KARL STORZ — ENDOSKOPE

en

Instructions for use
POWER LED 300

05-2024

CE

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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:

Product name	Article number
POWER LED 300	TL300

1.4 General signs and symbols

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

Practical tip

ⓘ This sign refers to useful and important information.

Actions to be performed

Action to be carried out by several steps:

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

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

⇨ Result of a completed action

Actions in safety notes or in the case of a single step:

- ▶ Step 1

Lists

1. Numbered list

– Unnumbered list, 1st level

– Unnumbered list, 2nd level

1.5 Description of warning messages

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

⚠ WARNING
WARNING

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

⚠ CAUTION
CAUTION

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

NOTICE
NOTICE

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

2 Normal use

2.1 Intended use

White-light light sources

White-light light sources are intended for white light illumination in diagnostic and surgical interventions.

White-light sources do not have body contact and are meant for short-term use.

2.2 Indications

White-light light sources are suitable for generating white-light illumination for medical investigations and visualization during diagnostic and surgical interventions.

2.3 Contraindications

Light sources, light cables and adapters must not be used for ophthalmologic interventions.

Light sources, light cables and adapters are not used in body contact with the patient but provide light illumination for medical imaging.

Furthermore, there are no contraindications for the use of the light sources, light cables and adapters directly associated with the product.

2.4 Clinical benefits

Light sources, light cables and adapters are widely used during endoscopic diagnostic and therapeutic procedures.

2.5 Residual risks

No residual risks directly related to the product were identified.

2.6 Target user populations

The application of the products in question is carried out under the responsibility of a medical specialist.

2.7 Patient population

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

2.8 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 and warning

⚠ WARNING

Danger due to non-observance of warnings and safety notes

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

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

3.1 Serious incidents

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

- – Death of a patient, user, or another person
- – Temporary or permanent serious deterioration in the medical condition of a patient, user, or another person
- – A serious threat to public health

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

3.2 Correct handling and product testing

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

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

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

3.3 Combination with other components

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

- ▶ Ensure that any additional devices connected to electrical medical devices comply with the relevant IEC or ISO standards.
- ▶ When connecting additional devices to medical electrical equipment, ensure that all configurations of the resulting system comply with the standardized requirements for systems (see IEC 60601-1). National laws and regulations take precedence over the aforementioned standards.
- ▶ Only combine the product with devices and components that the manufacturer has approved for combined use, see chapter *Possible combinations*.
- ▶ Only use devices and components that have standardized interfaces and do not breach the normal use of the product.
- ▶ Observe the instruction manuals and interface specifications of the devices and components used in combination.
- ▶ Do not make any modifications to the product.

3.4 Working in the field of vision

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

- Only use the product in the field of vision.

3.5 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.

3.6 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.
- 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, and third parties.

- Do not open the product.
- Do not touch the output jacks of the product and the patient at the same time during use
- 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.

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.

- The patient applied parts of the simultaneously used products must be type BF or type CF.

3.7 Damage due to ingress of liquid in electrical components

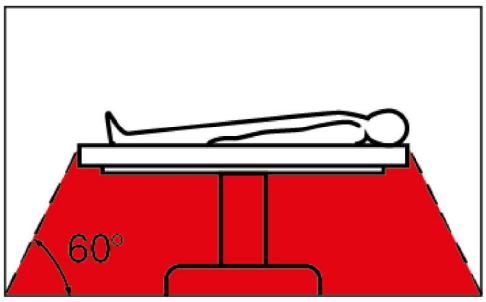
In the case of electrical products, individual components or the product itself may be live. Liquid ingress into an electrical product may result in a short circuit or an unintentional transfer of current. The product is damaged as a result and patients, users and third parties may be injured.

- 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 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.

3.9 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*.

3.10 Hot components

The high level of light intensity produced by the light source may cause the distal end, the light connections, and adjacent components to heat up. This can cause burns to patients, users, and third parties.

- Set the output of the adjustable light sources to a level that is just high enough to ensure optimal illumination of the operating area.
- Prevent the distal end, light connections, and adjacent components from coming into contact with tissue and operating room accessories.

3.11 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.

- Do not look into the light output.
- Set the output of the adjustable light sources to a level that is just high enough to ensure optimal illumination of the operating area.

