KARL STORZ — ENDOSKOPE

en **Instructions for use**
ENDOMAT SELECT
UP220

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CE 0123

Table of contents

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

This instruction manual is valid for:

Product name	Article number
ENDOMAT SELECT	UP220
Control cable for combination with UNIDRIVE S III ARTHRO	UP006
Control cable, length 100 cm	20701070

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

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 safety notes or in the case of a single step:

- ▶ Step 1

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.

1.6 Abbreviations

Abbreviation	Explanation
ART	Arthroscopy
BS	Bottle suction
CV	Clearvision
CYST	Cystoscopy
DS	Direct suction
ENT	Ear, nose and throat medicine
ERCP	Endoscopic retrograde cholangiopancreatography
FC	Flow-controlled
GI	Gastrointestinal
GYN	Gynecology
HYS	Hysteroscopy
IBS	Intrauterine BIGATTI Shaver
LAP	Laparoscopy
NEURO	Neurosurgery
PC	Pressure-controlled

Abbreviation	Explanation
PCN	Percutaneous nephroscopy
PRO	Proctology
RES	Resection
SPINE	Vertebral column
SURG	Surgery
THOR	Thoracoscopy
URO	Urology
URS	Ureterorenoscopy
VET	Veterinary medicine

2 Normal use

2.1 Intended purpose

Suction and irrigation pumps

Suction/irrigation pumps are used for the introduction of irrigation fluids into organs, joints, and operating fields as well as the suctioning of irrigation fluids and bodily fluids, secretions, tissue, and gases. Suction/irrigation pumps do not come into contact with the body.

Control cable

The connecting cables are used for electrical signal transmission. Connecting cables do not come into contact with the body.

2.2 Indications

Suction and irrigation pumps

The product provides irrigation or suction functions for the following disciplines:

- Urology
- Gynecology
- Surgery (thoracoscopy, laparoscopy, and proctology)
- Arthroscopy
- Spinal surgery

In addition, the pump with suction or irrigation function can be used for cleaning lenses.

For the product specifications, see the see chapter *Technical data* [p. 21].

Control cable

The connecting cable is used for electrical signal transmission. It does not depend on special indications.

2.3 Contraindications

Suction and irrigation pumps

The medical devices must not be used for procedures in direct contact with the central nervous system (CNS) and central cardiovascular system. The accessories must only be used with the intended devices. In general, medical devices must not be used on patients who are not part of the defined patient group, or if the operation itself is contraindicated. The use of pump systems is contraindicated if, in the opinion of the attending physician, the surgical method as such is contraindicated, or if the patient is not able to undergo surgery or anesthesia due to his or her general condition.

Use is contraindicated if, in the opinion of the attending physician, the device is not compatible with successful completion of the planned procedure due to its technical design.

The ENDOMAT SELECT must not be used for:

- ERCP
- Cholangioscopy (gastro)
- Spine lumbar (interlaminar access)
- Spine cervical
- Applications that require a non-pulsatile flow

- Administration of medication
- Thorax drainage
- Magnetic resonance tomography

Suction/irrigation modes without pressure monitoring must not be used for the dilatation of hollow organs or joints.

Control cable

- Use is contraindicated if, in the opinion of the attending physician, the device is not compatible with successful completion of the planned procedure due to its technical design.
- The accessories must only be used with the intended devices. In general, medical devices must not be used on patients who are not part of the defined patient group, or if the operation itself is contraindicated.
- The use of pump systems is contraindicated if, in the opinion of the attending physician, the surgical method as such is contraindicated, or if the patient is not able to undergo surgery or anesthesia due to his or her general condition.
- Pump systems (pump + associated tubing set) must not come into direct contact with the central nervous system (CNS) or the central cardiovascular system.

2.4 Target user populations

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

2.5 Patient groups

This product is intended for the following patient groups:

SURG, URO, ART, SPINE, ENT/NEURO, GI, VET

Patient group	Description
Gender	No restriction
Age	No restriction
Weight	>3.5 kg
Nationality	No restriction
Medical condition	Suitable for endoscopic interventions in the physician's judgement

GYN

Patient group	Description
Gender	Female
Age	No restriction
Weight	>3.5 kg
Nationality	No restriction
Medical condition	Suitable for endoscopic interventions in the physician's judgement

2.6 Intended application areas on the patient

The product can be used on patients in the following areas:

Discipline	Application area
SURG	Abdomen, thorax, procto
GYN	Uterus
URO	Lower and upper urinary tract
ART	Joints in the foot, knee, hip, shoulder, hand or finger
SPINE	Thoracic and lumbar vertebral column
ENT/NEURO	Cleaning endoscope lenses
GI	Upper and lower gastrointestinal tract

2.7 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
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 HIVE.

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.

- ▶ 1. Carefully read and observe all warnings and safety notes.
- ▶ 2. 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

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:
- – Completeness
- – Good working order
- – Correct assembly of the components
- – Functionality

3.3 Unsterile product

The product is not sterile when delivered. The use of non-sterile products 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.

3.4 Contaminated products

Contaminated products pose a risk of infection for users, patients, and third parties.

- ▶ Comply with national laws and regulations.
- ▶ Observe the guidelines of the Employer's Liability Insurance Association and equivalent organizations.

3.5 Disposable products

Disposable products are no longer safe after use. If disposable products are used again, there is a risk of infection and injury for patients, users, and third parties.

- ▶ Do not reprocess disposable products.

- Dispose of disposable products properly after use.

3.6 Combination with other components

Combination of the product with unsuitable instruments and devices can result in uncontrolled behavior and injury to patients, users, and third parties.

Additional devices connected to electrical medical devices must comply with the relevant IEC or ISO standards. Furthermore, all configurations must comply with the requirements for medical electrical systems (see Clause 16 of IEC 60601-1). If additional devices are connected to electrical medical devices, a medical system is configured that must satisfy the requirements for medical electrical systems. Local regulations take precedence over IEC and ISO standards. If you have any questions, please contact your local KARL STORZ representative or technical customer support.

- Only combine the product with devices and components that are approved for combined use by the manufacturer.
- Connect only devices that comply with IEC 60601 to signal inputs and signal outputs.
- Comply with national and local regulations.

3.7 Damaged products

Damaged products can result in injury to patients, users, or third parties.

- Before each use, check all components of the product for damage.
- Do not use damaged products.

3.8 Dangers from electrical current

An improper power supply may cause an electric shock and injure patients, users, or third parties. All electrical installations of the operating room in which the product is connected and used must meet 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. Failure to do so will void the guarantee.
- Always pull out the mains plug before carrying out any cleaning and maintenance work.
- Do not touch the output jacks of the product and the patient at the same time during use

3.9 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.

3.10 Electromagnetic interference

Medical electrical products are subject to special precautions regarding electromagnetic compatibility and must be installed and commissioned according to the tables on electromagnetic compatibility. If other products (e.g., for MRI, CT, diathermy, electrocauterization, or RFID) emit electromagnetic radiation, the function of the product may be impaired. High-frequency communication equipment can affect medical electrical products and impair their performance.

- Do not use the product in the vicinity of a magnetic resonance tomograph (MRT).
- Do not use the product next to or together with other devices. If such use is required, monitor the product and the other devices, and follow the relevant instructions for use in the event of malfunctions.
- Portable RF communications equipment including peripheral devices (e.g., antenna cables and external antennas) should be used no closer than 30 cm from the product, including cables specified by the manufacturer.
- Observe the information on electromagnetic compatibility, see chapter *Electromagnetic compatibility* [p. 68].
- In case of uncertainties, seek expert advice from KARL STORZ.
- Before use, a clinical/biomedical engineer or an EMC specialist should carry out an ad-hoc test of the electromagnetic radiation.
- To prevent increased electromagnetic emissions or reduced electromagnetic immunity of the product, only use accessories, transducers, and cables recommended or supplied by the manufacturer.

3.11 Failure of products

The product may fail during use.

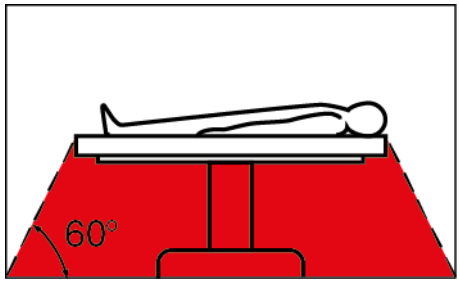
- Have a replacement product ready for each application or plan for an alternative surgical technique.

3.12 Observing ambient conditions

If the device is operated in an environment which is not suitable, patients, users and third parties may be injured.

- Always operate the product in the prescribed ambient conditions.

- 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.

3.13 Risks in IT networks

The integration of the product in an IT network can interfere with the function of the product or other devices in the IT network.

- Do not connect the product with an IT network or other devices. Only the KARL STORZ Service may use the interfaces for USB and Ethernet.

3.14 Modifications to the product

Modifications to the product reduce the safety of the product, and the user can be injured by electric shock as a result.

- Do not modify the product.

4 Product description

4.1 Description of operation

The ENDOMAT SELECT is a roller pump that can be used for irrigation and suction of fluids during operations in various disciplines of human and veterinary medicine. It is not possible to combine disciplines of human and veterinary medicine.

The device automatically adapts to suit the type of operation being performed by providing the optimum operating parameters when a tubing set for a specific discipline is attached, provided the product is enabled for the area of application. The product can be configured in such a way that only the areas of application that the user wants to use are displayed. Further disciplines can be retrofitted, and extended setting options are available with the Advanced software package.

In urological and arthroscopic applications, the irrigation pressure can also be increased briefly with a BOOST function. In other applications, either the irrigation flow or the irrigation pressure can be limited.

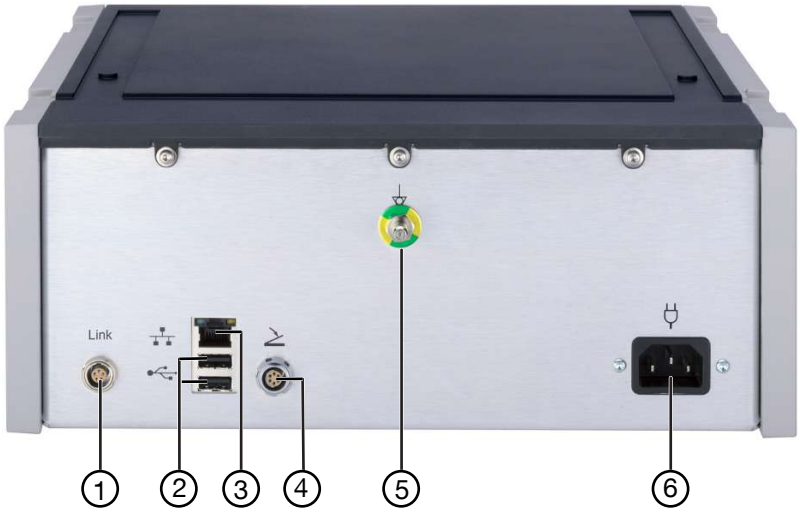
The product is operated and controlled via a touch screen. The current operating state can be checked by displaying the set and actual values of the irrigation pressure or flow. If the set value deviates continuously, an electronic safety circuit blocks the delivery or suction, and acoustic signals sound. An electronic auto-check system tests the various system components when the product is started and notifies the operator of any failures detected.

The range of functions of the product varies according to the installed software package. For the required accessories for the respective software package, see see chapter *Accessories and spare parts* [p. 66].

4.2 Product overview

ENDOMAT SELECT – Front view

1 Standby button
2 TFT touchscreen
3 Pump lever (cartridge locking lever)
4 Light barrier
5 Pump rollers



ENDOMAT SELECT – Rear view

1 Connection socket Link, e.g., for Calcuson
2 USB service interface
3 Ethernet interface (KARL STORZ HIVE) for service and UNIDRIVE Select
4 Connection socket, e.g., for footswitch
5 Potential equalization connector
6 Mains socket

Tubing set for single use

4.3 Touchscreen

1	Discipline name	4	Limitation of pressure
2	Start/stop irrigation/suction	5	Limitation of flow
3	Irrigation/suction display	6	Boost pressure increase

Irrigation or suction display

The irrigation or suction function is activated:

- Actual value: orange-colored line
- Set value: white marking

Limitation of pressure or flow

Whether the flow or pressure can be limited depends on the discipline and the installed Advanced software package.

Boost pressure increase

Boost pressure increase is only available in the disciplines of arthroscopy and urology. The boost pressure increase can be set with the button or footswitch in 10% steps from 10% – 50%.

4.3.1 Symbols on the user interface

Symbol	Meaning
	Start/stop Irrigation Standby/pump activated
	Start/stop Suction Standby/pump activated
	Start/stop Footswitch Suction using footswitch
	Lock open/closed
	Alarm audio
	Alarm audio paused (30 s)
	Back to procedure level
	Cancel on procedure level
	Confirm on procedure level
	Call up menu
	Cancel on menu level

Symbol	Meaning
	Confirm on menu level
	Back to menu level
	Scroll through the menu
	Scroll through pages

4.4 Possible combinations

It is recommended that the suitability of the products for the intended procedure be checked prior to use. Please note that the products listed here may not yet be available in all countries due to differences in approval requirements.

Products connected to medical electrical devices must comply with local and national regulations and IEC or ISO standards. Furthermore, all configurations must satisfy the requirements for medical electrical systems (IEC 60601-1, Section 16, 3rd edition). If additional devices are connected to electrical medical devices, a medical system is configured that must satisfy the requirements for medical electrical systems. Local regulations take precedence over IEC and ISO standards. If you have any questions, please contact your local KARL STORZ representative or technical customer support.

