KARL STORZ — ENDOSKOPE

en

Instructions for use
ENDOFLATOR 50

10-2024

CE 0123

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1 General information

1.1 Read the instructions for use

If the instructions for use are not followed, patients, users, and third parties may be injured or the product may be damaged.

- Read the instructions for use carefully and follow all the safety notes and warnings.
- Read the reprocessing instructions carefully and follow all the safety notes and warnings. The reprocessing instructions can be downloaded from www.karlstorz.com/ifu by entering the item number.
- Keep the instructions for use and reprocessing instructions in a safe place.

1.2 Read the instructions for use of compatible products

If the instructions for use of compatible products are not followed, patients, users, and third parties may be injured or the product may be damaged.

- Read the instructions for use of the compatible products carefully and follow all the safety notes and warnings.
- Read the reprocessing instructions of the compatible products carefully and follow all the safety notes and warnings.

1.3 Scope

The products listed here may not yet be available in all countries due to differences in approval requirements.

This instruction manual is valid for:

Insufflators With Heating

Product name	Item number
ENDOFLATOR 50	UI500

Tubing Sets

Product name	Item number
Insufflation Tube	UI004

1.4 General signs and symbols

The signs and symbols used in this document have the following meaning:

Practical tip

ⓘ This sign refers to useful and important information.

Actions to be performed

Action to be carried out by several steps:

✓ Prerequisite that must be met before carrying out an action.

1. Step 1
   ⇨ Interim result of an action
2. Step 2

⇨ Result of a completed action

Actions in the case of a single step:

▶ Step 1

Actions in safety notes:

▷ Step 1

▷ Step 2

Lists

1. Numbered list
   – Unnumbered list, 1st level
      – Unnumbered list, 2nd level

1.5 Description of warning messages

To prevent any injury to persons or damage to property, the warnings and safety notes in the instructions for use must be observed. The warnings use the following levels of danger:

⚠ WARNING

WARNING

Designates a possible imminent risk. If this is not avoided, it could lead to death or serious injuries.

⚠ CAUTION

CAUTION

Designates a possible imminent risk. If this is not avoided, it could lead to minor injuries.

NOTICE

NOTICE

Designates a possibly harmful situation. If this is not avoided, the products could be damaged.

2 Normal use

2.1 Intended use

Insufflators with heating

Insufflators with heating are intended to deliver and heat CO_2 for insufflation (creating and maintaining a cavity) or replacement of ambient air in laparoscopy, thoracoscopy, transanal endoscopy and endoscopic vessel harvesting. Insufflators are non-invasive and meant for short-term use.

Tubing sets

Tubing sets for insufflation are intended for transfer of CO_2 from the insufflator to the patient. Tubing sets for insufflation are non-invasive and meant for shortterm use.

2.2 Indications

The insufflator and its accessories are suitable for endoscopic examinations where CO_2 is required for insufflation. This includes:

- Laparoscopy
- Thoracoscopy
- Transanal Surgery
- Endoscopic Vessel Harvesting

2.3 Contraindications

The insufflator and its accessories must not be used for interventions in direct contact with the CNS (central nervous system) and central circulatory system.

Furthermore, there are no contraindications for the use of the insufflator and its accessories directly associated with the product.

2.4 Clinical benefits

The products deliver CO_2 to the patient at a set pressure and/or flow rate to allow the performance of insufflation during the following procedures:

- Laparoscopy: the CO_2 delivered by the insufflator distends the abdominal cavity to establish pneumoperitoneum which permits the visualization and the performance of endoscopic procedures.
- Transanal surgery: the CO_2 delivered by the insufflator distends the rectum and part of the descending colon to establish a cavity which permits the visualization and the performance of endoscopic procedures during transanal surgery.
- Endoscopic Vessel Harvesting: the CO_2 delivered by the insufflator is used to create a subcutaneous tunnel for visualization and dissection.
- Thoracoscopy: the CO_2 delivered by the insufflator is used to collapse the lung to create space for surgical maneuvers and visualization.

2.5 Application risks

The following risks have been identified in clinical literature in connection with insufflation:

- Mild hypothermia
- CO_2 embolism
- Emphysema requiring treatment

- Systemic acidosis
- Pneumothorax
- Hypotension
- Other pulmonary complications
- Other cardiovascular complications
- Postoperative ileus

2.6 Residual risks

No residual risks directly related to the product were identified.

2.7 Target user populations

The medical device may only be used by doctors and medical assistants with a relevant specialist qualification.

2.8 Patient population

There are no restrictions in terms of patient groups for this product.

2.9 Intended conditions of use

The product may only be used in hospitals and doctors' offices in suitable ambient conditions.

Condition	Operation
Frequency of use	One or more times a day
Length of use	Several minutes to several hours a day
Place of installation	Positioning on a level, vibration-free surface above patient height
Mobility	Can be moved if placed on a cart.
Combination	Can be used on the patient at the same time as other devices.
Control	Can be controlled via the KARL STORZ SCB.
Site	Placed outside of the sterile area.

3 Safety and warning

⚠ WARNING

Danger due to non-observance of warnings and safety notes

This chapter contains warnings and safety notes structured according to hazards and risks.

▷ Carefully read and observe all warnings and safety notes.

▷ Follow the instructions.

3.1 Serious incidents

A 'serious incident' includes incidents which, directly or indirectly, had, could have had or could have any of the following consequences:

– Death of a patient, user, or another person

– Temporary or permanent serious deterioration in the medical condition of a patient, user, or another person

– A serious threat to public health

▶ The manufacturer and appropriate authority must be notified of all serious incidents.

3.2 Correct handling and product testing

If the product is not handled correctly, patients, users, and third parties may be injured.

▶ Only persons with the necessary medical qualification and who are acquainted with the application of the product may work with it.

▶ Check that the product is suitable for the procedure prior to use.

▶ Check the product for the following properties, for example, before and after every use:

– Functionality

– Damage

– Changes to the surface

– In the case of several components: completeness and correct assembly

▶ Do not continue to use damaged products.

▶ Dispose of the product properly; see *Disposing of the product*.

3.3 Combination with other components

The use of unauthorized devices and components may result in injuries.

▶ Ensure that any additional devices connected to electrical medical devices comply with the relevant IEC or ISO standards.

▶ Ensure that all configurations comply with the requirements for medical electrical systems.

▶ Only combine the product with devices and components that the manufacturer has approved for combined use, see chapter *Possible combinations*.

▶ Only use devices and components that have standardized interfaces and do not breach the normal use of the product.

▶ Observe the instruction manuals and interface specifications of the devices and components used in combination.

▶ When using RF devices and accessories, it is important to verify normal operation in the configuration in which they will be used.

▶ Do not make any modifications to the product.

3.4 Product not clean

The product is not clean when delivered. The use of products that have not been cleaned poses a risk of infection for patients, users, and third parties.

- Reprocess the product in line with the reprocessing instructions before initial use and every subsequent use.

3.5 Dangers from electrical current

An improper power supply may cause an electric shock and injure patients, users, or third parties.

- Ensure that all electrical installations of the operation room in which the product is connected and used conform with the applicable IEC standards.
- Use either the power cord supplied by KARL STORZ or a power cord which has the same properties and which bears a national mark of conformity.
- The product may only be operated with the line voltage stated on the rating plate.
- Position the product appropriately so that the power cord can be unplugged at any time. The product is only voltage-free when the mains plug has been disconnected.
- Ensure potential equalization according to the applicable national rules and regulations.
- To ensure reliable protective earth grounding, connect the product to a properly installed socket that is approved for use in the operation room.
- Connect the product to a power supply with protective conductor.

In the case of electrical products, individual components or the product itself may be live. Live parts can cause electric shocks in the event of contact and injure patients, users, and third parties.

- Do not open the product.
- Have servicing carried out by KARL STORZ or a company authorized by KARL STORZ.
- Do not touch the output jacks of the product and the patient at the same time during use
- Always pull out the mains plug before carrying out any cleaning and maintenance work.

If several products supplied with energy are used simultaneously, the patient leakage currents accumulate. These leakage currents can exceed the limit values and injure patients.

- Only use products of the same type, for example, endotherapy device and application part of type CF.

3.6 Damage due to ingress of liquid in electrical components

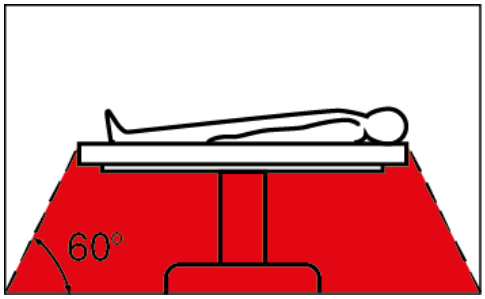
In the case of electrical products, individual components or the product itself may be live. Liquid ingress into an electrical product may result in a short circuit or an unintentional transfer of current. The product is damaged as a result and patients, users and third parties may be injured.

- Do not store liquids near the product or on the product.
- If liquid has entered the product, pull out the plug and allow the product to dry completely.

3.7 Risk of explosion and fire

The product can generate sparks, which cause combustible or flammable gases and liquids to ignite or explode. This may cause injuries to patients, users, and third parties.

- When using explosive narcotic gases: Operate the product outside of the hazard zone.



- Do not use the product in the presence of flammable anesthetics.
- The product must not be operated in oxygenated environments.
- Only connect or disconnect the power plug to or from the power supply outside explosive atmospheres.

3.8 Electromagnetic interference

Medical electrical devices are subject to special precautions regarding electromagnetic compatibility. If other devices (e.g., MRT, CT, diathermy, electrocautery, or RFID) emit electromagnetic radiation, the product's functionality may be impaired. High-frequency (HF) communication equipment can affect electrical medical devices and impair their performance.

- During installation and operation of the product, please take note of the information on electromagnetic compatibility, see chapter *Electromagnetic compatibility*.

3.9 Failure of products

The product may fail during use.

- Have a replacement product ready for each application or plan for an alternative surgical technique.

3.10 Observing ambient conditions

If the device is stored, transported, operated or reprocessed under unsuitable conditions, patients, users or third parties may be injured and the device can be damaged.

- Observe the ambient conditions listed in the instructions for use and reprocessing.

3.11 Functionality of the touch screen

If the functionality of the touch screen is limited, the product cannot be used correctly. Patients, users, and third parties may be injured.

- Do not use the product if the touch screen is defective.
- Do not tap the touch screen in several places at the same time.

4 Product description

4.1 Description of operation

The ENDOFLATOR 50 is an insufflation device for universal application in laparoscopic and thoracoscopic examinations and operations as well as transanal endoscopy and endoscopic vessel harvesting. The pressure and flow measurements and the pressure and flow controls can be used in different operating modes tailored to specific applications. The High Flow and Pediatrics modes can be selected.

For especially sensitive applications, the Pediatrics mode is available. The mode offers control with low insufflation pressure and special safety limits in the pressure and flow area. At low flow rates, a tighter control of the flow rate is possible.

The ENDOFLATOR 50 is designed for a high flow rate of up to 50 l/min for quick compensation of heavy gas losses during complicated laparoscopic operations. Insufflation tubes are available which heat the insufflation gas to body temperature.

The ENDOFLATOR 50 is operated directly on the touchscreen or from an external control center via the SCB interface. All data during the current operation is displayed simultaneously on the touchscreen.

4.2 Product overview

ENDOFLATOR 50 (UI500) – Front view

1 Power switch
2 Touch screen
3 Insufflation connection to the patient
4 Connection for patient tube heating
5 Room temperature sensor

ENDOFLATOR 50 (UI500) – Rear view

1 Gas connection (standard American type)
2 SCB sockets
3 Potential equalization connector
4 Power socket
5 Power fuse holder

Insufflation tube (UI004)

Holder for CO_2 cylinder, optional (UI005)

4.3 Possible combinations

It is recommended that the suitability of the products for the intended procedure be checked prior to use. Please note that the described products in this medium may not be available in all countries due to different regulatory requirements.

The product can be combined with gas filters or gas filters with connected insufflation tube. The product can also be combined with CO_2 supply tubes via the connection for high and low pressure tubes.

The product can be combined with the following components:

ENDOFLATOR 50	Gas filters and insufflation tubes
UI500	031200-10 031210-10 031122-25 UI004 UI007

Combinations with other products

Additional devices that support SCB can be connected via the SCB connection cable (20090170).

