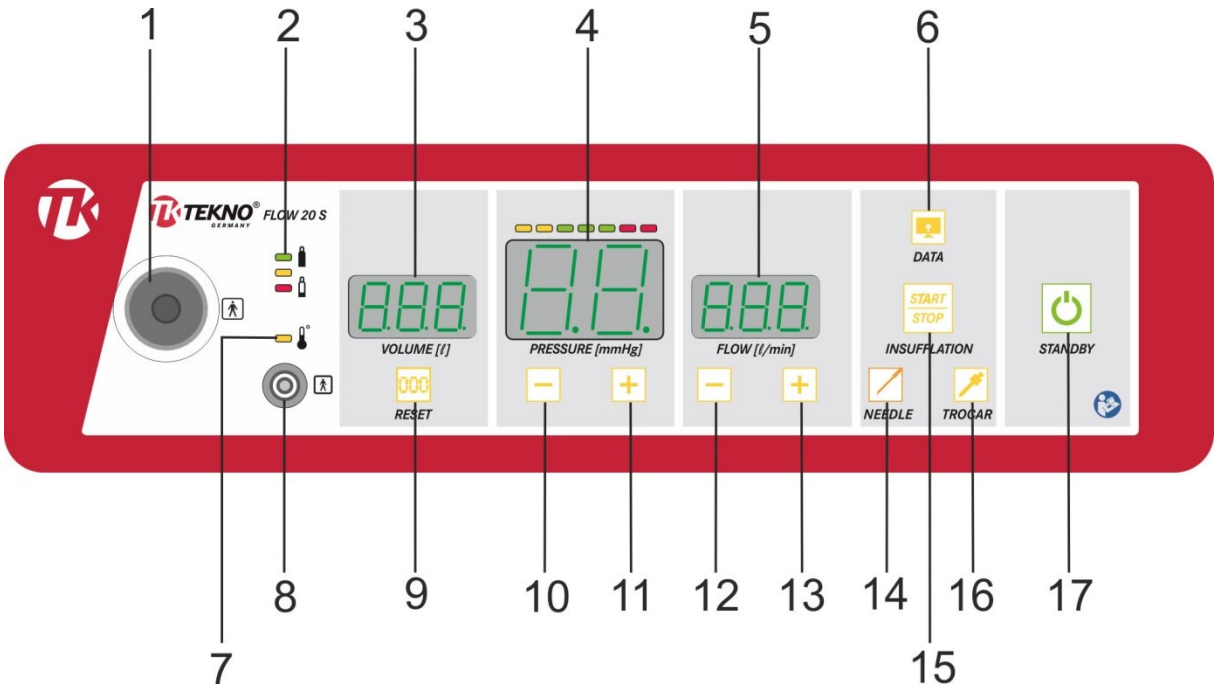


Fig. 2

1	Gas outlet/filter connection Connection piece for gas filter *(ISO connection)*	**10**	Pressure reduction button
2	Display for gas supply	**11**	Button for pressure increase
3	Display for insufflated gas quantity *(litres)*	**12**	Gas flow reduction button
4	Display for patient/setting pressure *(mmHg)* with overlying pressure trend display (deviation of the patient pressure to the set pressure)	**13**	Gas flow increase button
5	Display for gas flow *(L/min)*	**14**	Button for pre-insufflation mode
6	N/A	**15**	Button for start/stop *(insufflation)*
7	Display for heating function	**16**	Button for main insufflation mode
8	Connection for heating part	**17**	Standby button
9	Button for resetting the insufflated gas quantity		

Back

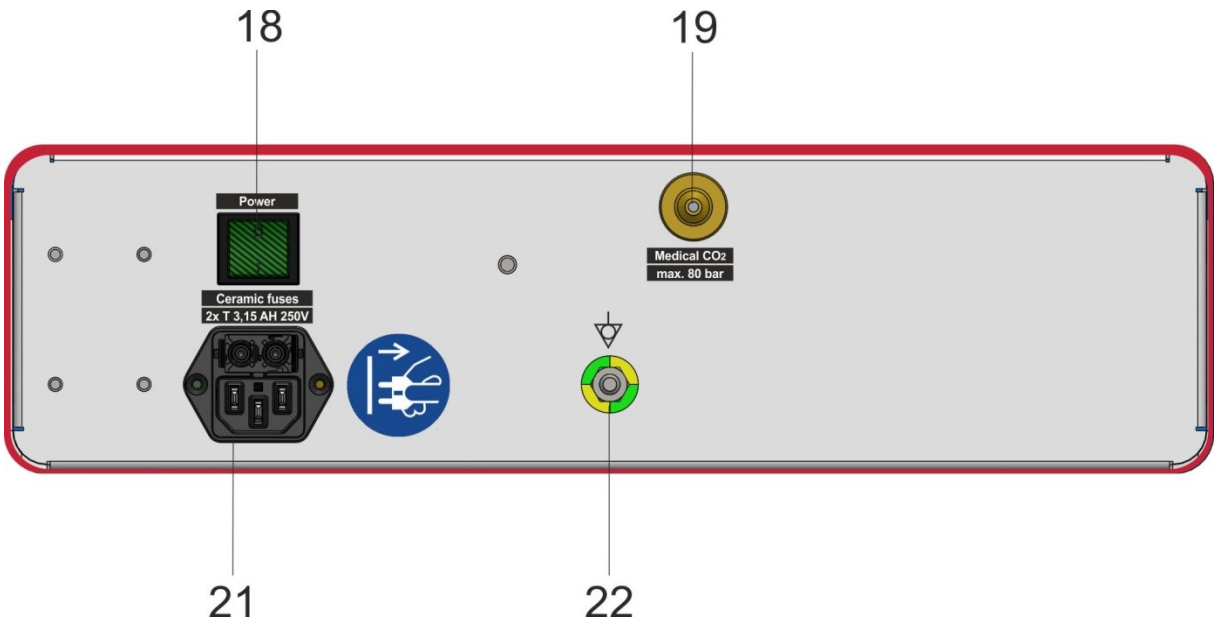


Fig. 3

18	Mains/power switch	**21**	Mains connection with miniature fuse holder *(**fuse type: T 3.15A H**)*
19	Connection for gas supply	**22**	Connection for equipotential bonding *(PE)*

First commissioning

Visually inspect the product before use. Make sure that the mechanical condition of the product will not affect safe operation.
Make sure that the device has been properly cleaned/disinfected and tested before use.

Setting up the device

The unit must be placed on an even surface that is secured against tippingin a dry environment!

Persons must not sit or lean on the device!

The device should be stored above the patient to counteract the backflow of contaminated fluids into the device!

The ambient temperature and the relative humidity must correspond to the specified values *(see "Storage and operating conditions" p. 8)*.