3.12 Functionality of the touch screen

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

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

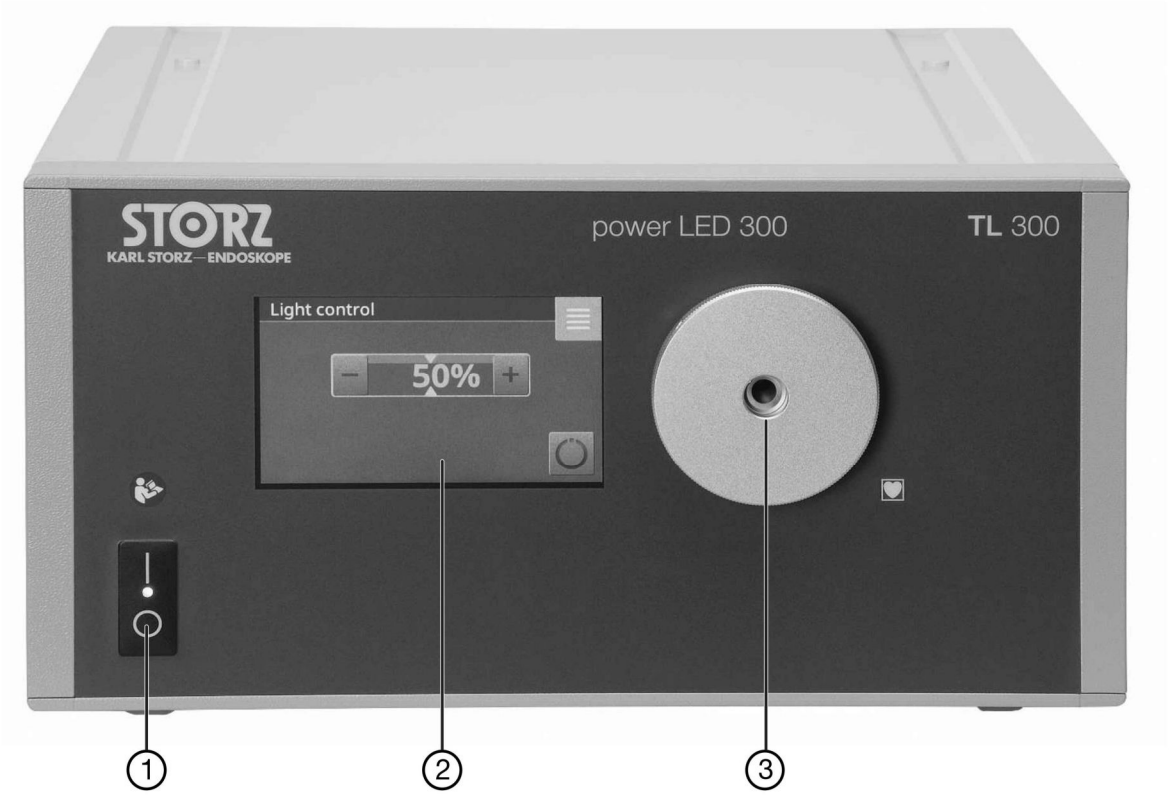
3.13 Failure of products

The product may fail during use.

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

4 Product description

4.1 Product overview



POWER LED 300 – Front view

1 Power switch
2 TFT touch screen
3 Light outlet point

POWER LED 300 – Back view

1	Grounding plug	3	Power fuse holder
2	Power cord socket	4	SCB connectors

4.2 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 basic system consists of the following components:

- Power LED 300
- Camera control unit (CCU), IMAGE1 S system
- Light cable with endoscope or videoendoscope

Compatibility with light cables

Series 495xx light cables are compatible with the standard adapter.

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

Compatibility with camera control units (CCU)

The light source can be connected to the KARL STORZ camera control unit (CCU).

