

STORZ

KARL STORZ — ENDOSKOPE

en **Instructions for use**
ENDOMAT SELECT
UP220



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<https://www.karlstorz.com/>

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06-2025

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1 General information

1.1 Read the instructions for use

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

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

1.2 Read the instructions for use of compatible products

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

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

1.3 Scope

This instruction manual is valid for:

Suction/irrigation pumps

Product name	Item number
ENDOMAT SELECT	UP220

1.4 General signs and symbols

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

Practical tip

-  This sign refers to useful and important information.

Actions to be performed

Action to be carried out by several steps:

- ✓ Prerequisite that must be met before carrying out an action.
- 1. Step 1
 - ⇒ Interim result of an action
- 2. Step 2
 - ⇒ Result of a completed action

Actions in the case of a single step:

- ▶ Step 1

Actions in safety notes:

- ▷ Step 1

- ▷ Step 2

Lists

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

1.5 Description of warning messages

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

▲ WARNING

WARNING

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

▲ CAUTION

CAUTION

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

NOTICE

NOTICE

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

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
GYN	Gynecology
HYS	Hysteroscopy
IBS	Intrauterine BIGATTI Shaver
LAP	Laparoscopy
NEURO	Neurosurgery
PC	Pressure-controlled
PCN	Percutaneous nephroscopy
PRO	Proctology

Abbreviation	Explanation
RES	Resection
SPINE	Vertebral column
SURG	Surgery
THOR	Thoracoscopy
URO	Urology
URS	Ureterorenoscopy
VET	Veterinary medicine

2 Normal use

2.1 Intended use

Suction/irrigation pumps

Suction/irrigation pumps are intended to irrigate irrigation fluid into organs, joints and on fields of intervention, as well as to suction off irrigation and body fluids, secretions, tissue and gases.

Suction/irrigation pumps do not have body contact.

2.2 Indications

The medical devices are suitable for endoscopic procedures where irrigation and suction functions are required. This includes procedures in the following medical fields:

- Urology
- Gynecology
- Surgery (Thoracoscopy, Laparoscopy and Proctology)
- Arthroscopy
- Spine Surgery

In addition, the pump with irrigation and suction function can be used in combination with UNIDRIVE SELECT and for lens cleaning of endoscopes.

2.3 Contraindications

The medical devices must not be used for interventions in direct contact with the CNS (central nervous system) and central circulatory 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 the successful completion of the planned intervention due to its technical design.

The Endomat Select must not be used with:

- ERCP
- Cholangioscopy (gastro)
- Spine lumbar (interlaminar approach)
- 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 dilatation of hollow organs and joints.

2.4 Clinical benefits

The products are involved in the delivery of fluid to and from the patient at a set pressure and/or flow rate to allow the performance of the following procedures:

- Hysteroscopy: the fluid delivered by the pump distends the uterine cavity to permit the visualization and the performance of endoscopic procedures in the uterine cavity. The pump can also be used for the suction of fluid from the uterine cavity when used in combination with the IBS (Intrauterine Bigatti Shaver).
- Arthroscopy: the irrigation fluid delivered by the pump distends the joint capsule to permit the visualization and the performance of arthroscopic procedures.
- Urology: the fluid delivered by the pump distends the urinary tract to permit the visualization and the performance of endoscopic procedures in the urinary tract. The pump can be also used for the suction of fluid from the urinary tract when used in combination with Calcuson or during resection.
- Surgery (Laparoscopy, Thoracoscopy, Proctology and Spine): the fluid delivered by the pump can be used to flush blood and debris from the operating field.
- ENT / Neurology: the fluid delivered by the pump can be used to flush the lens of the endoscope.

(Depending on the pumps or programs on the pumps used not all products are involved in all procedures)

2.5 Residual risks

No residual risks directly related to the product could be identified.

The following risks have been identified in clinical literature to be related to the use of irrigation fluid for distension of body cavities:

- Gas embolism
- Fluid overload / extravasation
- Hypotensive bradycardic events in arthroscopy
- Hypothermia in arthroscopy
- Intolerable pain and increased hypertension in hysteroscopy
- Perirenal hematoma

The side-effects described above relate to the use of irrigation fluid for distension of body cavities. No reliable data shows a difference in side-effects relating to the use of pumps compared to gravity induced irrigation. Therefore, the side-effects are considered acceptable with regards to the use of pumps.

2.6 Target user populations

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

2.7 Patient population

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

2.8 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

2.9 Intended conditions of use

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

Condition	Operation
Frequency of use	One or more times a day
Length of use	Several minutes to several hours a day
Place of installation	Positioning on a level, vibration-free surface
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.

- ▷ Carefully read and observe all warnings and safety notes.
- ▷ Follow the instructions.

3.1 Serious incidents

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

- Death of a patient, user, or another person
- Temporary or permanent serious deterioration in the medical condition of a patient, user, or another person
- A serious threat to public health
- ▶ The manufacturer and appropriate authority must be notified of all serious incidents.

3.2 Correct handling and product testing

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

- ▶ Only persons with the necessary medical qualification and who are acquainted with the application of the product may work with it.
- ▶ Check that the product is suitable for the procedure prior to use.
- ▶ Check the product for the following properties, for example, before and after every use:
 - Functionality
 - Damage
 - Changes to the surface

For detailed inspection criteria, see section *Inspecting the product*.

- ▶ Do not continue to use damaged products.
- ▶ Dispose of the product properly; see *Disposing of the product*.

3.3 Product not clean

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

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

3.4 Combination with other components

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

- ▶ Ensure that any additional devices connected to electrical medical devices comply with the relevant IEC or ISO standards.
- ▶ Ensure that all configurations comply with the requirements for medical electrical systems.
- ▶ Only combine the product with devices and components that the manufacturer has approved for combined use, see chapter *Possible combinations*.
- ▶ Do not make any modifications to the product.
- ▶ Connect only devices that comply with IEC 60601 to signal inputs and signal outputs.

3.5 Dangers from electrical current

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

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

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

- ▶ Do not open the product.
- ▶ Have servicing carried out by KARL STORZ or a company authorized by KARL STORZ.
- ▶ 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

3.6 Damage due to ingress of liquid in electrical components

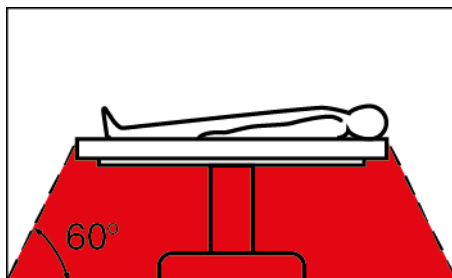
In the case of electrical products, individual components or the product itself may be live. Liquid ingress into an electrical product may result in a short circuit or an unintentional transfer of current. The product is damaged as a result and patients, users and third parties may be injured.

