KARL STORZ — ENDOSKOPE

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en **Instructions for use**
POWER LED 175

12-2020

CE

Table of contents

1 General information

1.1 Read the instructions for use

These instructions for use are intended to aid you in the proper installation, connection, and operation of this product.

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

1. Read the instructions for use carefully and follow them completely.
2. Keep the instructions for use clearly visible next to the product.

It is recommended to check the suitability of the products for the planned procedure prior to use.

1.2 Scope

This instruction manual is valid for:

Product	Article no.
POWER LED 175	20161420

1.3 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 warning messages describe 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.

ATTENTION
ATTENTION

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

2 Normal use

2.1 Intended use

White light sources are used for illumination in diagnostic and therapeutic procedures in endoscopy.

2.2 Indications

White light sources are designed for generating light in endoscopic diagnostic examinations and in surgical procedures.

2.3 Contraindications

White light sources are contraindicated for ophthalmologic procedures. For other procedures, the responsible physician must decide whether the prescribed application is admissible based on the general condition of the patient.

2.4 Patient groups

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

2.5 Target user populations

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

2.6 Intended conditions of use

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

Condition	Application
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 SCB.

3 Safety

3.1 Serious incidents

According to the Medical Device Regulation (MDR), a “serious incident” includes incidents that directly or indirectly had, could have had, or could have any of the following consequences (MDR, Art. 2, No. 65 [1]):

- 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 reprocessing

Incorrectly reprocessed products expose patients, users, and third parties to a risk of infection.

▶ Reprocess the product before use.

▶ A validated reprocessing procedure must be followed and the product must be reprocessed in line with the reprocessing instructions.

3.3 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.

3.4 Combination with other components

The use of unauthorized devices and components or unauthorized changes to the product can result in injuries.

Additional devices connected to electrical medical equipment must comply with the relevant IEC or ISO standards. Furthermore, all configurations must comply with the requirements for medical electrical systems (see IEC 60601-1-1 or Clause 16 of the 3rd edition of IEC 60601-1).

▶ Only combine the product with devices and components that are approved as medical devices.

▶ Comply with national and local regulations.

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

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

▶ Only make changes to the product if these changes are approved by KARL STORZ.

3.5 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.

3.6 Dangers from electrical current

An improper power supply may cause an electric shock and injure patients, users, or third parties. All electrical installations in the operation room in which the product is connected and used must meet 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.
- Only use BF or CF type devices and components.
- 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.
- Always pull out the mains plug before carrying out any cleaning and maintenance work.
- Connect the product to a power supply with protective conductor.
- 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. Routinely inspect the electrical plug and cord and do not use if the inspection reveals damage.

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, or third parties.

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

During operations, explosive anesthetic gases are used. If sparks occur, this may trigger explosions.

- Only connect or disconnect the power plug to or from the power supply outside explosive atmospheres.

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

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

3.7 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.

3.8 High light intensity

The high level of light intensity produced by the light source may lead to permanent eye damage or blindness, and may cause tissue and items facing the light output to heat up.

- Always select the lowest possible light setting during use.

- Make sure the light output is sufficiently far away from tissue and operating accessories.
- Never look into the light output when the light system is switched on.
- Switch off the light source before changing the light cable connection (adapter).
- Allow the product to cool down before changing the light cable connection (adapter).

3.9 Electromagnetic interference

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

- 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. 26].

The use of accessories and cables other than those specified in the instruction manual may result in increased emissions or decreased immunity of the product. When using other accessories and cables, the operator is responsible for checking compliance with IEC 60601-1-2 for this particular product.

- To prevent increased electromagnetic emissions or reduced electromagnetic immunity of the product, only use accessories, transducers, and cables recommended or supplied by the manufacturer.