Electrical connection

The device complies with protection class I (with protective conductor), has a wide-range input and should be operated with an AC voltage (100-240 VAC with 50-60 Hz) at a properly installed power socket.

The mains voltage input on the device is protected by two miniature fuses (type T 3.15A H), which can be replaced from outside in the event of a fault *(see Fuse replacement p. 29 in the chapter" Maintenance")*.

- Establish the electrical connection between the earthed socket and the rear mains connection (21). Use the supplied power cable.The power switch (18) must be in the "OFF" position when connecting the mains cable.

Warning: To avoid the risk of electric shock, this device may only be connected to a supply network with a protective conductor!

- Connect the equipotential bonding contact of the device (22) to the stationary equipotential bonding of the room or the equipment cart. Observe the locally applicable safety regulations!

Attention! When using the equipotential bonding, observe the requirements of the current edition of IEC 60601-1!

The connection must not be used as protective conductor connection!

Electrical connections

Connections between plugs and sockets/sockets must not be made without prior implementation of ESD precautions.

ESD precautions

- Connect all electrical devices that are connected to the device to an equipotential bonding *(via PE).*
- Use only the equipment and accessories which are mentioned in the manual.
  The employees should be informed and trained in ESD precautions.

The INSUFFLATOR is intended for use in an environment specified as follows. The user of the INSUFFLATOR should ensure that it is operated in such an environment.

Precautionary measures

Electromedical equipment is subject to special precautions with regard to electromagnetic compatibility *(EMC)*. This device must be installed, set up and operated in accordance with the intended use described in the manual and with the EMCdirectives.

Impact of mobile and portable RF communication devices
High-frequency emissions from mobile communication devices can affect the functioning of medical electrical devices. The operation of such mobile communication devices *(e.g. mobile phones, GSM phones)* in close proximity to electromedical devices should be avoided.

Equipment combinations/systems

Specifications according to DIN EN 60601-1, section 16:

Protective conductor connections of various connections can *(contingent on installation)* consist of potential differences that occur in the event of a fault *(interruption of a protective conductor connection of a device)* on the housing and represent a patient or user hazard! All devices connected to a combination should comply with DIN EN 60601-1 and be tested afterwards! If devices are used for the combination which do not comply with DIN EN 60601-1, measures must be taken to limit the case leakage current which may occur in the event of a fault (e.g. galvanic isolation by isolating transformer [protection class I] or additional protective conductor)!

The use of portable multiple sockets should be avoided as far as possible, as these represent an additional risk to user and patient!

Risks:

- Overload of the multiple socket due to high total power consumption!
- The supply of the entire system is only via a mains socket! Complete system failure possible!
- Increase of ground leakage current due to aggregation in the devices!

Should it not be possible to dispense with portable multiple sockets, the following points should be considered:

- They should be structurally compliant with DIN EN 60601-1 for devices!
- Observe total power consumption of all connected devices!
- It should be a portable multiple socket with an isolating transformer *(protection class I)* and galvanic isolation! The isolation transformer should meet the requirement of IEC 60989 (except for the maximum rated output power of 1kVA and the enclosure protection class IPX4)!
- During the installation, care should be taken that any subsequent mechanical damage caused by movement is precluded, and the ingress of liquids *(cleaning, disinfection)* is avoided!

Connection gas supply

- Check connections for cleanliness and damage before connecting to the gas supply (central gas supply or gas cylinder). There must be no contamination! Do not use damaged fasteners!
- When using a CO_2 **gas cylinder** *(med. carbon dioxide),* you can use the tools included in the delivery.
- Fix the gas cylinder in vertical position. This prevents the penetration of liquid CO_2 into the device.

Attention! Never affix the gas cylinder in a horizontal position.

- Make sure the gas cylinder is securely fastened!

Note: *The insufflator can optionally be connected to a central gas supply (see chapter "Central gas supply" p. 23)*

Attention! Observe the safety instructions and applicable health and safety guidelines for the use of a gas cylinder or a central gas supply (see chapter on Safety instructions)!
After all connections have been made, they must be checked for leaks (leakage test)!

Function check (general)

The insufflator should be switched on for 10 minutes before each use!

- Connect to the gas supply (port 19).
- Open the gas supply (turn the cylinder valve slowly anticlockwise to the left!)

Attention! ***When connecting the device to the gas supply, make absolutely sure of the correct gas type (CO_2) and the maximum permissible pressure (see note on the gas connection)!***

After maintenance work or repairs to the gas supply, a gas type check should always be carried out!

- Establish the electrical connection between the rear connection socket (21) and the mains socket using the supplied power cable.
- Switch on the device at the mains switch (18, back of the device). The device is now in standby. The standby button (17) on the front panel flashes green.
- By pressing the standby button, you bring the device into the operating mode (self-test is started)!

Automatic self-test

This test lasts about 10 seconds and is performed immediately after switching on the device. If there is not enough CO_2 gas *(pressure)*, this is indicated by the display and a warning tone.

After successful self-test, the last used pre-settings for setpoint pressure [mmHg] and setpoint flow [l/min] are selected.

Note: *Note that the pre-settings for the pre-insufflation/first insufflation flow are set separately with the Veress needle (= NEEDLE) and the main insufflation with the trocar (= TROCAR) and thus also saved separately.*

If an error is detected during the self-test, the display of the flow (5) displays the error number.

Attention! ***If an error is detected during the automatic self-test, contact the responsible service department immediately!***

Please also note the information in the chapter "Maintenance"!

Connecting the accessories

- Remove the sterile filter from the sterile packaging and insert it (by gently turning) on the patient outlet/filter connection (1)!
- Remove the sterile insufflation tube from the packaging and insert the end with the larger connection (ISO 15 conical) by gently turning it into the sterile filter at the patient exit/filter connection!
  Attention: when using the reusable hose set, it must be prepared before the first use (see accompanying documents)! The reusable tubing sets are not sterile when delivered!
- Then connect the instrument to the other end of the insufflation tube (LuerLock connection)! To do this, insert the LuerLock connector of the hose into the LuerLock connector of the instrument and lock the connection by turning the LuerLock connector clockwise (to the right)!

When using a heating unit, please observe the additional instructions under
"Gas heating (optional)" on p. 25!

Device/functional description

The device delivers a maximum gas flow of up to xx[1] litres/min.

The pressure is adjustable in the range of 1-30 mmHg.

Due to the different designs of the instruments and hose systems *(with regard to the nominal size)*, the actual achievable flow rate *(l/min)* can deviate from the possible device performance.

Therefore we recommend:

- the use of Luer-Lock connectors with maximum nominal diameters!
- the use of ("high-flow") Veress needles with a 2.7 mm diameter!
- the use of ("high-flow") trocars with a nominal size greater than or equal to 11 mm for a 10 mm endoscope!
- the use of ("high-flow") trocars with a nominal size greater than or equal to 7 mm for a 5 mm endoscope!