Expanded combinations

Can be combined with access systems with LUER-Lock connector.

Can be combined with access systems with HiCap connector.

4.4 Technical data

Designation	Value
Operating voltage (AC)	100–240 V
Operating frequency	50/60 Hz
Mains fuse	2 x T 2.5 AH 250 V
Average power input during flow 40 l/min (input pressure 60 bar)	230 W
Maximum current consumption	1.8 A
Electrical protection class	I

Designation	Value
Applied part type according to IEC 60601-1	CF
Degree of protection acc. to IEC 60529	IP 21
Gas input (maximum pressure)	100 bar
Maximum output pressure	Pediatrics 30 mmHg / High Flow 50 mmHg
Dimensions (W x H x D)	305 x 164 x 351 mm
Weight	7.7 kg

Mode	Intracavitary pressure	Flow
Pediatrics	1–15 mmHg Resolution: 1 mmHg	0.1–15 l/min Resolution: 0.1–2 l/min: 0.1 l/min 2–9.5 l/min: 0.5 l/min 10–15 l/min: 1 l/min
High Flow	1–30 mmHg Resolution: 1 mmHg	1–50 l/min Resolution: 1 l/min

4.5 Symbols employed

4.5.1 Symbols on the packaging

Symbol	Meaning
	Manufacturer
	Date of manufacture
	Medical device
	Article no.
	Serial number
	Batch code
	Number of products in the product packaging
	Unique Device Identifier
	Consult the printed or electronic instructions for use

Symbol	Meaning
	Unsterile
	Fragile, handle with care
	Keep dry
	Temperature limit
	Humidity limit
	Air pressure limit
	Transport conditions
	In one combined field surrounded by a border with the “conditions for transport” symbol: Temperature limit for transport
	In one combined field surrounded by a border with the “conditions for transport” symbol: Humidity, limit for transport
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	CE marking With this marking, the manufacturer declares the conformity of the product with the applicable EU regulations. A code number after the CE mark indicates the responsible notified body. The EU regulations relevant to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ.

4.5.2 Symbols on the product

Symbol	Meaning
	Follow the instructions for use. The color may differ on the product. The symbol is black/white on the packaging label.
	ON
	OFF
	Potential equalization connector
	Applied part of the type CF

4.5.3 Symbols on the type plate

Symbol	Meaning
	Manufacturer
	Date of manufacture
	Applied part of the type CF
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	Prevention of pollution by electronic devices
	Separate collection of electrical and electronic devices. Do not dispose of in household refuse.
	CE marking With this marking, the manufacturer declares the conformity of the product with the applicable EU regulations. A code number after the CE mark indicates the responsible notified body. The EU regulations relevant to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ.

4.5.4 Symbols on the user interface

Symbol	Meaning
	Scroll back to the previous screen
	Call up settings
	Call up procedure list
	Call up working area
	Delete procedure
	Increase value
	Decrease value
	Confirm entry
	Cancel entry
	Start/stop
	Pediatrics mode

Symbol	Meaning
	High Flow mode
	Gas bottle
	House connection
	Flow
	Pressure
	Alarm audio paused (30 s)
	Safety valve switched off
	House connection; input pressure OK
	House connection; input pressure too low or too high
	Gas bottle; input pressure > 30 bar
	Gas bottle; input pressure 20 – 30 bar
	Gas bottle; input pressure 10 – 20 bar

Symbol	Meaning
	Gas bottle; input pressure <10 bar
	Gas bottle; input pressure 1 bar
	Gas bottle; input pressure too high
	Gas consumption display (four-digit)
	Patient tube heating active
	Patient tube heating, heating control defective

4.6 Ambient conditions

For UI500

Transport and storage conditions	
Temperature	-10°C ... +60°C (14°F ...140°F)
Relative humidity (non-condensing)	5 – 95 %
Air pressure	500 – 1,080 hPa

Operating conditions	
Temperature	10°C ... 35°C (50°F ... 95°F)
Relative humidity (non-condensing)	15–85%
Max. operating altitude	3,000 m

For UI004

Transport conditions	
Temperature	-29 °C ... +50 °C (-20 °F ... +122 °F)
Relative humidity (non-condensing)	5 – 85 %

Storage conditions	
Temperature	-10°C ... +60°C (14°F ...140°F)

Operating conditions	
Temperature	10°C ... 35°C (50°F ... 95°F)
Relative humidity (non-condensing)	15–85%
Max. operating altitude	3,000 m

4.7 Safety features

4.7.1 Self-test

During power-up, the product performs a self-test when it is supplied with gas. If the self-test is negative, a corresponding error message is displayed and the product cannot be used properly.

The following tests are performed:

- Tightness test of the system (valves)
- Test of the pressure measurement
- Test of the flow measurement
- Functionality of the patient tube heating control

4.7.2 Monitoring during operation

The following parameters are monitored during operation:

- Excess pressure

  As soon as the intracorporeal pressure exceeds the specified setpoint value for more than 3 seconds during insufflation, an acoustic signal sounds and the gas supply is stopped. The excess pressure is decreased after 4 seconds when the safety valve is active.
- Operating mode-specific pressure
- Remaining gas supply

  If there is no CO_2 gas when the product is switched on, a warning signal sounds. A visual and acoustic alarm is output when the gas bottle is empty and the insufflation stops.
- Gas preheater

  The internal gas preheating is monitored by a second circuit, independently of the control. If a fault arises, the heating is switched off.
- Gas temperature to the patient

  The gas temperature and the energy output are recorded. If a system error occurs, the heating is switched off and the color of the symbol for the patient tube heating changes from white to red. This ensures that the gas temperature does not increase above 41 °C. Insufflation with cold CO_2 is still possible.

4.7.3 Passive safety measures

The product is equipped with the following safety measures:

- The pressure and flow recording are redundant.
- Both pressure control stages and the flow recording are equipped with safety pressure release valves.
- The function of the mechanical high pressure controller is monitored.

If the monitoring system detects a fault that prevents the safe functioning of the product, the product is put into "safe mode". The product can only be reset from this mode when the power supply is switched off.

5 Preparation

5.1 Unpacking the product

1. Carefully remove the product and accessories from the packaging.
2. Check the delivery for possible damage.
3. In the case of damage, hidden defects, and short deliveries, document their nature and extent and contact the manufacturer or supplier immediately.
4. Keep packaging for further transport.

5.2 Reprocessing the product

▶ Reprocess the product in line with the reprocessing instructions before using it.

5.3 Setting up the product

⚠ WARNING

Contamination! Risk of infection!

Gas and body fluid that flows back may contaminate the product. Patients, users, and third parties may be infected and the product may be damaged.

▷ Place the product higher than the patient.

When the product is installed, the position of the user must be taken into account. When operating the product, the user stands within a viewing cone with an angle of view of ±45° at a distance of approx. 30 to 70 cm from the front panel. For observation of the actual values during the application, a visual distance from the product of 2 m is assumed.

1. Place the product on a flat horizontal surface.
2. Place the product so that it can be visually observed during use.
3. Keep the product out of reach of patients.
4. Ensure adequate air circulation.

5.4 Installing the bottle holder (option)

The CO_2 bottle can be fastened to the product.

1. Screw the bottle holder to the back of the product using the enclosed screws (6 mm).

2. Insert the CO_2 bottle into the holder vertically and secure it using the locking clip.

5.5 Connecting the product

1. Connect the potential equipotential cable.

2. Connect the power cord. Push the power plug fully into the power socket.

3. Connect the SCB cable.

4. Connect the other end of the SCB cable to a KARL STORZ control device or other SCB devices; see the instructions for use for the OR1 SCB CONTROL.
5. To remove the SCB cable, pull on the plug. The SCB cable is equipped with a protection device to prevent if from being pulled out accidentally.

6. Connect the product to the central gas supply with the low-pressure tube (3.3 to 7 bar).

7. Alternatively, connect the product to a gas bottle.

5.6 Connecting a gas bottle

⚠ WARNING

Wrong gas! Risk of injury!

If the wrong gas is used, patients, users, and third parties can be injured.

- ▷ Only use medical CO_2 gas.

⚠ WARNING

Wrong placement! Risk of injury!

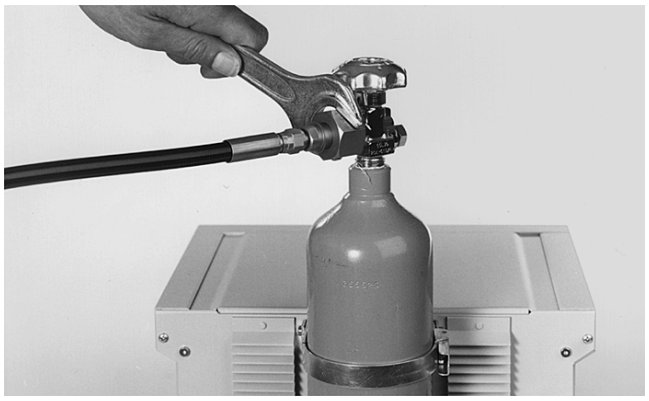
If the CO_2 bottle is incorrectly placed, patients, users, and third parties can be injured. The product can be damaged and its functionality cannot be guaranteed.

- ▷ Ensure that the CO_2 bottle is in a vertical position.
- ▷ Secure the CO_2 bottle to prevent it from falling over.

ⓘ When using a CO_2 bottle, the use of a filter is recommended. Contamination due to unclean gases can lead to product failure.

1. Connect the CO_2 gas tube to the product's KARL STORZ insufflator connector.

2. For a German connection to the CO_2 gas bottle (W21.8x1/14 thread) or an ISO connection to the CO_2 gas bottle (W27x2 thread), place the high-pressure tube on the outlet opening of the CO_2 bottle and screw it tight.



3. Then open the valve stopcock of the CO_2 bottle with an approx. ½ turn counterclockwise.

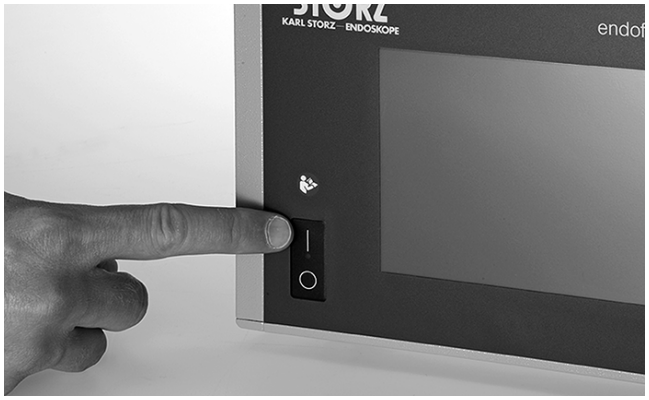
4. Alternatively, for a PIN-Index connection to the gas bottle, place the connecting piece of the high-pressure tube on the CO_2 bottle and screw it tight.

5. Then open the CO_2 bottle with the wrench.

5.7 Putting the product into operation

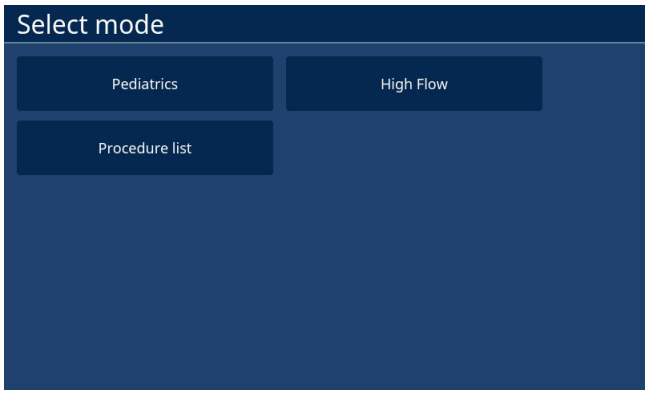
1. Ensure that the gas is connected.