The following camera control units (CCUs) can be combined:

- IMAGE1 S CONNECT (TC200)
- IMAGE1 S CONNECT II (TC201)
- IMAGE1 S H3-LINK (TC300)
- IMAGE1 S X-LINK (TC301)

- IMAGE1 S D3-LINK (TC302)
- IMAGE1 S 4U-LINK (TC304)

4.3 Technical data

Description	Value
Power supply (AC)	100–240 V
Operating frequency	50/60 Hz
Line fuse	2 x T 4.0 AH 250 V
Power consumption	175 VA
Electrical protection class	I
Applied part type according to IEC 60601-1	CF
Dimensions (L x H x W)	313 x 155 x 305 mm
Weight	8.6 kg

4.4 Symbols employed

4.4.1 Symbols on the packaging

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

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

4.4.2 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
	The potential equalization is responsible for equalizing the potentials of different metal parts that can be touched at the same time, or for reducing potential differences that could occur between the body, electromedical devices, and external live parts during use. The potential equalization complies with the requirements for a medical electrical system.
	Applied part of the type CF
	KARL STORZ SCB interface Remote control of functions and remote display of parameters

4.4.3 Symbols on the type plate

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

4.4.4 Symbols on the user interface

Symbol	Meaning
	Settings
	Standby
	Start/stop
	Increase value
	Decrease value

Symbol	Meaning
	Confirm
	Cancel
	Remove
	Scroll back
	Scroll forward
	Audio signals on/off

4.5 Ambient conditions

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

Operating conditions	
Temperature	10°C ... 40°C (50°F ... 104°F)
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 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 Inspecting products

Inspect all products used for damage, e.g.:

- Damaged power cord
- Damaged glass plate
- Damaged housing
- Sharp edges, sharp corners

5.3 Reprocessing the product

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

5.4 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.

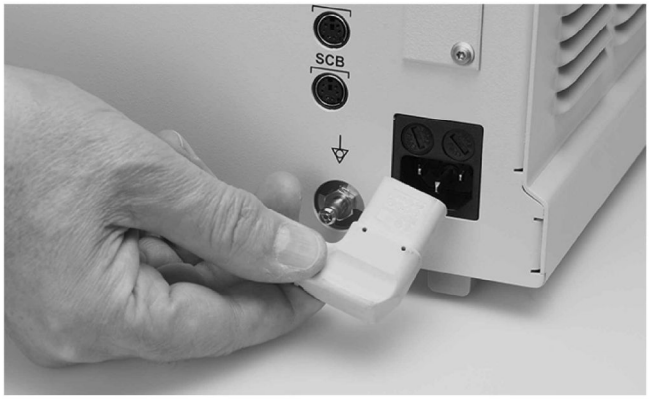
This product and connected components may only be used in medical rooms with electrical installations that conform to applicable national regulations. When the product is installed, the position of the user must be taken into account. When the product is being operated, the user stands within a viewing 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 reach of patients.

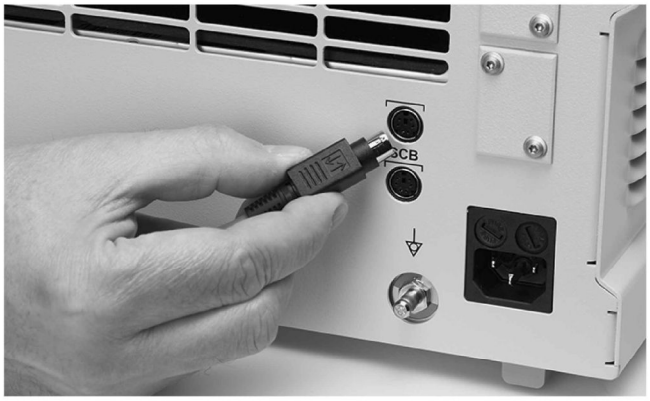
5.5 Connecting the product

1. Connect the potential equalization cable.

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



3. Connect 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 protection device to prevent if from being pulled out accidentally).

5.6 Connecting the light cable

⚠ WARNING

Hot light connections! Risk of burns!

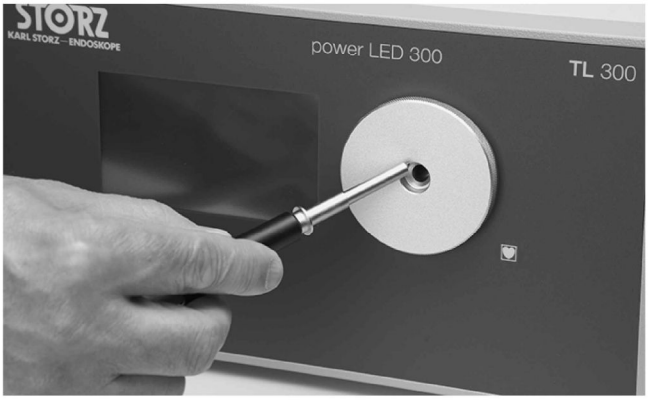
The high level of light intensity produced by the light source may cause the light connections and adjacent components to heat up. This can cause burns to users and third parties.

