KARL STORZ — ENDOSKOPE

en **Instructions for use**
Power LED Saphira

08-2021

CE 0123

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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	Item number
Power LED Saphira	TL410

1.4 General signs and symbols

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

Practical tip

ⓘ This sign refers to useful and important information.

Actions to be performed

Action to be carried out by several steps:

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

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

⇨ Result of a completed action

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

- ▶ Step 1

Lists

1. Numbered list

– Unnumbered list, 1st level

– Unnumbered list, 2nd level

1.5 Description of warning messages

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

⚠ WARNING

WARNING

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

⚠ CAUTION

CAUTION

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

NOTICE

NOTICE

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

1.6 Abbreviations

Abbreviation	Explanation
PDD	Photodynamic diagnosis The Power LED Saphira (TL410) is used for fluorescence contrast imaging (FCI) in accordance with IEC 60601-2-75. Therefore, describing the procedure performed with the Power LED Saphira (TL410) as photodynamic diagnosis (PDD) is not consistent with the definition of “photodynamic diagnosis” given in IEC 60601-2-75. Nevertheless, the term photodynamic diagnosis continues to be used, for historical reasons, as a synonym for FCI both in technical literature and in common usage. Therefore, we will continue to refer to any procedures involving the Power LED Saphira (TL410) as PDD applications.

2 Normal use

2.1 Intended use

PDD fluorescent light sources are used for white light illumination and stimulation during fluorescence imaging in the blue and UV spectral range for diagnostic and surgical procedures. PDD fluorescence light sources do not have body contact and are intended for short-term use.

2.2 Indications

PDD fluorescent light sources are intended for generating white light during medical examinations and for visualization during diagnostic and surgical procedures. Additionally, they are used for stimulation during fluorescence imaging in the blue and UV spectral range.

2.3 Contraindications

Light sources, light cables, and adaptors must not be used for ophthalmological procedures. Light sources, light cables, and adaptors do not come into direct contact with the patient's body, but provide light for medical imaging. Furthermore, there are no known contraindications relating directly to the light sources, light cables, and adaptors.

2.4 Target user populations

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

2.5 Patient groups

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

3 Safety

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.

▶ 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:

- Functional damage
- Sharp corners
- Sharp edges

▶ Do not continue to use damaged products.

3.3 Product not clean

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

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

3.4 Combination with other components

The use of unauthorized devices and components 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.

▶ Only combine the device with instruments and equipment that are approved for joint use.

▶ 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.

Note the following when using the product with HF devices: Certain devices or accessories can represent a hazard in lower power settings. During argon coagulation, for example, the risk of gas embolism increases if there is insufficient HF power.

3.5 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 operating 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 do so 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.

- Connect or disconnect the power plug to or from the power supply only outside of explosion hazard areas.

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.

3.6 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 High light intensity

- Always select the lowest possible light setting during use.
- Never look into the light output when the light system is switched on.

3.8 Dangers from UV radiation

The product can emit small amounts of UV light. UV radiation may lead to permanent eye damage or blindness.

- Never look directly into the light output when the light source is switched on.

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 modules coming into contact with tissue and operation room accessories.

3.10 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. 32].

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.

3.11 Failure of products

The product may fail during use.

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

3.12 Observing ambient conditions

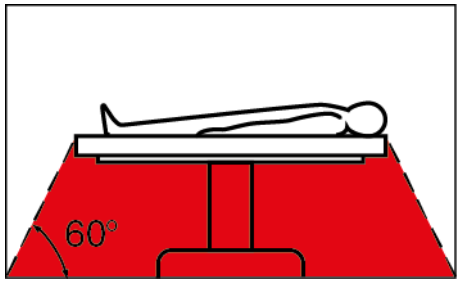
If the device is stored, transported, operated or reprocessed under unsuitable conditions, patients, users or third parties may be injured and the device can be damaged.

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

3.13 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.

3.14 Functionality of the touch screen

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

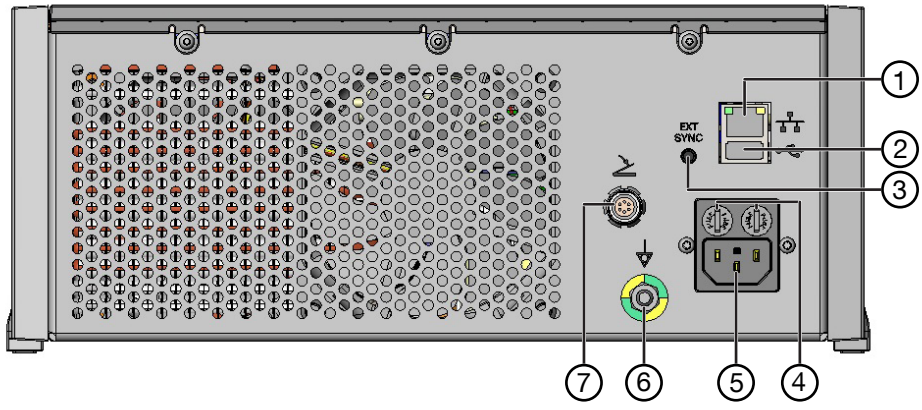
- Do not use the product if the touch screen is defective.