3.10 Failure of devices

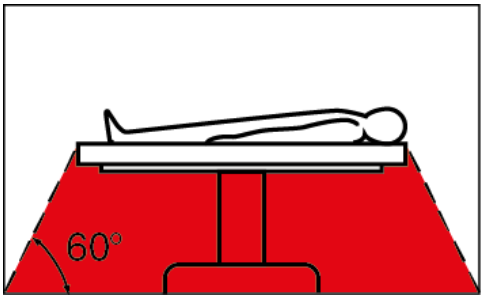
The product may fail during use.

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

3.11 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.

3.12 Safety functions

During power-up, the product performs a self-test. This enables faults or impermissible operating conditions to be detected; if a fault is detected, the product will switch to a safe state. No light is emitted.

Impermissible conditions during operation are indicated and the light goes out automatically if they are escalated. The cause of the fault can then be rectified or treatment can be completed under controlled conditions; see chapter Faults and messages [p. 32].

4 Product description

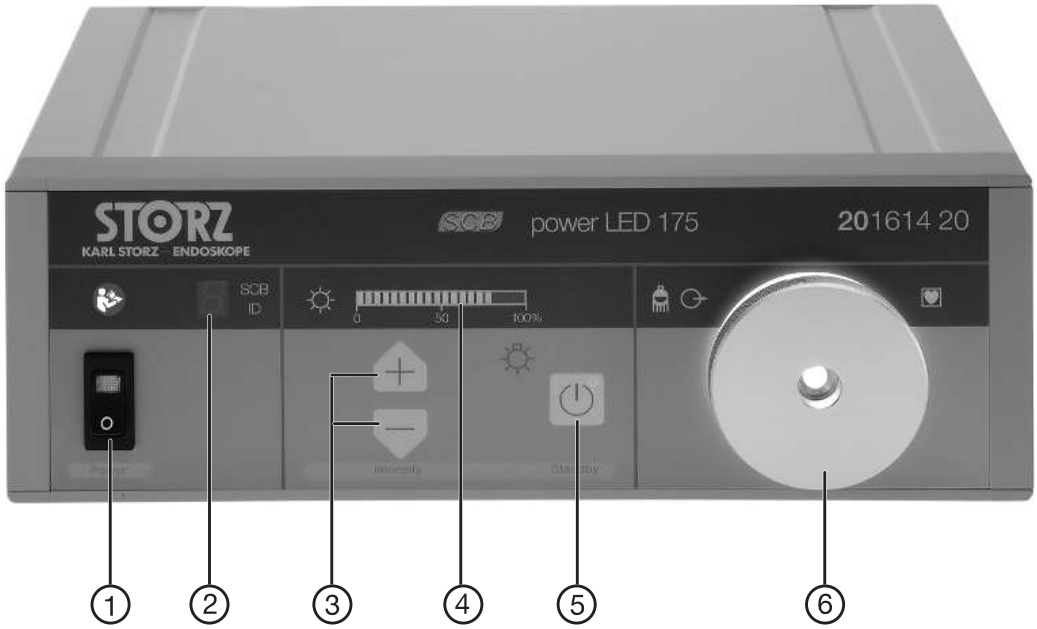
4.1 Description of operation

The cold light fountain POWER LED 175 is a high-power cold light source for diagnostic and therapeutic endoscopic applications.

The POWER LED 175 has the following characteristics:

- Efficiency: High light intensity combined with low power consumption.
- Comfortable working environment: Intelligent cooling concept for minimal noise emission.
- Durable: No costs or effort required to change the lamp if used properly.
- Integrated SCB function: Enables the light source to be controlled remotely and the system status information to be retrieved, while providing simple configuration during initialization.