- ▶ Switch off the light source before changing the light cable.
- ▶ Allow the product to cool down before changing the light cable.

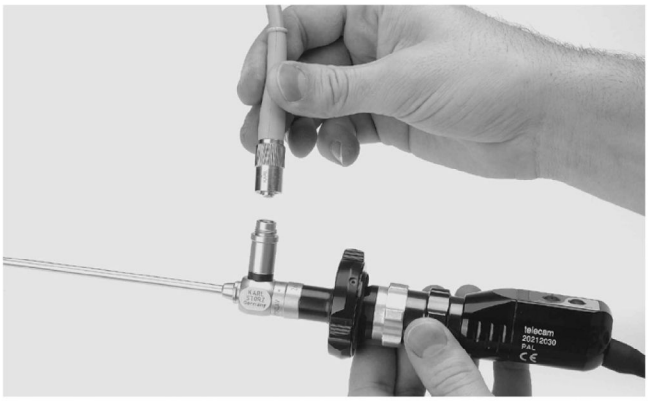
ⓘ The light outlet point is provided with an antiglare flap, which does not allow any direct outlet of light. Light only appears when the light cable is attached.

ⓘ We recommend using original KARL STORZ light cables, because light cables from other manufacturers may not be optimized for light transmission. The degree of protection against electric shock at the applied part as type CF according to IEC 60601-1 is guaranteed when using KARL STORZ light cables, see chapter *Accessories* [p. 32].

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.


telecam
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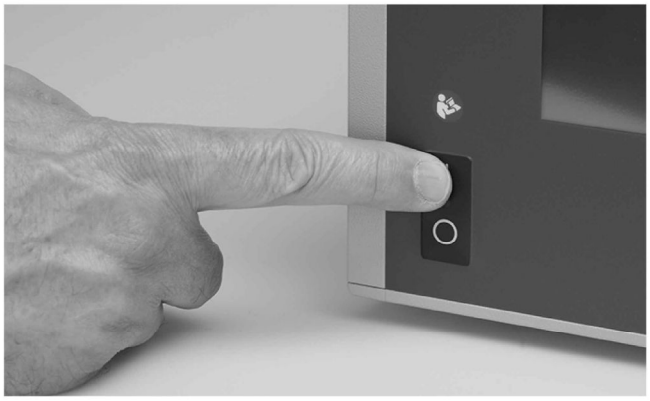
5.7 Putting the product into operation

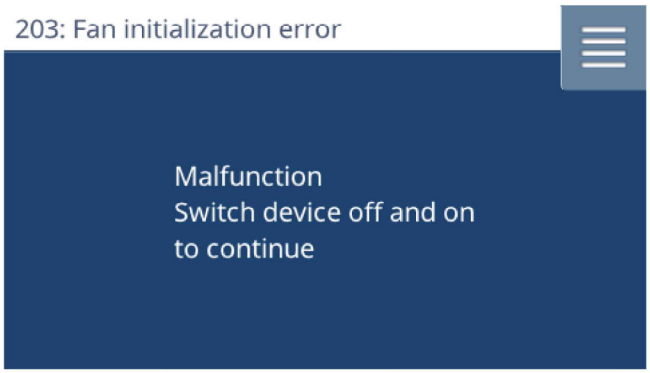
1. Switch the product on with the power switch.



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

⇨ After a successful self-test, the ready signal sounds and the light source is ready for use.

⇨ If the self-test fails, the product assumes the safe system state and an information signal sounds:

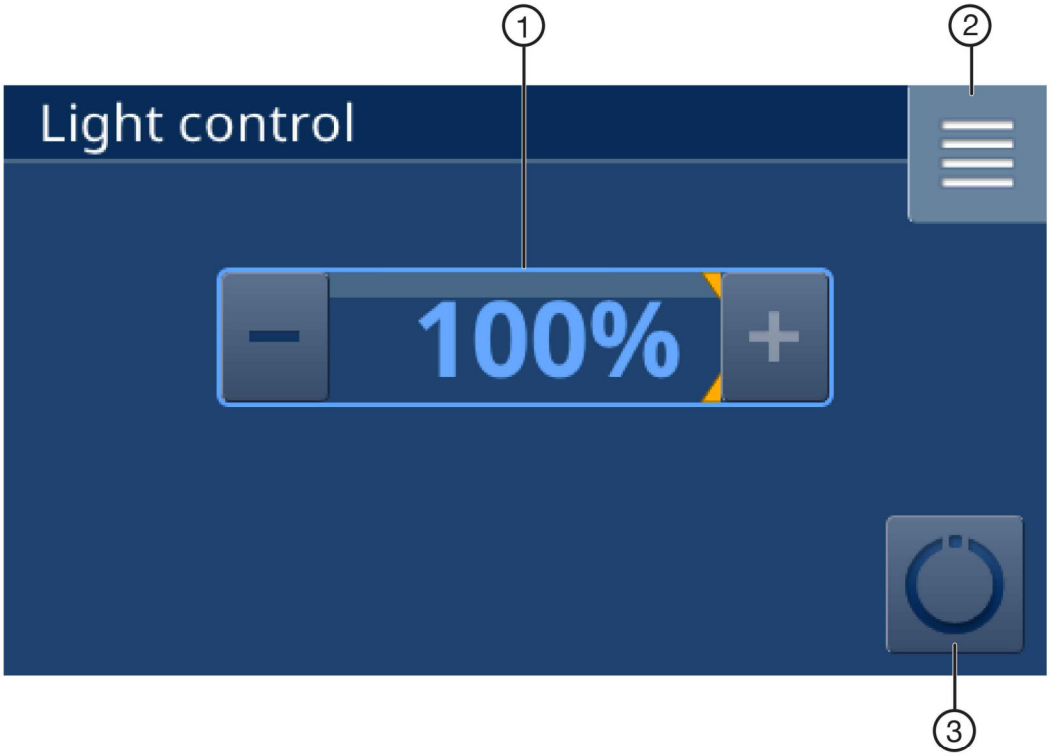


2. Switch the product on and off.
3. Check whether the product is correctly connected.

6 Application

6.1 User interface

The product is in manual standby mode after being switched on. The light switches off at a light intensity of 5%. The most recently used light intensity is displayed.



1 Adjust the brightness
2 Settings
3 Light on/off

The **Settings** button appears only when the light is switched off.

6.2 Switching the light on and off

1. Tap on the **Start/Stop** button to switch the light on and off: orange = on, blue = off.

2. To adjust the brightness, see chapter *Manual light adjustment* [p. 24].

6.3 Manual light adjustment

The brightness can be adjusted when the light is switched on or off.

1. Tap the **Plus** button to increase the brightness.
2. Tap the **Minus** button to decrease the brightness.

⇨ The set brightness is shown in %.

⇨ The orange triangles indicate the set value in relation to the possible setting range.

6.4 Automatic light control

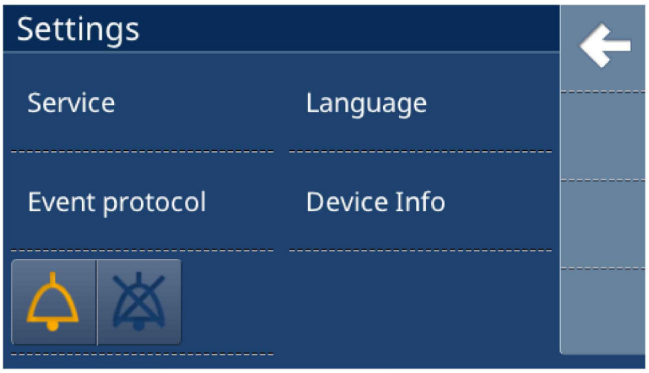
If the product is connected to the IMAGE1 S camera control unit via the SCB connecting cable, the light is controlled automatically and optimally adjusted to each situation, see instructions for use IMAGE1 S.