The following devices fulfil the requirements of IEC 60601-1, and the product may only be combined with these devices:

Product name	Article number
CALCUSON	27610020
UNIDRIVE Select	UM600
UNIDRIVE S III	20701020-1
UNIDRIVE S III ARTHRO	28723020-1

4.5 Operating modes

Operation as irrigation pump

1 From the irrigant solution bag

2 To the instrument

Operation as suction pump

1 From instrument/patient

2 To the collection container

4.6 Technical data

Designation	Value
Operating voltage (AC)	100 – 240 V
Operating frequency	50/60 Hz
Power consumption	82 VA
Electrical protection class	I
Applied part type according to IEC 60601-1	CF

Designation	Value
Degree of protection acc. to IEC 60259	IP 21
Irrigation pressure	HYS, URO, ART, SPINE: 20 – 150 mmHg
	LAP, GI: 100 – 300 – 500 mmHg (adjustable with "Advanced" package)
	Accuracy (up to 100 mmHg): ±10 mmHg Accuracy (100 – 150 mmHg): ±10%
Irrigation flow	Accuracy (0 – 3,500 ml/min): ± 20% Accuracy when using patient tubing 031162-10 for day sets: ± 25%
	HYS, URO, SPINE: 200 – 400 – 600 ml/min ART: 1,500 – 2,000 – 2,500 ml/min (adjustable with "Advanced" package for HYS, URO, SPINE, and ART)
	SURG: 100 – 2,500 ml/min (ADVANCED: 100 – 3,500 ml/min) GI: 100 – 1,000 ml/min ENT/NEURO: 50 – 65 – 80 – 95 – 110 – 130 ml/min Motor system: 50 – 65 – 80 – 95 – 110 – 130 ml/min
Suction flow	IBS Shaver: 100 – 300 ml/min RES: 100 – 1,000 ml/min CALCUSON: 300 – 1,000 ml/min HYS: 10 – 180 ml/min ART: 100 – 1,000 ml/min
Irrigation pressure	VET ART – Small Animal: 20 – 150 mmHg; increments: 10 mmHg Boost: 10% – 20% – 30% – 40% – 50%
	VET ART – Large Animal: 20 – 400 mmHg; increments: 10 mmHg Boost: 10% – 20% – 30% – 40% – 50%
	VET SURG – SURG: 100 – 300 – 500 mmHg
Irrigation flow	VET ART – Small Animal: 1,500 – 2,000 – 2,500 ml/min
	VET ART – Large Animal: 1,500 – 2,000 – 2,500 ml/min
	VET SURG – SURG: 100 – 3,500 ml/min; increments: 100 ml/min
Suction flow	VET SURG – Direct suction: 100 – 1,000 ml/min; increments: 100 ml/min
	VET SURG – Bottle suction: 300 – 1,000 ml/min; increments: 100 ml/min

Designation	Value
Operating volume	500 ml/min – 41 dBA 1,500 ml/min – 65 dBA 2,500 ml/min – 69 dBA 3,500 ml/min – 71 dBA
Dimensions (L x H x W)	370 x 124 x 305 mm
Weight	5.9 kg

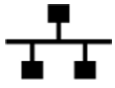
4.7 Symbols employed

4.7.1 Symbols on the packaging

Symbol	Meaning
	Manufacturer
	Date of manufacture
	Medical device
	Article no.
	Serial number
	Number of products in the product packaging
	Unique Device Identifier
	Consult the printed or electronic instructions for use
	Fragile, handle with care
	Keep dry

Symbol	Meaning
	Temperature limit
	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 directives. A code number after the CE mark indicates the responsible notified body. The EU directives relevant to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ.

4.7.2 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 (standby)
	Applied part of the type CF
	Connection socket, e.g., for footswitch
	Potential equalization connector
	Ethernet
	USB
	Alternating current
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	Medical device
	Prevention of pollution by electronic devices

Symbol	Meaning
	Separate collection of electrical and electronic devices. Do not dispose of in household refuse.
	Manufacturer
	Date of manufacture
	CE marking With this marking, the manufacturer declares the conformity of the product with the applicable EU directives. A code number after the CE mark indicates the responsible notified body. The EU directives relevant to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ.

4.8 Ambient conditions

Storage and transport conditions	
Temperature	-18°C ... +60°C (-0.4°F ... +140°F)
Relative humidity (non-condensing)	5 – 85%
Air pressure	500 – 1,080 hPa

Operating conditions	
Temperature	10°C ... 40°C (50°F ... 104°F)
Relative humidity (non-condensing)	15 – 80%
Max. operating altitude	3,000 m

4.9 System description

This chapter describes the requirements for medical electrical systems according to IEC 60601-1: Medical electrical equipment, section 16.

4.9.1 Definition

A medical electrical system is a combination of individual products, at least one of which has to be a medical electrical device. The products are interconnected by a functional connection or a multiple socket outlet.

A system with the ENDOMAT SELECT can consist of the following components:

- ENDOMAT SELECT (art. no. UP220) with CALCUSON (art. no. 27610020) and footswitch (art. no. 20014230)
- ENDOMAT SELECT (art. no. UP220) with UNIDRIVE Select (art. no. UM600)

  and footswitch (art. no. UF202)
- ENDOMAT SELECT (art. no. UP220) with UNIDRIVE S III (art. no. 20701020-1)

  and footswitch (art. no. 20014230)
- ENDOMAT SELECT and UNIDRIVE S III ARTHRO (art. no. 28723020-1)

The components can be connected with the following control cables:

- Control cable (art. no. 20701070) for CALCUSON and UNIDRIVE S III
- Control cable (art. no. UP006) for UNIDRIVE S III ARTHRO

The accessory components, such as transducers and probes, specified in the respective current catalog can also be used.

Other system components are not covered by these instructions for use. All changes and additions must be completely re-evaluated and documented in accordance with IEC 60601-1. Risk management must be observed in accordance with the standards. All instructions for use of the system components remain valid and must be observed. Components and equipment that are not part of the system may only be connected to the system with additional documentation, assessment, and additional notes for the user.

4.9.2 Application area

Aside from the applied parts, no other parts of the system are suitable for use within the patient environment.

4.9.3 Combination with non-medical products

The system must not be connected to other non-medical products. All deviations from this instruction require a new assessment of risks and additional documentation with warnings and notes for the user. All medical electrical components are considered products for the purposes of IEC 60601-1.

4.9.4 Multiple socket outlets

According to IEC 60601, Section 3, Term 3.67, a multiple socket outlet consists of one or more socket outlets that may be connected to or integrated in medical devices via flexible cables or leads to form a supply network or to provide a comparable voltage.

There are two permissible options for connecting to the line voltage supply:

- Each product is supplied from a separate wall socket outlet.
- Products are operated in combination via a multiple socket outlet in connection with isolation transformers (e.g., in a video trolley).

1. If using other connection methods or combinations of the entire system, take new measurements to ensure that the maximum leakage currents as per IEC 60601-1 are not exceeded.
2. Ensure that the multiple socket outlet can only be accessed with tools, so that the system cannot be subsequently modified.
3. Do not use freely accessible multiple socket outlets.
4. Do not use any additional multiple socket outlets or extension cables.
5. Do not place the multiple socket outlet on the floor.
6. Do not simultaneously touch the non-medical products and the patient in the patient environment.

4.9.5 Permissible system load

1. To determine the maximum load that must be absorbed by the system, follow the instructions for use of the products.
2. Check the maximum permissible load of a multiple socket outlet in connection with a KARL STORZ isolation transformer depending on the model used.

ⓘ If the isolation transformer is connected to the system via a multiple socket outlet, the isolation transformer is part of the medical electrical system.

4.9.6 Reprocessing

- The instructions for reprocessing the system components can be found in the respective instructions for use.

Further instructions are not intended for the system.

4.9.7 Maintenance

1. Required maintenance work can be found in the instructions for use of the system components.
2. When a video trolley is used, inspect the supply line for mechanical damage before each use of the system and arrange for a replacement to be carried out by a specialist if damage is detected.
3. After the initial assembly of all system components, perform a safety test according to IEC 62353. If the assembly is carried out at the factory, the protocol of the safety test is supplied.
4. Have the safety check carried out and recorded yearly by an electrician.

5 Preparation

5.1 Unpacking the product

1. Carefully remove the product and accessories from the packaging.
2. Check the delivery for missing items and any 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 Product installation

⚠ WARNING

Overheating! Risk of fire!

Insufficient ventilation can cause an internal build-up of heat, resulting in a safety shut-down. If the product overheats, there is a risk of fire. Patients, users, and third parties may be injured.

- ▶ Ensure that there is sufficient air circulation.
- ▶ Keep air inlets and outlets free.

⚠ CAUTION

Breakable glass! Risk of injury!

The glass of the screen will break if the product is dropped or sustains a significant impact. Patients, users or third parties can injure themselves on broken glass.

- ▶ Do not touch broken glass.
- ▶ Do not touch the glass parts of the product.
- ▶ Remove small glass parts from the product.
- ▶ Have the glass replaced by qualified service personnel.

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 – 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, whereby the tubing length is 2 m.

1. Set the product down on a horizontal, flat surface or a video cart.
2. Install the product out of reach of patients.

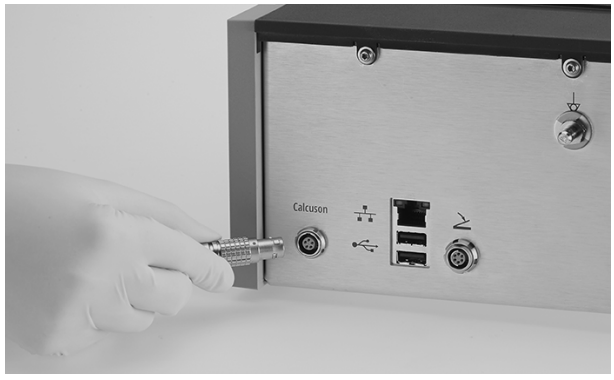
ⓘ This product and the connected accessories may only be used in medical rooms with electrical installations conforming to the applicable national regulations.

5.3 Connecting the product

1. Connect the potential equalization cable.

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

3. If necessary, connect the control cable (art. no. UP006) for combination with UNIDRIVE S III ARTHRO or the control cable (art. no. 20701070) for combination with CALCUSON or UNIDRIVE S III.



4. Connect the Ethernet cable for combination with UNIDRIVE Select (art. no. UM600).

5. Connect the other end of the Ethernet cable with UNIDRIVE Select, see instructions for use KARL STORZ UNIDRIVE Select.
6. To remove the Ethernet cable, pull on the plug as the Ethernet cable is secured on the plug with a protection device to prevent it from being pulled out accidentally.

The USB and Ethernet interfaces are reserved for the KARL STORZ Service. The product is not intended for connection with other devices via USB or Ethernet, except via Ethernet with UNIDRIVE Select.

5.4 Test the product

1. Check tubing set for leaks. Do not use leaky tubing sets.
2. Make sure that the tubes of the tubing set are not kinked and are securely fastened.
3. Check that the visual observation of the product is ensured.
4. To avoid unintentional excess pressure, check the set height difference after switching on the product.
5. If a software update has been carried out, check the configuration of the product.
6. Check the functionality of the product, see chapter *Venting the tubing system* [p. 51].

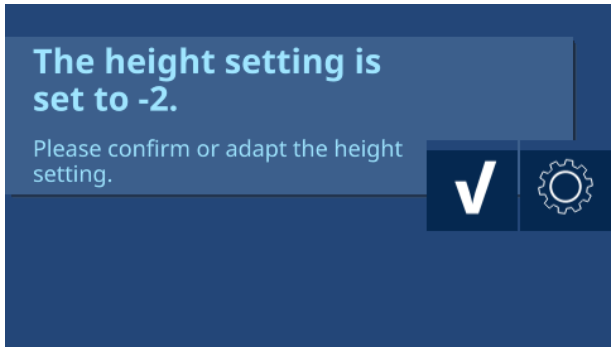
5.5 Putting the product into operation

1. Press the standby button to switch the device to ready mode.

⇨ The standby button lights up green, the product starts up and carries out a self-test.

⇨ Once the product has started up and the self-test is successful, the following start screen appears after 40 – 50 seconds:

⇨ Alternatively, a screen appears with height adjustment:



2. If the start screen appears, tap the button **Please press here to continue** to start the product.
   ⇨ After confirmation, a ready signal sounds, see chapter *Availability signal* [p. 62].
   WARNING! Risk of injury! Only use the device if the ready signal was audible.
   ⇨ The selection of disciplines appears:

3. If the screen with height adjustment appears, confirm the setting or call up the menu.

The height difference between the product and cavity (patient) can only be set with the Advanced software package.

