

STORZ

KARL STORZ — ENDOSKOPE

en **Instructions for use**
Power LED Rubina



01-2024

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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:

NIR Fluorescence light sources

Product name	Item number
Power LED Rubina	TL400

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

NIR Fluorescence light sources

NIR Fluorescence light sources are intended for generating white light illumination and for excitation during fluorescence imaging in the near infrared spectral range in diagnostic and surgical interventions.

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

2.2 Indications

NIR Fluorescence light sources are suitable for generating white-light illumination for medical investigation and visualization during diagnostic and surgical interventions.

Additionally, they are used for excitation during fluorescence imaging in the near infrared spectral range

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.

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.

Certain devices or accessories can represent a hazard at low power settings. During argon coagulation, for example, the risk of gas embolism increases if there is insufficient HF power.

- ▶ Ensure that there is always enough HF power when using the product simultaneously with HF devices.

3.4 Product not clean

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

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

3.5 Dangers from electrical current

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

- ▶ Ensure that all electrical installations of the operation room in which the product is connected and used conform with the applicable IEC standards.
- ▶ Use either the power cord supplied by KARL STORZ or a power cord which has the same properties and which bears a national mark of conformity.
- ▶ The product may only be operated with the line voltage stated on the rating plate.
- ▶ Position the product appropriately so that the power cord can be unplugged at any time. The product is only voltage-free when the mains plug has been disconnected.
- ▶ 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.

3.6 Damage due to ingress of liquid in electrical components

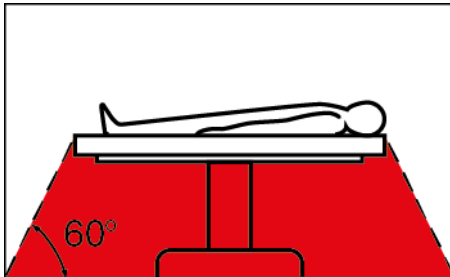
In the case of electrical products, individual components or the product itself may be live. Liquid ingress into an electrical product may result in a short circuit or an unintentional transfer of current. The product is damaged as a result and patients, users and third parties may be injured.

- ▶ 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 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.

3.10 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.

3.11 Functionality of the touch screen

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

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

3.12 Failure of products

The product may fail during use.

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

3.13 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 Product overview



Power LED Rubina, front

- | | | | |
|---|----------------|---|--------------------|
| 1 | Standby button | 3 | Light output point |
| 2 | Touchscreen | | |



Power LED Rubina, rear

- | | | | |
|---|-----------------------------------|---|----------------------------------|
| 1 | KS HIVE connector | 5 | Mains socket |
| 2 | USB port | 6 | Potential equalization connector |
| 3 | External sync interface connector | 7 | Footswitch connection |
| 4 | Line fuse holder | | |

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 IMAGING basic system consists of the following components:

- POWER LED Rubina
- Camera control unit (CCU)
- Light cable with endoscope or videoendoscope
- Footswitch

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 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)

Compatibility with footswitches













The UF101 footswitch is compatible with the light source.




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 input	220 VA
Electrical protection class	I
Applied part type according to IEC 60601-1	CF
Dimensions (L x H x W)	370 x 120 x 305 mm
Weight	7.4 kg
Light emitted (dependent on the mode)	Wavelength
White light	400–700 nm
Near infrared (NIR)	700–800 nm






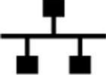


4.4 Symbols employed


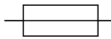

4.4.1 Symbols on the packaging

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
	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 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.
	OPAL1 NIR/ICG
EXT SYNC	EXT SYNC interface
	ON/OFF (standby)
	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
	KS HIVE socket
	USB
	Connection socket, e.g., for footswitch




Symbol	Meaning
	Alternating current
	Fuse
	Hot surface

4.4.3 Symbols on the type plate

Symbol	Meaning
	Manufacturer
	Date of manufacture
	Medical device
	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.
	Prevention of pollution by electronic devices
	Separate collection of electrical and electronic devices. Do not dispose of in household refuse.