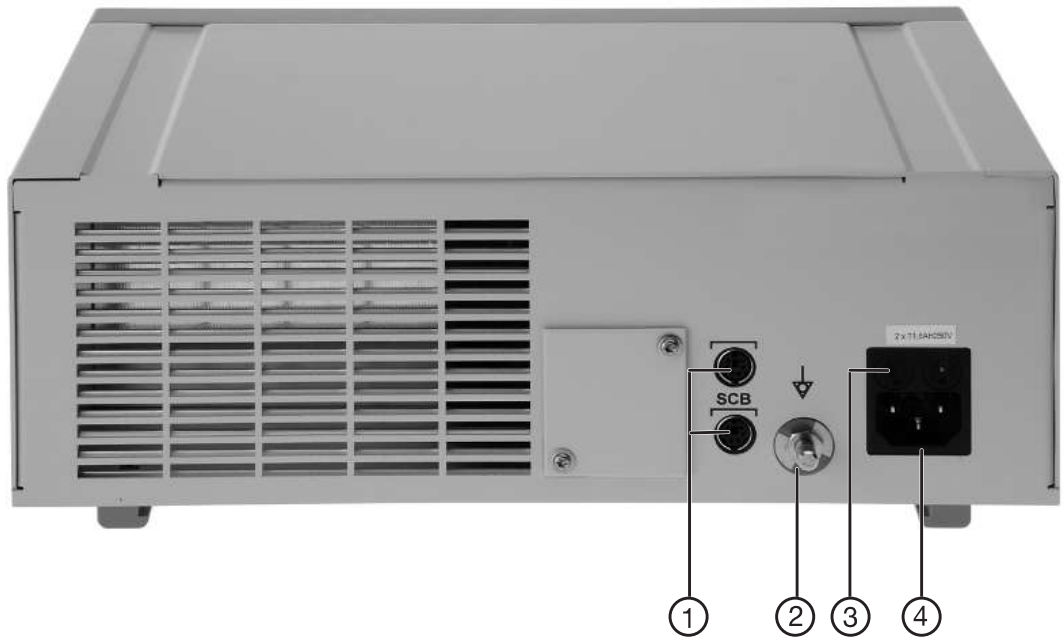
4.2 Product overview



POWER LED 175 – Front view

1	Power switch	4	LED display for current light intensity
2	SCB indicator display*	5	Standby button
3	Button to reduce/increase brightness	6	Light outlet point

* If an SCB system can manage several light sources and multiple POWER LED 175 light sources are available simultaneously, the SCB system assigns each light source its own number. The number enables the user to identify the individual light sources in the SCB system and make adjustments. If there is only one POWER LED 175 light source available in the SCB system, no number will appear. If the light source is being controlled remotely by a camera control unit (CCU), an “A” will appear.



POWER LED 175 – Back view

1	SCB connectors	3	Power fuse holder
2	Potential equalization connector	4	Power cord socket

4.3 Possible combinations

The basic system consists of the following components:

- POWER LED 175
- Camera control unit (CCU), IMAGE1 S™ system
- Light cable with endoscope or videoendoscope

The system can be used for flexible or rigid endoscopic interventions. Adapters can also be used in combination with light cables from other manufacturers.

Compatibility with light cables

Series 495xx light cables are compatible with the standard adapter (2108191). If the 495xx adapter series is used, light cables from other manufacturers can be used.

ⓘ Only KARL STORZ Hopkins telescopes are recommended in combination with KARL STORZ light cables.

Compatibility with camera control units (CCU)

The POWER LED 175 is connected to the IMAGE1 CONNECT (TC200) and a LINK module (modular CCU) via the KARL STORZ communication bus (SCB). The light intensity can be controlled automatically via the SCB with the modular CCU.

The following CCUs can be combined:

- IMAGE1 S™ CONNECT (TC200)
- IMAGE1 S™ H3-LINK (TC300)
- IMAGE1 S™ X-LINK (TC301)
- IMAGE1 S™ D3-LINK (TC302)

4.4 Technical data

Description	Value
Power supply (AC)	100 – 240 V (±10%)
Operating frequency	50/60 Hz
Line fuse	2 x T 1.6 AH 250 V
Power input	1.1 A
Electrical protection class	I
Applied part type according to IEC 60601-1	CF
Dimensions (L x H x W)	233 x 110 x 305 mm
Weight	4.6 kg