Advanced Continuous Flow (ACF)

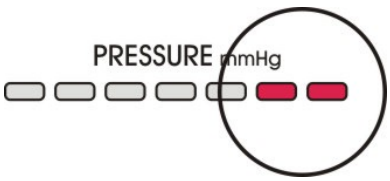
The advantage of the Advanced Continuous Flow technique is low insufflation pressure at high gas flow. This provides the patient with the highest level of safety.
The filter and tubing are specifically designed to use the Advanced Continuous Flow technique with the Insufflator.

Differential pressure indicator

On the LEDs above the pressure display (4), one can see a deviation of the current patient pressure to the setting pressure (***Note:*** *The transition between the LEDs is fluent, i.e. two adjacent LEDs of different colours can also be lit simultaneously)!*

- If the yellow LEDs *(left) are* lit, the set pressure in the patient has not yet been reached! **Patient pressure < set pressure**

- If the green LEDs *(middle)* light up, the set pressure in the patient is reached!
  Patient pressure = set pressure



- If the red LEDs *(right)* light up, the set pressure is exceeded *(overpressure)!*
  Patient pressure > set pressure!

[1] xx See rating plate

Automatic overpressure release function

The device is equipped with an automatic overpressure relief system.
The bleed function differentiates the amount of overpressure and responds with two different delay times.

- The drainage system can be switched on/off in the setup (default is switched on).
- The advance delay for "low" overpressures (4-10 mmHg) can be set in the setup (default is 10.0 sec). *(see Settings chapter "Device setup" p. 23, Parameter 006)*
- The delay time for "critical" overpressures (> 10 mmHg) can be set in the setup (default is 5.0 sec) *(see Settings chapter "Device setup" p. 23, Parameter 007)*

If the patient pressure exceeds the set pressure by more than min.4mmHg, the drainage system is activated. Activation takes place with the pre-set delay set in the setup (i.e.: The discharge function is only triggered after the delay has elapsed!).

The drainage system lets off gas until the set target pressure is reached again.

The use of additional sources of insufflation increases the intra-abdominal pressure. In this case, always observe the intra-abdominal pressure during the entire insufflation process.

The self-insufflation of non-pressure-controlled CO_2-cooled lasers and argon beamers can lead to the target pressure being exceeded. In these cases, adjust the setting values according to the circumstances!

Attention! ***If the overpressure-deflation function is triggered, under unfavourable circumstances a reflux of bodily or rinsing fluids may enter the insufflator! To avoid this as much as possible, care should be taken to store the device higher than the patient and to position the insufflation trocar above the fluid level in the abdomen!***

Additional protection

An additional and independent monitoring (independent of the above-mentioned "automatic overpressure-release-function") of the patient's pressure avoids an excessive pressure build-up in the patient!
In the case of a pressure build-up that is hazardous to the patient (even in a faulty operating state), the overpressure would be reduced! This function is triggered completely independently of the regular controls!

Operation of the device

Switching on the device

Attention! Before switching on the device, all connections must be properly inserted!

After all cable connections have been made, the insufflator can be put into operation.

- Switch on the insufflator with the power switch (18). The green lamp in the power switch lights up.
- The device is then in standby mode, indicated by the green flashing of the standby button (17).
- Slowly open the valve of the gas cylinder (about one turn to the left in the anticlockwise direction) or the central gas supply.
- Pressing the standby button switches the device to the operating mode. The device performs a self-test. This is visualised by a light sequence of the LEDs on the front panel. The operating mode is indicated by the green light (constant) of the standby button.

  Note: *If the unit detects an error in the self-test, the unit displays "Err" in display 3 and a 3-digit number code in display 5*
- If the system pressure is sufficient, the gas supply indicator lights up (2) green; a yellow light points to a speedy bottle change. A red flash will appear after a complete emptying of the bottle during insufflation.

Instructions for use / Preparation for insufflation

The buttons "NEEDLE **"** (14) and "TROCAR" (16) are used to select the insufflation mode:

- NEEDLE (14) = first insufflation
- TROCAR (16) = main insufflation

The selected mode is indicated by the button lighting up in yellow.

The first four seconds after selecting the mode, the display shows the setting values *(preset values).* You are in setting mode *(preset mode)* !

After five seconds, the currently measured values are displayed again *(or OFF if insufflation is not started)!*

Note: *The settings for the first insufflation and the main insufflation are saved (even after switching off!).*

On the LEDs above the pressure display (4), the user can directly read the deviation of the current patient pressure from the set pressure (differential pressure display, pressure tendency display):

- If the green LEDs *(middle)* light up, the set pressure in the patient is reached!
- If the yellow LEDs *(left)* light up, the set pressure has not yet been reached in the patient!
- If the red LEDs *(right)* light up, the set pressure is exceeded *(overpressure)*; the patient pressure is greater than the set pressure!

Note: *The transition between the LEDs is fluent, i.e. two adjacent LEDs of different colours can also be lit simultaneously!*

If the intra-abdominal pressure *(actual pressure)* rises 4 mmHg above the setting value for at least 4 seconds, the pressure indicator (4) flashes. In addition, a pulsating tone sounds. From then on, the delay time for the automatic "low" overpressure drain function will run. After expiry of the set time *(default is 10.0 seconds)*, the device will release the overpressure.

If the intra-abdominal pressure *(actual pressure)* rises 10 mmHg above the setting value for at least 2 seconds, the pressure indicator (4) flashes. In addition, a fast pulsing tone sounds. From then on, the delay time for the automatic discharge function "critical" overpressure will run. When the set time *(default is 5.0 seconds)* has elapsed, the unit releases the overpressure.
At pressures above 35 mmHg, the delay is generally 5.0 seconds!

Display of preset values
The yellow illuminated mode button indicates the currently set mode! Pressing the currently yellowed mode button "NEEDLE" (14) or "TROCAR" (16) switches the device to the setting mode. *(When the green lit mode button is pressed, the unit enters this mode and the pressure and flow values stored there are displayed.)*

Here you can control and change the preset values for pressure and flow.
Note that the pressure and flow values for first insufflation and main insufflation are set and saved separately.

General note:
Due to the different designs of the instruments and hose systems *(with regard to the nominal size)*, the actual achievable flow rate *(l/min)* can deviate from the possible device performance. The maximum nominal diameter of the trocars varies greatly among the different models. To utilise the optimum performance of the device, please choose a model with a maximum nominal diameter! (see Accessories p. 34)!

Pressure preselection

Pressing the pressure reduction button (10) or the pressure increase button (11) activates the setting mode.

For 4 seconds, the presets for pressure (4) and flow (5) show the preset values.

This "Preset Mode" is indicated by the text "SET" being displayed on the “amount of insufflated gas” display (3).

The nominal pressure, i.e. the pressure value to be set in the pneumoperitoneum, can be adjusted (reduced or increased) with the buttons 10 and 11 if necessary in the range 1...30 mmHg.