4.4.4 Symbols on the user interface

Symbol	Meaning
	Settings
	Cancel
	Confirm
	Scroll backwards
	Browse up
	Browse down
	Increase value
	Decrease value
	Footswitch
	Audio signal off

Symbol	Meaning
	Audio signal on
	Light on
	Light off

4.5 Ambient conditions

Transport and storage conditions	
Temperature	-18°C ... +60°C (-0.4°F ... +140°F)
Relative humidity (non-condensing)	5–85%
Air pressure	600–1,080 hPa
Operating conditions	
Temperature	0°C ... 40°C (32°F ... 104°F)
Relative humidity (non-condensing)	5–85%
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.

▲ CAUTION

Breakable glass! Risk of injury!

The front glass 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 continue to use the product.
- ▶ Do not touch the glass parts of the product.
- ▶ Remove small glass parts from the product.
- ▶ Have the product repaired by qualified service personnel.

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

1. Place the product on a horizontal, flat surface. Make sure that the power cord can be unplugged at any time.
2. Keep the product out of reach of patients.
3. Ensure adequate air circulation.

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.



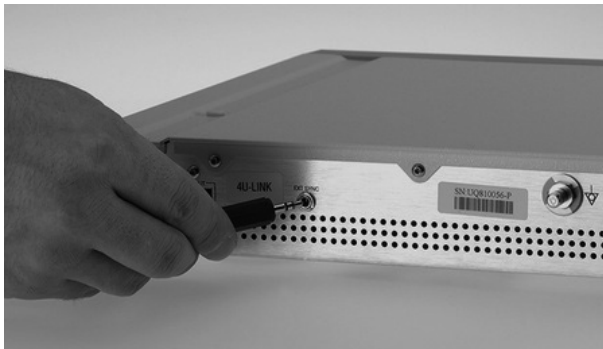
3. Insert the KS HIVE connecting cable into the socket until the plug audibly clicks into place.





4. Plug the SYNC connecting cable into the EXT SYNC socket.



5. Connect the other end of the SYNC connecting cable to the IMAGE1 S 4U LINK module.



5.6 Connecting 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.
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.



5.7 Connecting the footswitch

1. Insert the footswitch connecting cable fully into the socket.

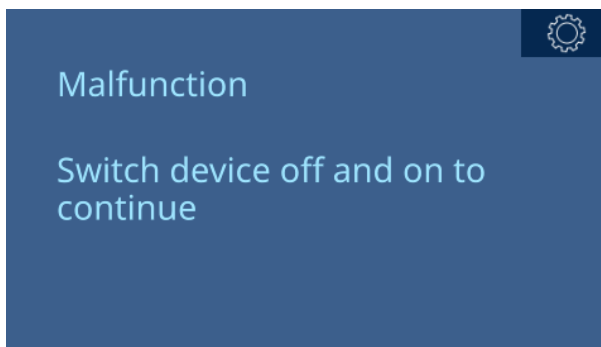


5.8 Putting the product into operation

1. Switch on the product using the Standby button.



- ⇒ The 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.
- ⇒ The following message appears on the screen:

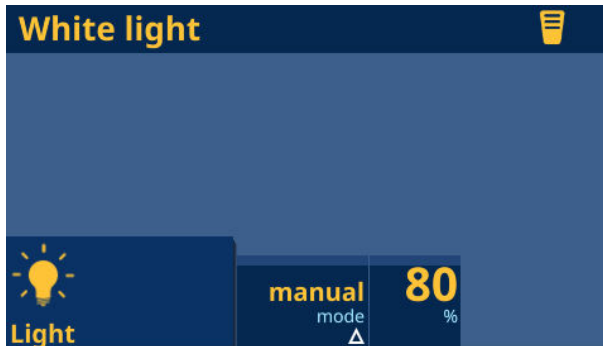


2. Switch the product on and off.
3. Check whether the product is correctly connected.
 - ⇒ The product is in manual white-light mode after being switched on, and the light is switched off.
4. Tap **Settings** to adjust the settings.