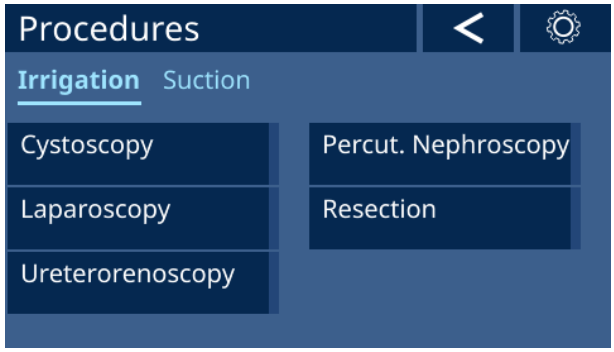
5.6 Selecting the discipline and procedure

1. Start the product, see chapter *Putting the product into operation* [p. 31].
   ⇨ The screen for selecting the discipline appears:

Human medicine

Veterinary medicine

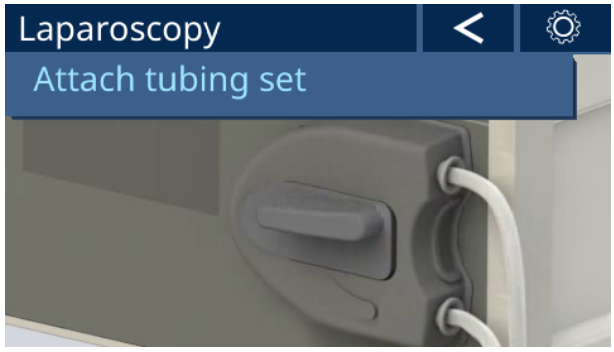
2. Select the discipline.
   ⇨ The screen for selecting the procedure appears:



Human medicine

Veterinary medicine

3. Select the procedure.
4. Follow the animation for installing the tubing set.



5.7 Installing the tubing set

⚠ WARNING

Non-sterile product! Risk of infection!

Cartridges and tubes are not supplied sterile. The use of non-sterile products poses a risk of infection for patients, users, and third parties.

- ▶ Inspect the product for visible contamination before use.
- ▶ Reprocess the product before initial use and before and after all subsequent applications. Use validated methods.
- ▶ Do not use contaminated products.

⚠ 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.

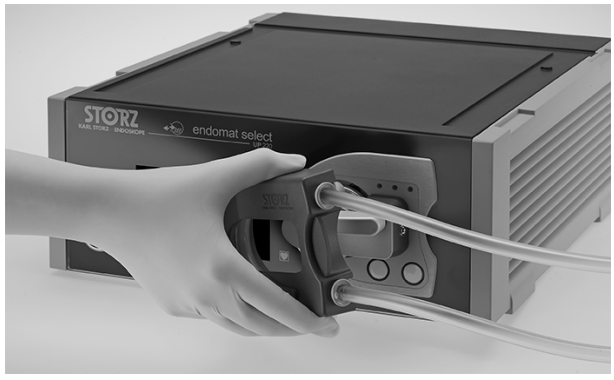
⚠ WARNING

Expiry date passed! Risk of infection!

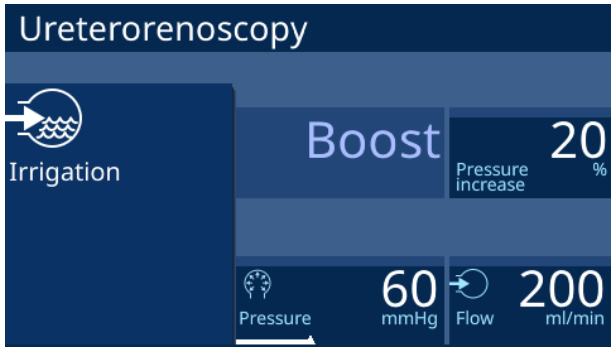
- ▶ Check the expiry date.
- ▶ Check the packaging for damage.
- ▶ Never use products that have passed the expired expiry date or have damaged or accidentally opened packaging but dispose of them properly.

✓ The product is switched on.

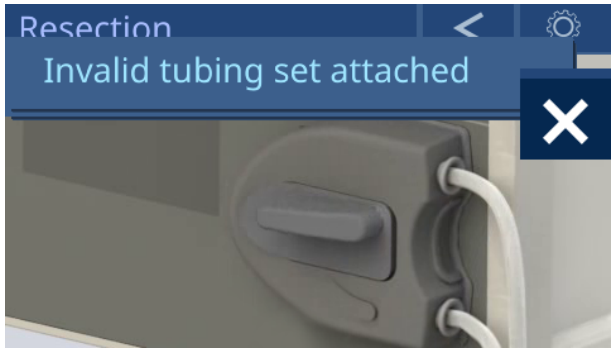
1. Install the tubing set. Make sure that the pump tubes are not crushed.



⇨ If the tubing set and procedure match, the last selected procedure appears, e.g.:



⇨ If the tubing set is not suitable, an error message appears:

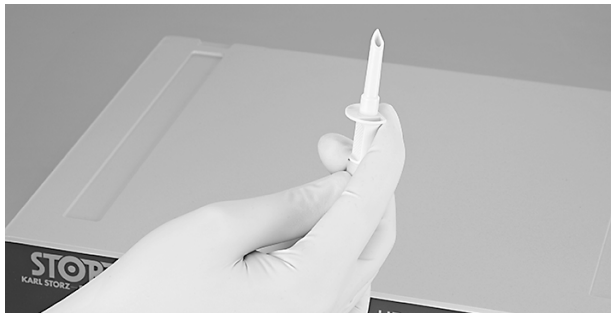


2. To change the procedure, tap on the **Arrow**.

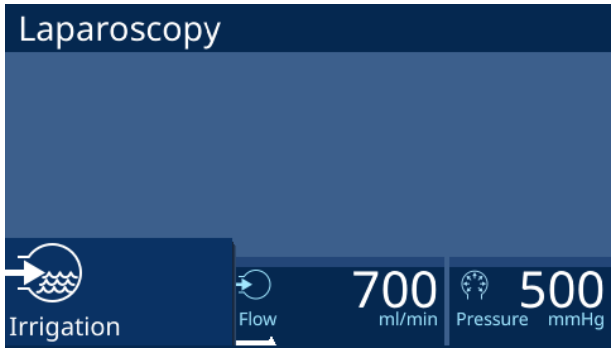
⇨ The discipline selection appears:

3. Select the desired discipline and procedure, see chapter *Selecting the discipline and procedure* [p. 32].
4. Turn the pump lever of the tubing set counterclockwise.

5. Connect the tubing ends with the irrigation bag (puncture needle) or with the irrigation connector on the instrument (LUER-Lock connector).



⇨ The selected procedure is displayed, e.g.:



6. To remove the tubing set, turn the pump lever clockwise to the 9 o'clock position.

(i) Reusable tubing sets are optionally available, see see chapter *Accessories and spare parts* [p. 66]. The instructions for use of the reusable tubing sets must be strictly observed.

5.8 Combined operation with CALCUSON (art. no. 27610020)

The CALCUSON is suitable for combined operation with the ENDOMAT SELECT. The products can be installed next to each other or at different levels on an equipment cart.

ENDOMAT SELECT and CALCUSON

1. Observe the instructions for use of the CALCUSON.
2. Observe the system description, see chapter *System description* [p. 25].
3. Observe the package insert of the tubing set (item no. 97000138).

5.8.1 Install the bottle holder

For installation, the bottle holder conversion kit (20300231) is required.

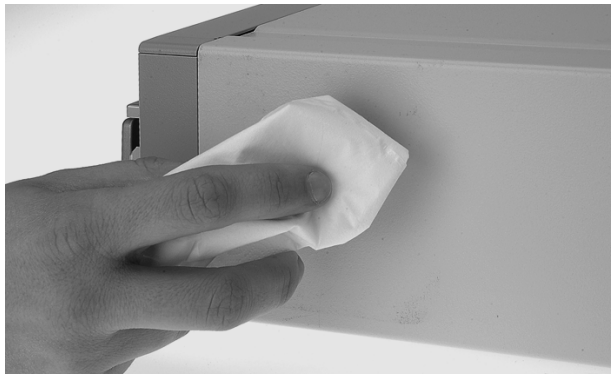
Components of the conversion kit:

- 1 bottle holder
- 1 suspension for the bottle holder
- 1 adhesion promoter (3M Automotive Adhesion Promoter 4298)

Accessories required:

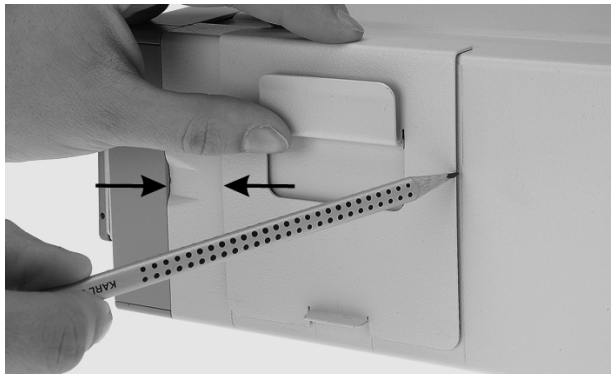
- Alcohol solution
- Dust- and lint-free cloth
- Pencil

1. Clean the surface with alcohol and a dust- and lint-free cloth.

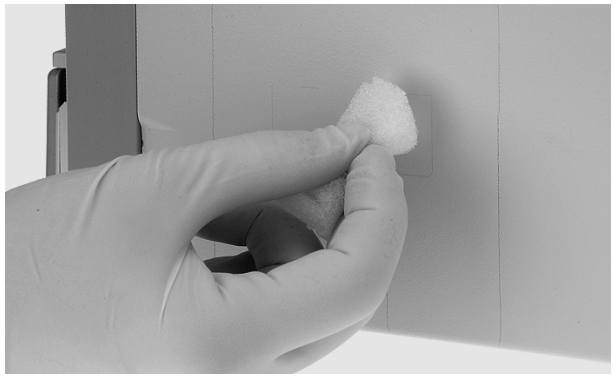


2. Allow the cleaned surface to dry. The adhesive surface must be dry, clean, and free of grease.

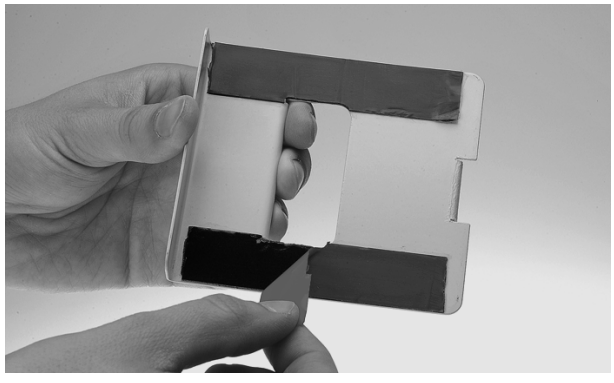
3. Mark the surface of the suspension on the right side of the product (as seen from the front) with a pencil. Maintain a distance of 2 cm from the side rail.



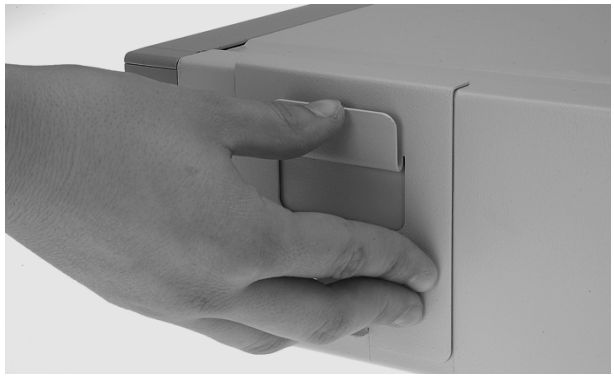
4. Apply the adhesion promoter thinly and evenly to the marked area.



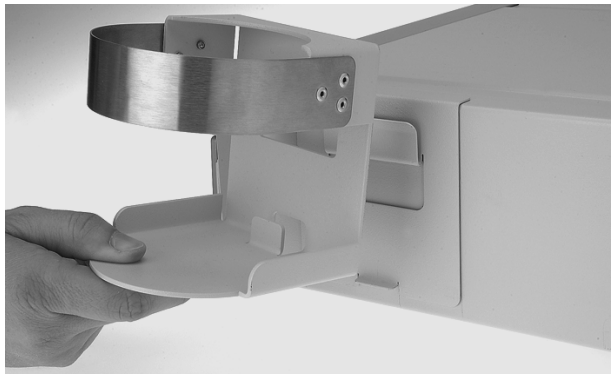
5. Apply the adhesion promoter only to surfaces that are completely covered, as the adhesion promoter contains a UV indicator that can be visible on treated surfaces.
6. Wait approx. 90 seconds. The adhesion promoter must be dry before an adhesive is applied.
7. Pull off the cover strips from the adhesive tape on the suspension.



8. Applying force, push the suspension onto the marked and treated surface. Proceed with caution, as the adhesive is difficult to remove again afterwards.



9. Allow the adhesive to dry sufficiently, as the adhesive develops its full bond strength only after several hours.
10. Hang the bottle holder in the suspension.

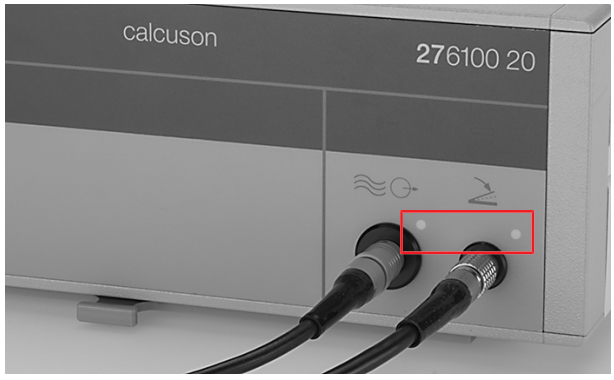


5.8.2 Putting the CALCUSON into operation

1. Connect ENDOMAT SELECT and CALCUSON to the optional control cable (art. no. 20701070).

⇨ The ENDOMAT SELECT can only be controlled with the CALCUSON footswitch.