6.5 Settings

1. Make sure that the light is switched off and the **Start/Stop** button turns blue.

2. Tap the **Menu** button.

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

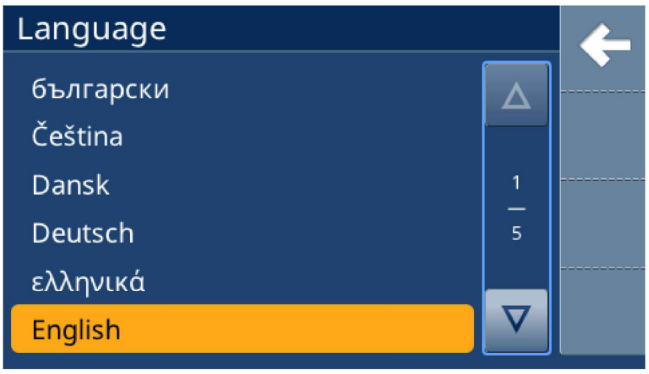


6.5.1 Service

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

6.5.2 Setting the language

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



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

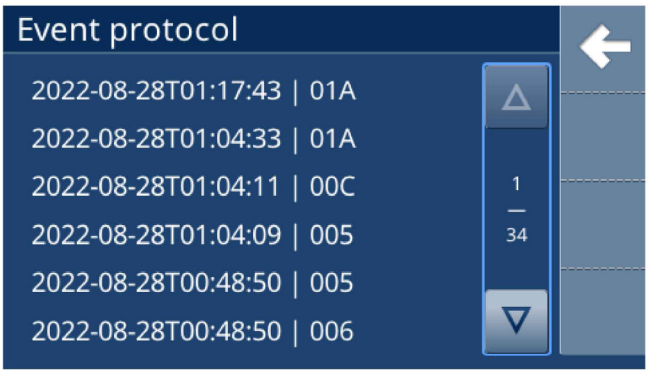
6.5.3 Event protocol

Alarms and information reports are saved in the event protocol at the time of occurrence.

Each line contains the following event data:

- Date
- Time
- Info ID

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

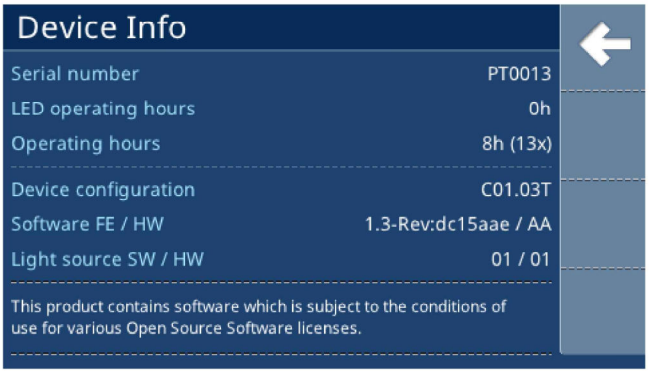


2. Browse back through the screen with the **Arrow**.

6.5.4 Product information

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

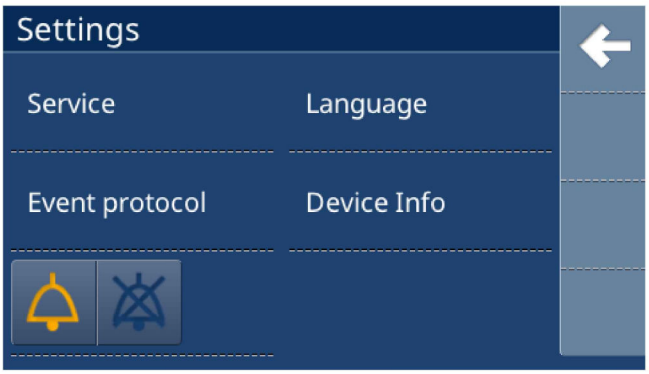
1. In the **Settings** screen, tap the **Device Info** sub-menu.
   ⇨ The **Device Info** screen appears.



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

6.5.5 Audio settings

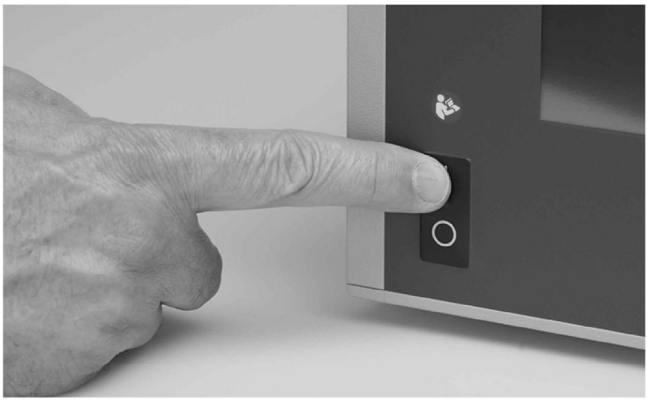
1. Tap on the **Audio signal on** and **Audio signal off** buttons to switch the acoustic signals on or off.
   ⇨ The function is active when the button turns orange.
   ⇨ When the audio signal is switched off, a crossed-out bell appears in the screen header.