4.5 Symbols employed

4.5.1 Symbols on the packaging

Symbol	Meaning
	Manufacturer
	Date of manufacture
	Medical device
	In accordance with US federal law (21 CFR 801.109), this product may only be sold to or on prescription from a licensed physician.
	Number of products in the product packaging
	Article no.
	Serial number
	CE conformity mark With this mark, the manufacturer declares the compliance of the products with the applicable regulation (EU) 2017/745. A code number after the CE mark indicates the responsible notified body.
	Humidity limit
	Temperature limit

Symbol	Meaning
	Keep dry
	Fragile, handle with care
	Consult instructions for use

4.5.2 Symbols on the product

Symbol	Meaning
	Follow instructions for use
	KARL STORZ SCB interface Remote control of functions and remote display of parameters
	Brightness
	Lamp/light source
	Ready/standby button
	Light outlet point
	Potential equalization connector
	Applied part of the type CF

4.5.3 Symbols on the type plate

Symbol	Meaning
	Manufacturer
	Date of manufacture
	Medical device
	In accordance with US federal law (21 CFR 801.109), this product may only be sold to or on prescription from a licensed physician.
	Prevention of pollution by electronic devices
	Separate collection of electrical and electronic devices. Do not dispose of in household refuse.
	CE conformity mark With this mark, the manufacturer declares the compliance of the products with the applicable regulation (EU) 2017/745. A code number after the CE mark indicates the responsible notified body.

4.6 Ambient conditions

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

Operating conditions	
Temperature	10 °C ... 40 °C
Relative humidity (non-condensing)	20 – 85%
Max. operating altitude	3,000 m

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 evidence of shipping 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 Testing the product

1. Inspect the product for visible contamination. Do not use if contaminated.
2. Inspect the product for the following characteristics:

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

5.3 Setting up the product

⚠ 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.

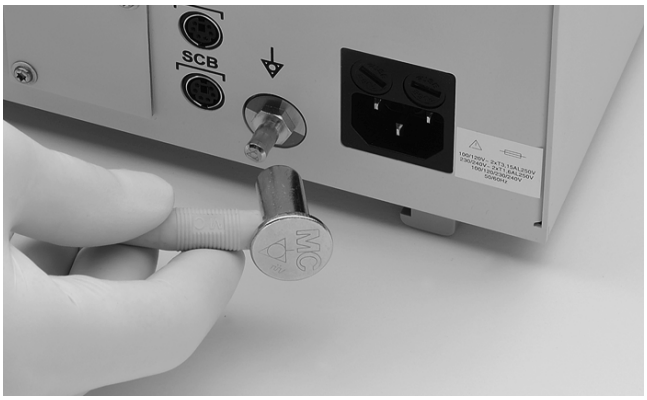
- ▶ Ensure that there is sufficient air circulation.
- ▶ Keep air inlets and outlets free.

This product and connected components may only be used in medical rooms with electrical installations that conform to applicable national regulations. 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.

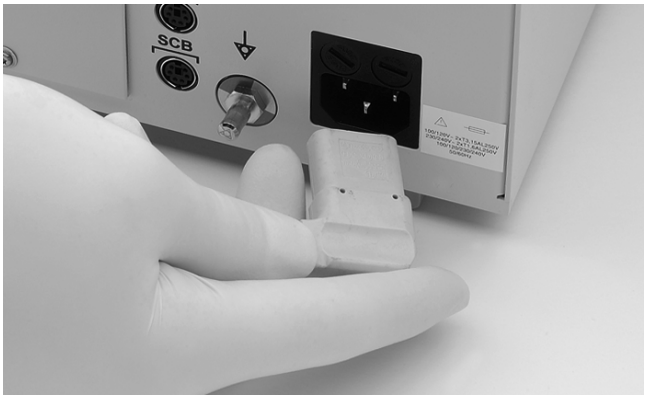
1. Set the product down on a horizontal, flat surface or a video cart.
2. Position the product so that it is in the user's field of vision.
3. Keep the product out of the reach of patients.

5.4 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 the SCB cable.