Note: *Pressing and holding the buttons speeds up the setting process.*

From a preselected pressure greater than 16 mmHg, the pressure indicator (4) flashes for 4 seconds. The device will then indicate that you have selected a pressure value above the commonly used pressure values.)

Flow preselection

Pressing the flow reduction button (12) or the flow increase button (13) activates the preset mode.

For 4 seconds, the pressure and flow indicators (3 and 4) show the preset values for pressure and flow.

This "Preset Mode" is indicated by the text "SET" being displayed on the “amount of insufflated gas” display (5).

The flow setpoint can be set with buttons 12 and 13:

12 = reduction of the flow setpoint.

13 = increase of the flow setpoint.

Setting:

- First insufflation *(NEEDLE):* 1 to 5 litres per minute.
- Main *insufflation (TROCAR)*: 1 to xx litres per minute *(xx = device dependent)*

Note: *Pressing and holding the buttons speeds up the setting process.*

Separate setting and storage

The settings for the preselected flow values are preselected and saved separately for the respective mode, NEEDLE or TROCAR.

Note: *The setting values are not lost after switching off!*

Device setup

You can access the setup menu by pressing (and holding down) the START/STOP button (15) while switching on the device with the STANDBY button (17). The display shows:

- SEt UP -

Each adjustable function is described with a number and a letter combination in the following table!

- By pressing the buttons "Pressure down" (10) or "Pressure up" (11) you can select the different points. Press the START/STOP button (15) to go to the corresponding setting values (setting values are shown in the display).
- At this point you can now use the buttons (12) and (13) in full steps and the buttons (10) and (11) for changes of ten!
- Press the START/STOP button (15) again to save the changed value and return to the selection menu.
- Press the RESET button (9) to exit the setup menu and the insufflator will reboot.

Setting parameters:

No.	Display	Description	Value	Default
001	b0	Volume control for the front buttons	0..25	2
002	b1	Volume control for the warning signal - risks (Overpressure)	0..25	25
003	b2	Volume control for the warning signal - carbon dioxide cylinder is almost empty	0..25	10
004	b3	Volume control for the warning signal - negative pressure	0..25	5
005	C9	Central gas supply	On/ OFF	OFF
006	t1	Delay for overpressure relief function "low" overpressure (4-10 mmHg) in sec.	5..30.0	10.0
007	t2	Delay for overpressure relief function "critical" overpressure (> 10 mmHg) in sec.	5..30.0	5.0
008	bo	Drain function	On/ OFF	On
009	L4	Intensity button illumination yellow - "night design"	0..200	130
010	L9	Intensity button illumination green - "night design"	0..200	0
011	PU	Purge function Gas quantity in litres	0..10.0	0
...				
099	So	Software version		

Setting parameters

Central gas supply

The device can be setup to be converted to a central gas supply. The minimum pressure at the gas inlet must be 5 bar *(= 72.5 PSI).* If the device is set to supply via a central gas supply system, the text appears after the self-test for 5 seconds: "CEntrAL" on the displays!

Safe application of pneumoperitoneum

If the Veress needle has been inserted correctly but the insufflation has not yet started, the correct position of the Veress needle can be checked by lifting the abdominal wall. In this case, a negative value must be displayed on display 4 (actual pressure).

Diagnostic procedures

For the use of the Veress needle and trocars with a small insufflation channel, the device was equipped with a special control mode in the range of 1 to 5 litres per minute. This mode can be selected with the "NEEDLE" button (14).

Attention! The use of a sterile filter is mandatory!

Functional test

When the Veress needle is connected and opened with a preselected pressure of more than 10 mmHg and a flow rate of 2 l/min, an actual flow of at least one litre per minute must be set. If this is not the case, either the needle is blocked or the device is defective. In the latter case, stop using the device and contact the service department immediately.

Rinse the insufflation line

Before beginning insufflation, use the connected insufflation tube to insufflate 500 ml of gas into the ambient air to replace the air in the insufflation tube with carbon dioxide gas.

Attention! Note that there is also air in the unit and in the high-pressure hose after the gas cylinder has been replaced. This air must be removed separately after each bottle change. Insufflate about 3-4 litres against the environment.

Start insufflation

Reset the gas volume display (3) to zero with the reset button RESET (9).

Pre-insufflation

- On the device, select the pre-insufflation mode by pressing the "NEEDLE" button (14)!
- Insert the Veress needle and open the closure. If the Veress needle has been inserted correctly but the insufflation has not yet started, the correct position of the Veress needle can be checked by lifting the abdominal wall. In this case, a negative value must be displayed on display 4 (actual pressure).
- Start the insufflation procedure by pressing the START/STOP button (15).
- The intra-abdominal pressure, the flow and the insufflated or consumed gas quantity can be conveniently read on the displays 4, 5 and 3.

Main insufflation

- After the pneumoperitoneum has been attached, you can use the "TROCAR" button (16) to switch to the main insufflation mode with a high-flow trocar.
- Start the insufflation procedure by pressing the START/STOP button (15).
- The intra-abdominal pressure, the flow and the insufflated or consumed gas quantity can be conveniently read on the displays 4, 5 and 3.

Stopping insufflation

- Press START/STOP button (15).
- Close the gas cylinder valve and remove the insufflation tube.
- The text "OFF" appears on the flow display (5).

  Note: *The pressure indicator (4) and over-pressure monitoring is also active when insufflation is completed.*

Gas heating (optional)