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

3.7 Risk of explosion and fire

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

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



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

3.8 Electromagnetic interference

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

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

3.9 Failure of products

The product may fail during use.

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

3.10 Observing ambient conditions

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

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

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.

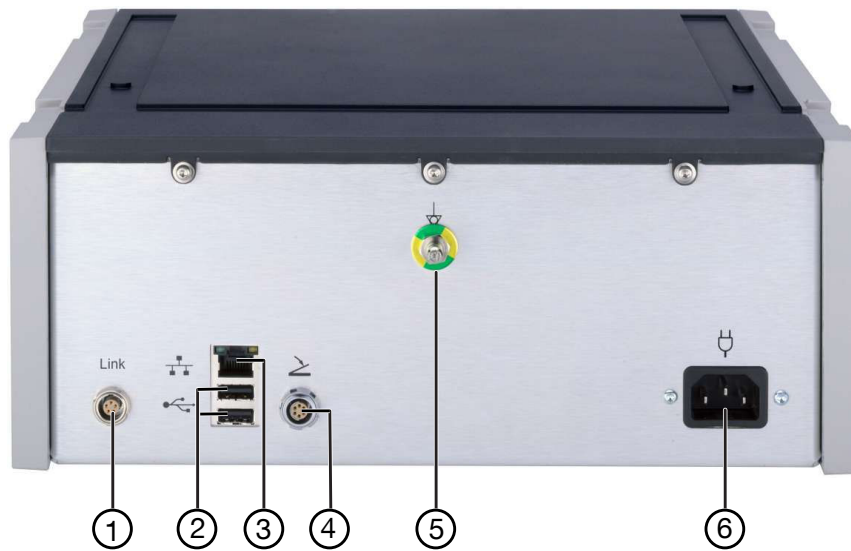
- i** The range of functions of the product varies according to the installed software package. For the required accessories for the respective software package, see chapter *Accessories and spare parts* [p. 59].

4.2 Product overview



ENDOMAT SELECT – Front view

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



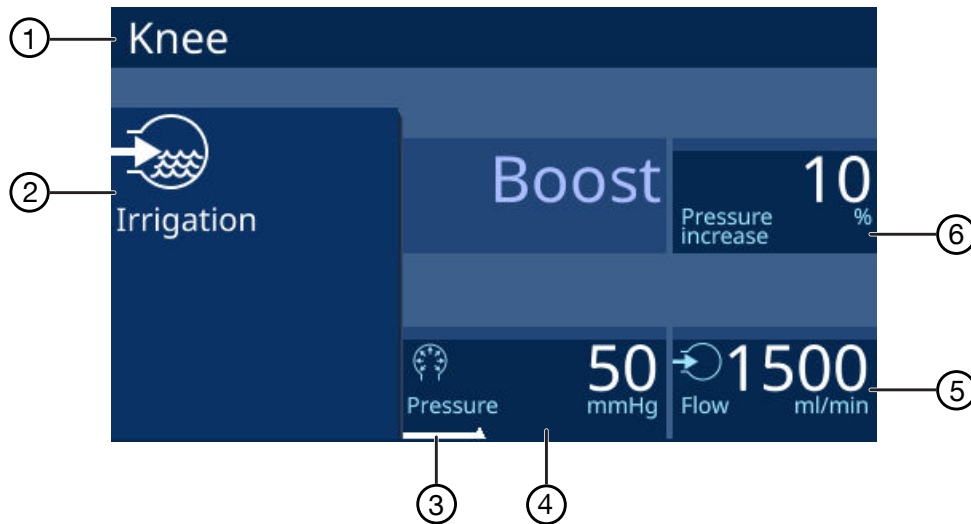
ENDOMAT SELECT – Rear view

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



Tubing set for single use

4.3 Touchscreen



- | | | | |
|---|----------------------------------|---|-------------------------|
| 1 | Discipline name | 4 | Limitation of pressure |
| 2 | Start/stop irrigation or suction | 5 | Limitation of flow |
| 3 | Irrigation or 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% to 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
	Increase value
	Decrease value
	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 described products in this medium may not be available in all countries due to different regulatory requirements.

The product can be combined with the following components:

Combination with tubing sets

Pump	Tubing Set
UP220	031563-10
	031564-10
	031523-10
	031524-10
	030647-10
	031647-10
	031531-10
	031529-10
	UP007
	UP008
	UP009
	UP010

Combination Pump – Control Cable – UNIDRIVE Select

Pump	Control Cable	UNIDRIVE Select
UP220	WO10275	UM600

Combination with footswitches

Pump	Footswitches
UP220	UF101
	UF101W
	UF102
	UF102W

Combination with other products

Article	Order no.
Suction bottle, 5 l, can be sterilized	20300050
Suction Bottle, 0.5 l	20300051
Sealing Cap, for 1.5 l and 5 l bottles	20300034
Sealing Cap for Suction Bottle 20300051	20300039
Bottle Holder, for bottle 5 l	20300032
Bottle stand, for suction bottle	20300231
Support Element	20300033

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

2 To the collection container















4.6 Technical data




Designation	Value
Power supply (AC)	100–240 V
Operating frequency	50/60 Hz
Power input	82 VA
Electrical protection class	I
Applied part type according to IEC 60601-1	CF
Degree of protection acc. to IEC 60529	IP 21D
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%

Designation	Value
Irrigation flow	Accuracy (0–3,500 ml/min): $\pm 20\%$ Accuracy when using patient tube 031162-10 for day sets: $\pm 25\%$
	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: 10–130 ml/min; increments: 10 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
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






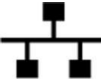





4.7 Symbols employed





4.7.1 Symbols on the packaging

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

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

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

4.8 Ambient conditions

Transport and storage 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 devices, at least one of which has to be a medical electrical device. The devices 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 (UP220) with UNIDRIVE Select (UM600) and footswitch (UF201)

The components can be connected with the following control cables:

- Control cable (WO10275) for UNIDRIVE Select

The accessory components, such as transducers and probes, specified in the relevant 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 cart).
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.
 - ① 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 cart 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 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 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. To avoid unintentional excess pressure, check the set height difference after switching on the product.
4. If a software update has been carried out, check the configuration of the product.
5. Check the functionality of the product, see chapter *Venting the tubing system* [p. 45].

5.3 Reprocessing the product

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

5.4 Product installation

⚠ WARNING

Intercavitary pressure displayed incorrectly! Risk of injury!

The intercavitary pressure is measured at the device output. If there is too great a height difference between the product and the patient, the intercavitary pressure will be displayed incorrectly.

- ▷ Set up the product at patient height.

⚠ 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 $\pm 45^\circ$ 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, with a tubing length of 2 m.

1. Set the product down on a horizontal, flat surface or a video cart.
2. Keep the product out of reach of patients.
- ① This product and the connected accessories may only be used in medical rooms with electrical installations conforming to the applicable national regulations.