2. Turn on the product using the power switch.

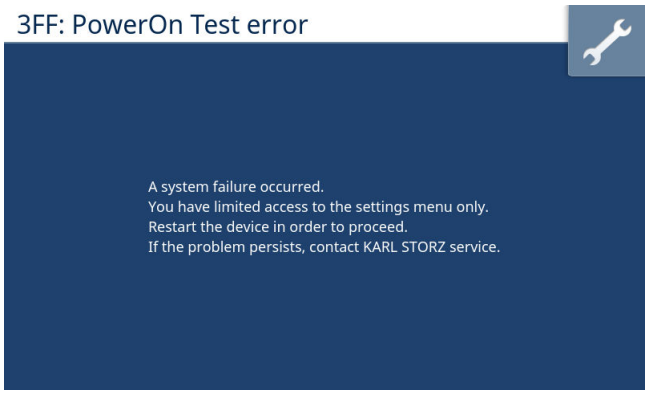


⇨ The following start screen appears and the self-test is performed:

⇨ After a successful self-test, the information signal sounds and the mode selection appears:



⇨ The following messages are possible during the self-test:



3. If there is pressure on the device output, close the stopcock.
4. If the stopcock cannot be closed, remove the insufflation tube to allow the self-test to be performed without pressure.
5. If the self-test fails, switch the product off and on and check whether the product is connected correctly.

5.8 Selecting the mode

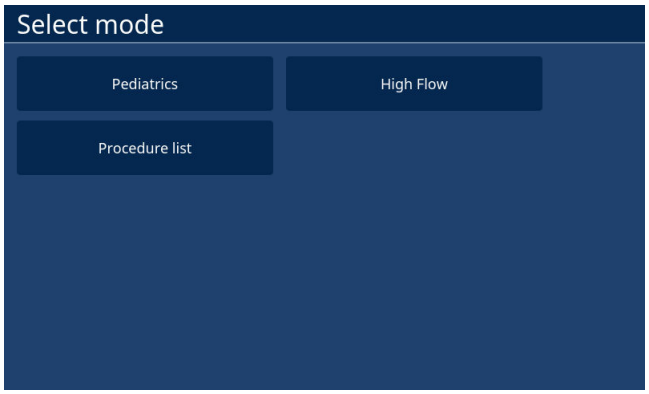
⚠ CAUTION

Product not ready for use! Risk of injury!

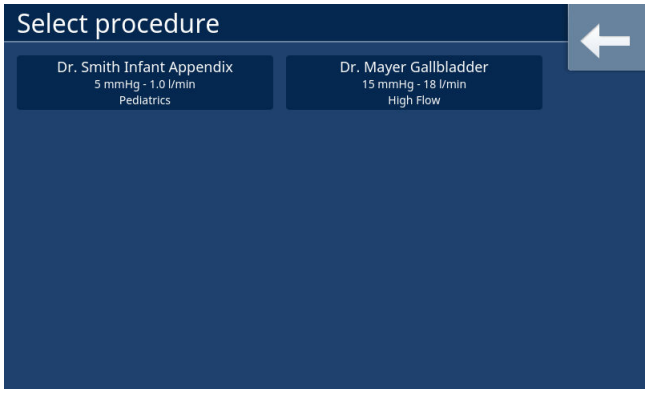
Using the product once the mode has been selected but the product is not yet ready for use may injure the patient.

- ▷ After selecting the mode, always wait for the ready signal to sound before using the product.
- ▷ If the ready signal does not sound, do not continue to use the product.

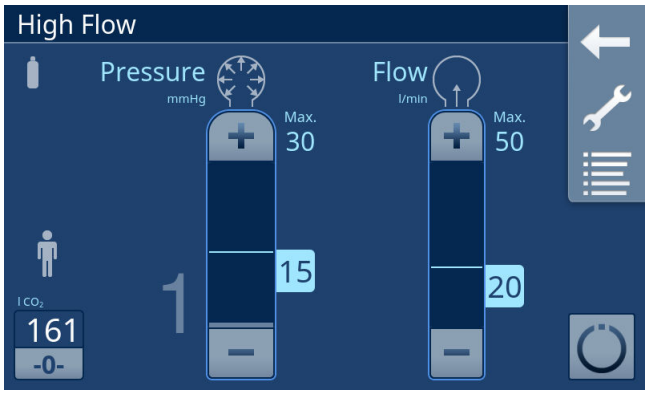
1. Start the product.
   - ⇨ Mode selection appears:



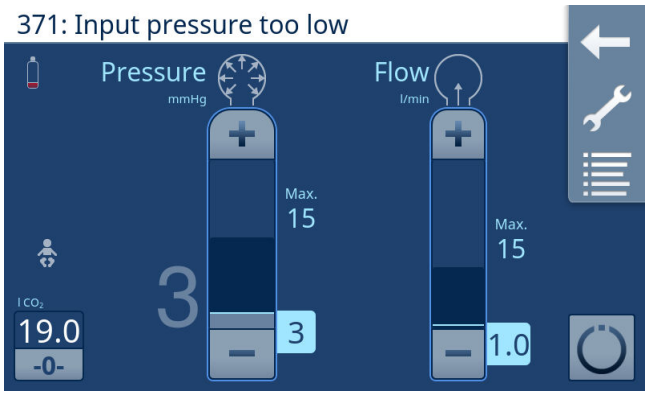
2. In the procedure list, select the desired mode or a procedure. At least one procedure must be stored for the procedure list to appear.



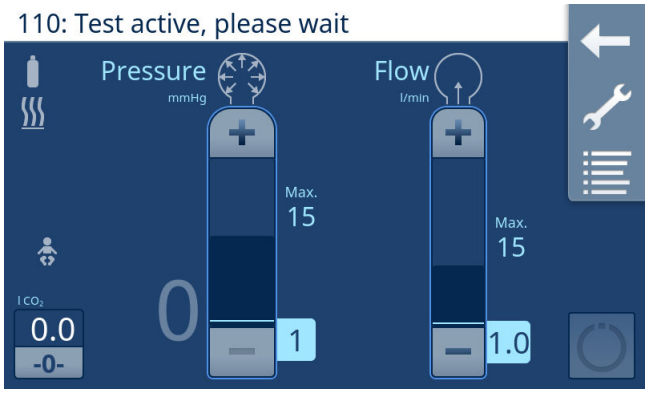
⇨ An availability signal sounds and the screen with the working area of the selected mode appears; e.g., High Flow:



⇨ If no gas is connected or the input pressure is too low, the following error message appears:



3. Check whether the gas bottle is open or has to be replaced.
   ⇨ If the gas supply was provided late, the self-test has been delayed and the following message appears:



The intended use is only possible after the self-test has been successfully completed.

The last operating parameters used for a mode are saved and called up again after a successful restart:

Mode	Operating parameter	Setting	Setting after restart
High Flow	Pressure	1–15 mmHg	1–15 mmHg
		16–30 mmHg	15 mmHg
	Flow	1–20 l/min	1–20 l/min
		≥ 21 l/min	20 l/min
Pediatrics	Pressure	1–12 mmHg	1–12 mmHg
		13–15 mmHg	12 mmHg
	Flow	0.1–1 l/min	0.1–1 l/min
		≥ 1.1 l/min	1 l/min

5.9 Connecting the insufflation filter and insufflation tube

⚠ WARNING

Expiry date passed! Risk of infection!

- ▷ Check the expiry date.
- ▷ Check the packaging for damage.
- ▷ Never use products that have passed the expired expiry date or have damaged or accidentally opened packaging but dispose of them properly.

⚠ WARNING

Disposable products! Risk of infection!

The reprocessing of disposable products can lead to infections in patients, users and third parties as well as damage to the product.

- ▷ Never reprocess disposable products.
- ▷ Dispose of disposable products in accordance with the applicable regulations.

⚠ WARNING

Contamination! Risk of infection!

Gas and body fluid that flows back may contaminate the product. Patients, users, and third parties may be infected and the product may be damaged.

- ▷ Use a sterile insufflation filter between the insufflation connection and the insufflation tube.
- ▷ Replace the insufflation filter after every use.

⚠ CAUTION

Wrong tubing set! Risk of injury!

If a heatable insufflation tubing set from KARL STORZ is not used when the patient tube heating is utilized, the product can be damaged. A damaged product can injury the patient.

- ▷ Only operate the product with a heatable insufflation tubing set from KARL STORZ.

1. Attach the sterile insufflation filter to the insufflation connection.

2. Attach the insufflation tube to the insufflation filter.
3. Connect the other end of the insufflation tube to the VERESS needle or the trocar.

ⓘ In the case of the single-use insufflation tube set, the insufflation filter is firmly connected to the tube.

5.10 Connecting the heatable patient tube

⚠ WARNING

Expiry date passed! Risk of infection!

- ▷ Check the expiry date.
- ▷ Check the packaging for damage.
- ▷ Never use products that have passed the expired expiry date or have damaged or accidentally opened packaging but dispose of them properly.

⚠ WARNING

Disposable products! Risk of infection!

The reprocessing of disposable products can lead to infections in patients, users and third parties as well as damage to the product.

- ▷ Never reprocess disposable products.
- ▷ Dispose of disposable products in accordance with the applicable regulations.

⚠ CAUTION

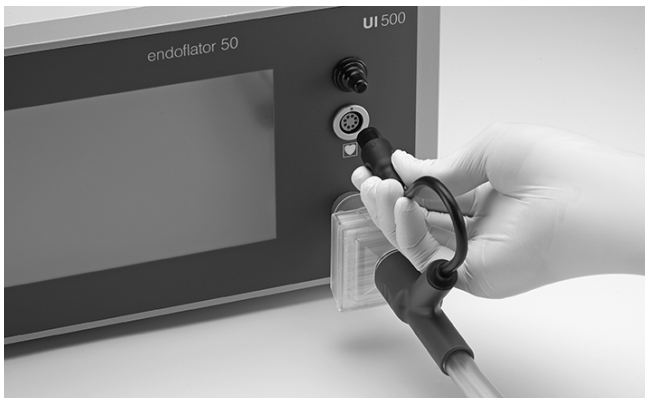
Wrong tubing set! Risk of injury!

If a heatable insufflation tubing set from KARL STORZ is not used when the patient tube heating is utilized, the product can be damaged. A damaged product can injury the patient.

- ▷ Only operate the product with a heatable insufflation tubing set from KARL STORZ.

The gas can be preheated to body temperature.

1. Connect the heatable insufflation tubing set (article no. 031210-10).



   ⇨ The heating function is active and appears in the working areas with the following symbol:

   ⇨ The CO_2 gas is heated to body temperature and automatically adapts to various flow rates.

2. If the heating symbol appears red, the control of the patient tube heating is defective; remove the connecting cable and perform the insufflation without heating.

5.11 Checking the functioning and sealing before use

⚠ CAUTION

Leakage! Risk of injury!

If the system is leaky, the intraabdominal pressure can increase uncontrollably.

- ▷ Check the system for leaks.
- ▷ Only work with a leak-tight system.

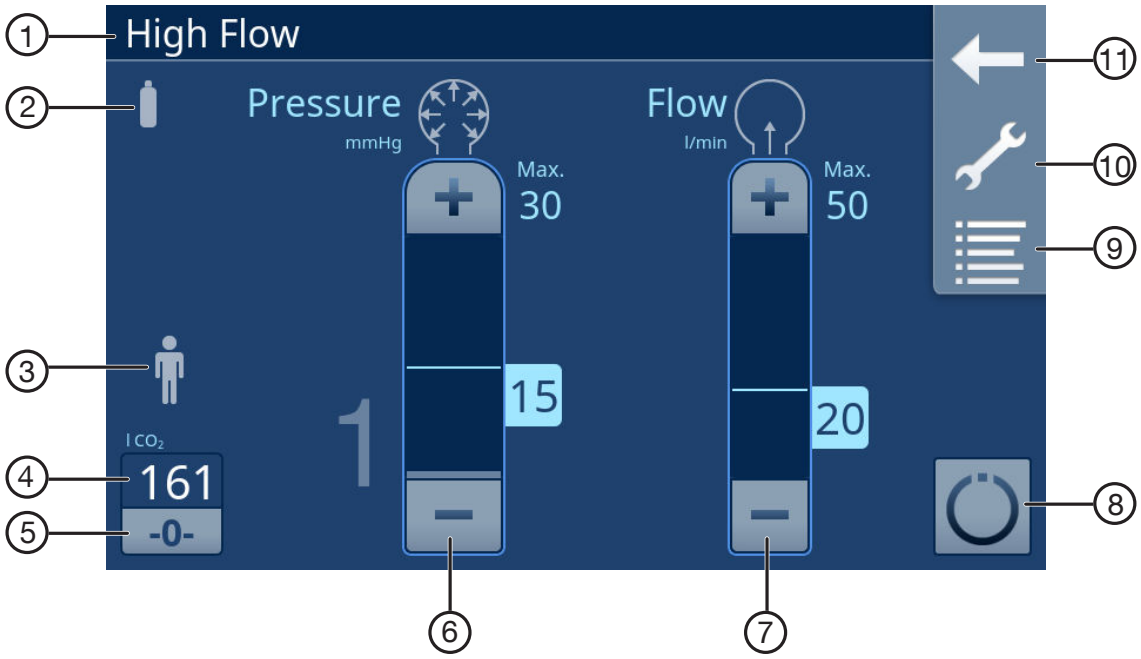
1. Select the desired mode, e.g., **Pediatrics**; see chapter *Selecting the mode* [p. 30].
2. Set the setpoint values 12 mmHg and 1 l/min.
3. Connect the instrument, e.g. trocar or Veress needle, to the insufflation tube and open the insufflation stopcock on the instrument.
4. Start the insufflation.
   ⇨ After approx. 10 s, the flow display reaches stationary conditions with 1 l/min ±0.1 l/min.
   ⇨ The cavity pressure remains at 0 mmHg.
5. If no flow is displayed, do not use the product and send it in for repair.
6. If the pressure is not 0 mmHg but another positive or negative value is shown, remove the insufflation tube and switch the product on and off again. Then start again with step 3.