2. Turn on the CALCUSON at the power switch.
   ⇨ The pilot lamps (1) and (2) light up green.



3. Actuate the first position of the footswitch (art. no. 20014230) to start the suction of the ENDOMAT SELECT.
4. Actuate the second position of the footswitch to activate the CALCUSON.
   ⇨ The green pilot lamp (1) lights up when ultrasonic energy is emitted. The function is being performed correctly.

5.9 Combined operation with UNIDRIVE Select (UM600)

The UNIDRIVE Select is suitable for combined operation with the ENDOMAT SELECT. The products can be installed next to each other or at different levels on an equipment cart.

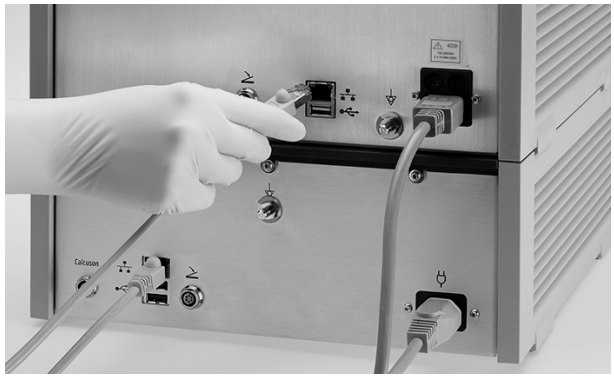
ENDOMAT SELECT and UNIDRIVE Select

1. Observe the instructions for use of the UNIDRIVE Select.
2. Observe the system description, see chapter *System description* [p. 25].
3. Observe the package insert of the tubing set (item no. 97000138).

5.9.1 Putting UNIDRIVE Select into operation

In combined operation with the UNIDRIVE Select, the tubing set (art. no. 031531-01) must be used for the ENDOMAT SELECT.

1. Connect ENDOMAT SELECT and UNIDRIVE Select to the Ethernet cable.



   ⇨ The ENDOMAT SELECT can only be controlled with the footswitch of the UNIDRIVE Select.
2. Observe the instructions for use of the UNIDRIVE Select.

5.10 Combined operation with UNIDRIVE S III (art. no. 20701020-1)

The UNIDRIVE S III is suitable for combined operation with the ENDOMAT SELECT. The products can be installed next to each other or at different levels on an equipment cart.

ENDOMAT SELECT and UNIDRIVE S III

1. Observe the instructions for use of the UNIDRIVE S III.
2. Observe the system description, see chapter *System description* [p. 25].
3. Observe the package insert of the tubing set (item no. 97000138).

5.10.1 Putting UNIDRIVE S III into operation

In combined operation with the UNIDRIVE S III, the tubing set (art. no. 030647-10) must be used for the ENDOMAT SELECT.

1. Connect ENDOMAT SELECT and UNIDRIVE S III to the optional control cable (art. no. 20701070).

   ⇨ The ENDOMAT SELECT can only be controlled with the footswitch of the UNIDRIVE S III.
2. Actuate the footswitch (art. no. 20016230) to the first position to start the suction of the ENDOMAT SELECT.
3. Press the footswitch all the way down to activate the Shaver as well.

5.11 Combined operation with UNIDRIVE S III ARTHRO

The UNIDRIVE S III ARTHRO is suitable for combined operation with the ENDOMAT SELECT. The products can be installed next to each other or at different levels on an equipment cart.

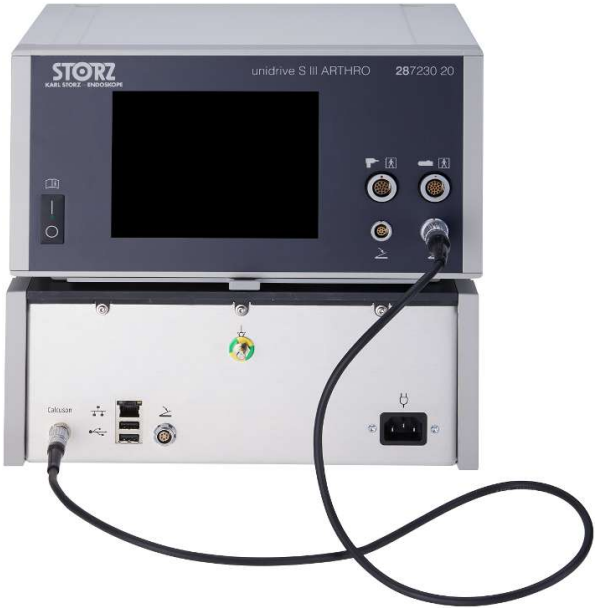
ENDOMAT SELECT and UNIDRIVE S III ARTHRO

1. Observe the instructions for use for the UNIDRIVE S III ARTHRO.
2. Observe the system description, see chapter *System description* [p. 25].
3. Observe the package insert of the tubing set (item no. 97000138).

5.11.1 Putting UNIDRIVE S III ARTHRO into operation

In combined operation with the UNIDRIVE S III ARTHRO, the tubing set (item no. 031523-10) must be used for the ENDOMAT SELECT.

1. Connect ENDOMAT SELECT and UNIDRIVE S III to the optional control cable (UP006).



⇨ The shaver can only be operated via the head buttons of the handpiece.

2. Install the tubing set, see chapter *Installing the tubing set* [p. 34].
3. Vent the tubing system, see chapter *Venting the tubing system* [p. 51].
4. Activate the shaver on the handpiece.

⇨ The ENDOMAT SELECT increases the intracavity pressure via the "boost" function. The pressure increase compensates for the loss of fluid caused by the suction connected to the shaver.

5.12 Connecting the tubing set for indirect suction

⚠ CAUTION

Contamination! Risk of infection!

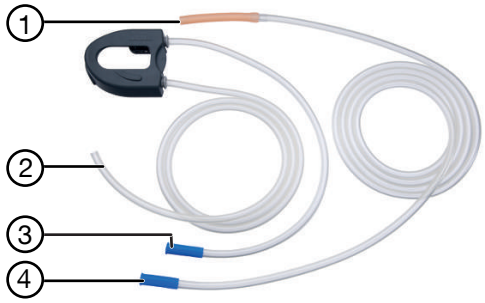
Solid particles in the aspirated liquid may perforate the pump head tubing and contaminate the product.

- Use the suction bottle.
- Check the pump head tubing regularly.

For indirect suction, the CALCUSON and the disposable tubing set (item no. 031647-10) are used. In addition, a suction bottle can be inserted between ENDOMAT SELECT and the suction instrument to filter solid components such as stone calculus (urology) from the suctioned liquid. This prevents perforation of the pump head tubing.

Filling the suction bottle with water reduces the volume of air. As a result, fluid is suctioned more quickly when the suction is started on the ENDOMAT SELECT. When the suction stops on the ENDOMAT SELECT, no more fluid is suctioned in.

CALCUSON, ENDOMAT SELECT, and suction bottle

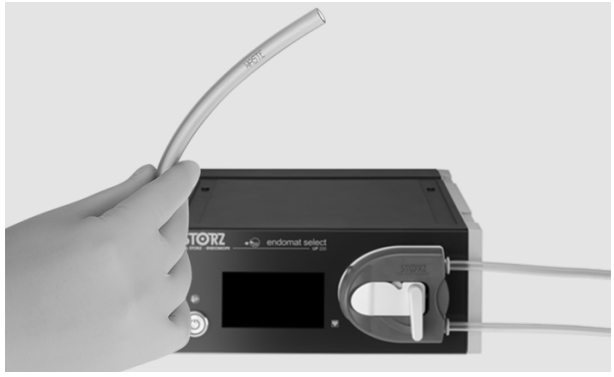


Disposable tubing set (item no. 031647-10)

1. Fill the suction bottle at least ¾ full with water.
2. Place the lid with tube nozzles on the suction bottle.
3. If necessary, place the suction bottle in the bottle holder on the product, see chapter *Install the bottle holder* [p. 37].
4. Install the tubing set, see chapter *Installing the tubing set* [p. 34].

5. Attach the inflow tube (3) of the tubing set to the suction bottle connection with tray.

6. Place the outflow tube (2) of the tubing set into a collection container.



7. Attach the blue tubing end (4) of the 2nd tube to the 2nd suction bottle connection with pipe.

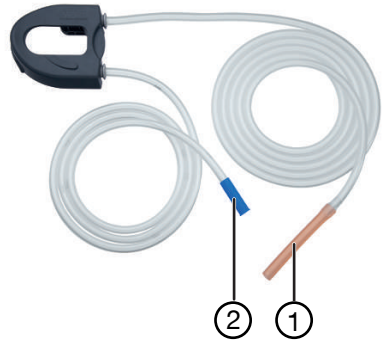
8. Connect the orange tubing end (1) to the instrument (transducer).

9. Vent the tube and probe before use, see chapter *Venting the tubing system* [p. 51].

If there is a height gradient between the patient and the suction bottle, the suction bottle may run full. Therefore, the suction bottle must be placed at the height of the patient.

5.13 Connecting the tubing set for direct suction

Direct suction is used for ablations, hysteroscopies, arthroscopies, and in conjunction with the IBS. The disposable tubing set (item no. 030647-10) is used for this purpose.



Disposable tubing set (item no. 030647-10)

1. Install the tubing set, see chapter *Installing the tubing set* [p. 34].
2. Connect the inflow tube (1) to the connector on the instrument.
3. Connect the outflow tube (2) to the collection container.

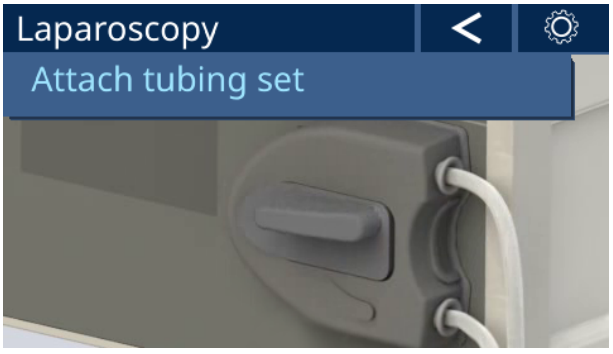
4. Vent the tubing system, see chapter *Venting the tubing system* [p. 51].

6 Application

6.1 Menu

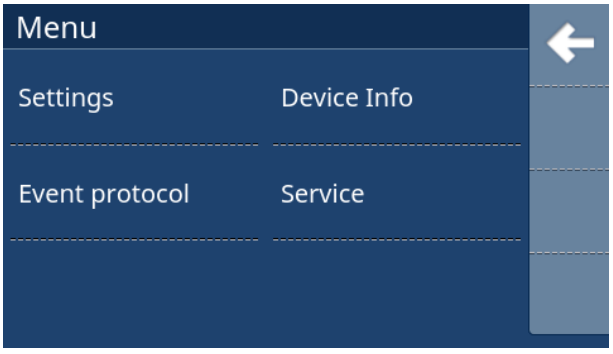
In the menu, various settings and management fields can be selected.

1. Turn the pump lever of the tubing set to the 9 o'clock position.



2. Tap the**Cog wheel** button to open up the menu.

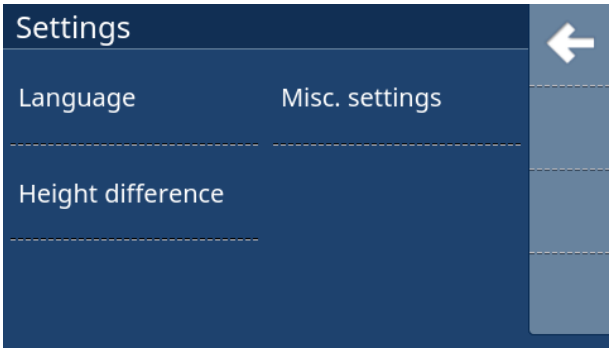
⇨ The *Menu* screen appears with the following sub-menus:



6.2 Settings

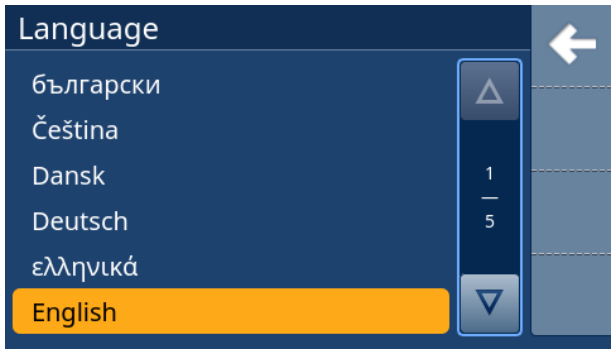
1. In the **Menu** screen, tap the **Settings** sub-menu.

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



6.2.1 Setting the language

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



2. Select the language and confirm with the **Checkmark**.
   ⇨ The *Settings* screen appears.
3. Browse back through the screen with the **Arrow**.

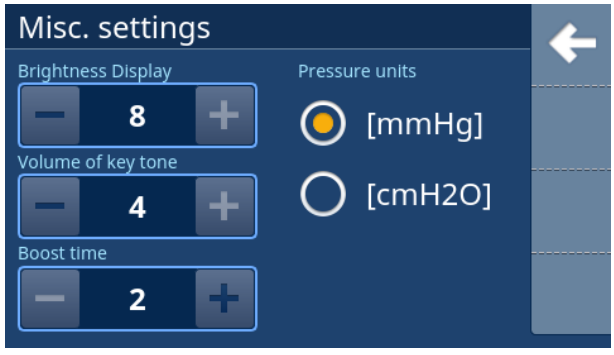
6.2.2 Other settings

When the VET software package is installed, the following settings can be made in the *Other settings* screen:

Setting	Comment
Monitor brightness	Adjustment range: 1 – 8
Key tone volume	Adjustment range: 0 – 4 0 = mute
Boost time	Delay time/duration of increased pressure Adjustment range: 2 – 60 s Up to 10 seconds in 2-second increments, thereafter in 5-second increments
Pressure unit	mmHg or cmH2O can be selected

✓ The VET software package is installed.