Before use, a clinical/biomedical engineer or an EMC specialist should carry out an ad-hoc test of the electromagnetic radiation.

5.5 Connecting the product

1. Connect the potential equalization cable.



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




3. Connect a footswitch if required.



4. Connect the Ethernet cable for combination with UNIDRIVE Select (UM600).



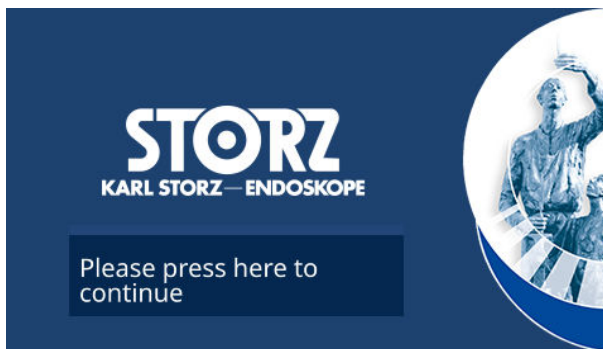
5. Connect the other end of the Ethernet cable to UNIDRIVE Select, see instructions for use of the KARL STORZ UNIDRIVE Select.
 6. To remove the Ethernet cable, pull on the plug as the Ethernet cable is secured on the plug with a protection device to prevent it from being pulled out accidentally.
- 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

5.6 Putting the product into operation

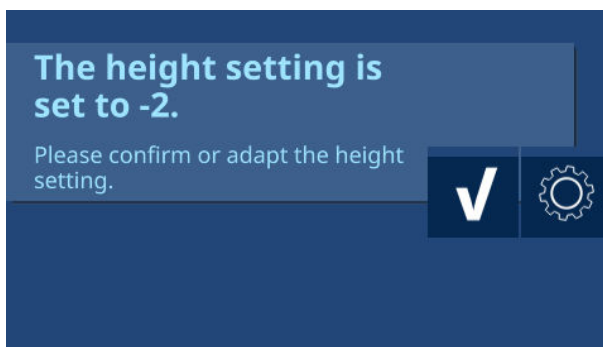
1. Press the STANDBY button to switch the product to ready mode.



- ⇒ The 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. 56].
 - ⇒ The selection of disciplines appears:



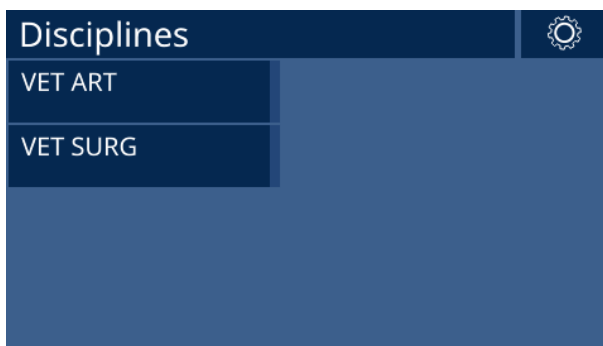
3. If the screen with height adjustment appears, confirm the setting or call up the menu.
 - ⓘ The height difference between the product and cavity (patient) can only be set with the Advanced software package.

5.7 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:



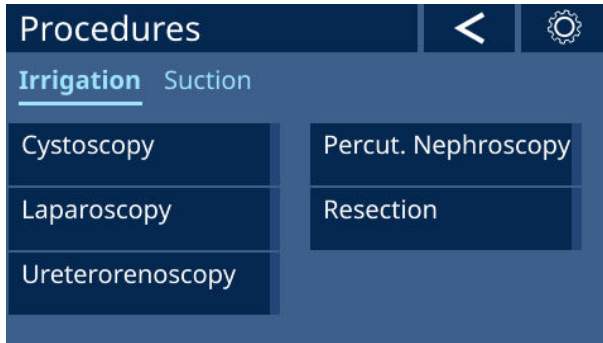
Human medicine



Veterinary medicine

2. Select the discipline.

⇒ The screen for selecting the procedure appears:



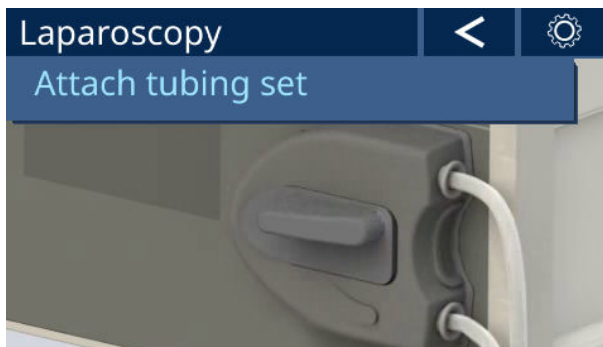
Human medicine



Veterinary medicine

3. Select the procedure.

4. Follow the animation for installing the tubing set.



5.8 Installing the tubing set

⚠ WARNING

Non-sterile product! Risk of infection!

Reusable 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!

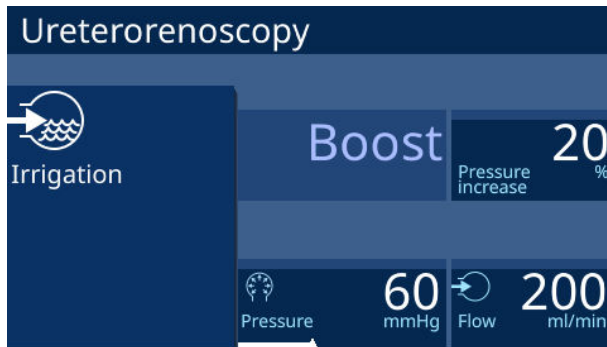
- ▷ Check the expiry date.
- ▷ Check the packaging for damage.
- ▷ Never use products that have passed the expired expiry date or have damaged or accidentally opened packaging but dispose of them properly.

1. Make sure the product is switched on.

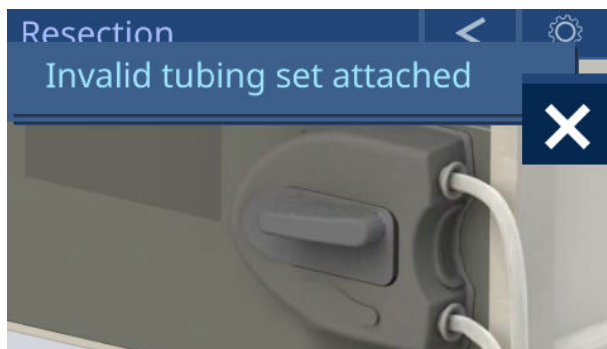
2. Install the tubing set. Make sure that the pump tubes are not crushed.