7. Close the insufflation stopcock on the instrument.
   ⇨ Pressure is built up, rises above the setpoint value, and is reduced after a few seconds via the safety valve.
   ⇨ Depending on the mode and instrument, the message “301: Occlusion” or alarm “303: High pressure” appears.
8. Observe the instrument behavior for approx. 20 s.
   ⇨ When the message “301: Occlusion” appears, a steady pressure between the setpoint value and the maximum adjustable pressure is established after a maximum of 4 insufflation blows.
   ⇨ When the alarm “303: High pressure” appears, the pressure build-up and pressure reduction are repeated cyclically.
   ⇨ The flow display may only have values > 0 l/min for a short time. If the target pressure is reached only slowly when the insufflation stopcock is closed or a stationary flow value of 0.2 l/min or higher occurs, the filter/patient tube/instrument system is leaky.
9. Check the plug connections and replace the tubing set if necessary.

6 Application

6.1 Working area

When a mode has been selected, the working area of the mode appears. In the working area, the setpoint values for pressure and flow are set and the insufflation can be started directly. The procedure list and the settings can be called up in the working area.



1	Mode	7	Set flow values
2	Gas bottle pressure display	8	Start and stop insufflation
3	Mode symbol (High Flow, Pediatrics)	9	Procedure list
4	Gas consumption display	10	Settings
5	Reset gas consumption display	11	Browse back
6	Set pressure values		

6.2 Setting operating parameters

⚠ CAUTION

Excess pressure! Risk of injury!

Excess pressure or flow can lead to embolisms, emphysema, etc. This may harm the patient.

- ▷ Select the lowest possible pressure and flow needed to achieve the desired distension.
- ▷ Observe warning messages.
- ▷ If an excess pressure warning occurs, observe the functions of the product.
- ▷ If the insufflation or the safety valve is deactivated, take suitable measures to reduce the pressure.

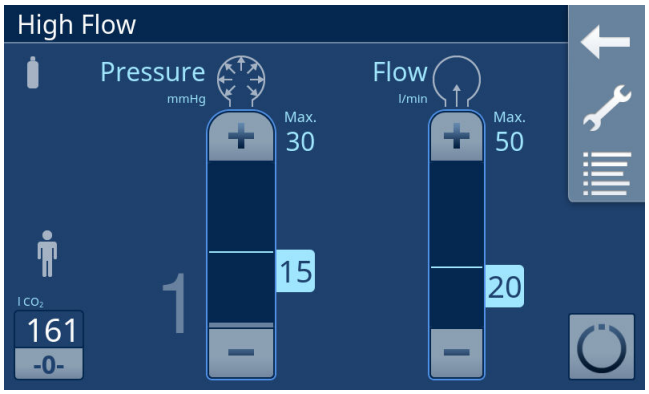
⚠ CAUTION

Interruption of gas supply! Risk of injury!

If the gas supply is interrupted, the necessary cavity may collapse. This will restrict carrying out the rest of the procedure and the patient may be harmed.

- ▷ Observe warning messages.
- ▷ If a warning is displayed, stop the procedure and restore the gas supply.
- ▷ Restart insufflation.

1. Select the desired mode, e.g., **High Flow**, see chapter *Selecting the mode* [p. 30].
   - ⇨ The last operating parameters used appear in the working area:



2. If the required cavity pressure is ≤ 15 mmHg and a maximum flow of 15 l/min is sufficient, select **Pediatrics** mode.
3. Check the preset setpoint values for **Pressure** and **Flow** and adjust them with the **Plus** and **Minus** buttons. Use the lowest possible pressure and flow values for insufflation.
4. Alternatively, open the procedure list and select a stored procedure, see chapter *Opening the procedure list* [p. 39].

⇨ The working area of the selected procedure appears.

Recommended settings

Mode	Group	Weight	Flow range
Pediatrics	Children < 1 year	approx. 1–9 kg	0.1–0.5 l/min
	Children 1–3 years	approx. 10–15 kg	0.5–1.0 l/min
	Children 3–4 years	approx. 16–19 kg	1.0–2.0 l/min
	Children 4–14 years	≥ 20 kg	> 2.0 l/min
	All children	< 25 kg	≤ 14.0 l/min

The flow rates for laparoscopic interventions in newborns, infants, toddlers, and children are recommendations. The treating physician is solely responsible for selecting suitable flow and pressure values.

6.3 Performing insufflation

⚠ CAUTION

Increased intercavitary pressure! Risk of injury!

If external forces act on the cavity, the intercavitary pressure can increase and pressure fluctuations can result. This can cause injury to the patient.

- ▷ Make sure that no external forces are acting on the cavity.

⚠ CAUTION

Continuous operation! Risk of injury!

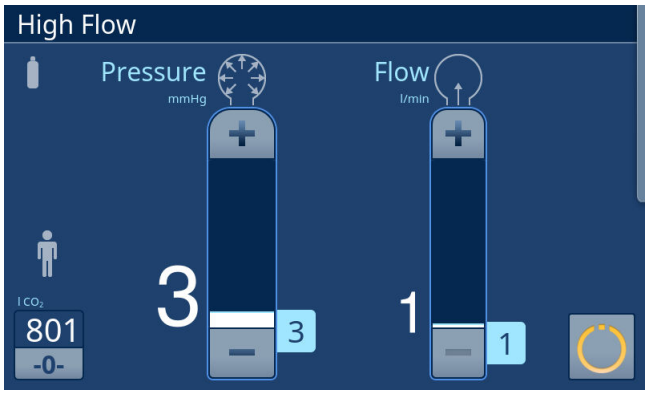
If the product is operated for longer than 24 hours, the safety and functionality of the product is no longer guaranteed. Patients, users, and third parties can be injured.

- ▷ After 24 hours of continuous operation, switch off the product and disconnect the patient tube.
- ▷ Switch the product on again.
  - ⇨ The self-test of the safety system is carried out.
  - ⇨ There must not be any pressure at the device output; otherwise no self-test can be performed and correct operation cannot be guaranteed.
- ▷ Before starting the operation, observe the warning messages on the product.

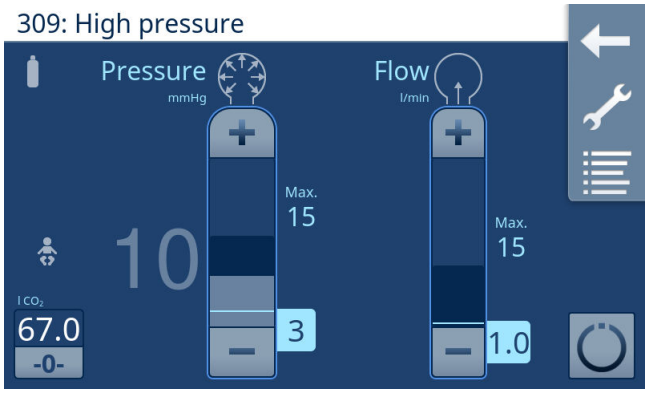
1. Before starting insufflation, rinse the entire system with 1 l CO_2.
2. When a heatable insufflation tubing set is used, switch the device on and preheat it at least 5 minutes before use.
3. Tap the **-0-** button to reset the volume display of the gas consumption.

4. In the case of single-use tubing sets, cut the tube off behind the LUER-Lock connector if a HICAP connector is used. In the case of reusable insufflation tubes, disconnect the male LUER-Lock.
5. Introduce the VERESS needle and open the locking lever.

6. Tap the **Start/Stop** button to start the insufflation.
   ⇨ The pressure, flow, and volume of the consumed gas are continuously displayed.



   ⇨ If the patient pressure rises above the preset value, an acoustic warning signal sounds and the pressure is reduced via the safety valve after 4 s delay time.



To utilize the maximum flow in the High Flow mode, HiCap instruments fitted with a suitable connection must be used. The LUER lock connector at the end of the insufflation tube must be removed.

6.4 Ending the insufflation

1. Close the valve of the CO_2 bottle.
2. Remove the insufflation tube and the insufflation filter from the product.

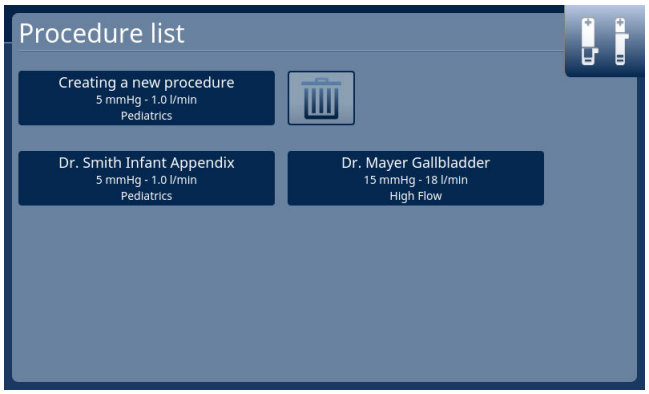
The Secuvent safety valve is not suitable for reducing pressure after the intervention.

6.5 Opening the procedure list

The pressure and flow values of a mode can be stored in the procedure list. In the procedure list, stored procedures can be called up and new procedures can be stored. A maximum of 30 procedures can be stored; the last used procedure is at the top of the procedure list.

✓ A mode is selected (see chapter *Selecting the mode* [p. 30]).

1. In the working area of the mode, tap the **Procedure list** button.
   ⇨ The procedure list appears:



2. Tap the **Working area** button to open the working area.

6.6 Creating a procedure

✓ A mode is selected (see chapter *Selecting the mode* [p. 30]).

✓ The values for the procedure have been entered, Setting operating parameters.

1. Open the procedure list, Opening the procedure list.
2. In the procedure list, tap the **Create a new procedure** button.
   ⇨ The **Assign procedure name** screen appears:

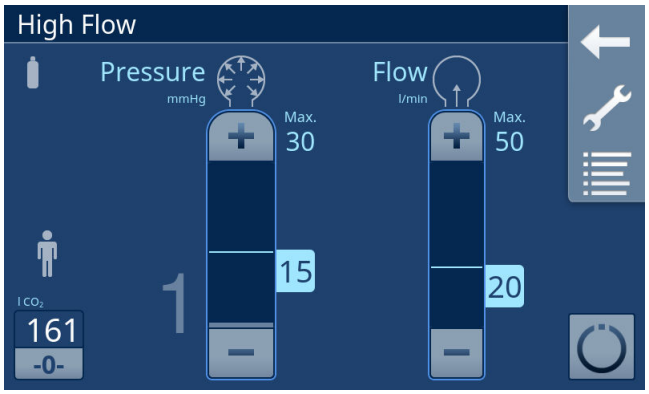
3. Enter the procedure name and confirm.

⇨ The procedure is stored in the procedure list and the working area of the selected procedure appears.