4 Product description

4.1 Product overview

Power LED Saphira, front

1 Standby button
2 Touchscreen
3 Light output point



Power LED Saphira, rear

1 KS HIVE connector
2 USB port
3 External sync interface connector (inactive)
4 Line fuse holder
5 Power cord socket
6 Potential equalization connector
7 Footswitch connection

4.2 Possible combinations

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

The product can be combined with the following components:

– Light cables

- Camera control units (CCU)
- Footswitches

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	180 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

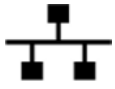
4.4 Symbols employed

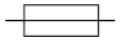
4.4.1 Symbols on the packaging

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
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	CE conformity mark: With this mark, the manufacturer declares the compliance of the products with the applicable standards and directives. A code number after the CE mark indicates the responsible notified body.

4.4.2 Symbols on the product

Symbol	Meaning
	Follow instructions for use
	OPAL1 PDD
	ON/OFF (standby)
	Visible radiation
	Potential equalization connector
	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
	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

Symbol	Meaning
	Browse down
	Increase value
	Decrease value
	Footswitch
	Audio signal off
	Audio signal on
	Light on
	Light off

4.5 Ambient conditions

Storage/transport conditions	
Temperature	-18°C ... +60°C (16.4°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 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 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.

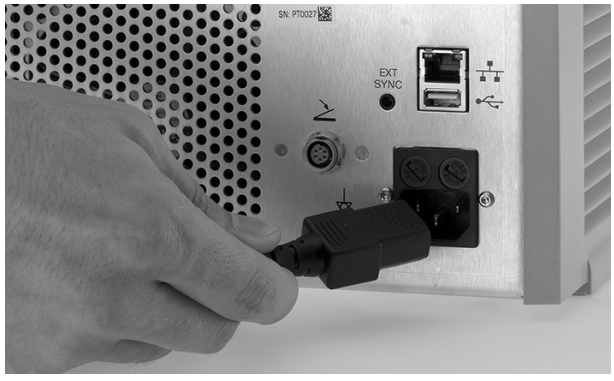
- ▶ Do not touch broken glass.
- ▶ Do not continue to use the product.
- ▶ Do not touch the glass parts of the product.
- ▶ Remove small glass parts from the product.
- ▶ Have the product repaired by qualified service personnel.

1. Set the product down on a horizontal, flat surface or a video cart. Make sure that the power cord can be unplugged at any time.
2. Keep the product out of reach of patients (> 1 m).
3. Ensure adequate air circulation.

5.3 Connecting the product

1. Connect the potential equalization cable.

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



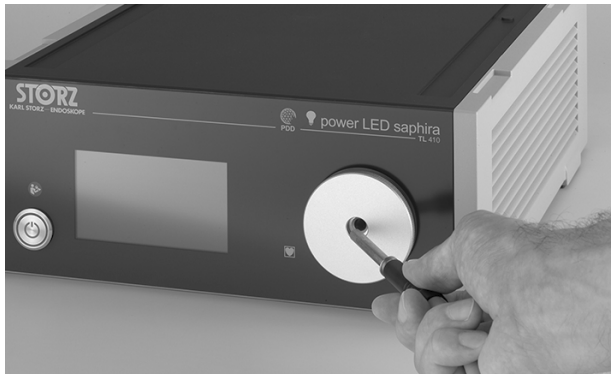
3. Insert the KS HIVE connecting cable into the socket until the plug audibly clicks into place.

5.4 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 the light cable engages. Hold the light cable only by the handle, never by the cable.



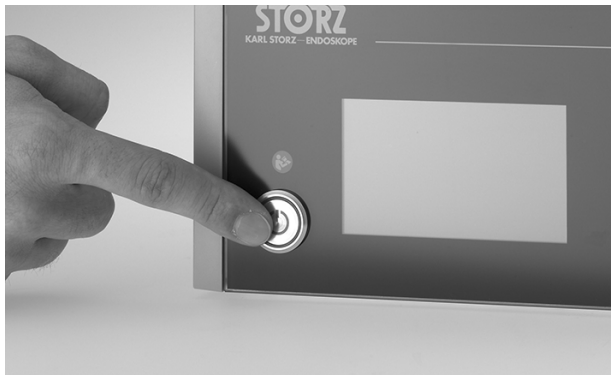
2. Secure the light cable onto the endoscope screw base.