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



2. Enter the desired setting and confirm with the **Checkmark**.
   ⇨ The *Settings* screen appears.
3. Browse back through the screen with the **Arrow**.

6.2.3 Setting height difference

If the Advanced or VET software package is installed, the difference in height between the product and the cavity (patient) can be compensated. Setting the height difference corrects the pressure measurement and pressure control. To avoid unintentional excess pressure, the height difference setting must be checked after the product is turned on.

To ensure precise pressure measurement, the product must be placed at the height of the patient. If the product is placed above or below the patient, the pressure of the water column can cause major mismeasurements. If the product is above the patient, a positive value must be entered. One unit of the setting range corresponds to the device height of 110 mm. Example: If the product is 2 unit heights below the patient, the value -2 must be entered.

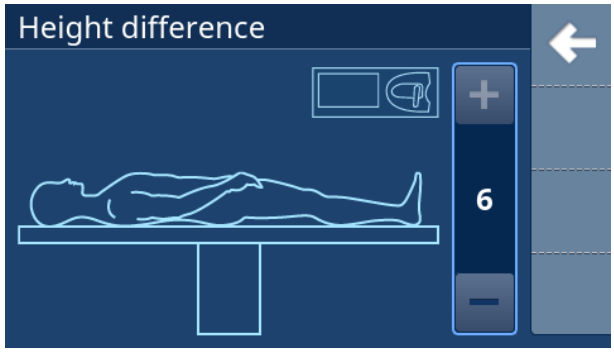
If a positive height difference is set, the product calculates the additional hydrostatic pressure at this height. A permanent actual value (white bar) is displayed, which can also be seen when the pump is not activated.

If a negative height difference is set, the product calculates the missing hydrostatic pressure and adds this pressure to the measured pressure value. The set values remain limited to the maximum values.

If the set and actual height difference between the product and patient do not match, the displayed pressure does not correspond to the actual pressure.

✓ The Advanced or VET software package is installed.

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



2. Enter the height difference between the product and the patient, adjustment range: +6 … -6. Keep the height difference as low as possible.
3. Confirm the setting with a **Checkmark** .
   ⇨ The *Settings* screen appears.
4. Browse back through the screen with the **Arrow**.

6.3 Event log

Alarms and information reports are saved in the event log together with the time of occurrence and can be exported to the Service area. A maximum of 200 entries are displayed, and the most recent entry is in the top line on page 1.

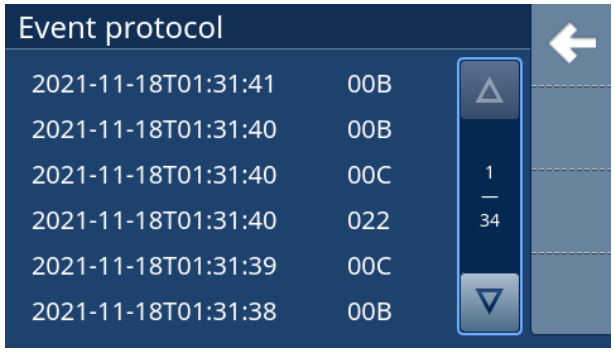
Each line contains the following event data:

- Current date
- Time
- Info ID

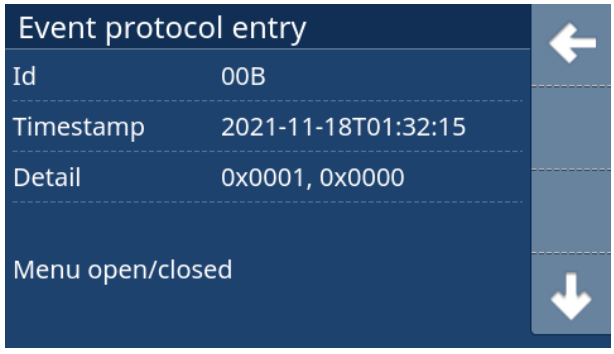
The event log is backed up in the event of voltage drops and upon switching off, and it contains entries relating to switch-on and switch-off times.

The entire event log has a capacity of 50,000 entries. If the maximum number of entries is exceeded, the oldest entries are overwritten by new ones.

1. In the *Menu* screen, tap on the *Event log* sub-menu.
   ⇨ The *Event log* screen appears.



2. To open an entry, tap on the corresponding line.
   ⇨ The selected event log entry appears.



3. Browse up, down and back with the **Arrows**.

6.4 Product information

Information on the product can be queried, e.g., serial number, software version and operating hours.

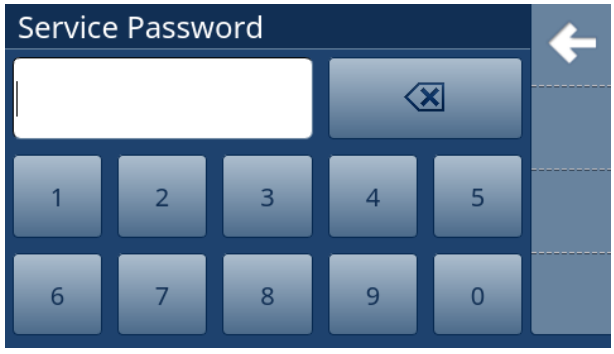
1. In the *Menu* screen, tap on the *Device info* sub-menu.
   ⇨ The *Device info* screen appears.

2. Browse back through the screen with the **Arrow**.

6.5 Services

The Service menu is reserved for the authorized service technicians, and, for this reason, the access is password-protected. The possible settings are described in the service manual.

1. In the *Menu* screen, tap on the *Service* sub-menu.
   ⇨ The *Service password* screen appears.



2. Cancel the screen with the **Cross**.
   ⇨ The *Menu* screen appears.
3. Browse back through the screen with the **Arrow**.

6.6 Venting the tubing system

6.6.1 SURG

1. Have a collecting container ready to catch irrigation fluid as it runs out.

2. Tap on the **Irrigation** button and let the roller pump run until all of the air has been released from the tubing system.

⇨ The displayed actual value of the irrigation flow (orange-coloured line) must match the set value (white marking).

3. Slowly close the filling tap on the instrument.

⇨ The roller pump stops the irrigation.

6.6.2 HYS/URO/ART/SPINE

1. Have a collecting container ready to catch irrigation fluid as it runs out.
2. Tap on the **Irrigation** button and let the roller pump run until all of the air has been released from the tubing system.

3. Slowly close the filling tap on the instrument.

⇨ If the actual value of the irrigation pressure (orange-colored line) exceeds the set value (orange marking), the roller pump stops the irrigation.

6.6.3 Suction

1. Press the footswitch.

2. Close the patient tubing with your finger and check whether a vacuum forms.

6.7 Using ENDOMAT SELECT as an irrigation pump

⚠ WARNING

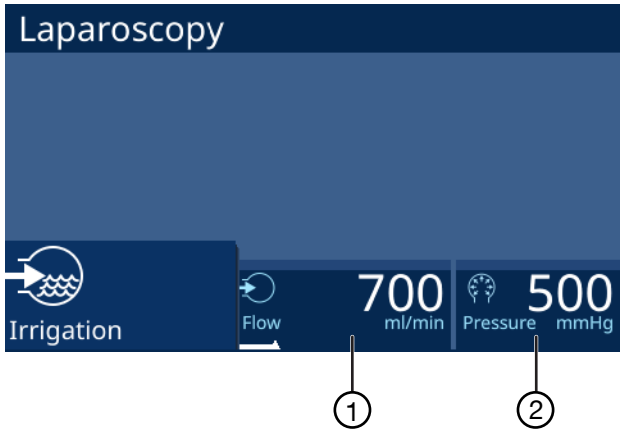
Active roller pump! Risk of crushing!

An activated roller pump can start at any time, and the rollers of the pump can cause crushing.

- Never reach into the pump.
- Do not wear loose clothing.
- Bind long hair together.

The irrigation flow or the irrigation pressure can be freely selected depending on the area of application that is specified by the tubing set. For the other parameters, a 3-stage limitation can be set. Some parameters can only be set with the Advanced or VET software package.

6.7.1 Setting the irrigation flow (SURG/VET SURG)



1	Irrigation flow set value	2	Pressure limit Advanced or VET software package required

The irrigation flow can be set to the following values:

Irrigation flow	Values
SURG	100 – 2,500 ml/min Advanced: 100 – 3,500 ml/min
VET SURG	100 – 3,500 ml/min

1. Tap on the set value for the irrigation flow and set using the **Plus** and **Minus** buttons independently of the pump status in 100 ml/min increments.
   ⇨ The set value is displayed as a number and with a white marking.
2. Alternatively hold the set value down and use the slider to set the set value.
3. Release the slider.
   ⇨ The set value appears.
4. Tap on the pressure limit.
   ⇨ The following pressure values appear for selection: 100 mmHg, 300 mmHg and 500 mmHg.
5. Tap on the desired value.
   ⇨ The value is shown as the pressure limit.
6. Tap on the **Irrigation** button to activate the roller pump.
   ⇨ The actual value of the irrigation flow is displayed as an orange-colored line.
7. Tap on the **Irrigation** button again to deactivate the roller pump.

ⓘ The standard value of the pressure limit without an installed Advanced software package is 500 mmHg.

6.7.2 Set the irrigation flow (ENT/NEURO)

In combination with irrigation sheaths, the ENDOMAT SELECT can be used to clean the distal lenses (endoscope window) during the CLEARVISION procedure. As long as the footswitch is activated, the pump irrigates the distal objective lens with fluid.

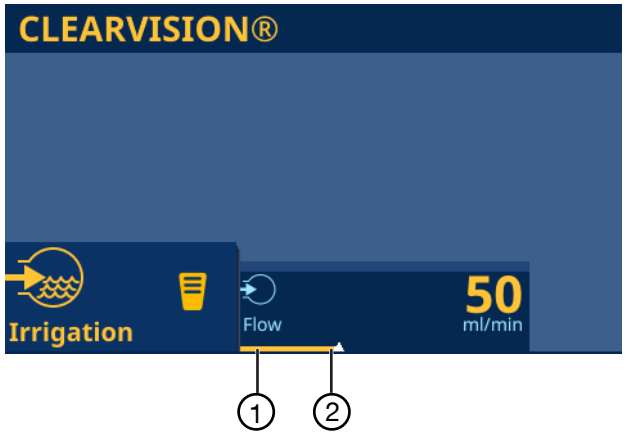
The footswitch has 2 different positions:

Lens cleaning mode (position 1)

The lens cleaning mode starts when the footswitch pedal is pressed halfway down to the first resistance. Continuous oscillation of the pump head causes drops of liquid to be delivered to the lens and then retracted. A cycle in progress is fully completed when the footswitch pedal is released. Finally, residual liquid is drawn into the irrigation sheath when the direction of rotation of the pump head is reversed.

Continuous irrigation mode (position 2)

Continuous irrigation mode starts when the footswitch pedal is quickly pressed to the stop. Irrigation solution is pumped without oscillation through the irrigation shaft to the lens as long as the footswitch pedal is depressed.

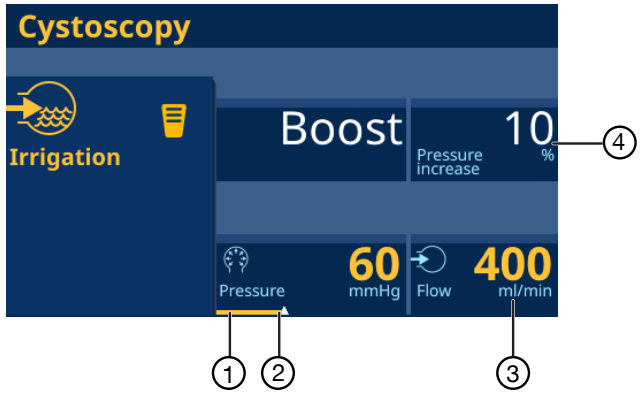


1 Irrigation flow actual value (orange) 2 Irrigation flow set value (white)

1. Tap on the set value of the irrigation flow and set with the **Plus** and **Minus** buttons independently of the pump status: 50 – 65 – 80 – 95 – 110 – 130 ml/min.
   ⇨ The set value is displayed as a number and with a white marking.
2. Alternatively hold the set value down and use the slider to set the set value.
3. Release the slider.
   ⇨ The set value appears.
4. Tap on the **Footswitch** button to activate the roller pump.
5. Press the footswitch pedal to position 1 or position 2 to start the irrigation process.
   ⇨ The actual value of the irrigation flow is displayed as an orange-colored line.
6. Tap on the **Footswitch** button again to deactivate the roller pump.

6.7.3 Set irrigation pressure (HYS/URO/ART/SPINE/VET ART)

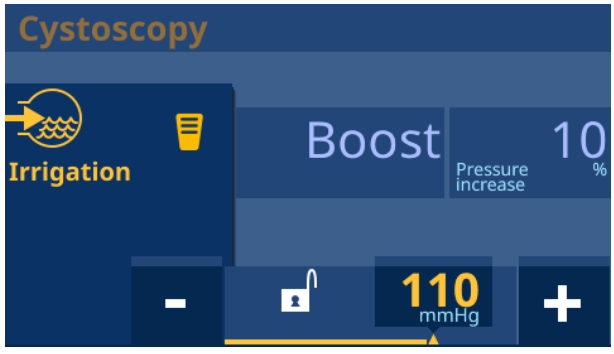
For all pressure-controlled procedures, the irrigation pressure can be set between 20 and 150 mmHg, except for VET ART "Large Animal", for which an irrigation pressure of up to 400 mmHg is possible.