2. Confirm the screen with the **Checkmark** or cancel it with the **Cross**.

6.6 Switching off the product

1. Switch the product off with the power switch.



6.7 Information signals

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. To prevent confusion between the signals when the conditions exist only for a very short time, the signals are displayed for at least 5 s.

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

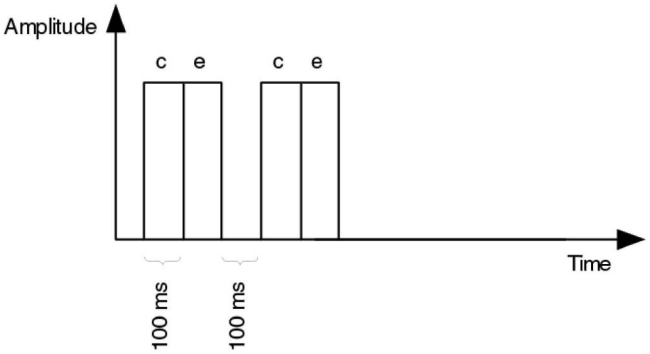
6.7.1 Visual information signal

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

6.7.2 Acoustic information signal

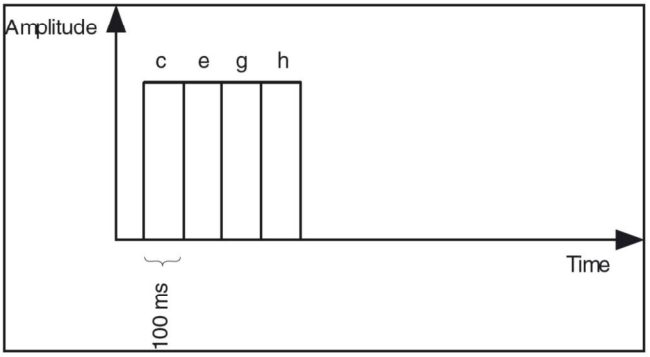
The acoustic information signal is issued for as long as the signal conditions apply. However, at least one complete signal sequence sounds. Acoustic signals can be temporarily switched on or off in Settings and are are always active when the product is restarted.

The pitch of the information signal is modulated at a frequency of 1.5 Hz by ± 2 Hz at a time. 5 different harmonics are generated and the sound sequence occurs once. Signals indicating the product's safety state are repeated and sound every 15 s.



6.7.3 Availability signal

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



Harmonics of the availability signal

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:

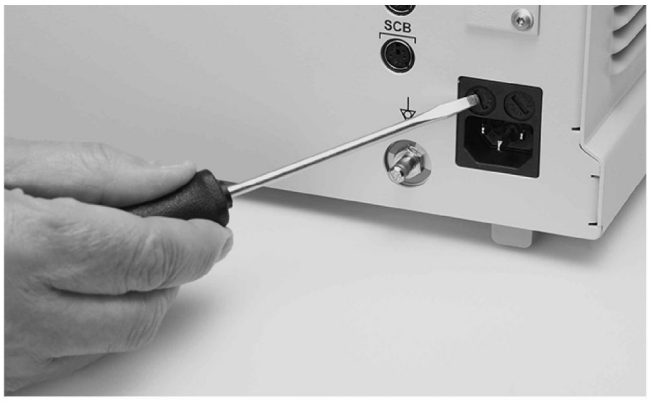
Interval	Activity	To be performed by
annually	Safety test	KARL STORZ service technicians

- ▶ Check the device configuration after every software update.