⇒ 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:



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

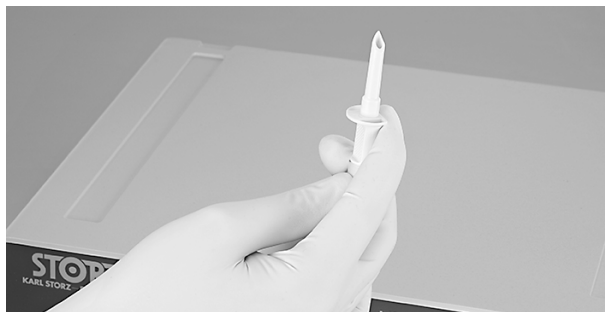
⇒ The discipline selection appears:



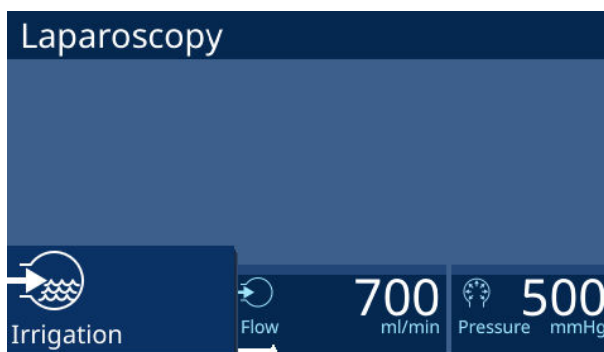
4. Select the desired discipline and procedure, see chapter *Selecting the discipline and procedure* [p. 32].
5. Turn the pump lever of the tubing set counterclockwise.



6. Connect the tubing ends to the irrigation bag (puncture needle) or to the irrigation connector on the instrument (LUER lock).



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



7. To remove the tubing set, turn the pump lever clockwise to the 9 o'clock position.
 - ⓘ Reusable tubing sets are optionally available, see see chapter *Accessories and spare parts* [p. 59]. The instructions for use of the reusable tubing sets must be strictly observed.

5.9 Combined operation with UNIDRIVE Select ENT/NEURO/ SPINE

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.

5.9.1 Putting UNIDRIVE Select into operation

In combined operation with the UNIDRIVE Select, the tubing set (031531-01) must be used for the ENDOMAT SELECT.

1. Connect the 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 Select GYN

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.

5.10.1 Putting UNIDRIVE Select into operation

In combined operation with the UNIDRIVE Select, the tubing set (030647-10) must be used for the ENDOMAT SELECT.

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



- ⇒ The ENDOMAT SELECT can only be controlled with the footswitch of the UNIDRIVE Select.
2. Actuate the footswitch to the first position to start the suction on the ENDOMAT SELECT.
 3. Press the footswitch all the way down to start the shaver as well.

5.11 Combined operation with UNIDRIVE Select ART

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.

5.11.1 Putting UNIDRIVE Select into operation

In combined operation with the UNIDRIVE Select, the tubing set (031523-10) must be used for the ENDOMAT SELECT.

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



- ⇒ The ENDOMAT SELECT can only be controlled with the UNIDRIVE Select using either the handpiece head buttons or a footswitch.
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. 45].
 4. Activate the shaver on the handpiece or using the footswitch.
- ⇒ 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 direct suction

Direct suction is used for ablations, hysteroscopies, arthroscopies, and in conjunction with the IBS. The disposable tubing set (item 030647-10) is used for this purpose.



Disposable tubing set (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.



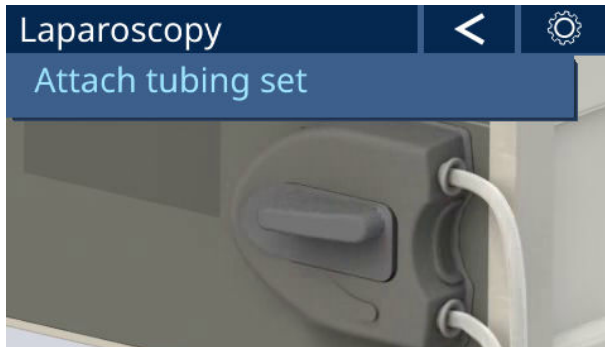
4. Vent the tubing system, see chapter *Venting the tubing system* [p. 45].

6 Application

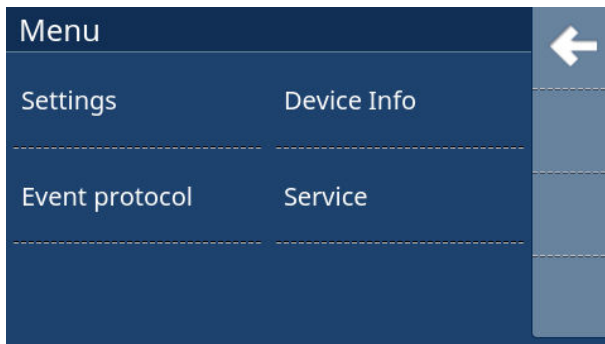
6.1 Menu

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.

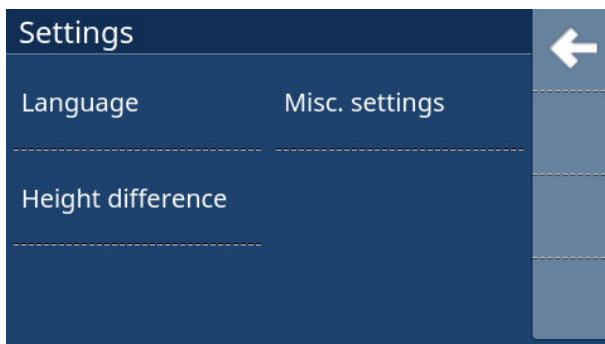


2. Tap the **Cog wheel** button to open up the menu.
- ⇒ The **Menu** screen appears with the following sub-menus:



6.2 Settings

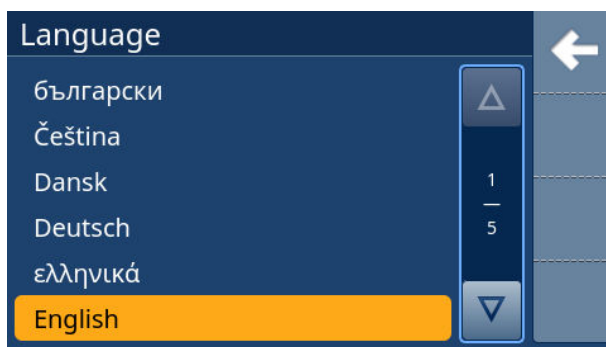
1. In the **Menu** screen, tap the **Settings** sub-menu.
- ⇒ The **Settings** screen appears with the following sub-menus:



6.2.1 Setting the language

1. In the **Settings** screen, tap on 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

If the Advanced or 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 cmH ₂ O can be selected

- ✓ The Advanced or 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.