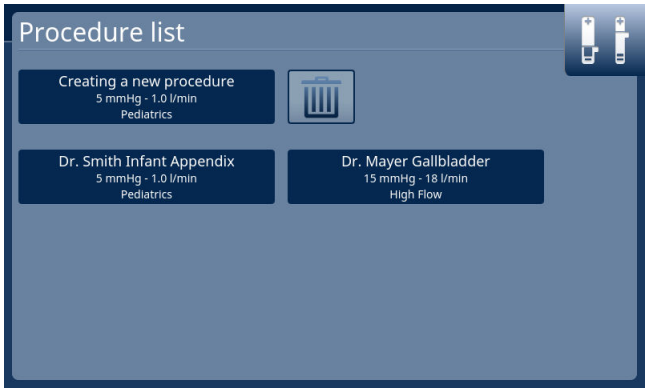
6.7 Editing a procedure

✓ The procedure list is open, see chapter *Opening the procedure list* [p. 39].

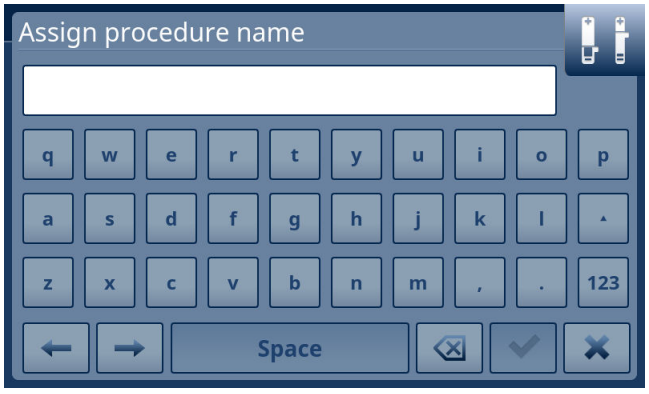
1. Tap a procedure in the procedure list.
   ⇨ The working area of the selected procedure appears, e.g. **High Flow**:



2. Adjust the setpoint values for **Pressure** and **Flow** with the **Plus** and **Minus** buttons.
3. Tap the **Procedure list** button.
   ⇨ The procedure list appears:



4. In the procedure list, tap the **Create a new procedure** button.
   ⇨ The **Assign procedure name** screen appears:



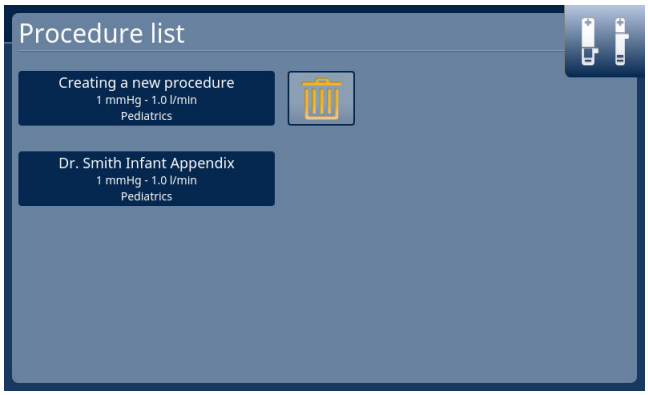
5. Enter the existing procedure name again and confirm.

⇨ The new values are saved in the existing procedure, and the working area of the selected procedure appears.

6.8 Deleting a procedure

✓ The procedure list is open, see chapter *Opening the procedure list* [p. 39].

▶ In the procedure list, tap the **Delete procedure** button and then tap the procedure.



⇨ The procedure is deleted.

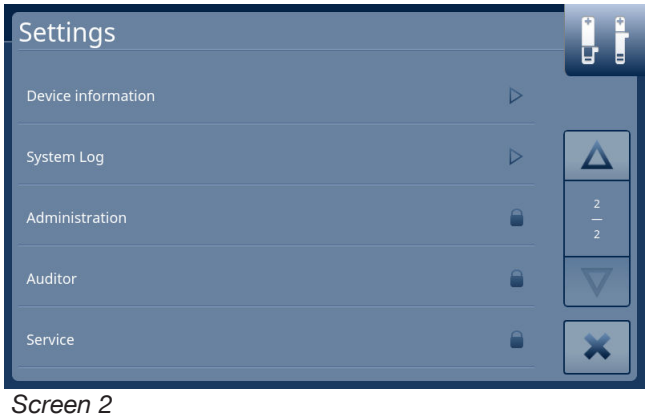
6.9 Settings

The settings can be called up in the working area of the respective mode.

1. Tap the **Settings** button.

⇨ The **Settings** screen appears with the following sub-menus:

Screen 1



Screen 2

6.9.1 Setting the language

The screen language is preset to English.

To change the language, proceed as follows:

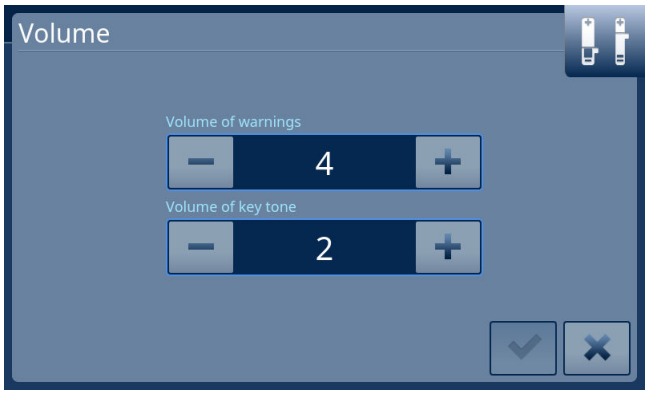
1. In the **Settings** screen, tap on the **Language** sub-menu.
   ⇨ The **Language** screen appears:

2. Select the desired language and confirm.
3. Tap the **Working area** button to open the working area.

6.9.2 Adjusting the volume

The volume for warning signals and button tones can be adjusted.

1. In the **Settings** screen, tap the **Volume** sub-menu.
   ⇨ The **Volume** screen appears:



2. Select the desired volume for **Warning signals** and **Button tone**:
   Adjustment range for warnings: 1 to 4
   Adjustment range for button tones: 0 to 4

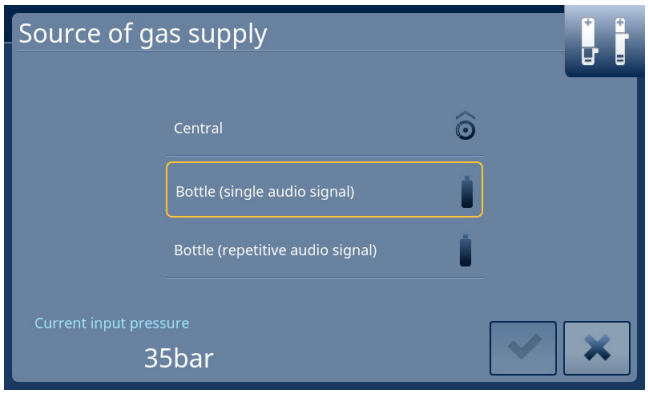
The volume setting for alarms and information signals is summarized under **Warning signals**. The volume setting for alarms and information signals is coupled. Since alarm signals always have to be louder than information signals, the information signal is set to mute at the lowest volume setting *1*.

3. Confirm the settings.
4. Tap the **Working area** button to open the working area.

6.9.3 Selecting the source of gas supply

In the **Source of gas supply** screen, it is possible to specify whether the gas is supplied from a central house connection or from a bottle. If the bottle pressure falls below 10 bar, a warning can be given with a single or recurring audio signal.

1. In the **Settings** screen, tap the **Source of gas supply** sub-menu.
   ⇨ The **Source of gas supply** screen appears:



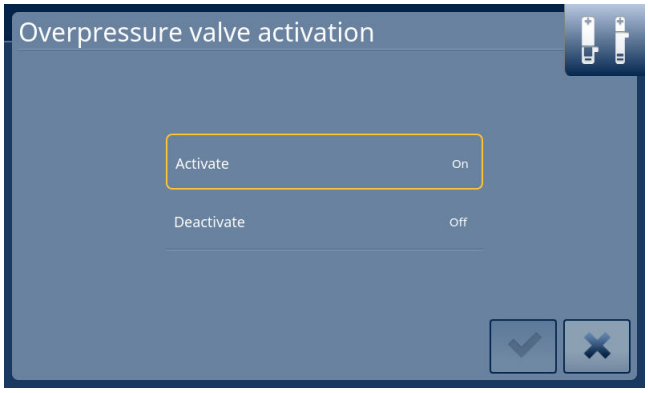
2. Select the *Central* entry for the house connection or the *bottle* entry with desired audio signal.
3. Confirm the selection.
4. Tap the **Working area** button to open the working area.

6.9.4 Activating the safety valve

When the safety valve is activated, excess pressure is reduced after 4 s. When the safety valve is deactivated, the following symbol appears in the working area:

A deactivated safety valve becomes active again after restarting.

1. In the **Settings** screen, tap the **Safety valve actuation** sub-menu.
   ⇨ The **Safety valve actuation** screen appears:



2. Activate or deactivate the safety valve and confirm.
3. Tap the **Working area** button to open the working area.

6.9.5 Device information

1. In the **Settings** screen, tap the **Device information** sub-menu.
   ⇨ The **Device information** screen appears.

2. Tap the **Working area** button to return to the working area.

6.9.6 System log

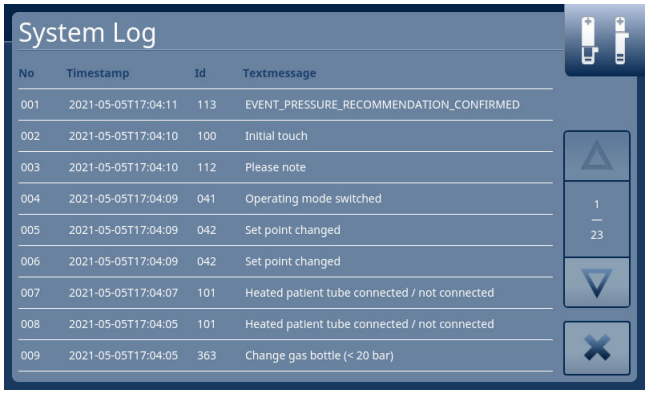
In the system log, alarms as well as user and service information are saved with their time of occurrence. Each entry occupies one row and consists of the following information:

- Consecutive number
- Time stamp
- ID
- Text message

A maximum of 50,000 entries can be saved; the newest entry has the number 000. When the maximum number has been exceeded, the oldest entries are overwritten.

The system log is backed up in the event of voltage drops and when the device is switched off, and it contains entries relating to switch-on and switch-off times. The entries can be exported in the administrator area.

1. In the **Settings** screen, tap the **System Log** sub-menu.
   ⇨ The **System Log** screen appears:



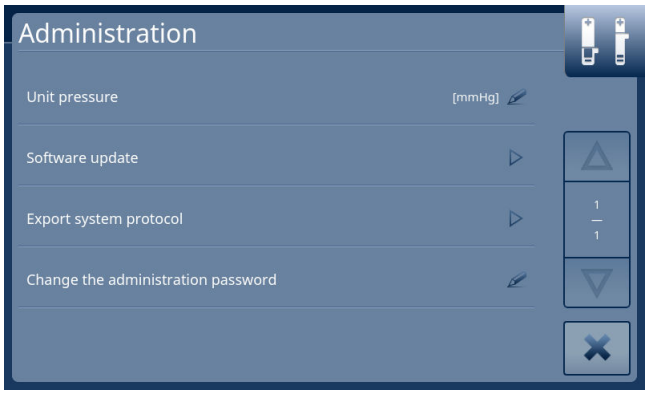
2. Tap the **Working area** button to open the working area.

6.9.7 Administration

The **Administration** screen is password-protected. The password on delivery is `2132`. The operator is responsible for changing the password, if necessary.

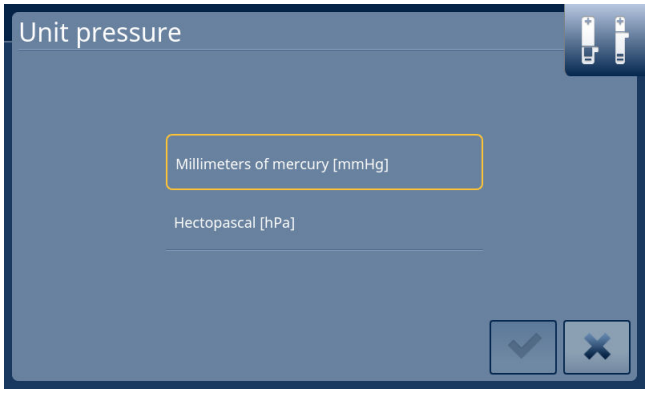
1. In the **Settings** screen, tap the **Administration** sub-menu.
   ⇨ The **Password administration** screen appears:

2. Enter the password and confirm.
   ⇨ The **Administration** screen appears:



6.9.7.1 Setting pressure units

1. In the **Administration** screen, tap the **Unit pressure** sub-menu.
   ⇨ The **Unit pressure** screen appears:



2. Select the desired unit and confirm.
3. Tap the **Working area** button to open the working area.

6.9.7.2 Exporting the system log

For service purposes, data can be exported via the service interface using an USB stick.