1	Irrigation pressure set value (orange)	3	Flow limit Advanced or VET software package required
2	Irrigation pressure set value (white)	4	Percentage pressure increase (boost) (URO/ART/VET ART)

1. Tap on the set value of the irrigation pressure and use the **Plus** and **Minus** buttons to set this value independently of the pump status in 10 mmHg increments: 20 - 150 mmHg. Start with the lowest possible pressure needed to achieve the desired distension.
   ⇨ The set value is displayed as a number and with a white marking.
2. Alternatively hold the set value down and use the slider to set the set value.
3. Release the slider.
   ⇨ The set value appears.
4. Increase the distension pressure until a clear, liquid medium is achieved.
5. To set a value of >100 mmHg for urological and gynecological applications, tap on the **Plus** button until the following message appears:

6. Confirm the message with the **Checkmark** and set the value up to a maximum of 150 mmHg if necessary with the **Plus** button.



7. Tap on the pressure increase and select a setting: 10% – 20% – 30% – 40% – 50%...
   ⇨ The boost lag is 2 s. When the Advanced software package is installed, the lag can be extended to up to 60 s.
8. Tap on the flow limit.
   ⇨ The following values are shown for selection:
   HYS/URO/SPINE: 200 – 400 – 600 ml/min
   ART/VET ART: 1,500 – 2,000 – 2,500 ml/min

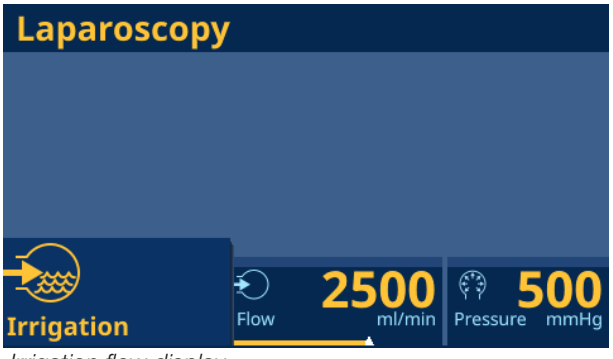
9. Tap on the **Irrigation** button or the **Footswitch** button to activate the roller pump.
   ⇨ The actual value of the irrigation pressure is displayed as an orange-colored line.
10. Tap on the **Irrigation** button or the **Footswitch** button again to deactivate the roller pump.

ⓘ The boost is activated when the ENDOMAT SELECT is connected to the UNIDRIVE S III ARTHRO via the control cable UP006 and the shaver on the UNIDRIVE S III ARTHRO is activated or the boost button is pressed using the finger.

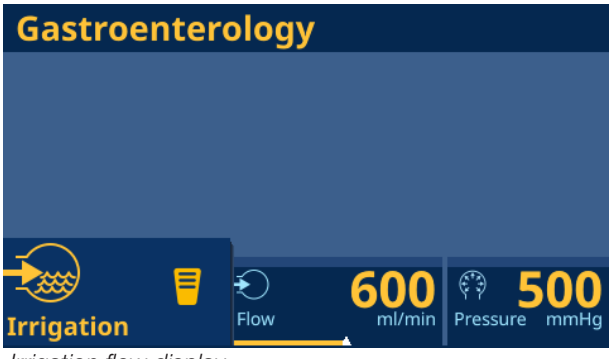
ⓘ Without the Advanced software package installed, the standard values of the flow limit are 400 ml/min (HYS and URO), 200 ml/min (SPINE) and 1,500 ml/min (ART).

6.7.4 Starting and stopping the irrigation process

1. Tap on the **Irrigation** button or the **Footswitch** (ENT/NEURO) button to start the irrigation process.
   ⇨ The orange-colored line shows the actual value for the irrigation flow or the irrigation pressure, depending on the application.



Irrigation flow display



Irrigation flow display

Irrigation pressure display

2. Tap on the **Irrigation** button or the **Footswitch** button again to stop the irrigation process.

6.8 Using ENDOMAT SELECT as a suction pump

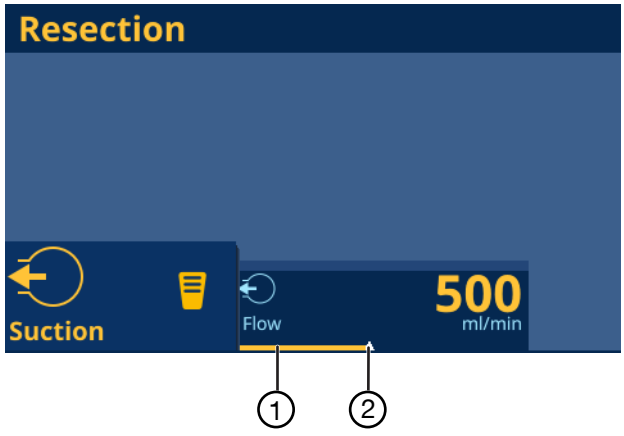
⚠ WARNING

Active roller pump! Risk of crushing!

An activated roller pump can start at any time, and the rollers of the pump can cause crushing.

- Never reach into the pump.
- Do not wear loose clothing.
- Bind long hair together.

6.8.1 Setting the suction flow (IBS Shaver / RES / HYS / ART / CALCUSON / VET SURG)



1 Suction flow actual value (orange)

2 Suction flow set value (white)

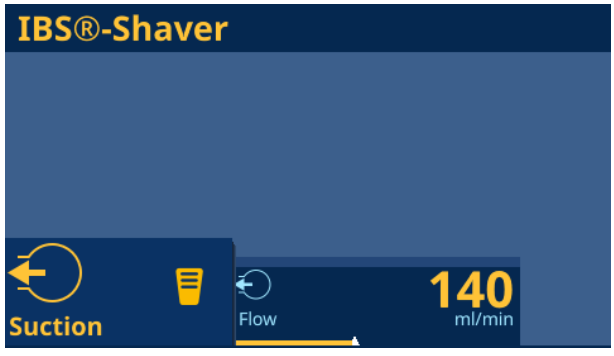
The suction flow can be set to the following values

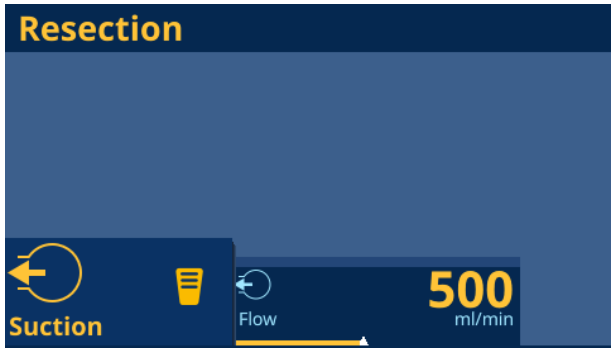
Suction flow	Values
IBS Shaver	100 – 300 ml/min
RES/VET SURG Direct Suction	100 – 1,000 ml/min
CALCUSON/VET SURG Bottle Suction	300 – 1,000 ml/min
ART	100 – 1,000 ml/min
HYS	10 – 180 ml/min

1. Tap on the set value for the suction flow and use the **Plus** and **Minus** buttons to set the set value in 20 ml/min increments (IBS) or 100 ml/min increments (RES/CALCUSON) independently of the pump status.
   ⇨ The set value is displayed as a number and with a white marking.
2. Alternatively hold the set value down and use the slider to set the set value.
3. Release the slider.
   ⇨ The set value appears.
4. Tap on the **Suction** button or the **Footswitch** button to activate the roller pump.
   ⇨ The actual value of the suction flow is displayed as an orange-colored line.
5. Tap on the **Suction** button or the **Footswitch** button again to deactivate the roller pump.

6.8.2 Starting and ending the suction

1. Tap on the **Footswitch** button or the **Suction** button to start the suction process.
   ⇨ The orange-colored line shows the actual value of the suction flow.





2. Tap on the **Footswitch** button or the **Suction** button again to stop the suction process.

7 Maintenance, servicing, repairs, and disposal

7.1 Maintaining the product

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 Alarm and information signals

7.2.1 Alarm signals

⚠ WARNING

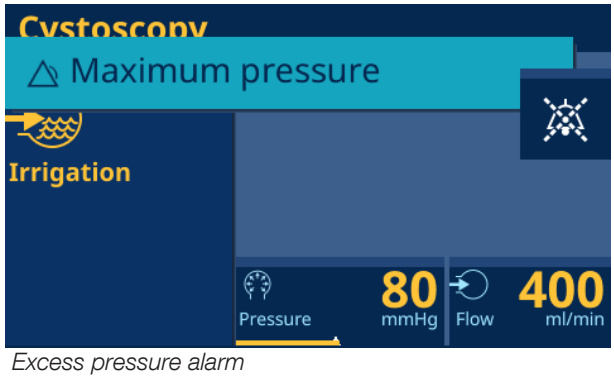
Excess pressure alarm! Risk of injury!

If the product continues to be used in the event of an excess pressure alarm, the patient can be injured.

- ▶ Stop the treatment.
- ▶ Remove the cause of the excess pressure alarm.

The alarm signals are output as long as the signal conditions are present. The alarms are displayed for a minimum of 5 seconds, and at least one tone sequence is output. The alarm thresholds and alarm delays are pre-programmed as fixed settings.

The excess pressure alarm "301: Maximum pressure" signals an excessive pressure at the output of the product and is triggered when the pressure exceeds 150 mmHg for a maximum of 2 seconds during pressure-regulated irrigation applications in urology and gynecology.



Excess pressure alarm

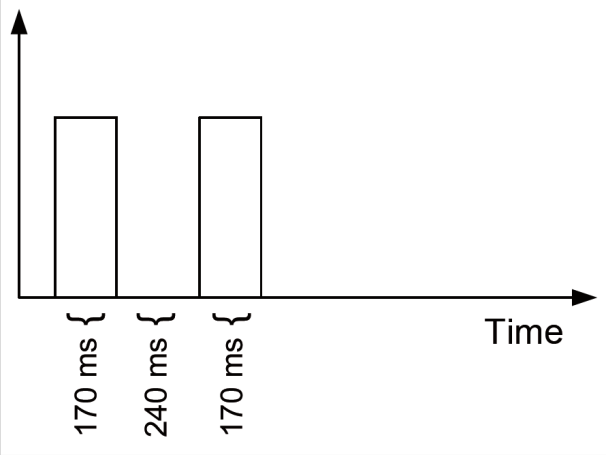
7.2.1.1 Visual alarm signal

The alarm is displayed with blue text on a cyan background in the title line. The alarm will overwrite any other text messages.

7.2.1.2 Acoustic alarm signal

The alarm signal is a burst of 2 tones lasting for 170 ms each, with a pause of 240 ms:

– Tone 1: frequency 320 Hz, volume 74 dBA
– Tone 2: frequency 254 Hz, volume 74 dBA



Excess pressure alarm – acoustic signal

If an alarm condition is present, at least one complete tone sequence will be output.

1. Tap the bell button to deactivate the signal for 30 seconds.

7.2.1.3 Checking the alarm function

1. Switch on the product.
2. Tap the button on the start screen.
   ⇨ The availability signal sounds and confirms that the alarm signal is functioning correctly.
3. Check the alarm conditions, see chapter *Checking the excess pressure alarm* [p. 63].

7.2.2 Information signals

Information signals are self-explanatory messages that explain the behavior of the product 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 product. All other information signals are output as long as the signal conditions exist. 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.

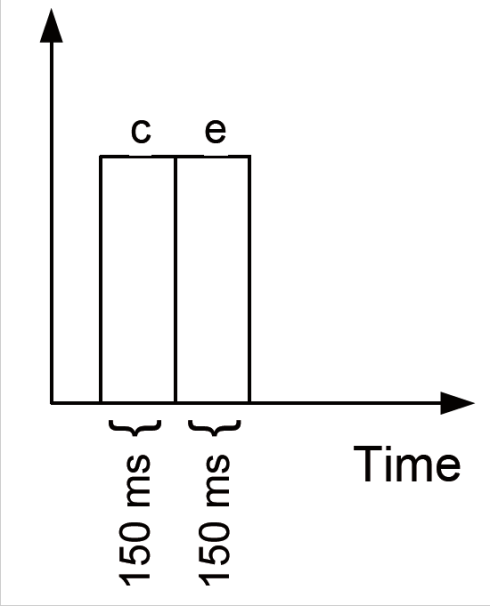
Signals of a higher priority overwrite signals of lower priority, or signals of lower priority are suppressed as long as signals of higher priority are present. In the event of multiple signal conditions with the same priority, the most recently detected condition will appear in the title line.

7.2.2.1 Visual information signal

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

7.2.2.2 Acoustic information signal

The acoustic information signal is a double tone c-e (263 Hz – 330 Hz) with a duration of 300 ms and a volume of 63 dBA.

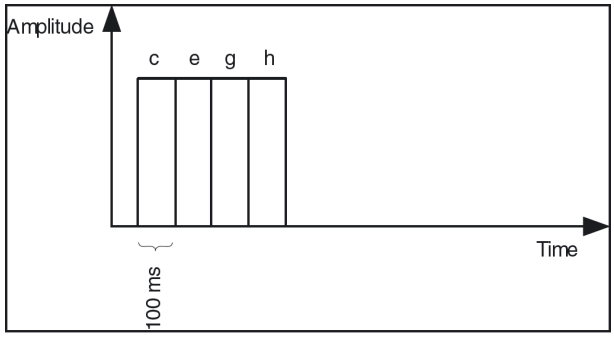


Acoustic information signal

Depending on the priority of the message, the tone sequence will either be repeated or output once. If messages indicate an inoperable product, or if the message "300: High pressure" appears, the tone sequence is repeated every 20 seconds. For all other messages, the information signal sounds once.