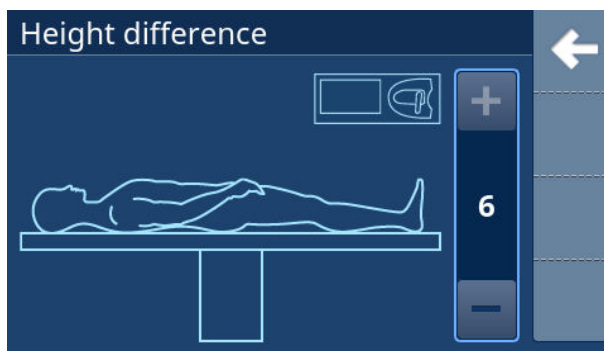
Example: If the product is 2 unit heights below the patient, the value -2 must be entered.

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 to -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:

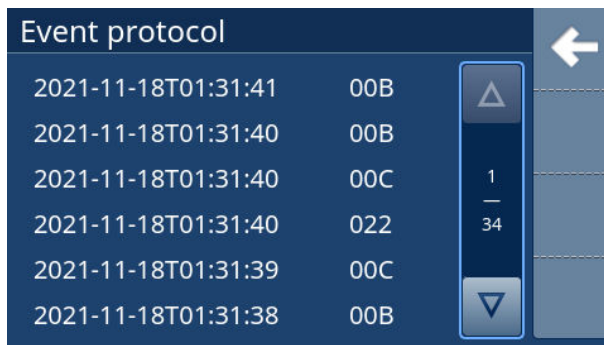
- Current date

- Time
- Info ID

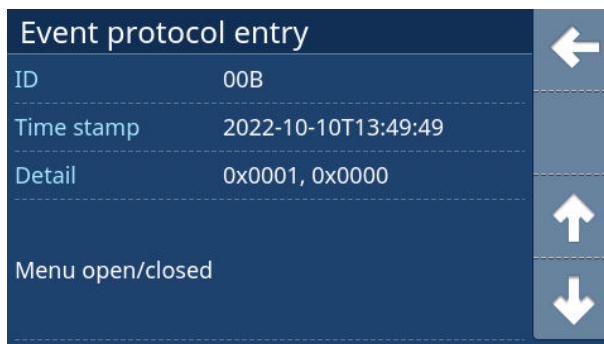
The event log is backed up in the event of voltage drops and upon switching off, and it contains entries relating to switch-on and switch-off times.

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 area is password-protected and can only be accessed by the KARL STORZ technical customer service or authorized persons. The possible settings are described in the service manual.

6.6 Venting the tubing system

⚠ WARNING

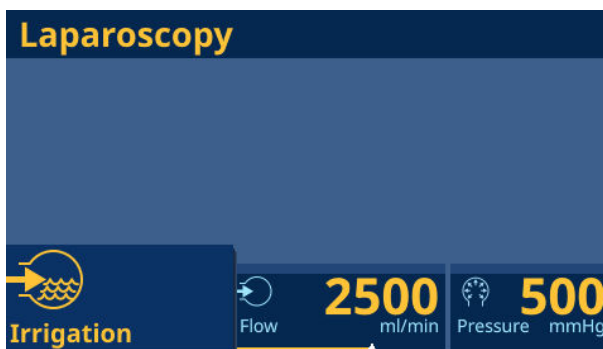
Active roller pump! Risk of crushing!

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.

6.6.1 SURG

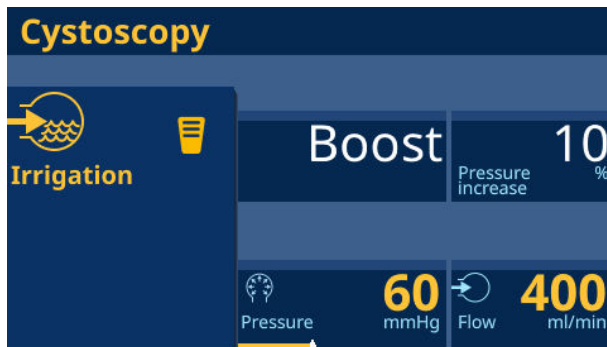
1. Have a collecting container ready to catch irrigation fluid as it runs out.
2. Tap on the **Irrigation** button and let the roller pump run until all of the air has been released from the tubing system.



- ⇒ 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

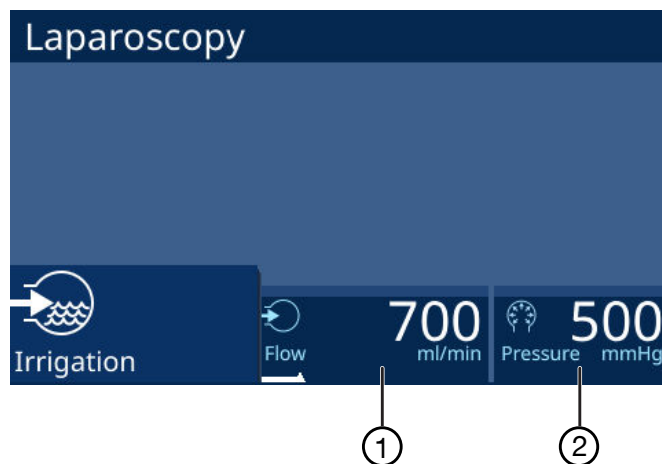
Active roller pump! Risk of crushing!

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

- 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.
- Alternatively hold the set value down and use the slider to set the set value.
- Release the slider.
 - ⇒ The set value appears.
- Tap on the pressure limit.
 - ⇒ The following pressure values appear for selection: 100 mmHg, 300 mmHg and 500 mmHg.
- Tap on the desired value.
 - ⇒ The value is shown as the pressure limit.
- Tap on the **Irrigation** button to activate the roller pump.
 - ⇒ The actual value of the irrigation flow is displayed as an orange-colored line.
- 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.

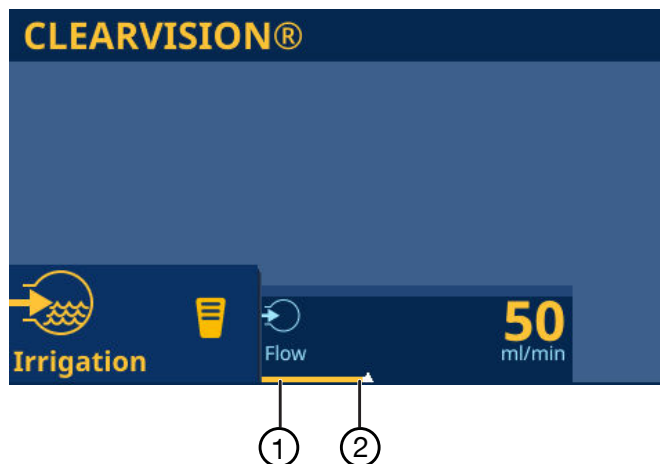
The footswitch has 2 different positions:

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)