1. Remove the cover on the back of the device with a Torx screwdriver (T10).

2. Insert a USB stick into the USB interface.

3. In the **Administration** screen, tap the **Export system protocol** sub-menu.
   ⇨ The export starts.
   ⇨ If the export was successful, the following message appears:

4. Tap the **Working area** button to open the working area.
5. Remove the USB stick and screw the cover onto the back of the device again.

6.9.7.3 Changing the password

1. In the **Administration** screen, tap the **Change administration password** sub-menu.
   ⇨ The **Change administration password** screen appears:

2. Enter the new password and confirm.
   ⇨ The **Change administration password** screen appears:

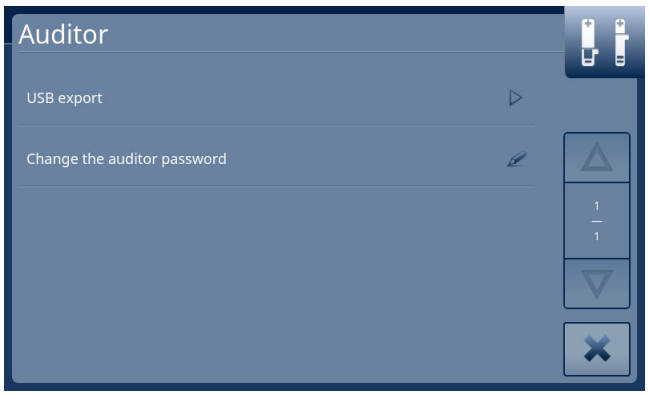
3. Enter the new password again and confirm.
4. Tap the **Working area** button to open the working area.

6.9.8 Auditor

The **Auditor** screen is password-protected. The password on delivery is: `1994`. The operator is responsible for changing the password, if necessary.

1. In the **Settings** screen, tap the **Auditor** sub-menu.
   ⇨ The **Auditor password** screen appears:

2. Enter the password and confirm.
   ⇨ The **Auditor** screen appears:



6.9.8.1 Exporting the audit trail

In audit logs, activities in the system are recorded that concern network and system settings. The collected audit logs can be exported as an audit trail via USB stick.

1. Remove the cover on the back of the device with a Torx screwdriver (T10).

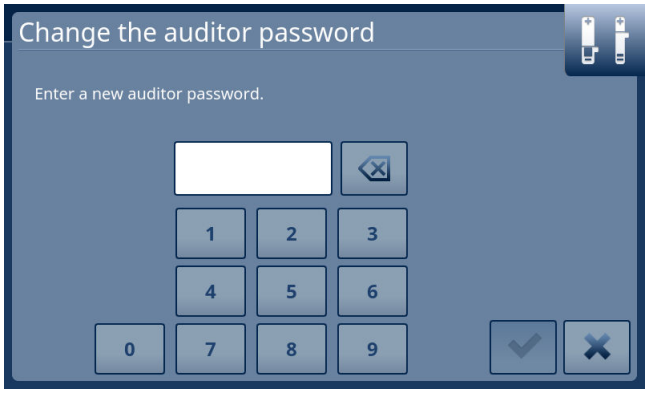
2. Insert a USB stick into the USB interface.

3. In the **Auditor** screen, tap the **USB export** sub-menu.
   ⇨ The export starts.
   ⇨ If the export was successful, the following message appears:

4. Tap the **Working area** button to open the working area.
5. Remove the USB stick and screw the cover onto the back of the device again.

6.9.8.2 Changing the password

1. In the **Auditor** screen, tap the **Change the auditor password** sub-menu.
   ⇨ The **Change the auditor password** screen appears:



2. Enter the new password and confirm.
   ⇨ The **Change the auditor password** screen appears:

3. Enter the new password again and confirm.
4. Tap the **Working area** button to open the working area.

6.9.9 Service

The service area is reserved for the service employees of KARL STORZ. The settings are described in the service manual.

6.10 Alarm and information signals

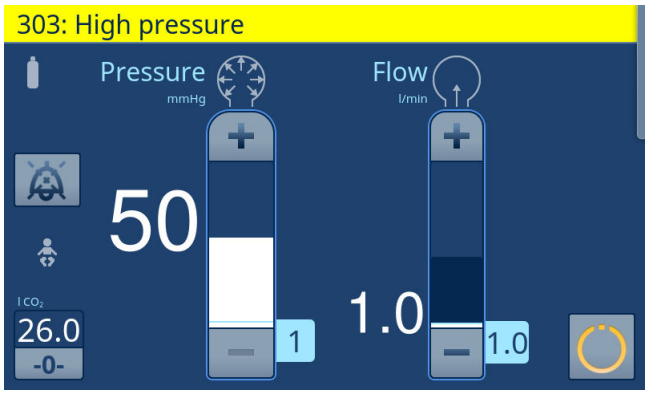
Alarm and information signals are self-explanatory messages that explain the behavior of the device and support the user with the operating functions. These signals improve the usability of the device and support service technicians in troubleshooting.

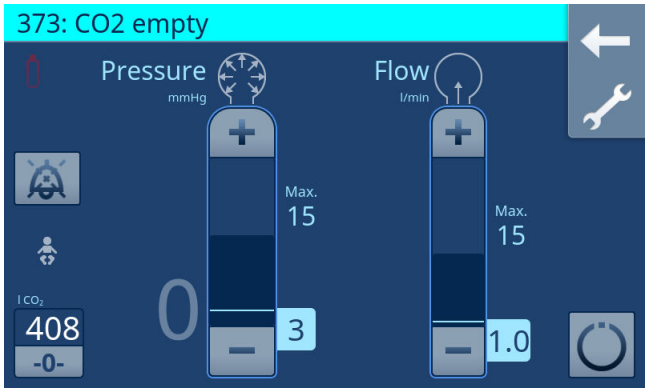
Information signals are continuously output when they indicate the cause of an inoperable device. All other alarm and information signals are output as long as the signal conditions are present. The minimum duration of the display is 5 s. The signals are ordered according to priority. Alarm signals have a higher priority than information signals.

Information signals are divided into five different priorities. Signals of a higher priority overwrite signals of lower priority, or signals of lower priority are suppressed as long as signals of higher priority are present. In the event of multiple signal conditions with the same priority, the most recently detected condition will appear in the title line.

6.10.1 Alarm specification

The product issues two alarms: "303: High pressure" and "373: CO_2 empty".





Alarm signals are not latching, i.e., the alarm signal is only issued for the duration that the signal condition is present. The alarms are displayed for a minimum of 5 s, and at least one tone sequence is output. The alarm thresholds and alarm delays are programmed as fixed settings. After a production stop or a power failure, the last set volume is adopted.

6.10.1.1 Excess pressure alarm

⚠ CAUTION

Excess pressure! Risk of injury!

- ▷ If an excess pressure warning occurs, observe the functioning of the product.
- ▷ If the insufflation or the safety valve is deactivated, take suitable measures to reduce the pressure.

The excess pressure alarm "303: High pressure" indicates that an excessive cavity pressure was measured at the device output. The excess pressure alarm is activated 3 s after the cavity pressure measurement.

The product has a safety valve that reduces the excess pressure after 4 s when the safety valve has not been deactivated and when the insufflation is active.

ⓘ The automatic pressure reduction for setpoint values near or at the maximum of the setting range does not take place at 16 mmHg (Pediatrics) or 31 mmHg (High Flow), but only at a particular excess pressure; see the table.

Mode	Setting	Excess pressure
Pediatrics	>12 mmHg	4 mmHg
High Flow	>26 mmHg	5 mmHg

When the insufflation is switched off, the pressure is not automatically reduced.

The excess pressure alarm is triggered at the following measured values:

Mode	Measured cavity pressure over setpoint value	Cavity pressure
Pediatrics	3 – 4 mmHg	≥16 mmHg
High Flow	4 – 5 mmHg	≥31 mmHg

The warning thresholds of the excess pressure are given with a resolution of one decimal place since the calculation depends on the setpoint value:

Mode	Pressure setpoint	Warning threshold
Pediatrics	1 – 15 mmHg	2.6 – 4 mmHg or pressure ≥16 mmHg
High Flow	1 – 30 mmHg	3.6 – 5 mmHg ≥31 mmHg

6.10.1.2 Gas empty alarm

⚠ CAUTION

Gas empty alarm! Risk of injury!

- ▷ Restore the gas supply.
- ▷ Restart the insufflation.

The gas empty alarm "373: CO_2 empty" indicates that the gas supply has failed during the application and insufflation has been deactivated.

The activation and deactivation thresholds of the alarm are the following:

Threshold	Input pressure
Activation	<1 bar
Deactivation	>1.5 bar

6.10.1.3 Visual alarm signal

The alarms are displayed in the title line as follows:

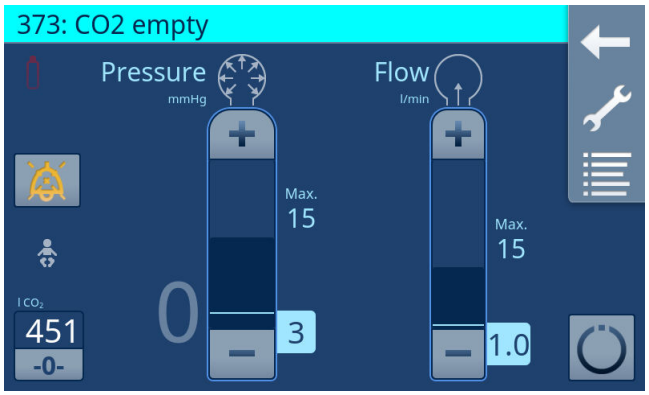
- Medium priority: blue font on yellow background
- Low priority: blue font on cyan background

6.10.1.4 Acoustic alarm signal

If a condition for an acoustic signal is present, at least one complete tone sequence will be output. The volume of the audio signals is set to the maximum at the factory and can be adjusted in the settings. The maximum volume is 74 dBA; the minimum volume is 49 dBA for the “freshfish” device version and 58 dBA for the “trumpetfish” device version.

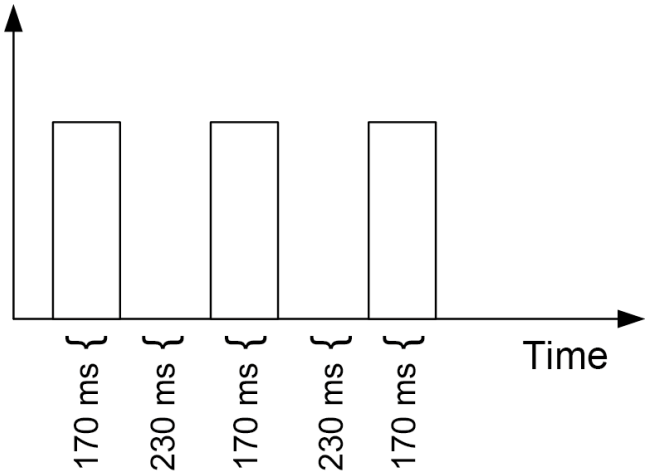
The functioning of the alarm system is verified when the availability signal sounds after a mode has been selected.