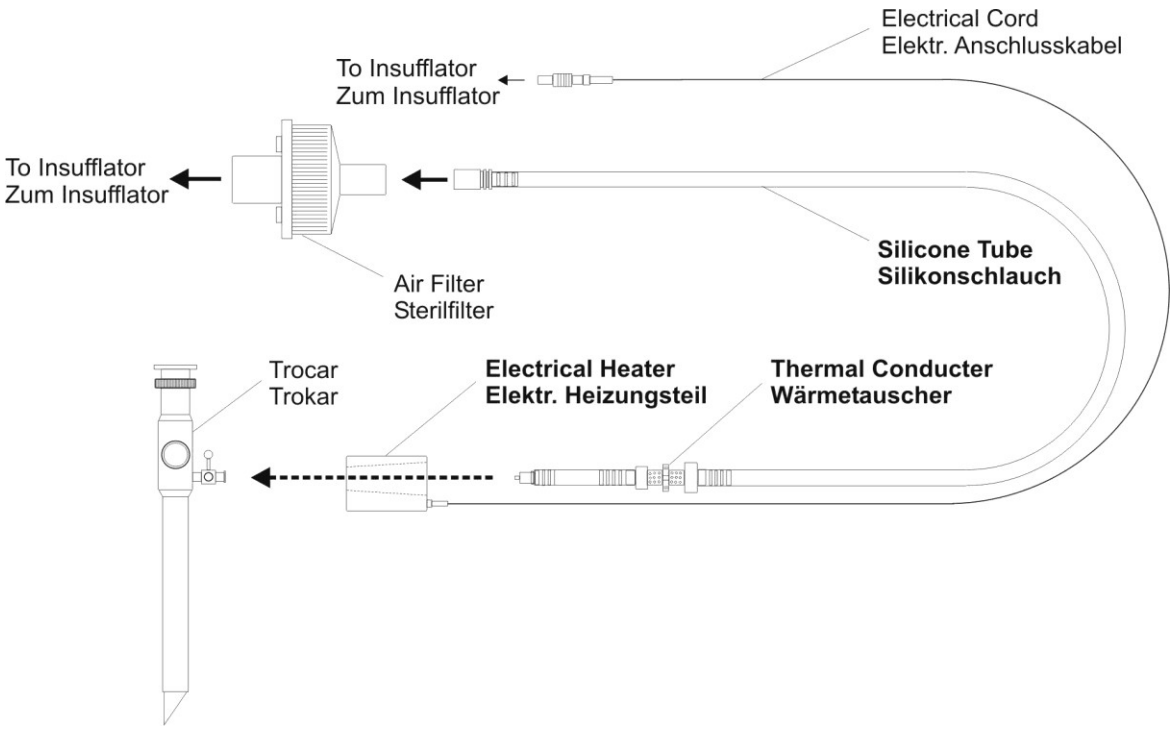
The gas heater is used to heat the insufflation gas to body temperature. With this additional feature, you can minimise hypothermia of the patient by the action of the insufflation gas.

If the gas heating is to be used, the special insufflation hose with heat exchanger (hose set LAP-H) is required!

For this purpose, the heat exchanger (as shown below in the drawing) is introduced into the heating part.
After the electrical connection between the heating part and the insufflator is made, the heating part starts to heat.

Supply the hose system with heat exchanger and the heating part after the operation for reprocessing *(see chapter "Reprocessing" from p. 30)*.

Note: *The life of the heat exchanger and the electrical heating part is limited to 2 years or 100 applications and must be replaced after either of these limits are met!*



Operating instructions

Fresh air

To avoid signs of fatigue, ensure a good supply of fresh air. For operations with high CO_2 consumption, i.e. for longer operations or in operations with frequent instrument changes, the CO_2 content in the air increases, which can lead to fatigue.

Reserve bottle

Keep a filled CO_2 bottle at the ready when the insufflator is not connected to a central gas supply. Only then can a premature termination of the procedure be avoided.

Note: *Ask your dealer for an automatic changeover valve for uninterrupted gas supply when using gas cylinders!*

Leaking insufflation system

If the gas flow is too high and the cause is not clear, check the system for a leak. In a leaky system, the pressure measurement of the insufflator leads to incorrect pressure values, which can in turn lead to increased insufflation pressure.

Back-up insufflator

A replacement device should be kept available for the possibility that the insufflation device may fail during surgery. Only then can a premature termination of the procedure be avoided.

Liquid in the system

Do not use the insufflator if liquids have entered or touched the housing *(including the gas outlet).*

Errors and warnings

If there is a device defect, the insufflator must not be used until it has been serviced by an authorised service technician. A device defect can normally be detected automatically by the insufflator during the device self-test after switching on or during insufflation operation. After the error has been detected, an error number and "Err" appear on the displays. The error number specifies the error and should be reported to the responsible service department. This allows the driver to determine or limit the cause of the fault beforehand and ensure a quick repair (see also chapter "Maintenance" from p. 28)!

Display	Actions
Red gas cylinder indicator (2) flashes and a pulsating warning sound is heard	The corresponding gas cylinder is empty or closed; it should be exchanged or opened.
Yellow gas cylinder indicator (2) lights up and a pulsating warning sound is heard	The cylinder pressure is so low that only a small amount of CO_2 is available for the operation. The CO_2 bottle should be replaced as soon as possible.
Red LEDs of the pressure trend indicator light up, the pressure indicator (4) flashes and a pulsating warning tone is audible	Intra-abdominal pressure is 4 mmHg higher than selected. The cause of the pressure increase must be determined and eliminated.
"Err" is displayed on the volume display (3) and a number is displayed on the flow display (5)	A device error was detected here. If this error occurs again after switching the device on and off, contact the service. The insufflator must no longer be used.
The pressure gauge (4) flashes in SET UP	For laparoscopy, a pressure greater than 16 mmHg, i.e. greater than the usual insufflation pressure values, was selected. *(see also chapter "User instructions" p. 8)*
Display for Gas Heating (7)	This indicator lights up as soon as the heater has been connected correctly and is in normal heating mode. If the display switches off during operation or starts to flash, there is a defect or error. Disconnect the application part from the device. Notify the responsible service.

Displays	Meaning
OFF	The insufflation has been stopped.
CO_2	Replace the gas cylinder with a filled one.
CentrAL	The appliance is set up for use with a central gas supply *(briefly appears on display when switching on the appliance)*. *(see also chapter "Gerätesetup" p. 23)*

Maintenance

Service work

Attention! ***The device must be checked once a year by authorised service personnel (electrical safety check in accordance with DIN EN 62353 (VDE 0751-1))!***

To do this, the device must be connected to the mains connection cable used; if relevant, electrical application parts are also to be sent to the manufacturer or to an authorised service technician!

The customer (or operator) is obliged to clean and disinfect the device and accessories according to the instructions in this document (or the instructions supplied separately) before returning them to the manufacturer! The return must be accompanied by proof of this reprocessing!
Please use the "Return shipment form" on the website of the manufacturer under and note the return conditions specified there!
We reserve the right to exclude obviously contaminated or heavily contaminated products from processing and to return them to the sender!

Services such as changes, calibrations or repairs may only be carried out by the manufacturer or by authorised service technicians!

Having the technical documentation of the device alone does not constitute an authorisation for technically trained personnel by the manufacturer to open or repair the device. This excludes the interventions described in this text (i.e. this operating manual).

After every servicing, the operator of the device must obtain a certificate containing details of the work carried out, the date and the executing company, and fill in the maintenance log attached to this user manual.

The liability for the operational safety of the device by the manufacturer expires in the event that service work is carried out by unauthorised specialists, the prescribed intervals for checking and safety inspection (STK) are not complied with, as well as unauthorised opening of the device and intervention in the device by unauthorised persons and when using unauthorised spare parts.

Address:

Service
Tekno-Medical Optik-Chirurgie GmbH Sattlerstrasse 11 D-78532 Tuttlingen-Nendingen GERMANY Telephone: +49 (0) 7461 – 170 10 Fax: +49 (0) 7461 – 170 150 www.tekno-medical.com mail@tekno-medical.com

Exchanging mains fuses

The mains fuses are located on the back of the device, above the IEC connection, in a small fuse drawer (21).