4. Connect the other end of the SCB cable to a KARL STORZ control device or other SCB devices; see the instruction manual for the KARL STORZ SCB control NEO system.
5. To remove the SCB cable, pull on the plug (the SCB cable is equipped with a device to provide protection against pulling out accidentally).

5.5 Connecting the light cable

⚠ WARNING

High energy! Risk of burns!

The light source transmits high-energy light at high surface temperatures which can damage tissue.

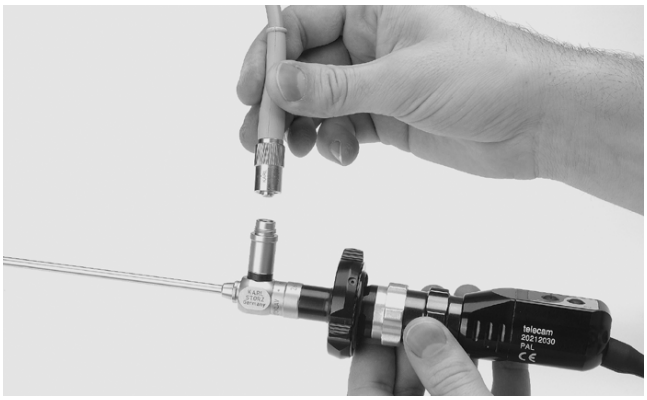
- ▶ Keep the light source away from tissue.

ⓘ The light outlet point is provided with an antiglare flap, which does not allow any direct outlet of light. Light only appears when the light cable is attached.

We recommend using original KARL STORZ light cables, because light cables from other manufacturers may not be optimized for light transmission.

1. Insert the light cable into the light outlet point until it engages. Hold the light cable only by the handle, never by the cable.

2. Connect the light cable by twisting the knurled screw on the endoscope screw base through a quarter turn.



5.6 Putting the product into operation

Monitor the product as it is starting up for signs of any button or display faults.

▶ Switch the product on with the power switch.

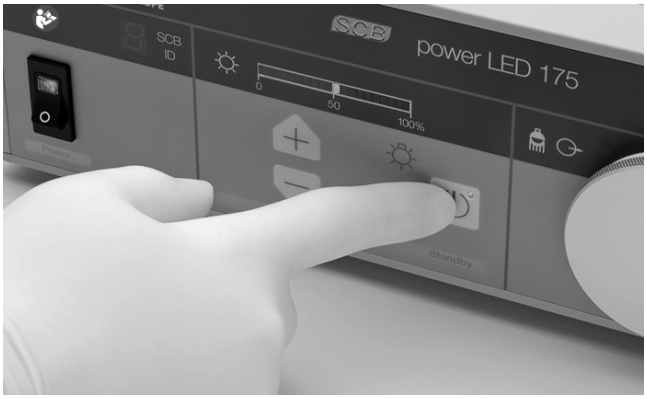
⇨ On successful completion of the self-test, a short signal sounds and the product starts up in standby mode.

⇨ The light source is at the lowest intensity setting (approx. 5%) and the most recent value set is displayed.

6 Application

6.1 Activating the most recent setting

▶ Press the *standby* button to activate the most recent light intensity setting.



⇨ The LED integrated in the *standby* button goes out.

6.2 Setting the brightness

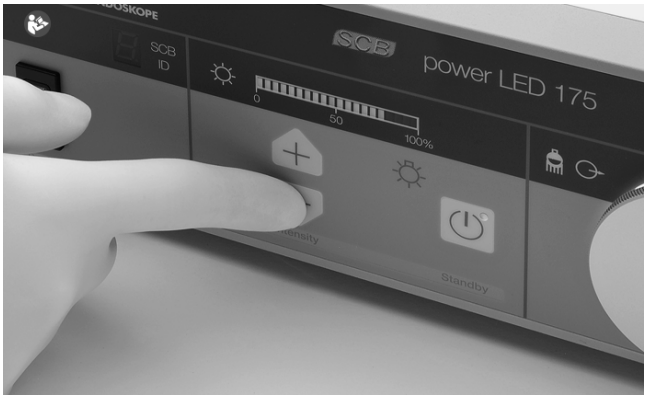
⚠ WARNING

No visual contact! Risk of injury!