Availability signal

The availability signal sounds after the system self-test and as soon as the button on the start screen is tapped, see chapter *Putting the product into operation* [p. 31]. 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.

7.2.3 Checking the excess pressure alarm

The excess pressure alarm is only present in the disciplines of urology and gynecology and can be checked as follows:

1. Switch on the product.
2. Correctly insert the pressure-regulated tubing set (031523-01).
3. Choose one of the following procedures if available: Uro – CYST, PCN or URS, Gyn – HYS.
4. Set the set value to 50 mmHg.
5. Securely attach the leakage tester or pressure cuff to the bottom tubing connection.
6. Pump up the leakage tester and generate a pressure of up to 170 mmHg.

⇨ The visual and acoustic excess pressure alarm is output.

7.2.4 Checking information signals

Information signals can be checked as follows:

1. Switch on the product.
2. Correctly insert the pressure-regulated tubing set (031523-01).
3. Select one of the following procedures, if available: Uro – CYST, Gyn – HYS, SPINE ART – knee, VET ART – small animal.
4. Set the set value to 50 mmHg.
5. Securely attach the leakage tester or pressure cuff to the bottom tubing connection.
6. Pump up the leakage tester and generate the following pressure: Uro – CYST / Gyn – HYS = 60 mmHg, SPINE / ART – knee / VET ART – small animal = 300 mmHg.

⇨ The visual and acoustic excess pressure warning is output.

7.3 Safety inspection in accordance with IEC 62353

⚠ WARNING

Risk of injury due to product deficiencies!

Patients, users, and third parties may be injured as a result of deficiencies with the product and accessories.

- ▶ 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

1. Perform a functional test, see chapter *Venting the tubing system* [p. 51].
2. Document the results of the safety test.

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.

8 Accessories and spare parts

8.1 Accessories

Item	Order no.
Power cord, length 300 cm	400A
Power cord, US version, 200 cm	400B
Pump Tube	UP013
Membrane	UP014
Metal filter	20300038
One-Day Tubing Set, irrigation, PC	031563-10
One-Day Tubing Set, irrigation, FC	031564-10
Tubing Set, irrigation, PC	031523-10
Tubing Set, suction, BS	031647-10
Tubing Set, suction, DS	030647-10
Tubing Set, irrigation, FC	031524-10
Tubing Set, irrigation, CV	031529-10
Tubing set, irrigation, GI mode, for single use, sterile, package of 10	031525-10
Tubing set, irrigation, UNIDRIVE, for single use, sterile, package of 10	031531-10
Tubing Set, suction, BS	UP010
Tubing Set, suction, DS	UP009
Tubing Set, irrigation, FC	UP007
Tubing Set, irrigation, PC	UP008
Leakage tester	13242XL

For IBS Shaver and RES recommended accessories

Article	Order no.
Suction bottle, 5 l, can be sterilized	20300050
Sealing Cap, for 1.5 l and 5 l bottles	20300034
Bottle Holder, for bottle 5 l	20300032
Support Element	20300033

Required accessories for operation with CALCUSON

Item	Order no.
Suction Bottle, 0.5 l	20300051
Sealing Cap for Suction Bottle 20300051	20300039
Bottle stand, for suction bottle	20300231
Control Cable	20701070

Required accessories for operation with UNIDRIVE SIII ARTHRO

Item	Order no.
Control Cable	UP006

Required accessories for ENT/NEURO

Article	Order no.
One-pedal footswitch, two-stage	UF102
One-pedal footswitch, two-stage, wireless	UF102W

Required accessories for GI or recommended accessories for boost actuation

Article	Order no.
One-pedal footswitch, one-stage	UF101
One-pedal footswitch, one-stage, wireless with receiver and power supply unit	UF101W

Recommended accessories for operation with UNIDRIVE Select

Article	Order no.
Ethernet cable, (OR1) patch cable, CAT6a, length 2.0 m, UL-listed	WO10275

9 Electromagnetic compatibility

9.1 General notes on the operating environment

The product is suitable for use in professional healthcare settings. Professional healthcare facilities include 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 HF-shielded room of an ME system for MRT).

ⓘ The emission characteristics of this product make it suitable for use in professional healthcare facilities as well as in a residential environment (CISPR 11 Class B). This product offers adequate protection to radio communication service. In the rare event of interference to the radio transmission operation, the user might need to take mitigation measures, such as relocating or re-orienting the product.

9.2 Accessories and lines

Accessories and lines for EMC compliance				
Type	**Shielded**	**Length [m]**	**Ferrite**	**Use**
PA	No	>3	No	Potential equalization
Power cord	No	1	No	Power supply

9.3 Table 1 – Compliance level for immunity tests

Guidelines and manufacturer's declaration – electromagnetic immunity

The product is intended for use in the electromagnetic environment specified below. The user of the product should make sure that it is used in such an environment.

Interference immunity tests	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
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	Floors should be made of wood, concrete, or covered with ceramic tiles. If floors are covered with synthetic material, the relative humidity must 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	± 2 kV for power lines ± 1 kV for input and output lines	The power supply quality should be that of a typical commercial or hospital environment.

Interference immunity tests	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
	100 kHz repetition	100 kHz repetition	
Surges acc. to IEC 61000-4-5	± 1 kV voltage outer conductor – outer conductor ± 2 kV voltage outer conductor – ground	± 1 kV voltage outer conductor – outer conductor ± 2 kV voltage outer conductor – ground	The power supply quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations acc. to IEC 61000-4-11	Voltage dip: Dip to 0% for 1 cycle at 0° phase angle Dip to 70% for 25/30 cycles at 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 at 0° phase angle Dip to 70% for 25/30 cycles at 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 product requires continued operation in the event of interruptions to the power supply network, it is recommended that the product be operated with an uninterruptible power supply or a battery.
Magnetic field at the power frequency (50/60 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 install the product further from sources of electromagnetic fields or to install magnetic shielding. Before the product is installed, the electromagnetic field should be measured to ensure that it is sufficiently low.
Immunity test acc. to IEC 61000-4–3 for radiated, radio-frequency electromagnetic fields	3 V/m 80 MHz to 2.7 GHz * Refer to Table 2 for wireless proximity RF 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 band	3 V_{rms} on 150 kHz to 80 MHz 1 kHz 80% AM modulation 6 V_{rms} in ISM band	

9.4 Table 2 – Test levels for proximity fields from HF wireless communications equipment

Test frequency MHz	Frequency band MHz	Radio service	Modulation	Immunity test level V/m	Compliance level V/m
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	27	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine wave	28	28
710	704 – 787	LTE band 13 and 17	Pulse modulation 217 Hz	9	9
745					
780					
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation 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 217 Hz	28	28
1845					
1970					
2450	2400 – 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
5500					
5785					

9.5 Table 3 – Test levels for radiated and conducted immunity tests

Guidelines and manufacturer's declaration – electromagnetic immunity

The product is intended for use in the electromagnetic environment specified below. The user of the product should make sure that it is used in such an environment.

Interference immunity tests	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Conducted HF disturbances acc. to IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	Portable and mobile HF communications equipment should be used no closer to any part of the

Interference immunity tests	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Radiated HF disturbances acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distances: $d = 1.2 \sqrt{P}$ Where P is the rated power of the transmitter in watts [W] according to the information provided by the transmitter manufacturer and d is the recommended separation distance in meters [m]. Field strengths from fixed HF transmitters as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range [b]. $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Interferences may occur in the vicinity of equipment marked with the following symbol: 

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by absorptions and reflections of buildings, objects, and people.

[a] Field strengths from fixed transmitters, e.g., base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location where the device is used exceeds the above compliance levels, the device should be monitored to ensure proper function. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the product.

[b] Over the frequency range from 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

9.6 Table 4 – Emission class and group

Guidelines and manufacturer's declaration – electromagnetic emissions

The product is intended for use in such an environment as specified below. The customer or user of the device should ensure that it is used in such an environment.

Interference emission measurements	Conformity	Electromagnetic environment – Guidelines
RF emissions according to CISPR 11	Group 1	The product uses RF energy for its internal function only. Therefore, its RF emissions are very low and are not likely to cause any interference affecting nearby electronic equipment.
RF emissions according to CISPR 11	Class B	The product is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions acc. to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions acc. to IEC 61000-3-3	Compliant	

9.7 Table 5 – Recommended separation distances between portable and mobile HF communications devices and the product

The device is intended for use in an electromagnetic environment in which HF disturbances are controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communications equipment (transmitters) and the product as recommended below, according to the maximum output power of the communications device.

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

For transmitters whose maximum rated power is not listed in the table above, the recommended separation distance d in meters (m) can be estimated using the equation from the respective column, whereby P is the maximum rated power of the transmitter in watts (W) according to the transmitter manufacturer.

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

Note: These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by absorptions and reflections of buildings, objects, and people.

The product was tested for compatibility with HF surgical devices in accordance with IEC 60601-2-2 Appendix BB.

10 Errors and messages

10.1 Troubleshooting

Fault	Possible causes	Actions
Product has failed	Bad connection between product mains plug - connection socket	▶ Push the mains plug firmly into the connection socket
	Power supply failure	▶ Check that there is electricity to the wall outlet
	Internal fuse defective	▶ Contact Service
Inadequate suction power	Leakage occurring in tubing system	▶ Check the tubing line and replace it if necessary ▶ Check the sealing cap is correctly seated
No suction	Plunger ball blocking suction inlet	▶ Check the fluid level and empty the glass if necessary ▶ Clean the plunger ball and check for freedom of movement
	The bacterial filter on the suction bottle is moist and impermeable	▶ Change the bacterial filter
No irrigation pressure	The tubing is leaky or not connected correctly	▶ Check tubing and connections and replace them if necessary ▶ Send product for repair
	Defective control electronics	

10.2 Software messages

Message	Possible cause	Actions
102: Attach tubing set again	Last sensor test more than 24 h ago, deviation in pressure values	▶ Remove the tubing set briefly and then start the pump again
150: Pump stopped	Communication or pressure measurement disrupted	Function of the product is interrupted

Message	Possible cause	Actions
		▶ Re-activate pump if error message is automatically reset
180: Paused	Transient discrepancy between redundant pressure measurement values	Transient sensor discrepancy, the pump continues automatically
190: Cartridge detection error	Cartridge detection electronics error	▶ Switch the product off and on ▶ Contact KARL STORZ Service if the error reoccurs
191: Cartridge locking error	Cartridge locking electronics error	▶ Switch the product off and on ▶ Contact KARL STORZ Service if the error reoccurs
20C: Restart necessary in < 4 h	The product was in continuous operation for more than 20 hours	After 24 hours of continuous operation, the pump can no longer be restarted
20D: Sensor test overdue	The product was in continuous operation for more than 24 hours	▶ Switch the product off and on
259: Electronics error	BE: Internal error	▶ Switch the product off and on ▶ Contact KARL STORZ Service if the error reoccurs
300: High pressure	Stopcock on instrument closed	▶ Observe the surgical field ▶ Ensure pressure reduction
301: Maximum pressure	Excess pressure alarm in URO and HYS application if 150 mmHg is exceeded	▶ Observe the surgical field

Message	Possible cause	Actions
		▶ Ensure pressure reduction
500: Main functions not active	FE: A touchscreen activation lasting more than 25 seconds has been detected	Acoustic and visual signal – the product can still be operated. A calibration of the touchscreen can be started. ▶ Activate the touchscreen for 25 seconds to start the calibration ⇨ A text message appears. ▶ Check the touchscreen and clean it if necessary This text message can also appear in the event of a touchscreen short circuit. ▶ Switch the product off and on ▶ Contact KARL STORZ Service if the error reoccurs
501: Touch calibration	FE: A touchscreen activation lasting more than 30 seconds has been detected	The text message is part of the calibration procedure of the touchscreen (see text message 500) and is displayed after the touchscreen is touched continuously for 30 seconds ▶ Release the touchscreen and touch it again within 5 seconds in order to start calibration

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

KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34, 78532 Tuttlingen/Germany
Postfach 230, 78503 Tuttlingen/Germany
Phone: +49 7461 708-0, Fax: +49 7461 708-105
E-mail: info@karlstorz.com

KARL STORZ Endoskope Berlin GmbH
Scharnhorststr. 3, 10115 Berlin/Germany
Phone: +49 30 30 69090, Fax: +49 30 30 19452

KARL STORZ Endoscopy Canada Ltd.
7171 Millcreek Drive, Mississauga, Ontario L5N 3R3 Canada
Phone: +1 905 816-4500, Fax: +1 905 816-4599
Toll free (Canada only) Phone: 1-800-268-4880, Fax: 1-800-482-4198 (Canada only)
E-mail: info-canada@karlstorz.com

KARL STORZ Endoscopy America, Inc.
2151 East Grand Avenue, El Segundo, CA 90245-5017, USA
Phone: +1 424 218-8100, Fax: +1 424 218-8525
Toll free (USA only) Phone: 1 800 421-0837, Fax: 1 800 321-1304 (USA only)
E-mail: communications@ksea.com

KARL STORZ Veterinary Endoscopy America, Inc.
1 South Los Carneros Road, Goleta, CA 93117, USA
Phone: +1 805 968-7776, Fax: +1 805 685-2588
E-mail: info@karlstorzvet.com