6 Application

6.1 Switching the light on and off

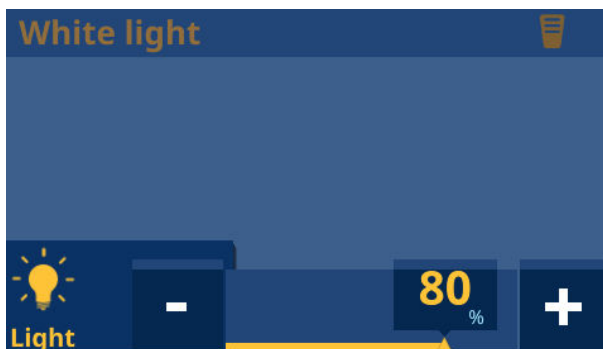
1. Tap the **Light** button to switch the light on and off: orange = on, white = off.



6.2 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.



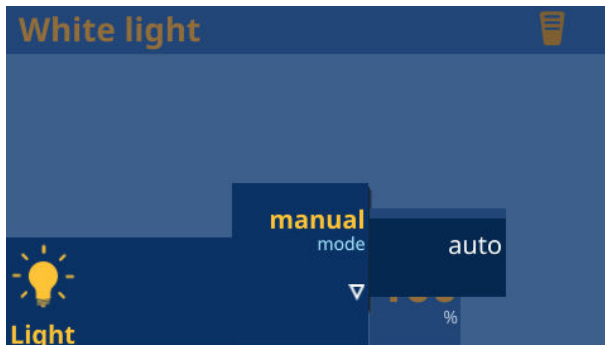
2. Tap the **Minus** button to decrease the brightness.
3. Alternatively, move the slider.
 - ⇒ The set brightness is shown between 5 and 100%.

6.3 Automatic light control

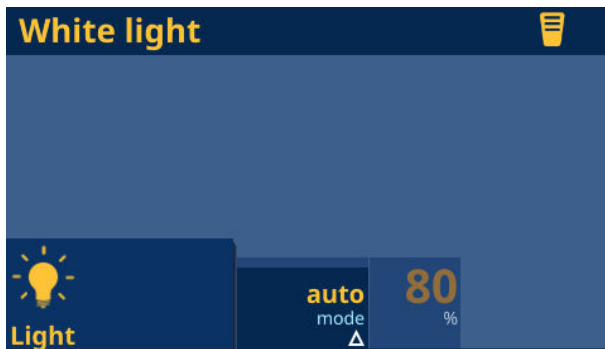
If the product is connected to the IMAGE1 S camera control unit via the KS HIVE connecting cable, the light is controlled automatically and optimally adjusted to each situation.

- ✓ IMAGE1 S with software release version 4.0 or higher is connected.

1. Tap the **Manual** button.



2. Tap the **Auto** button.

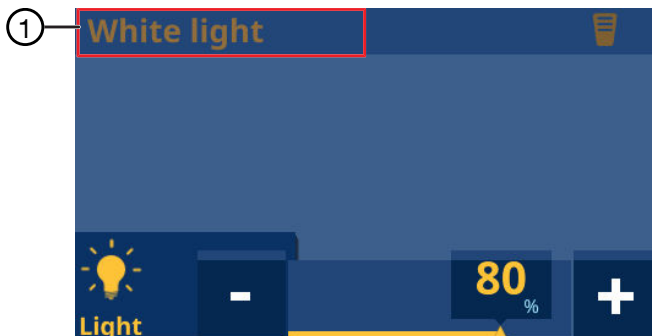


3. Tap the **Light** button to switch the light on.
⇒ The light intensity is automatically controlled via the camera control unit.
4. Tap the **Manual** button to deactivate the automatic light control.
5. Switch on the automatic light control again via the camera control unit; see the IMAGE1 S instructions for use.

6.4 Changing the light mode

The light mode (white light and NIR mode) can be called up using the:

- Camera head buttons (connected with IMAGE1 S)
- IMAGE1 S menu
- Footswitch (connected with light source)



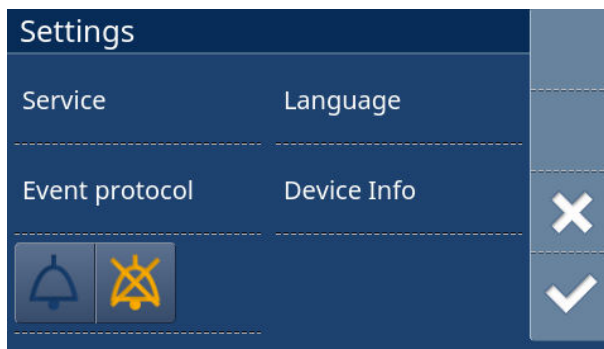
1 Light mode display

The following modes are available:

Mode	Description
White light	Displays the white light information on the IMAGE1 S
Monochromatic	Displays the NIR information on the IMAGE1 S
Overlay	Displays the white light information with overlaid fluorescent information on the IMAGE1 S
Intensity Map	Displays the white light information with overlaid fluorescent information (in false colors depending on the fluorescent intensity) on the IMAGE1 S

6.5 Settings

1. Make sure that the light is switched off and the **Light** button turns white.
 2. Tap the **Settings** button.
- ⇒ The **Settings** screen appears with the following sub-menus:

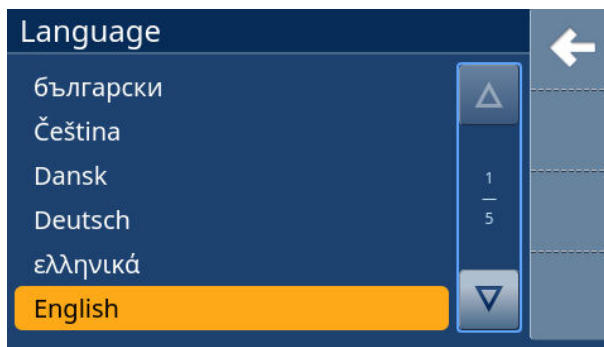


6.5.1 Service

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**.

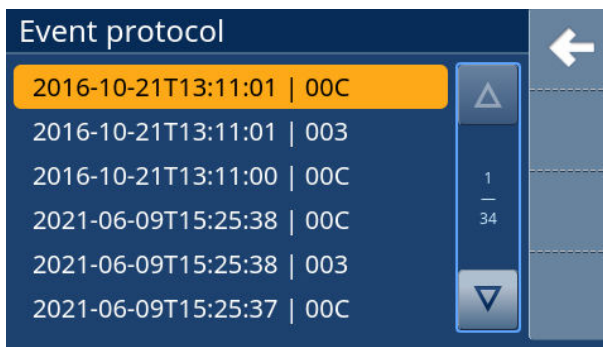
6.5.3 Event protocol

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

Each line contains the following event data:

- Date
- Time
- Alarm/info ID

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



⇒ The **Event log** 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.

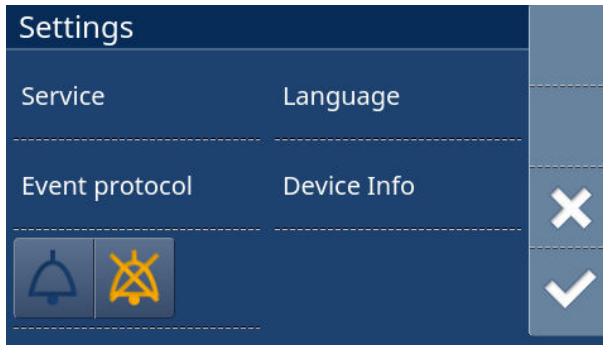


⇒ The **Device info** screen appears.

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

- ▶ Switch off the product using the **Standby** button.

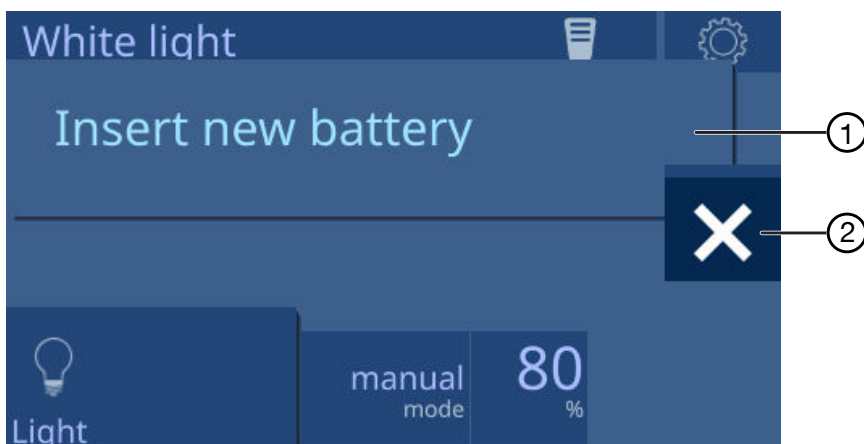
6.7 Information signals

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 without flashing.