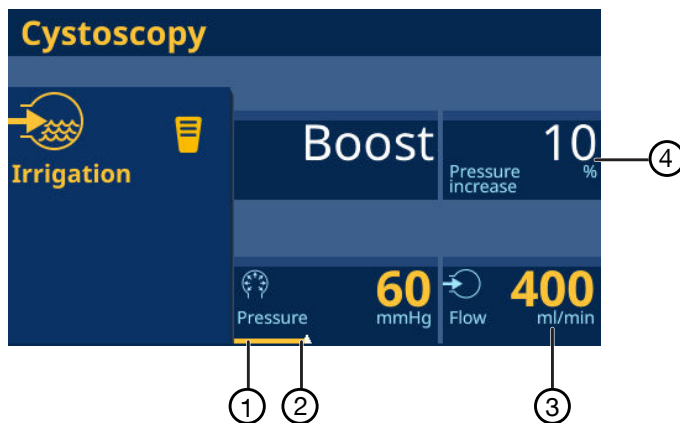
⚠ WARNING

Irrigation pressure too high! Risk of embolism!

If the irrigation pressure is too high, this can result in an embolism. This may lead to injury/death.

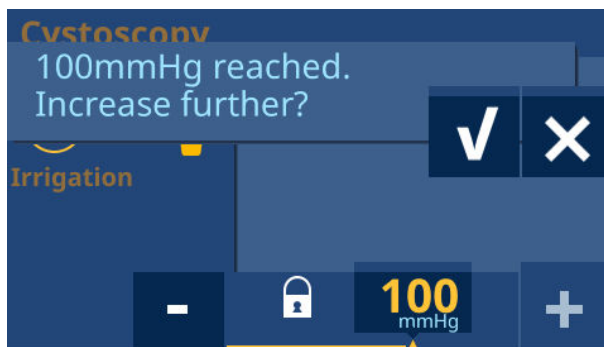
- ▷ Start the procedure with the lowest possible pressure.
- ▷ Carefully increase the distension pressure until a clear, liquid medium is achieved.
- ▷ If an excess pressure alarm sounds, stop the treatment immediately and eliminate the causes.

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.

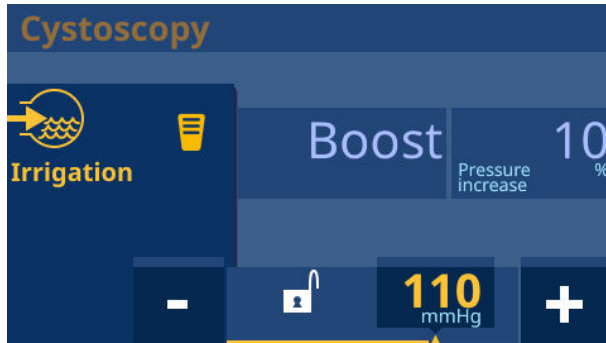


- | | | | |
|---|--|---|---|
| 1 | Irrigation pressure set value (orange) | 3 | Flow limit
Advanced or VET software package required |
| 2 | Irrigation pressure set value (white) | 4 | Percentage pressure increase (boost)
(URO/ART/VET ART) |

1. Tap the set value of the irrigation pressure and use the **Plus** and **Minus** buttons to adjust it in 10 mmHg increments (20 to 150 mmHg) independently of the pump status. 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 the **Plus** button until the following message appears:



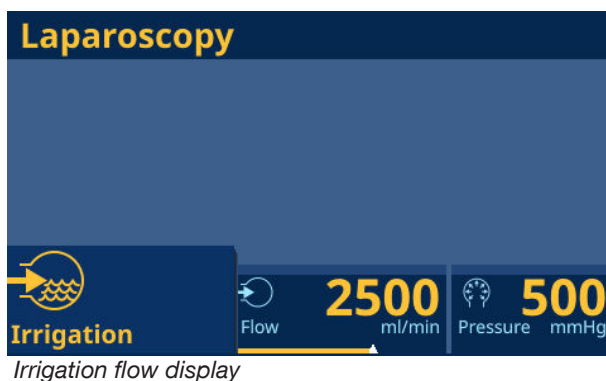
- Confirm the message with the **Checkmark** and use the **Plus** button to set the value up to a maximum of 150 mmHg if necessary.

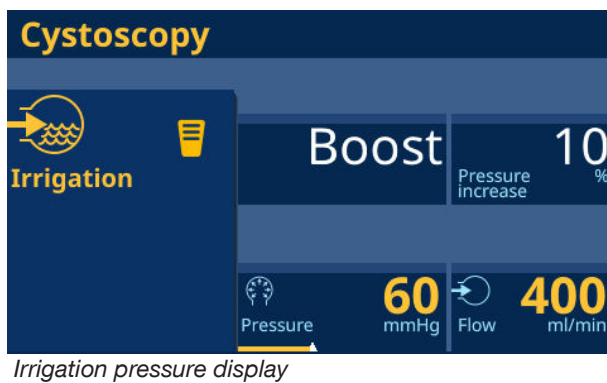
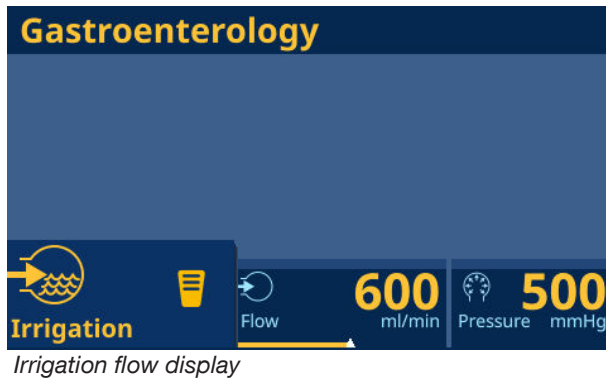


- Tap the pressure increase and select a setting: 10% – 20% – 30% – 40% – 50%.
 - ⇒ The boost lag is 2 s. If the Advanced software package is installed, the lag can be extended to up to 60 s.
- Tap the flow limit.
 - ⇒ The following values are shown for selection:
HYS/URO/SPINE: 200 – 400 – 600 ml/min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

- 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.