KARL STORZ Endoscopia Latino America, Inc.
815 N. W. 57th Avenue, Suite 480, Miami, FL 33126-2042, USA
Phone: +1 305 262-8980, Fax: +1 305 262-8986
E-mail: info@ksela.com

KARL STORZ Endoscopia México S.A. de C.V.
Edificio Atlantic, Oficina 3G, Calle D e/ 1ra y 3ra, 10400 Vedado, Havanna, Cuba
Phone: +537 836 95 06, Fax: +537 836 97 76
E-mail: kstorzcuba@gmail.com

KARL STORZ Endoscopia México S.A. de C.V.
Av. Ejercito Nacional No. 453 Piso 2, Colonia Granada, Alcaldia Miguel Hidalgo, C.P. 11520, Mexico City, Mexico
Phone: +52 (55) 1101 1520
E-mail: mx-info@karlstorz.com

KARL STORZ Marketing América Do Sul Ltda.
Rua Joaquim Floriano, nº. 413, 20º andar – Itaim Bibi, CEP-04534-011 São Paulo, Brazil
Phone: +55 11 3526-4600, Fax: +55 11 3526-4680
E-mail: br-info@karlstorz.com

KARL STORZ Endoscopia Argentina S.A.
Zufriategui 627 6° Piso, B1638 CAA – Vicente Lopez, Provincia de Buenos Aires, Argentina
Phone: +54 11 4718 0919, Fax: +54 11 4718 2773
E-mail: info@karlstorz.com.ar

KARL STORZ Endoskopi Norge AS
Stamveien1, 1483 Hagan, Norway
Phone: +47 6380 5600, Fax: +47 6380 5601
E-mail: post@karlstorz.no

KARL STORZ Endoskop Sverige AB
Storsätragränd 14, 127 39 Skärholmen, Sweden
Phone: +46 8 505 648 00
E-mail: kundservice@karlstorz.se

KARL STORZ Endoscopy Suomi OY
Taivaltie 5, 01610 Vantaa, Finland
Phone: +358 (0)96824774, Fax: +358 (0)968247755
E-mail: asiakaspalvelu@karlstorz.fi

KARL STORZ SE & Co. KG
Representative Office
Žalgirio St. 94, LT9300 Vilnius, Lithuania
Phone: +370 5 272 0448, Mobile: +370 685 67 000
E-mail: info-lt-lv@karlstorz.com

KARL STORZ Endoskopi Danmark A/S
Skovlytoften 33, 2840 Holte, Denmark
Phone: +45 45162600, Fax: +45 45162609
E-mail: marketing@karlstorz.dk

KARL STORZ Endoscopy (UK) Ltd.
415 Perth Avenue, Slough, Berkshire, SL1 4TQ, United Kingdom
Phone: +44 1753 503500, Fax: +44 1753 578124
E-mail: info-uk@karlstorz.com

KARL STORZ Endoscopie Nederland B.V.
Displayweg 2, 3821 BT Amersfoort, Netherlands
Phone: +31 (0)33 4545890
E-mail: info-nl@karlstorz.com

KARL STORZ Endoscopy Belgium N.V.
Phone: +31 (0)33 4545890
E-mail: info-be@karlstorz.com

KARL STORZ Endoscopie France S.A.S.
12, rue Georges Guynemer, Quartier de l'Europe, 78280 Guyancourt, France
Phone: +33 1 30484200, Fax: +33 1 30484201
E-mail: marketing-fr@karlstorz.com

KARL STORZ Endoskop Austria GmbH
Landstraßer Hauptstr. 148/1/G1, 1030 Vienna, Austria
Phone: +43 1 71 56 0470, Fax: +43 1 71 56 0479
E-mail: storz-austria@karlstorz.com

KARL STORZ Endoscopia Ibérica S.A.
Parque Empresarial San Fernando, Edificio Munich – Planta Baja, 28830 Madrid, Spain
Phone: +34 91 6771051, Fax: +34 91 6772981
E-mail: info-es@karlstorz.com

KARL STORZ Endoscopia Italia S.r.l.
Via dell'Artigianato, 3, 37135 Verona, Italy
Phone: +39 045 8222000, Fax: +39 045 8222001
E-mail: info-ita@karlstorz.com

KARL STORZ Croatia d.o.o.
Capraška 6, 10000 Zagreb, Croatia
Phone: +385 1 6406 070, Fax: +385 1 6406 077
E-mail: info@karlstorz.hr

KARL STORZ Endoskopija d.o.o.
Cesta v Gorice 34b, 1000 Ljubljana, Slovenia
Phone: +386 1 620 5880, Fax: + 386 1 620 5882
E-mail: pisarna@karlstorz.si

KARL STORZ Polska Sp. z o.o.
ul. Bojkowska 47, 44-100 Gliwice, Poland
Phone: +48 32 706 13 00, Fax: +48 32 706 13 07
E-mail: info-pl@karlstorz.com

KARL STORZ Endoszkóp Magyarország Kft.
Toberek utca 2. fsz. 17/b, HU-1112 Budapest, Hungary
Phone: +36 195 096 31, Fax: +36 195 096 31
E-mail: info-hu@karlstorz.com

KARL STORZ Endoscopia Romania srl
Str. Prof. Dr. Anton Colorian, nr. 74, Sector 4, 041393 Bucharest, Romania
Phone: +40 (0)31 4250800, Fax: +40 (0)31 4250801
E-mail: info-ro@karlstorz.com

KARL STORZ Endoskope Greece M.E.P.E.*
Patriarhou Grigoriou E' 34, 54248 Thessaloniki, Greece
Phone: +30 2310 304868, Fax: +30 2310 304862
E-mail: info-gr@karlstorz.com
*Repair & Service Subsidiary

KARL STORZ Industrial**
Gedik Is Merkezi B Blok, Kat 5, D 38-39, Bagdat Cad. No: 162, Maltepe
Istanbul, Turkey
Phone: +90 216 442 9500, Fax: +90 216 442 9030
**Sales for Industrial Endoscopy

OOO KARL STORZ Endoskopy – WOSTOK
Derbenyevskaya nab. 7, building 4, 115114 Moscow, Russia
Phone: +7 495 983 02 40, Fax: +7 495 983 02 41
E-mail: Info-ru@karlstorz.com

TOV LLC KARL STORZ Ukraine
Avenue Geroyiv Stalingrada Str. 2D, office 717 Kyiv, 04210/Ukraine
Phone: +38 095 000-895-0, +38-097-000-895-0, +38 073 000-895-0
E-mail: marketing@karlstorz.com.ua

KARL STORZ SE & Co. KG Representation Office
Sabit Orudschow 1184, apt. 23, 1025 Baku, Azerbaijan
Phone: +99 450 613 30 60
E-mail: info-az@karlstorz.com

KARL STORZ ENDOSKOPE – East Mediterranean and Gulf (Offshore) S.A.L.
Spark Tower 1st floor Charles Helou St., Horch Tabet – Sin El Fil, Beirut,
Lebanon
Phone: +961 1 501105, Fax: +961 1 501950
E-mail: info@karlstorz-emg.com

KARL STORZ Endoscopy (South Africa) (Pty) Ltd.
P.O. 6061, Roggebaai, 8012 Cape Town, South Africa
Phone: +27 21 417 2600, Fax: +27 21 421 5103
E-mail: info@karlstorz.co.za

TOO KARL STORZ Endoskopy Kasachstan
Saryarka, 6, BC "Arman", off. 910, 010000 Astana, Republic of Kazakhstan
Phone: +7 7172 552-549, 552-788, Fax: -444
E-mail: info@karlstorz.kz

KARL STORZ ENDOSKOPE East Mediterranean & Gulf (branch)
Building West Side 7A – Unit 7WA – 3008, Dubai Airport Free Zone, P.O. Box
54983, Dubai – United Arab Emirates
Phone: +971 (0)4 2958887, Fax: +971 (0)4 3205282
Service Hotline: +971 (0)4 3415882
E-mail: info-gne@karlstorz-emg.com

KARL STORZ Endoscopy India Private Limited
11th Floor, Dr. Gopal Das Bhawan, 28, Barakhamba Road, New Delhi
110001, India
Phone: +91 11 4374 3000, Fax: +91 11 4374 3010
E-mail: corporate@karlstorz.in

KARL STORZ SE & CO. KG
Interchange 21 Tower, Level 33, 399 Sukhumvit Road, North Klongtoey,
Wattana, 10110 Bangkok, Thailand
Phone: +84 28 3823 8000 Fax: +84 28 3823 8039
E-mail: infovietnam@karlstorz.com

KARL STORZ SE & Co. KG
Resident Representative Office
14th Floor, MPlaza Saigon, 39 Le Duan, District 1, Ho Chi Minh City, Vietnam
Phone: +84 28 3823 8000, Fax: +84 28 3823 8039
E-mail: infovietnam@karlstorz.com

KARL STORZ Endoscopy China Ltd.
Room 2503-05, 25F AXA Tower, Landmark East, No. 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong, People's Republic of China
Phone: +852 28 65 2411, Fax: +852 28 65 4114
E-mail: inquiry@karlstorz.com.hk

KARL STORZ Endoscopy (Shanghai) Ltd., Beijing Branch
Room 1805-1807, Building B, 18F Beijing IFC, No. 8, Jianguomenwai Street,
Chaoyang District, 100022, Beijing, People's Republic of China
Phone: +86 10 5638188, Fax: +86 10 5638199
E-mail: info@karlstorz.com.cn

KARL STORZ Endoscopy (Shanghai) Ltd., Shanghai Branch
Room 701A Building 5 & Room 501 Building 7, No. 3000 Longdong Avenue,
Pilot Free Trade Zone, 201203, Shanghai, People's Republic of China
Phone: +86 21 60339888, Fax: +86 21 60339808
E-mail: info@karlstorz.com.cn

KARL STORZ Endoscopy (Shanghai) Ltd., Chengdu Branch
Room 803-805, 8F Jin Jiang International Building, No. 1 West Linjiang
Road, Wuhou District, 6100414, Chengdu, People's Republic of China
Phone: +86 28 86587977, Fax: +86 28 86587975
E-mail: info@karlstorz.com.cn

KARL STORZ Endoscopy (Shanghai) Ltd., Shenyang Branch
Room 2001-2005, 20F N-MEDIA International Center, No. 167 Youth Avenue,
Shenhe District, 110014, Shenyang, People's Republic of China
Phone: +86 24 23181118, Fax: +86 24 23181119
E-mail: info@karlstorz.com.cn

KARL STORZ Endoscopy (Shanghai) Ltd., Guangzhou Branch
Room 02B & 03 & 04A, 35F Teem Tower, No. 208 Tianhe Road, Tianhe
District, 510620, Guangzhou, People's Republic of China
Phone: +86 20 87321281, Fax: +86 20 87321286
E-mail: info@karlstorz.com.cn

KARL STORZ Endoscopy Asia Marketing Pte Ltd.
No. 8 Commonwealth Lane #03-02, Singapore 149555, Singapore
Phone: +65 69229150, Fax: +65 69229155
E-mail: infoasia@karlstorz.com

KARL STORZ Endoscopy Singapore Sales Pte Ltd
No. 8 Commonwealth Lane #03-02, Singapore 149555, Singapore
Phone: +65 69229150, Fax: +65 69229155
E-mail: infoasia@karlstorz.com

KARL STORZ SE & Co. KG Representative Office Indonesia
Sinarmas MSIG Tower Level 37, Jl. Jend. Surdirman No. Kav. 21, South
Jakarta
DKI Jakarta 12920
E-mail: infoindonesia@karlstorz.com

KARL STORZ Endoscopy Korea Co. Ltd.
9F Hyowon-Building, 97, Jungdae-ro, Songpa-gu, 05719 Seoul, Korea
Phone: +82-70-4350-7474, Fax: +82-70-8277-3299
E-mail: infokorea@karlstorz.com

KARL STORZ Endoscopy Taiwan Ltd.
12F, No. 192, Sec. 2, Chung Hsin Rd., Sindian District, New Taipei City,
Taiwan
Phone: +886 933 014 160, Fax: +886 2 8672 6399
E-mail: info-tw@karlstorz.com

KARL STORZ SE & Co. KG Representative Office Philippines
1901 Picadilly Star Bldg., 4th Avenue, BGC, Taguig City 1636, Philippines
Phone: +63 2 317 45 00, Fax: +63 2 317 45 11
E-mail: phillippines@karlstorz.com

KARL STORZ Endoscopy Japan K. K.
Stage Bldg. 8F, 2-7-2 Fujimi, Chiyoda-ku, Tokyo 102-0071, Japan
Phone: +81 3 6380-8622, Fax: +81 3 6380-8633
E-mail: info@karlstorz.co.jp

KARL STORZ Endoscopy Australia Pty. Ltd.
68 Waterloo Road, Macquarie Park NSW 2113, P O Box 50 Lane Cove NSW
1595, Australia
Phone: +61 (0)2 9490 6700, Fax: +61 (0)2 9420 0695
Toll free: 1800 996 562 (Australia only)
E-mail: info@karlstorz.au

www.karlstorz.com

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KARL STORZ—ENDOSKOPE

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KARL STORZ SE & Co. KG
Dr.-Karl-Storz-Straße 34
78532 Tuttlingen

Postfach 230
78503 Tuttlingen
Germany

Phone: +49 7461 708-0
Fax: +49 7461 708-105
E-mail: info@karlstorz.com
www.karlstorz.com