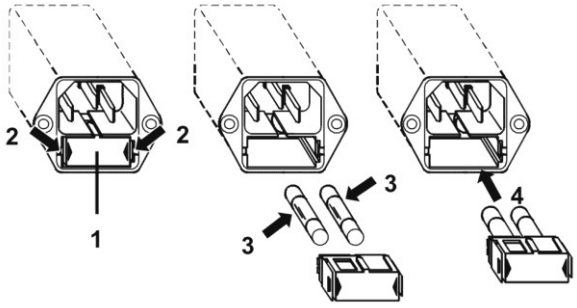
To change the fuses, proceed as follows:

- Switch off the device!
- **PULL OUT MAINS PLUG!**
- Release the fuse drawer (1) by using a pointed object to unlock the two side clips (2) of the drawer and pull out the drawer.
- Remove the fuses (3).
- Check the fuses! If necessary, use an ohm meter to measure the continuity of the fuses.
- Insert new fuses according to the labelling on the fuse drawer or on the rating plate!

Attention! Only use ceramic fuses with high switching capacity (I_a = 1500 A) as per IEC 60127-2/V, H (see techn. specifications/rating plate)!

- Put the fuse drawer (*with the small catch downwards)* back into the slot provided (4). The drawer must audibly click into place on both sides.
- Connect power cable
- Turn on device

Then put the device into operation. If you replace a defective fuse with a new one and blow it out again, this indicates a fault in the device. In this case, send the device (*disinfected)* to your dealer for inspection.



Replacement of the gas cylinder

Be extremely careful when changing the liquid-CO_2-filled gas cylinder, which is under high pressure. The pressure in the system can rise above 80 bar. Never attempt to disconnect the gas supply line before closing the cylinder valve. Only then can the high-pressure hose be loosened carefully and slowly. Slowly vent the gas in the high pressure hose before completely loosening the connections.

Reprocessing

The regulations and laws mentioned in this section refer to Germany! In other countries, the regulations and laws valid there must be adhered to! Inquire in advance about the local regulations in your country!

General information

Legislation includes various rules that must be followed. In addition to health and safety regulations, the Infection Protection Act and Dangerous Goods Ordinance, mention should be made in particular of the Medical Devices Act *(MPG)*, including the recommendations of the Robert Koch Institute on the "Hygiene Requirements for the Reprocessing of Medical Devices".
Regulations and guidelines, in part:

- Council Directive 93/42/EEC on medical devices with updates
- Law on medical devices *(Medical Devices Act/MPG)*
- Ordinance on Medical Devices (MPV)
- Ordinance on the Establishment, Operation and Use of Medical Devices *(Medical Devices Operator Ordinance, MPBetreibV)*
- "Hygiene requirements for the reprocessing of medical devices". Recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices *(BfArM)*
- Guidelines for Hospital Hygiene and Infection Prevention
  - Hygiene requirements for the reprocessing of medical devices
  - List of disinfectants and procedures tested and approved by the RKI,
- German Society for Hygiene and Microbiology *(DGHM):* Disinfectant list

The effectiveness of disinfection measures against the causative agent of Creutzfeldt-Jakob disease, including its new variant, is exemplified in the statements in Bundesgesundheitsblatt 39 (1996) 382-283, 41 (1998) 279-285, 45 (2002) 376-394 and 47 (2004) 36-40, for example.

- German Occupational Health and Safety Act
- Infection Protection Act (*IFSG)* Act on the Prevention and Control of Infectious Diseases in Humans
- Biological Agents Ordinance
- Chemicals Act
- Workplace regulation and directives
- Ordinance on Hazardous Substances
- Safety rules to prevent fire and explosion hazard due to alcoholic disinfectants ZH 1/598
- Accident Prevention Regulation *(UVV)*
- Training guidelines of the German Society for Sterile Supply (Deutsche Gesellschaft für Sterilgutversorgung e.V.) *(DGSV; PO Box 210 529, 72028 Tübingen)*

Degree of contamination

Gross contamination of medical devices should be removed immediately after use. The drying of blood and tissue is to be prevented as much as possible, for example by wiping external contaminants and flushing the cavities immediately after use, in particular to avoid impairment of the cleaning function *(drying of infectious agents in protective colloids).*

1. Residual contamination could dislodge and cause complications for patients *(e.g. granulomas, wound healing disorders).*
2. Residual contamination could affect the technical functioning of instruments *(e.g. obstruction of channels, valves).*
3. Residual contamination can impede disinfection.
4. Residual contamination can affect sterilisation processes.

Attention! The cleaning and disinfection equipment used must conform to the standard DIN EN ISO 15883 (type-tested according to DIN EN ISO 15883)!

Protection against infections and chemical burns

Attention! Surgical residue on the instruments and hoses, bodily particles from patients, cleaning agents and cleaning additives pose hazards!

To protect against hazardous chemicals and potentially infectious material, protective equipment with eye protection and face mask, moisture-resistant clothing and suitable chemical-resistant gloves must be worn!

To protect against toxic vapours, ensure adequate ventilation!

When reprocessing reusable products, observe the special hygiene regulations for critical medical devices!

The silicone hoses and heating parts of the insufflator are steam-sterilisable.
Validation was performed for the effective germicidal effect of steam sterilisation on these application parts.

Safety instructions for suspected cases of CJD/vCJD

Subject to new scientific evidence, the following procedure should be followed:

In general, disposable instruments should be used in elective invasive procedures on lymphoid tissue in patients with evidence of a vCJD, or an increased risk of having or developing CJD. These are to be destroyed through incineration after use.

It is not recommended to use and reprocess the heating part and the silicone hose in suspected cases of CJD/vCJD!

In an emergency endoscopy with unexplained diagnosis:

- First separate disposable products and place them as waste in a safe container for incineration (*AS[2] 180103/C waste)*,
- Carefully remove gross contaminants from the medical devices that may later be reprocessed,
- Avoid injuries at all costs *(no hand-to-hand handover of instruments),*
- Do not overload containers and strainers,
- Organise instruments, place with open joints or hinges,
- Close container securely *(e.g. seal both sides)* and
- On the accompanying document, confirm delivery of the container to the CSSD/processor.

Until the diagnosis has been confirmed *(CJD/vCJD confirmed, unexplained or safely excluded)*, the instrument is to remain in a designated place under the responsibility of a designated person. The notification of the diagnosis is made in writing by the responsible doctor and is documented on the accompanying document. The responsible hospital hygienist must be informed about the procedure. If the diagnosis is confirmed or ultimately becomes clear *(CJD/vCJD)*, dispose of and destroy the applied medical devices *(see "Requirements for hygiene in the treatment of medical devices", Bundesgesundheitsblatt)* by incineration *(AS[2] 180103).*

Contaminated waste

Objects contaminated with infectious material must be disposed of as infectious waste, AS 180103 *(C waste).* Injury-proof disposal of sharp and pointed objects *(cannulas, etc.)* in puncture-proof, unbreakable disposal containers *(cannula ejector)*, then in the disposable container for waste incineration *(type-approved plastic disposable container)* – not in the DESI container. Liquid-filled disposable containers *(blood, secretions)* that are not emptied must also be placed in the disposable container. All C waste contaminated with CJD prions is sent to be incinerated.