- Tap the **Bell** button to deactivate the acoustic signals for 30 s. This affects all alarm and information signals.
  - ⇨ The bell appears yellow during this time:



Medium priority alarm signal

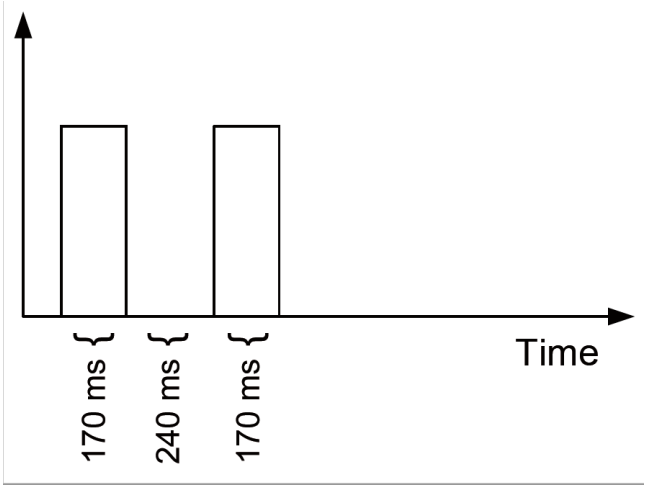
The alarm signal is a burst of 3 tones lasting for 170 ms each, with a pause of 230 ms. The burst is repeated every 10 s and generates 4 harmonics:



Low priority alarm signal

The alarm signal is a burst of 2 tones lasting for 170 ms each, with a pause of 240 ms. The burst is repeated every 16 seconds and generates 4 harmonics:

- Tone 1: frequency 320 Hz
- Tone 2: frequency 254 Hz

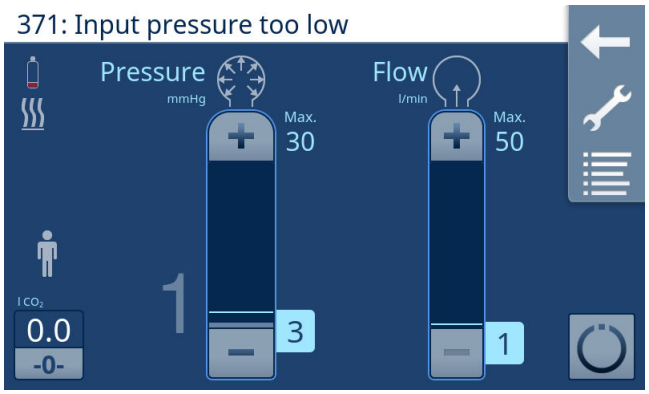


Function confirmation of the alarm system

The functioning of the alarm system is confirmed when the availability signal sounds after a mode has been selected. For checking the conditions of the gas empty signal, see chapter *Checking the gas empty alarm* [p. 56].

6.10.2 Information signals

Information signals notify the user if the operating states of the insufflation system deviate from the expected value ranges, e.g., the gas supply pressure.

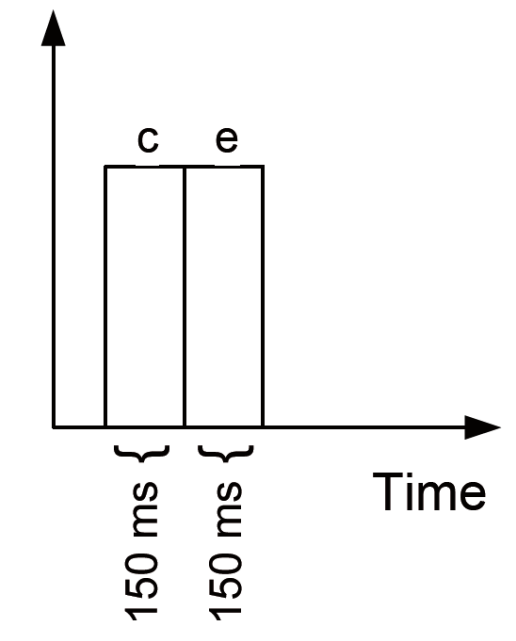


6.10.2.1 Visual information signal

The information signal is displayed with blue writing on a white background in the title line.

6.10.2.2 Acoustic information signal

The acoustic information signal is a double tone c-e (263 Hz – 330 Hz) lasting 300 ms.

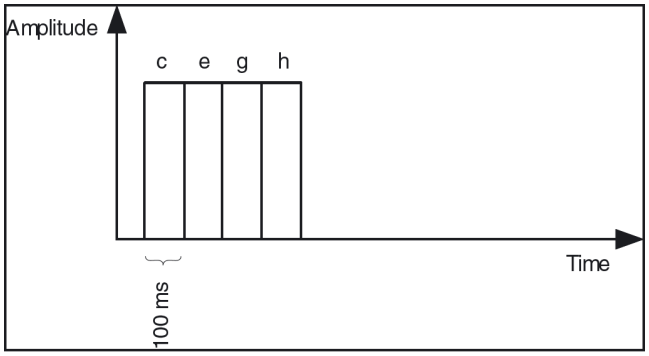


Acoustic information signal

Depending on the priority of the message, the tone sequence will either be repeated or output once. If messages indicate an inoperable device, or if the message "371: Bottle pressure <10 bar" appears, the tone sequence is repeated every 20 s. For all other messages, the information signal sounds once.

Availability signal

The pitch of the availability signal is modulated with a frequency of 1.5 Hz by ± 2 Hz each time. 5 different harmonics are generated.



Harmonics of the availability signal

Button tones

When a button on the touch screen is tapped, a short beep is heard. The volume of this beep can be adjusted or turned off independently of the volume of all other information signals in the settings.

6.10.3 Checking the excess pressure alarm

The excess pressure alarm can be checked as follows:

1. Connect the stopcock of the instrument to the insufflation tube.
2. Start the insufflation.
3. Stop the insufflation.

4. When the insufflation is stopped, reduce the setpoint value by 6 mmHg so that the warning threshold is exceeded.

⇨ The visual and acoustic excess pressure alarm is output.

Since the automatic pressure reduction does not work when the insufflation is deactivated, the excess pressure condition is maintained when the system is sealed.

6.10.4 Checking the gas empty alarm

The gas empty alarm can be checked as follows:

1. Before switching on the product, briefly turn on the gas supply and close it again.
2. Switch on the product.
3. After a successful self-test, start the insufflation with a flow limit of >1 l/min.

⇨ When the inlet pressure has been reduced, the gas empty alarm sounds.

6.10.5 Checking information signals

Information signals can be checked as follows:

1. Before switching on the product, briefly turn on the gas supply and close it again.
2. Switch on the product.
3. Set "Bottle repetitive audio signal" in the settings for the gas supply system.
4. After a successful self-test, start the insufflation with a flow limit of >1 l/min.
5. Stop the insufflation immediately when the message "371: Input pressure too low" appears when the gas supply is closed.

The tightness of the system is sufficient to verify the characteristics of the information signals.

7 Maintenance, servicing, repairs, and disposal

7.1 Maintaining the product

⚠ WARNING

Risk of injury due to product degradation!

Patients, users and third parties may be injured as a result of product and accessory degradation.

- ▷ Shut down the product.
- ▷ Have the deficiencies repaired by persons authorized by KARL STORZ.

If they are not described in more detail here, maintenance activities may only be performed by KARL STORZ or by a company authorized by KARL STORZ.

7.1.1 Maintenance

The following maintenance intervals are recommended:

Interval	Activity	To be performed by
annually	Safety test	KARL STORZ service technicians

7.2 Changing a fuse

- ✓ The product is switched off.
- ✓ The power cord is disconnected from the product.

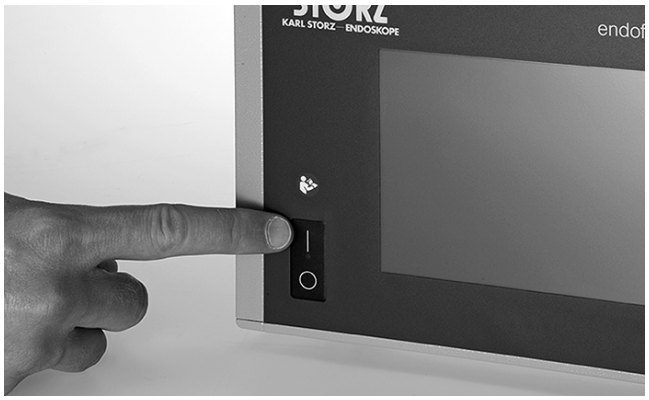
1. Use a screwdriver to remove the screw inserts on the line fuse holder.

2. Remove the defective fuse.

3. Insert the new fuse and tighten to 0.4 Nm. Only use fuses with the specified values, see chapter *Technical data* [p. 15].

4. Place the screw inserts back into the line fuse holder.
5. Connect to the power supply.

6. Switch on the product and test for proper operation.



7.3 Safety inspection in accordance with IEC 62353

⚠ WARNING

Risk of injury due to product degradation!

Patients, users and third parties may be injured as a result of product and accessory degradation.

- ▷ Shut down the product.
- ▷ Have the deficiencies repaired by persons authorized by KARL STORZ.

Regardless of the national accident prevention regulations and testing intervals for medical devices, for this device safety checks must be performed as repeat inspections according to IEC 62353 and recorded by a qualified electrician at least once a year. Detailed specifications regarding the scope and execution of the safety inspection can be found in the service manual.

7.3.1 Visual inspection

1. Check the product and accessories for any mechanical damage.
2. Check labels for readability.

7.3.2 Electric measurements

ⓘ Limit values for electrical measurements can be found in the current IEC 62353.

1. Measure the protective ground resistance.
2. Measure the earth leakage current.
3. Measure the touch current.
4. Measure the patient leakage current.

7.3.3 Functional test

A complete functional test comprises the following checks:

7.3.3.1 Checking the function in the low flow range (pediatrics)

1. Set the Pediatrics mode with the following operating parameters: 10 mmHg, 0.5 l/min.
2. Connect the insufflation tube (031200) with the trocar LUER-Lock connector. Ensure that the gas can flow out.
3. Start the insufflation.
   ⇨ The flow slowly increases to 0.5 l/min ±0.1 l/min.
4. When the stationary condition has been reached, reduce the flow setpoint to 0.1 l/min.
   ⇨ The actual flow decreases to 0.1 l/min ±0.1 l/min. The cavity pressure display remains at 0 mmHg.
5. If an excessive flow is displayed when the tube is open, a fault is present: Send the product in for repair.
6. If the flow setpoint is 0.1 l/min, keep the LUER-Lock connector closed or close the stopcock.
7. After closing, set the nominal pressure with perhaps a slight excess pressure; the Secuvent and the excess pressure warnings must not be activated. Note that CO_2 diffuses through the tube and the pressure decreases over a long period.

7.3.3.2 Checking the Pediatrics function

1. Set the Pediatrics mode with the following operating parameters: 10 mmHg, 1 l/min.
2. Connect the insufflation tube (031200) with the trocar LUER-Lock connector.
3. Start the insufflation.
   ⇨ When the tube is open, the flow display increases and reaches 1 l/min ±0.1 l/min after approx. 10 s at the end of the insufflation phases. The cavity pressure display remains at 0 mmHg.
4. When the stationary state is reached, keep the LUER-Lock connector closed or close the stopcock.

⇨ After closing, the excess pressure is reduced via the Secuvent and the message "301: Occlusion" appears.

⇨ After a maximum of 5 insufflation blasts, the pressure adjusts to 10 to 15 mmHg without the Secuvent reducing pressure.

⇨ The message "301: Occlusion" is updated after each insufflation blast and is maintained until the LUER-Lock connector or the stopcock is opened again.

7.3.3.3 Checking the High Flow function

1. Set the High Flow mode with the following operating parameters: 16 mmHg, 1 l/min.
2. Connect the insufflation tube (031200) with the trocar LUER-Lock connector.
3. Start the insufflation.
   ⇨ When the tube is open, the flow display increases and reaches 1 l/min ±0.1 l/min after approx. 10 s at the end of the insufflation phases. The cavity pressure display remains at 0 mmHg.
4. When the stationary state is reached, keep the LUER-Lock connector closed or close the stopcock.

⇨ After closing, the excess pressure is reduced via the Secuvent and the message "301: Occlusion" appears.

⇨ After a maximum of 5 insufflation blasts, the pressure adjusts to 16 to 30 mmHg without the Secuvent reducing pressure.

⇨ The message "301: Occlusion" is updated after each insufflation blast and is maintained until the LUER-Lock connector or the stopcock is opened again.

7.4 Repairing the product

Repair work may only be performed by KARL STORZ or by a company authorized by KARL STORZ. The interventions described in this instruction manual are exempt from this rule.

▶ Please contact your local KARL STORZ subsidiary or authorized dealer (see the list of subsidiaries).

Contaminated devices may not be shipped. To prevent contact infections and airborne infections, products must first be decontaminated. KARL STORZ reserves the right to send back contaminated products.