7.2 Changing a fuse

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

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

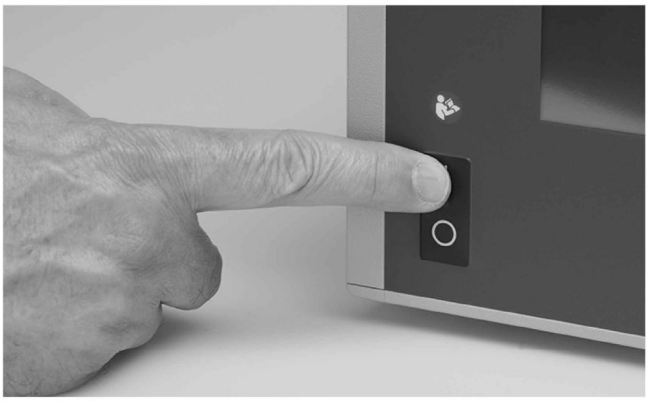


2. Remove the defective fuse.

3. Insert a new fuse. Only use fuses with the specified values; see chapter see chapter *Technical data* [p. 14].

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

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



7.3 Safety inspection in accordance with IEC 62353

⚠ WARNING

Risk of injury due to product degradation!

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

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

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

7.3.1 Visual inspection

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

7.3.2 Electric measurements

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

1. 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
Three-way adaptor for light source	TL005
SCB Connecting Cable, 100 cm	20090170
Power cord, length 300 cm	400A
Power cord, US version, 200 cm	400B

ⓘ Not all articles are available in all regions.

8.2 Spare parts

Article	Order no.
Mains fuse, 100 – 240 V, T 4.0 AH 250 V AC, IEC 127 format	2027690

9 Electromagnetic compatibility

9.1 General notes on the operating environment

Special environment

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

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

ⓘ The emission characteristics of this product make it suitable for use in 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 equiptment 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 Accessories, transducers and cables

⚠ WARNING

Reduced immunity! Malfunction!

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

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

⚠ WARNING

Degradation of performance! Malfunction!

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

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

The following accessories and cables are defined for EMC compliance.

Type	Shielded	Maximum length	Contains ferrite	Use
PE	No	>3 m	No	Potential equalization
Power cord	No	3 m	No	Connection of device to AC mains.

9.3 Test-Tables

9.3.1 Table 1 – Compliance level for immunity tests

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

Interference immunity tests	EN/IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
	100% for 250/300 cycles	100% for 250/300 cycles	
Magnetic field at the supply frequency (50 Hz/60 Hz) acc. to IEC 61000-4-8	30 A/m at 50 Hz/60 Hz	30 A/m at 50 Hz/60 Hz	If image distortion occurs, it may be necessary to position the equipment further from sources of power frequency magnetic fields or to install magnetic shielding. Before installing the device, the electromagnetic field should be measured to ensure that it is sufficiently low.
Immunity test acc. to IEC 61000-4–3 for high-frequency electromagnetic fields	3 V/m 80 MHz to 2.7 GHz see chapter *Table 2 – Test levels for proximity fields from RF wireless communications equipment* [p. 36] for wireless HF near field test levels	3 V/m 80 MHz to 2.7 GHz	-
Immunity to conducted disturbances, induced by radio-frequency fields acc. to IEC 61000-4-6	3 V_{rms} on 150 kHz to 80 MHz 1 kHz 80% AM modulation 6 V_{rms} in ISM frequency bands between 0.15 MHz and 80 MHz	3 V_{rms} on 150 kHz to 80 MHz 1 kHz 80% AM modulation 6 V_{rms} in ISM frequency bands between 0.15 MHz and 80 MHz	-
Magnetic field in close proximity, IEC 61000-4-39	8 A/m @ 30 kHz (CW modulation) 65 A/m @ 134.2 kHz (pulse modulation) 7.5 A/m @ 13.56 kHz (pulse modulation)	8 A/m @ 30 kHz (CW modulation) 65 A/m @ 134.2 kHz (pulse modulation) 7.5 A/m @ 13.56 kHz (pulse modulation)	-

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

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

9.3.3 Table 3 – 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	

10 Errors and messages

10.1 Troubleshooting

Fault	Possible causes	Actions
Product failed	Power supply failure	▶ Have the power supply checked
	Defective fuse	▶ Replace fuses as described in the 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
	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	Soiled end faces of the light cable or the endoscope	▶ 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
Light intensity regulation displays “erratic behavior”	Internal error with input preparation	▶ Touch the **Standby** button once to reset to “Normal behavior”

11 Overview of mitigating warnings

The original English warning text is as follows:

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

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