[2] *AS = Waste code according to the European Waste Catalogue*

Cleaning the device

If required, the device can be cleaned externally with a cleaning agent which protects the paint *(observe the instructions of the respective manufacturer).*

- For disinfection, use an aqueous solution with 1-4% glutaraldehyde or 70% isopropanol *(alcohol)!*
- When using alcohol, ensure that the device has cooled down to avoid the risk of ignition!

  Note: *Observe the local regulations on the use of alcohol!*

Attention! The device must never be sterilised!

It is important to ensure that no liquids penetrate into the housing!

When cleaning the device, please proceed as follows:

- Switch off the device!
- **PULL OUT MAINS PLUG!**

  If applicable, remove any existing electrical connections *(e.g. heating unit, interface for data output)!*
- Clean the device.

  Note: *A soft cloth or blotting paper should be used to apply the cleaning or disinfecting liquids to avoid scratches on the surface and to be able to better dose and distribute the liquid.*
- Dry.

  Note: *After cleaning with flammable liquids, allow the unit to dry for at least 1 hour before turning it on again. Otherwise, there is a risk that an explosive mixture of air and cleaning agent will ignite when switched on.*

Preparation of the accessories

The effectiveness of automated cleaning, disinfection and sterilisation procedures was tested as part of the validation for the preparation of the hose systems and application parts.
An independent testing laboratory has confirmed the basic suitability of the treatment procedure described in the instructions for the products.

Instruments and accessories intended for reuse must be thoroughly cleaned immediately after use!

Brand-new, reusable, non-sterile accessories should be treated as if they were used!

Thorough cleaning eliminates both microorganisms and organic matter. Any failure to remove organic matter adversely affects the process of sterilisation.

For reusable accessories, the manufacturer recommends the following procedure:

- Follow the reprocessing recommendation for the products!
- Immediately after use, begin the reprocessing treatment *(avoid allowing residue to dry)*!
- If necessary, disassemble parts (observe corresponding instructions on the products)!

Note: *The service life of the silicone hose is limited to 2 years or 50 applications and must be replaced after either of these limits are met!*

The service life of the heating part is limited to 2 years or 100 applications and must be replaced after either of these limits are met!
In case of damage or restrictions to functioning, the product must be replaced immediately!

Please follow the reprocessing recommendations that accompany the different products separately!

Technical specifications

Electrical specifications	
Mains voltage	100 - 240 V/AC
Mains frequency	50 - 60 Hz
Current consumption	max. 1.4 A
Mains fuses *(2pcs.)*	T 3.15 A/H
Insufflation specifications	
Insufflation pressure	1 - 30 (max. 65) mmHg
Accuracy of pressure gauge	± 5%
Gas flow	1 - xx[3] litre/min
Accuracy of gas flow display	± 10%
Other specifications	
Insufflation gas	Medical carbon dioxide gas CO_2 / max. 80 bar
Gas connection	UNF 7/16” male
Dimensions *(W x H x D)*	355 x 105 x 285 mm
Mass	about 6.7 kg
Housing	Sheet steel, powder coated
Operating conditions	
Temperature range	+10 - +40°C
Relative humidity	20 - 80 %
Atmospheric pressure/altitude	1020 - 700mbar / approx. 0 - 3000m
Storage/transport conditions	
Temperature	-20 - +70°C
Humidity	10 - 90 %
Atmospheric pressure/altitude	1020 - 350mbar / approx. 0 - 8000m
Classification	
Device type	Insufflator
Protection class	I (protective earthing)
Degree of protection	IP 20
Certified in accordance with	IEC 60601-1
Compliant (EMC) with	IEC 60601-1-2: 2014 for use in professional healthcare facilities (CISPR 11: Group 1, Class A)
MPG class	IIb
CE marking	CE 0124

[3] Depending on the device version/see designation of the device

Accessories

Description		Order no.
Sterile filters for CO_2 insufflators ➢ *Disposable articles*	50 pieces 100 pieces 250 pieces 500 pieces	**754-1502** 952-0005 952-0006 952-0008
Disposable insufflation tube, highflow, 2.5m ➢ *LL-M terminal* ➢ *sterilised*	15 pieces 90 pieces	952-0032-15 952-0032-90
Silicone hose set 2.5m ➢ *reusable, steam-sterilisable* ➢ *LL-M terminal* ➢ *unsterilised*	5 pieces	952-0004-05
Silicone hose set with heat exchanger *(for insufflators with heating)* ➢ *with heat exchanger and silicone tube piece* ➢ *reusable, steam-sterilisable* ➢ *LL-M terminal* ➢ *unsterilised*	5 pieces	952-0003-05
Heating unit (without heat exchanger) *(for insufflators with heating)* ➢ *reusable, steam-sterilisable* ➢ *with silicone tube piece* ➢ *for insufflators with heating*		**754-1525**
Insufflation trocar high flow		888-9220
Veress needle high flow		888-9121
High pressure hose DIN (German)/DIN (German) ➢ *CO_2 150 bar, 6 x 1000mm,* ***hose completely stainless steel***	1m	952-1020
High pressure hose UNF/DIN (German) ➢ *CO_2 150 bar, 6 x 1000mm,* ***hose completely stainless steel***	1m	952-1021
High pressure hose UNF/UNF ➢ *CO_2 150 bar, 6 x 1000mm,* ***hose completely stainless steel***	1m	952-1022
High pressure hose UNF/PIN index ➢ *CO_2 150 bar, 6 x 1000mm,* ***hose completely stainless steel***	1m	952-1025
High pressure hose UNF/ISO ➢ *CO_2 150 bar, 6 x 1000mm,* ***hose completely stainless steel***	1m	952-1026
Open-end spanner for high-pressure hose SW 32 - (ISO)		952-0030
Open end spanner for high pressure hose SW 30 - DIN (German)		952-0029
Open-end spanner for high-pressure hose SW 27 - DIN (German)		952-1027
Open-end spanner for high-pressure hose SW 17 - (UNF)		952-1017
CO_2 gas cylinder 0.75 kg, PIN-INDEX connection		952-0002
Power cable EU (German) standard 1.8m		214-0001
Power cable US standard 1.8m		214-0002
Fuse T 3.15A H		113-0025

Appendix

Electromagnetic compatibility (EMC)