7.5 Disposing of the product

The product meets the requirements of the Directive on Waste Electrical and Electronic Equipment (WEEE).

Within the scope of application of this directive, KARL STORZ SE & Co. KG is responsible for the proper disposal of this product.

1. The product must be disposed of in accordance with the applicable national laws and regulations at a suitable collection point for the reprocessing of electrical and electronic equipment.
2. Contact KARL STORZ SE & Co. KG, a KARL STORZ branch or an authorized dealer to find out the address of the collection point in your area.
3. Dispose of accessories in compliance with country-specific laws and regulations.

8 Accessories and spare parts

8.1 Accessories

For UI500

Item	Order no.
Insufflation tubing set, ENDOFLATOR 50	031210-10
Insufflation tubing set, with gas filter	031200-10
Insufflation tubing set, ENDOFLATOR 50	UI007
Insufflation tube	UI004
Filter, insufflation	031122-25
Low pressure tube, CO_2, 150 cm	UI001
Low pressure tube, CO_2, 300 cm	UI002
Low pressure tube, CO_2, 600 cm	UI003
CO_2 high pressure tube, American/German	20400021
High pressure tube, American/Pin-Index	20400022
High-Pressure Tube, American and German connection, 102 cm	20400027
CO_2 high pressure tube, Pin-Index	20400028
CO_2 high pressure tube, American/ISO	20400222
HP inline filter	20400032
Universal wrench	20400030
Bottle stand, fold-away	UI005
Leakage tester	13242XL
Power cord, length 300 cm	400A
Power cord, US version, 200 cm	400B

Additional accessories, insufflation tubes, Veress needles, and trocars; see www.karlstorz.com, KARL STORZ catalogs, or on site with a KARL STORZ employee.

8.2 Spare parts

For UI500

Item	Order no.
FUSE/ASM/T2.50AH/5x20mm	ET15-1708090
O-rings 8 x 1 – NBR 40	ET15-1823090

9 Electromagnetic compatibility

9.1 General notes on the operating environment

Special environment

The product is suitable for use in close proximity to an active HF electrosurgical device in professional healthcare facility environments. Professional healthcare facility includes physician offices, dental offices, limited care facilities, freestanding surgical centers, freestanding birth centers, multiple treatment facilities, hospitals (emergency rooms, patient rooms, intensive care, surgical rooms, outside the RF shielded room of an ME system for MRT).

ⓘ This product has been evaluated for compatibility with high-frequency surgical equipment.

ⓘ The emission characteristics of this product make it suitable for use in industrial areas and hospitals (CISPR 11 Class A) and other professional healthcare environment. If it is used in a residential environment (for which CISPR 11 Class B is normally required), this equipment might not offer adequate protection to radio communication service. The user might need to take mitigation measures, such as relocating or re-orienting equipment.

⚠ WARNING

Electromagnetic interferences! Malfunction!

Use of this product adjacent to or stacked with other equipment could result in improper operation.

- ▷ This situation should be avoided.
- ▷ If such use is necessary: Verify that this equipment and the other equipment are operating normally.

⚠ CAUTION

MR unsafe!

This product is MR unsafe.

- ▷ Keep the product away from the Magnetic Resonance Imaging (MRI) Scanner Room and mobile MRI scanner.

9.2 Essential performance

Essential performance of the product is mentioned below:

- The patient must be protected against too high insufflation pressures.
- In "high flow"-mode:
  - The insufflator never generates a cavity pressure higher than the maximum set pressure 30 mmHg + 30 % for more than 5 s, under normal conditions and with use errors.
  - During single fault condition, it is secured that there is a stop of insufflation of gas into patient when the device output pressure is greater or same as 55 mmHg and insufflation volume is more than 75 ml.
- In "Pediatrics"-mode:
  - The insufflator never generates a cavity pressure higher than the maximum set pressure 15 mmHg + 30 % for more than 5 s, under normal conditions and with use error.
  - During single fault condition, it is secured that there is a stop of insufflation of gas into patient when the device output pressure is greater or same as 33 mmHg and insufflation volume is more than 50 ml.

– The insufflator secures that insufflation gas which comes into patient never exceed temperature of 41 °C permanent.
  An overshoot of temperature is allowed under time of 1 min and within the following thresholds:

Average gas temperature	Maximum allowed temperature
40 °C to 41 °C	42 °C
37 °C to 40 °C	41 °C + 2x (40 °C minus average gas temperature)
below 37 °C	37 °C

In case of the essential performance is lost or degraded: in the unlikely scenario that the electromagnetic disturbance did affect the device to such a degree that the essential performance was no longer maintained,

– the pressure and flow of the CO_2 could exceed the maximum defined value
– - the temperature of the heated tubing could exceed the maximum defined temperatures

and could harm the patient.

In case the Essential performance is lost or degraded stop the device (proceed to the next step if, and only if, the step did not successfully stop the insufflator or a save state was met):

1. Deactivate insufflation via the GUI.
2. In case of high pressure: deflate the cavity via instrument.
3. Press the power button.
4. Disconnect the power cable.

9.3 Accessories, transducers, and cables

⚠ WARNING

Reduced immunity! Malfunction!

The use of an accessory, transducers and cables with the product other than those specified in this manual may result in increased emissions or decreased immunity.

▷ Preferably use the accessories specified in the manual.
▷ When using other than those specified in this manual, it becomes the responsibility of the user to determine compliance with IEC 60601-1-2.

⚠ WARNING

Degradation of performance! Malfunction!

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) could result in degradation of the performance of the product.

▷ Use portable communications equipment no closer than 30 cm (12 inches) to any part of the product, including cables.

The following accessories and cables are defined for EMC compliance.

Type	Shielded	Maximum length	Contains ferrite	Use
PA	No	> 3 m	No	Potential equalization
SCB cable	Yes	≥ 1 m	No	Connection to the SCB network, other SCB devices
Power cord	No	3 m	No	Power connection
031210-01	No	3 m	No	Heatable insufflation tubing set (patient tube heating)

9.4 Test-Tables

9.4.1 Table 1 – Compliance level for immunity tests

Interference immunity tests	EN/IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	The relative humidity should be at least 30%.
Electrical fast transients/bursts acc. to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines 100 kHz repetition	± 2 kV/± 1 kV for power lines ± 1 kV for input and output lines 100 kHz repetition	The power supply quality should be that of a typical commercial or hospital environment.
Surges acc. to IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to ground	± 1 kV line(s) to line(s) ± 2 kV line(s) to ground	The power supply quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and fluctuations of the power supply acc. to IEC 61000-4-11	Voltage dip: Dip to 0% for 1 cycle @ 0° phase angle Dip to 70% for 25/30 cycles @ 0° phase angle Dropout to 0% for 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° phase angles Voltage interruption: 100% for 250/300 cycles	Voltage dip: Dip to 0% for 1 cycle @ 0° phase angle Dip to 70% for 25/30 cycles @ 0° phase angle Dropout to 0% for 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° phase angles Voltage interruption: 100% for 250/300 cycles	The power supply quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation in the event of interruptions to the power supply network, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.

Interference immunity tests	EN/IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Magnetic field at the supply frequency (50 Hz/60 Hz) acc. to IEC 61000-4-8	30 A/m at 50 Hz/60 Hz	30 A/m at 50 Hz/60 Hz	If image distortion occurs, it may be necessary to position the equipment further from sources of power frequency magnetic fields or to install magnetic shielding. Before installing the device, the electromagnetic field should be measured to ensure that it is sufficiently low.
Immunity test acc. to IEC 61000-4–3 for high-frequency electromagnetic fields	3 V/m 80 MHz to 2.7 GHz see chapter *Table 2 – Test levels for proximity fields from RF wireless communications equipment* [p. 65] for wireless HF near field test levels	3 V/m 80 MHz to 2.7 GHz	-
Immunity to conducted disturbances, induced by radio-frequency fields acc. to IEC 61000-4-6	3 V_{rms} on 150 kHz to 80 MHz 1 kHz 80% AM modulation 6 V_{rms} in ISM frequency bands between 0.15 MHz and 80 MHz	3 V_{rms} on 150 kHz to 80 MHz 1 kHz 80% AM modulation 6 V_{rms} in ISM frequency bands between 0.15 MHz and 80 MHz	-
Magnetic field in close proximity, IEC 61000-4-39	8 A/m @ 30 kHz (CW modulation) 65 A/m @ 134.2 kHz (pulse modulation) 7.5 A/m @ 13.56 kHz (pulse modulation)	8 A/m @ 30 kHz (CW modulation) 65 A/m @ 134.2 kHz (pulse modulation) 7.5 A/m @ 13.56 kHz (pulse modulation)	-

9.4.2 Table 2 – Test levels for proximity fields from RF wireless communications equipment

Test frequency MHz	Frequency band [a] MHz	Radio service [a]	Modulation	Immunity test level V/m	Compliance level V/m
385	380–390	TETRA 400	Pulse modulation [b] 18 Hz	27	27
450	430–470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine wave	28	28
710 745	704–787	LTE band 13 & 17	Pulse modulation [b] 217 Hz	9	9

Test frequency MHz	Frequency band [a] MHz	Radio service [a]	Modulation	Immunity test level V/m	Compliance level V/m
780					
810	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation [b] 18 Hz	28	28
870					
930					
1720	1700–1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE band 1, 3, 4, 25, UMTS	Pulse modulation [b] 217 Hz	28	28
1845					
1970					
2450	2400–2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modulation [b] 217 Hz	28	28
5240	5100–5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9	9
5500					
5785					

If necessary to achieve the immunity test level, the distance between the transmitting antenna and the product may be reduced to 1 meter. The 1 meter test distance is permitted by IEC 61000-4-3.

[a] For some radio services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50% duty cycle square wave signal.

[c] As an alternative to FM modulation, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.

9.4.3 Table 3 – Emission class and group

Emission measurements	Compliance	Electromagnetic environment – guidance
RF emissions as per CISPR 11	Group 1	The product uses RF energy only for its internal function. The customer or user of the product should make sure that it is used in such an environment. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic product.
RF emissions as per CISPR 11	Class A	The product is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions as per IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions as per IEC 61000-3-3	Complies	

10 Errors and messages

10.1 Troubleshooting

Fault	Possible causes	Actions
Product failed	Power supply failure	▶ Have the power supply checked
	Defective fuse	▶ Replace fuses as described in the instructions for use. Make sure to use the correct fuse type
Warning message "Control stopped (system error)"	Product defective	▶ Switch the product on and off ▶ Contact Service ▶ Before doing so, open the system log in the settings and note the following from the last 5 entries: – Time stamp – ID – Text message – Detail ▶ Tap the respective line to call up the information on the detail
No gas flow		▶ Observe warning messages ▶ Switch the product on and off ▶ Contact Service
No pressure build-up	Too much leakage	▶ Increase flow setpoint
	Instrument resistance too high	▶ Replace instrument
	Leaky insufflation system	▶ Check the plug connections of the accessories and the tightness of the trocar ▶ Replace the tube or tubing set and perform a function test ▶ Replace the filter and perform a function test ▶ Contact Service
The product is switched on, the heatable patient tube is not connected, and the patient heating symbol lights up red	Defective product; the patient heating is permanently switched off	▶ Continue to work without the patient tube heating ▶ Contact Service

Fault	Possible causes	Actions
The heatable patient tube is connected, the patient heating symbol lights up red, and the message "Defective patient tube heating" appears	Fault or defective product The patient heating is permanently switched off	▶ Continue to work without the patient tube heating ▶ Contact Service
The heatable patient tube is connected, the patient heating symbol first lights up white and then red, and the message "Defective heating tube, please replace" appears	Patient heating defective	▶ Remove the defective tube ▶ Connect a new tube ⇨ The patient heating symbol lights up white and the tube is ready for operation ⇨ If the symbol continues to light up red, the product is defective ▶ Contact Service
When heated insufflation tubes are used at the same time as HF devices, an error message appears	Stray radiation from HF device	▶ Place the cable from the applicator of the HF device 10 cm away from the heated insufflation tube ▶ Change the HF device type ▶ Pull out the gas heating plug to end the intervention without gas heating

11 Overview of mitigating warnings

The original English warning text is as follows:

 WARNING	To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
 WARNING	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
 WARNING	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
 WARNING	Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
 WARNING	No modification of this equipment is allowed.

12 Subsidiaries

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