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

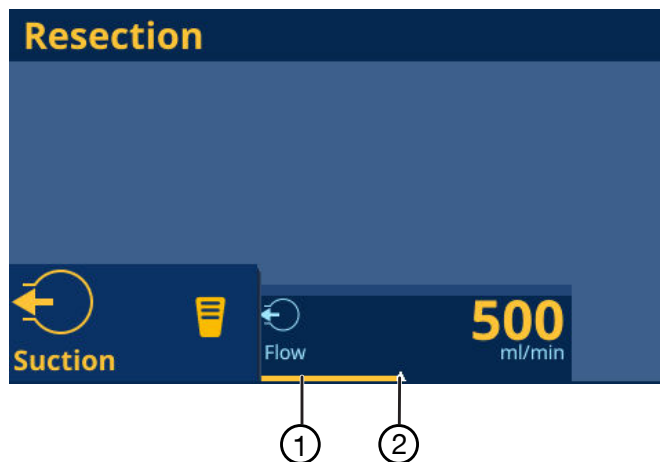
⚠ WARNING

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)

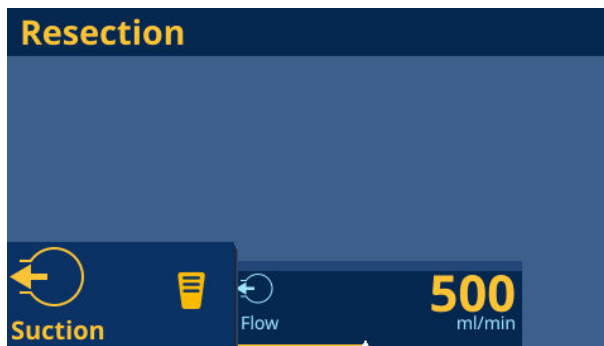
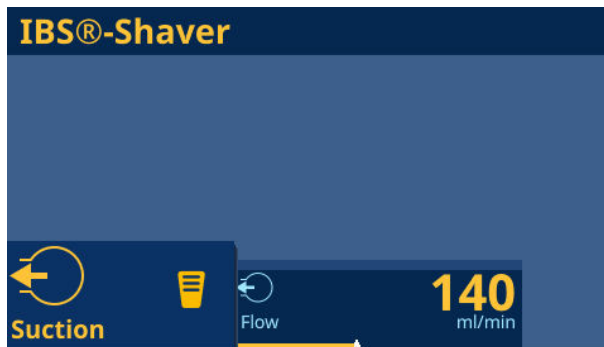
The suction flow can be set to the following values

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

⚠ WARNING

Risk of injury due to product degradation!

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

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

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

7.1.1 Maintenance

The following maintenance intervals are recommended:

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

7.2 Alarm and information signals

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.

7.2.1 Alarm signals

⚠ WARNING

Irrigation pressure too high! Risk of embolism!

If the irrigation pressure is too high, this can result in an embolism. This may lead to injury/death.

- ▷ Start the procedure with the lowest possible pressure.
- ▷ Carefully increase the distension pressure until a clear, liquid medium is achieved.
- ▷ If an excess pressure alarm sounds, stop the treatment immediately and eliminate the causes.

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 programmed as fixed settings.

The excess pressure alarm “301: Maximum pressure” signals 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

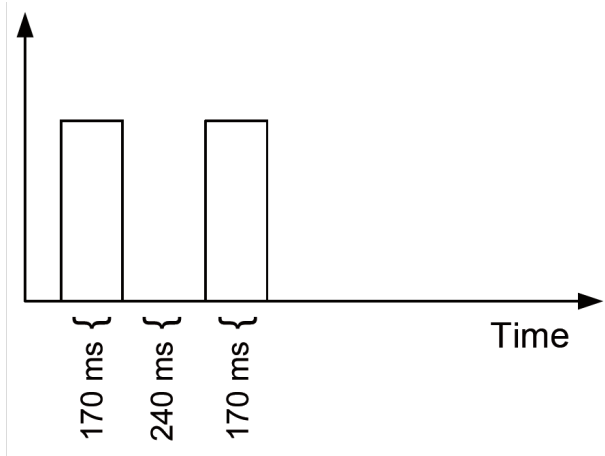
7.2.1.1 Low priority visual alarm signal

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 Low priority 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.

- ▶ 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. 57].

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.

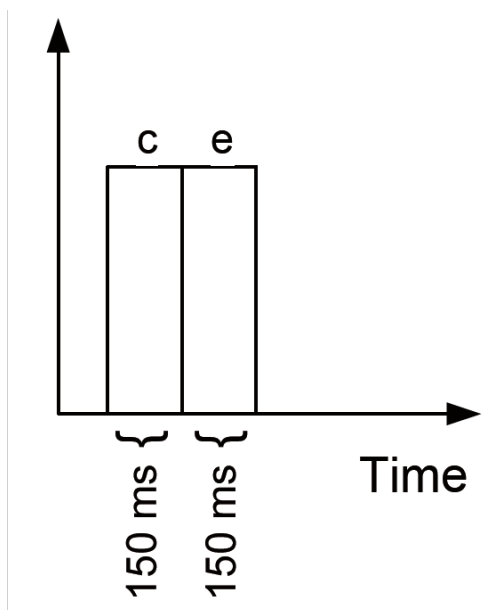
Information signals are continuously output when they indicate the cause of an inoperable product. All other information signals are output as long as the signal conditions exist. The minimum duration of the display is 5 s.

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.

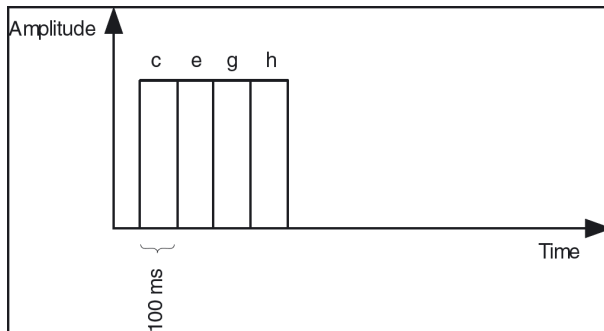


Acoustic information signal

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 degradation!

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

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

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

7.3.1 Visual inspection

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

7.3.2 Electric measurements

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

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

7.3.3 Functional test

1. Perform a functional test, see chapter *Venting the tubing system* [p. 45].
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
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, 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
Suction Bottle, 0.5 l	20300051
Sealing Cap for Suction Bottle 20300051	20300039
Bottle stand, for suction bottle	20300231

Recommended accessories for IBS Shaver and RES

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 ENT/NEURO

Article	Order no.
One-pedal footswitch, two-stage	UF102
One-Pedal Footswitch, two-stage, wireless, comprising: footswitch, receiver, power supply unit	UF102W

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

8.2 Spare parts

For UP007, UP008, UP009, UP010

Item	Order no.
Pump Tube	UP013
Membrane	UP014


9 Electromagnetic compatibility

9.1 General notes on the operating environment

Special environment

The product is suitable for use in close proximity to an active HF electrosurgical device in professional healthcare facility environments. Professional facility environments 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 RF shielded room of an ME system for MRT).

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

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

WARNING

Electromagnetic interferences! Malfunction!

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

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



CAUTION

MR unsafe!

This product is MR unsafe.