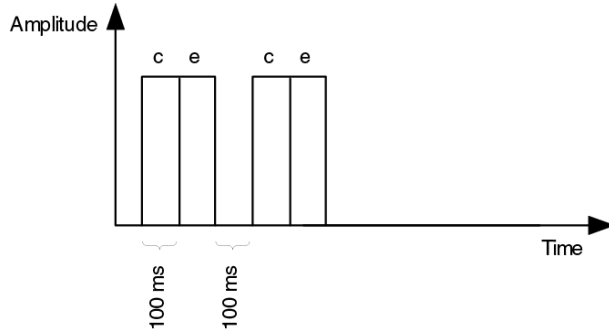
1 Text display of an information signal

2 Close information signal

6.7.2 Acoustic information signal

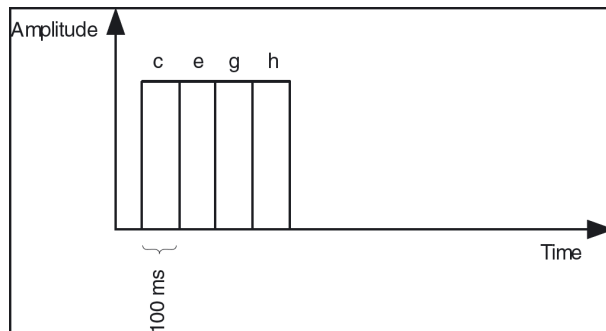
The acoustic information signal is issued for as long as the signal conditions apply. However, at least one complete signal sequence sounds. Acoustic signals can be temporarily switched on or off in Settings and are always active when the product is restarted.

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

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

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



2. Remove the defective fuse.

3. Insert the new fuse. Only use fuses with the specified values, see chapter *Technical data* [p. 13].



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



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



7.3 Safety inspection in accordance with IEC 62353

⚠ WARNING

Risk of injury due to product degradation!

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

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

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

7.3.1 Visual inspection

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

7.3.2 Electric measurements

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

1. 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
Power cord, length 300 cm	400A
Power cord, US version, 200 cm	400B
One-pedal footswitch, one-stage	UF101
OR1 patch cable CAT6a 2.0 m UL	WO10275
Synch connecting cable, 3.5mm, 100 cm	TL006

 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).

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

WARNING

Electromagnetic interferences! Malfunction!

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

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



CAUTION

MR unsafe!

This product is MR unsafe.

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

9.2 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	No	Potential equalization
Mains 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	<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.

Interference immunity tests	EN/IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Magnetic field at the supply frequency (50 Hz/60 Hz) acc. to IEC 61000-4-8	30 A/m at 50 Hz/60 Hz	30 A/m at 50 Hz/60 Hz	If image distortion occurs, it may be necessary to position the equipment further from sources of power frequency magnetic fields or to install magnetic shielding. Before installing the device, the electromagnetic field should be measured to ensure that it is sufficiently low.
Immunity test acc. to IEC 61000-4-3 for high-frequency electromagnetic fields	3 V/m 80 MHz to 2.7 GHz see chapter <i>Table 2 – Test levels for proximity fields from RF wireless communications equipment</i> [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					

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

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

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

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

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

9.3.3 Table 3 – Emission class and group

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






10 Errors and messages

10.1 Troubleshooting

Fault	Possible causes	Actions
Product failed	Power supply failure	▶ Have the power supply checked
	Defective fuse	▶ Replace fuses as described in the 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”
Touchscreen does not react	Touchscreen was actuated during the start process	▶ Switch the product off and on
	Touchscreen is wet	▶ Wipe with a clean, dry cloth
Device certificate expired	Certificate not up to date	▶ Check and set the date and time ▶ Contact Service
Incorrect time stamp	Date and time are not set	▶ Check and set the date and time

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

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