Using the product outside the field of vision can cause injury to tissue and damage to accessories.

▶ Only activate the product under visual contact.

1. Press the *plus* or *minus* button to increase or reduce the brightness.



⇨ The selected value appears on the LED display.

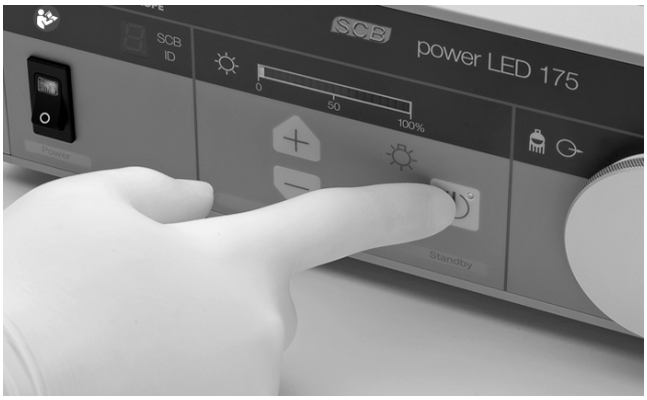
2. Press and hold the *plus* or *minus* button to activate the Autorepeat function.

⇨ The value continues to change in the selected direction until the maximum or minimum setting is reached.

ⓘ The product should only be used if the input buttons are in perfect working order.

6.3 Activating the lowest setting

▶ Press the *standby* button to activate the lowest light intensity.



⇨ The LED integrated in the *standby* button lights up.

6.4 Switching off the product

▶ Switch the product off with the power switch.

7 Maintenance, servicing, repairs, and disposal

7.1 Maintenance

Maintenance work may only be carried out by KARL STORZ or a company authorized by KARL STORZ.

Interval	Maintenance work	To be performed by
annually	Safety inspection	KARL STORZ Service technicians

7.2 Changing a fuse

⚠ WARNING

Undesired current flow! Risk of injury!

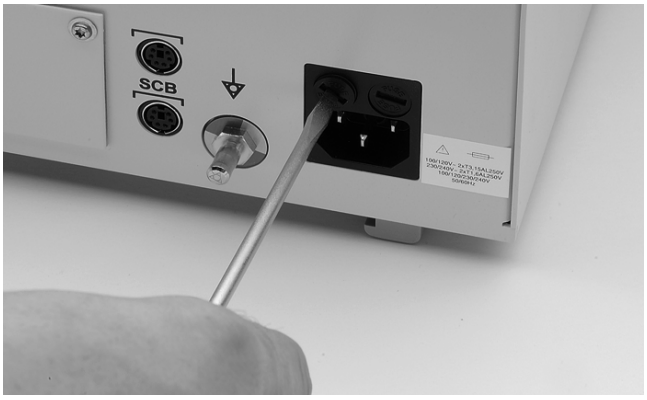
Live parts of the equipment can cause severe injuries due to electric shock.

- ▶ Do not open the housing.
- ▶ Make sure that the connection to the power supply is disconnected.
- ▶ Request a KARL STORZ service technician for service work.

✓ The product is switched off.

✓ The power cord is disconnected from the product.

1. Remove the screw inserts on the power fuse holder with a screwdriver.



2. Remove the defective fuse.
3. Insert a new fuse. Only use fuses with the specified values; see chapter Technical data [p. 13].