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

9.2 Essential performance

Essential performance of the product is set out below:

- In the case of pressure-dependent procedures, the pump is stopped during normal operation, in the event of a single fault, and in the event of foreseeable misuse if the output pressure measured by the monitoring system exceeds 170 mmHg for more than 5 seconds or 370 mmHg for more than 220 ms.
- In the case of flow-controlled procedures, the pump drive voltage is interrupted within 280 ms under normal conditions, in the event of a single fault, and in the event of foreseeable misuse if the speed of the pump motor does not match the set target value.

In the event that the essential performance is lost or degraded:

- In the unlikely event that EMC disturbances impair the device to such an extent that the essential performance is no longer maintained, the pressure and flow values of the irrigation fluid may exceed the defined maximum values and harm the patient.

If the essential performance is lost or degraded, use the following steps to stop the device (proceed with the next step if the previous step has not stopped the pump successfully):

1. Deactivate the pump via the user interface.

2. Press the power switch.
3. Disconnect the power cord.

9.3 Accessories, transducers, and cables

⚠ WARNING

Reduced immunity! Malfunction!

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

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

⚠ WARNING

Degradation of performance! Malfunction!

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

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

The following accessories and cables are defined for EMC compliance.

Type	Shielded	Maximum length	Contains ferrites	Use
PE	No	> 3 m	No	Potential equalization
Power cord	No	1 m	No	Power connection
Network cable	Yes	< 3 m	No	Network connection
Footswitch (20014230)	Yes	< 3 m	No	Device control
Footswitch (UF101, UF102)	Yes	< 3 m	No	Device control

9.4 Table 1 – Compliance level for immunity tests

Interference immunity tests	EN/IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	The relative humidity should be at least 30%.
Electrical fast transients/bursts acc. to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV/± 1 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 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
	100 kHz repetition	100 kHz repetition	
Surges acc. to IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to ground	± 1 kV line(s) to line(s) ± 2 kV line(s) to ground	The power supply quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and fluctuations of the power supply acc. to IEC 61000-4-11	<u>Voltage dip:</u> Dip to 0% for 1 cycle @ 0° phase angle Dip to 70% for 25/30 cycles @ 0° phase angle Dropout to 0% for 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° phase angles <u>Voltage interruption:</u> 100% for 250/300 cycles	<u>Voltage dip:</u> Dip to 0% for 1 cycle @ 0° phase angle Dip to 70% for 25/30 cycles @ 0° phase angle Dropout to 0% for 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° phase angles <u>Voltage interruption:</u> 100% for 250/300 cycles	The power supply quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation in the event of interruptions to the power supply network, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Magnetic field at the supply frequency (50 Hz/60 Hz) acc. to IEC 61000-4-8	30 A/m at 50 Hz/60 Hz	30 A/m at 50 Hz/60 Hz	If image distortion occurs, it may be necessary to position the equipment further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
Immunity test acc. to IEC 61000-4-3 for high-frequency electromagnetic fields	3 V/m 80 MHz to 2.7 GHz see chapter <i>Table 2 – Test levels for proximity fields from RF wireless communications equipment</i>	3 V/m 80 MHz to 2.7 GHz see chapter <i>Table 2 – Test levels for proximity fields from RF wireless communications equipment</i>	-

Interference immunity tests	EN/IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
	[p. 64] for wireless HF near field test levels	[p. 64] for wireless HF near field test levels	
Immunity to conducted disturbances, induced by radio-frequency fields acc. to IEC 61000-4-6	3 V _{rms} on 150 kHz to 80 MHz 1 kHz 80% AM modulation 6 V _{rms} in ISM frequency bands between 0.15 MHz and 80 MHz	3 V _{rms} on 150 kHz to 80 MHz 1 kHz 80% AM modulation 6 V _{rms} in ISM frequency bands between 0.15 MHz and 80 MHz	-
Magnetic field proximity IEC 61000-4-39	65 A/m @ 134.2 kHz (pulse modulation) 7.5 A/m @ 13.56 MHz (pulse modulation)	65 A/m @ 134.2 kHz (pulse modulation) 7.5 A/m @ 13.56 MHz (pulse modulation)	-

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

Test frequency MHz	Frequency band ^{a)} MHz	Radio service ^{a)}	Modulation	Immunity test level V/m	Compliance level V/m
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	27	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine wave	28	28
710	704 – 787	LTE band 13 & 17	Pulse modulation ^{b)} 217 Hz	9	9
745					
780					
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation ^{b)} 18 Hz	28	28
870					
930					
1720	1700 – 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE band 1, 3, 4, 25, UMTS	Pulse modulation ^{b)} 217 Hz	28	28
1845					
1970					

Test frequency MHz	Frequency band ^{a)} MHz	Radio service ^{a)}	Modulation	Immunity test level V/m	Compliance level V/m
2450	2400 – 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modulation ^{b)} 217 Hz	28	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	9	9
5500					
5785					

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

^{a)} For some radio services, only the uplink frequencies are included.

^{b)} The carrier shall be modulated using a 50% duty cycle square wave signal.

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

9.6 Table 3 – Emission class and group

Emission measurements	Compliance	Electromagnetic environment – guidance
RF emissions as per CISPR 11	Group 1	The product uses RF energy only for its internal function. The customer or user of the product should make sure that it is used in such an environment. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic product.
RF emissions as per CISPR 11	Class B	The equipment 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 as per IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions as per IEC 61000-3-3	Complies	

10 Errors and messages

10.1 Troubleshooting

Fault	Possible causes	Actions
Product 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
	Defective control electronics	▶ Send product for repair






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 ▶ 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

Message	Possible cause	Actions
191: Cartridge locking error	Cartridge locking electronics error	<ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ Switch the product off and on
259: Electronics error	BE: Internal error	<ul style="list-style-type: none"> ▶ Switch the product off and on ▶ Contact KARL STORZ Service if the error reoccurs
300: High pressure	Stopcock on instrument closed	<ul style="list-style-type: none"> ▶ Observe the surgical field ▶ Ensure pressure reduction
301: Maximum pressure	Excess pressure alarm in URO and HYS application if 150 mmHg is exceeded	<ul style="list-style-type: none"> ▶ Observe the surgical field ▶ Ensure pressure reduction
500: Main functions not active	FE: A touchscreen activation lasting more than 25 seconds has been detected	<p>Acoustic and visual signal – the product can still be operated. A calibration of the touchscreen can be started.</p> <ul style="list-style-type: none"> ▶ Activate the touchscreen for 25 seconds to start the calibration ⇒ A text message appears. ▶ Check the touchscreen and clean it if necessary <p>This text message can also appear in the event of a touchscreen short circuit.</p> <ul style="list-style-type: none"> ▶ 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	<p>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</p> <ul style="list-style-type: none"> ▶ 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	<p>To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.</p>
 WARNING	<p>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.</p>
 WARNING	<p>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.</p>
 WARNING	<p>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.</p>
 WARNING	<p>No modification of this equipment is allowed.</p>

12 Subsidiaries

KARL STORZ SE & Co. KG

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