Warnings and notes

Warning: The use of the Insufflator next to other equipment or with other equipment in a stacked arrangement should be avoided, as it may result in improper operation.
In particular, adverse effects/influences on the operation should be expected in the vicinity of RF surgical equipment or in or near RF-shielded rooms for magnetic resonance imaging! In these cases, the Insufflator should be monitored closely and, if necessary, the interference removed through repositioning/alignment!
Note: When used in home health care applications (CISPR 11 Group 1 Class B requirement), the insufflator may not provide adequate protection of radio services! In this case too, the user must take corrective action if necessary by repositioning or realignment of the device! The essential performance characteristic (max. pressure 65 mmHg) is retained even with the assumption of interference!
Warning: The use of accessories other than those supplied by the manufacturer (in particular mains cables of different lengths than 1.8-2.0m or heating parts with electrical connection to the Insufflator of other manufacturers and/or other lengths than 2.5m) may cause increased electromagnetic emissions or lead to a lower electromagnetic interference immunity of the Insufflator and lead to faulty operation!
Warning: Portable RF communication devices (radios and their accessories such as antennas and antenna cables) should not be used at a distance of less than 30 cm (12 inches) from the Insufflator and the electrical leads connected to it (e.g. power cable, heating cable)! Failure to observe this may result in impairment to the general performance characteristics of the Insufflator!
Note: The INSUFFLATOR is designed to operate in an electro-magnetic environment in which radiated RF disturbances are controlled. The user of the INSUFFLATOR can help to prevent electromagnetic interference by specifying the minimum distance of 0.3m (12inch) or the exact calculated distance (knowing the exact power of the transmitter) according to the formula given in the table below between portable and mobile RF communications equipment (transmitters) and the INSUFFLATOR.
Note: This guideline may not apply in all situations. The propagation of electromagnetic waves is influenced by the absorption and reflection of buildings, objects and people.
The field strength of stationary transmitters, such as base stations of radio telephones, mobile services, radio services, AM and FM radio and television stations, wireless stations and repeaters, cannot be accurately predicted by theory. In order to determine the electromagnetic environment as a result of stationary RF transmitters, an examination of the location is recommended. If the detected field strength at the location of the INSUFFLATOR exceeds the test level indicated above, the INSUFFLATOR must be observed for its normal operation at each point of use. If unusual performance is observed, it may be necessary to take additional measures, such as the reorientation or repositioning of the INSUFFLATOR.

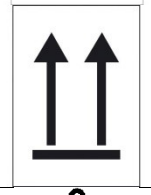
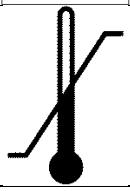
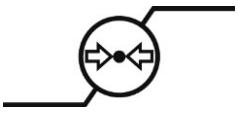
Manufacturer's declaration – Electromagnetic emissions

Emissions test	Conformity	Electromagnetic environment – guide
Conducted emissions according to IEC/CISPR 11:2015 (L + N, 150 kHz - 30 MHz)	Group 1 Class A	The INSUFFLATOR uses RF energy only for its internal functions. Therefore, its RF transmission is very low and it is unlikely that neighbouring electronic devices will be disturbed. **The INSUFFLATOR is suitable for use in professional healthcare facilities** (e.g. medical practices, clinics, operating theatres, intensive care units, hospital rooms, emergency rooms and accident clinics).
Emitted interference As per IEC/CISPR 11:2015 (3m, 30 MHz – 1GHz, 0 - 360°, h + v pol.)	Group 1 Class A	
Harmonics As per IEC 61000-3-2:2014	Class A	
Voltage fluctuations/flicker As per IEC 61000-3-2:2013	Yes	

Manufacturer's declaration – Electromagnetic immunity

Immunity tests	Test level	Fulfils	Electromagnetic Environment – Guidelines
Discharge of static electricity (ESD) As per IEC 61000-4-2	± 2; 4; 6; 8 kV Contact discharge ± 2; 4; 8; 15 kV Air discharge	Yes	Floors should be made of concrete or wood or covered with ceramic tiles. If the floor is covered with synthetic material and does not provide ESD protection, the relative humidity should be at least 30%.
High frequency electromagnetic fields As per IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM 1kHZ	Yes	**Recommended protective distance:** **0.3m (12 inches)** **at the typical assumed transmission power in the corresponding frequency band** With the formula below, with "P" as the transmitter power rating in watts (W) as specified by the transmitter manufacturer, "D" as the minimum distance in metres (m) and "E" as the immunity test level, possible minimum distances can be calculated and corrected if the nominal power of the transmitter is known: **$d = 6 \sqrt{P} : E$** In the vicinity of devices bearing the following symbols, interference is possible. 
High frequency electromagnetic fields As per IEC 61000-4-3 In the immediate vicinity of wireless communication devices	28 V/m 385, 450, 810, 870, 930 MHz 50% PM 18Hz	Yes	
	28 V/m 1720, 1845, 1970, 2450 MHz 50% PM 217Hz	Yes	
	9 V/m 710, 745, 780, 5240, 5500, 5785 MHz 50% PM 217Hz	Yes	
Magnetic field at the supply frequency (50/60 Hz) As per IEC 61000-4-8	30 A/m 50Hz, 60Hz x, y, z axis	Yes	Magnetic fields at the mains frequency should correspond to the typical values found in the hospital environment.
fast transient Electrical disturbances/bursts As per IEC 61000-4-4	± 2 kV 100kHz Supply lines ± 1 kV 100kHz Data and signal lines	Yes	The quality of the supply voltage should be that of a typical professional healthcare facility (non-public supply network).
Surges (Surges) As per IEC 61000-4-5	± 0.5; 1 kV (L + N) ± 0.5; 1; 2 kV (L + PE, N + PE)	Yes	
Conducted RF disturbances As per IEC 61000-4-6	6 V_{eff} 150 KHz to 80 MHz 80% at 1kHz (Mains cable, POAG earthing cable, electr. supply line for heating part)	Yes	
Voltage dips as per IEC 61000-4-11	100% 10ms (at 0, 45, 90, 135, 180, 225, 270 and 315°) 100% 20ms, 30% 500ms (at 0°)	Yes	
Voltage interruption as per IEC 61000-4-11	100% 5000ms	Yes	If the user of the INSUFFLATOR requires continued functioning even in the event of power interruptions, it is recommended that the INSUFFLATOR be powered from an uninterruptible power supply!

Treatment symbols

	Protect from moisture
	Protect from direct sunlight
	Caution: fragile
	This side up
	Storage and transport conditions Temperature range (from ..to ..)
	Storage and transport conditions Pressure range (from ..to ..)
	Storage and transport conditions Humidity range (from ..to ..)

Maintenance log

Operator	
Address	
Serial no.:	

Maintenance activities	Surname	Date	Signature

Operator	
Address	
Serial no.:	

Maintenance activities	**Surname**	**Date**	**Signature**

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