4. Introduce the screw inserts into the power fuse holder again.
5. Connect the power supply again.

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

7.3 Safety inspection in accordance with IEC 62353

⚠ WARNING

Risk of injury due to product 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. Inspect the device safety fuses

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

7.3.3 Functional test

1. Perform a functional test in line with the instructions for use.
2. Document the results of the safety inspection.

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

Article	Order no.
All KARL STORZ light cables	495xx
Adaptor for light cables from other manufacturers	495xx
SCB conneting cable, length 100 cm	20090170
Power cord (grounded)	400A
Power cord “hospital grade” (USA)	400B
All KARL STORZ videoendoscopes except GI	See catalog; corresponding disciplines

8.2 Spare parts

Article	Order no.
Line fuse T 1.6 AH 250 V, pack of 10	1973290

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 cables

Accessories and cables for EMC compliance				
Type	**Shield**	**Length [m]**	**Ferrite**	**Use**
PE	No	>3	No	Potential equalization
Power cord	No	3	No	Power connection

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 should make sure that it is used in such an environment.

Interference immunity tests	EN/IEC 60601 test level	Conformity 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 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 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	Conformity 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 on power supply input lines 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 Dip 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 Dip 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 power frequency (50/60 Hz) acc. to IEC 61000-4-8	30 A/m at 50 Hz / 60 Hz	100 A/m at 50 Hz / 60 Hz	If image distortion occurs, it may be necessary to install the product further away 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 high-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 interference, induced by high-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	10 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 & 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					
1,720	1,700 – 1,990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE band 1, 3, 4, 25, UMTS	Pulse modulation 217 Hz	28	28
1,845					
1,970					
2,450	2,400 – 2,570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modulation 217 Hz	28	28
5,240	5,100 – 5,800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
5,500					
5,785					

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 should make sure that it is used in such an environment.

Interference immunity tests	EN/IEC 60601 test level	Conformity level	Electromagnetic environment – Guidelines
Conducted RF disturbances acc. to IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	10 V_{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the

Interference immunity tests	EN/IEC 60601 test level	Conformity level	Electromagnetic environment – Guidelines
Radiated RF 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 distance: $d = 1.2 \sqrt{P}$ 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 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 Interference 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 with regard to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location where the product is being used exceeds the compliance levels above, the product should be monitored to ensure that it is functioning as intended. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the product.

[b] Over the frequency range 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 Faults and messages

10.1 Product faults

Symptom	Possible causes	Actions
Constant tone after switching on and dark light intensity display	Hardware problem	▶ Send product to KARL STORZ for repair
	Overheating	▶ Switch off the product and let it cool down
Warning signal (2 short beeps) sounds every 15 seconds and the fields in the light intensity display flash at the same time	Overheating, critical temperature not reached	The product remains in operation until the critical temperature is reached. When the temperature drops back down, the signal stops. ▶ Eliminate the cause of overheating ▶ Reduce light intensity ▶ End treatment if applicable ▶ Allow the product to cool down
	Overheating, critical temperature reached	The cold light is switched off when the critical temperature is reached. When the temperature drops back down, the signal stops and the cold light remains switched off (restart block). ▶ Switch the product off and back on again. Check that the product has cooled down to the permissible temperature
Product failed	Power supply failure	▶ Have the power supply checked
	Defective fuse	▶ Replace fuses as described in the instruction manual. Make sure to use the correct fuse type
	Power plug and socket improperly connected	▶ Push the power plug firmly into the socket on the product
No light emission	Electronics faulty	▶ Contact Service

Symptom	Possible causes	Actions
	Overheating due to covered air vents	▶ Uncover air vents ▶ Switch off the product and let it cool down (10 –15 min) ▶ Ensure adequate air circulation
No light emission, power switch lit (on)	Significant vibration during operation	▶ Switch the product off and back on again
	Power supply unit or LED defective	▶ Send product to KARL STORZ for repair
Insufficient light	End faces of the light cable and/or the endoscope are dirty	▶ Clean the end faces of the light cable and the light outlet surfaces of the endoscope
	Light cable or endoscope defective	▶ Replace the light cable or endoscope
	LED service life has been exceeded	▶ Send product to KARL STORZ for repair
No light emission, power switch lit (on), LED brightness display flashing	LED defective	▶ Send product to KARL STORZ for repair
	Fan defective	
	Temperature sensor defective	
	Product overheating	▶ Switch off the product and let it cool down

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