5.5 Connecting the footswitch

1. Insert the footswitch connecting cable fully into the socket. To do this, align the red dot on the cable with the red dot on the footswitch socket.

5.6 Putting the product into operation

1. Switch on the product using the **Standby** button.

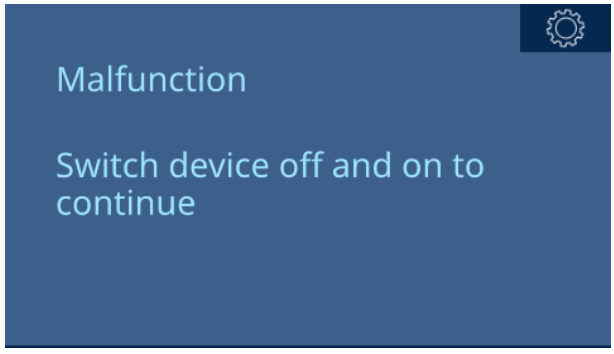


⇨ The start screen appears and the self-test is performed.

⇨ 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 state and an information signal sounds.

⇨ The following message appears on the screen:

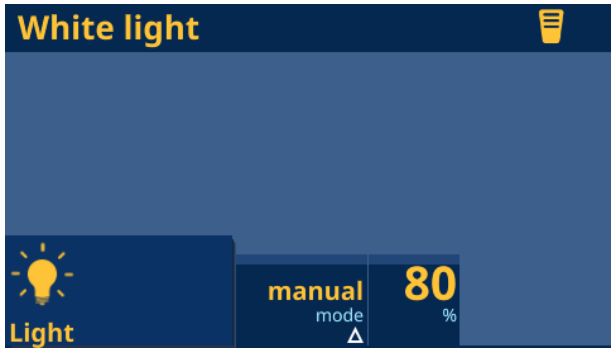


2. Switch the product off and back on.
3. Check whether the product is correctly connected.
   ⇨ The product is in manual white-light mode after being switched on, and the light is switched off.
4. Tap the **Settings** button to adjust the settings.

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

⚠ WARNING

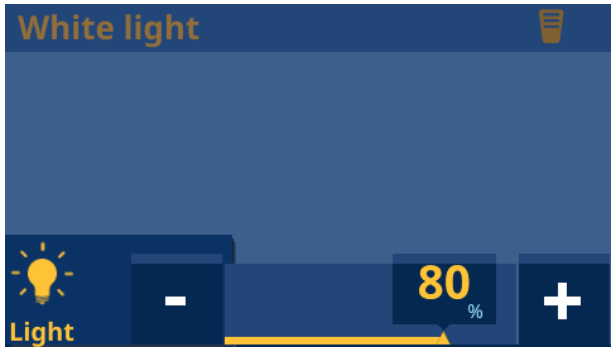
No visual contact! Risk of injury!

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

- ▶ Only activate the product under visual contact.

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.

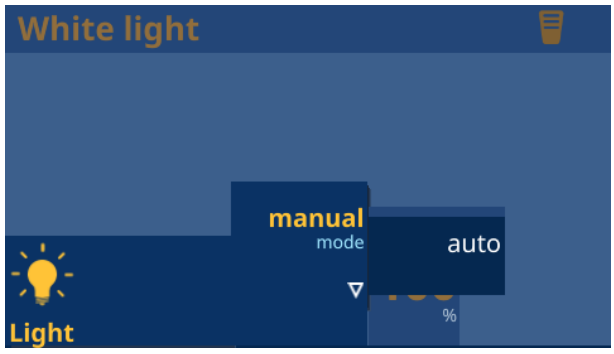
⇨ The set brightness is shown between 5 and 100%.

6.3 Automatic light control

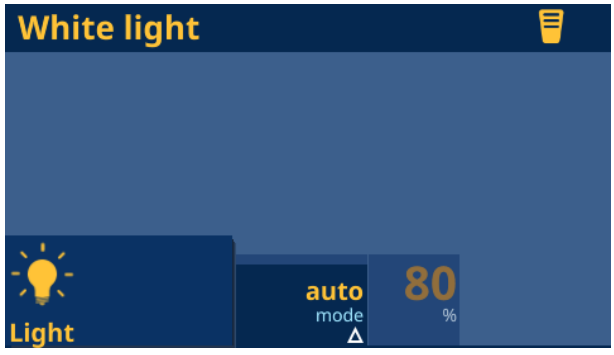
If the product is connected to the IMAGE1 S camera control unit via the KS HIVE connecting cable, the light is controlled automatically and optimally adjusted to each situation.

✓ IMAGE1 S with software release version 4.3 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.

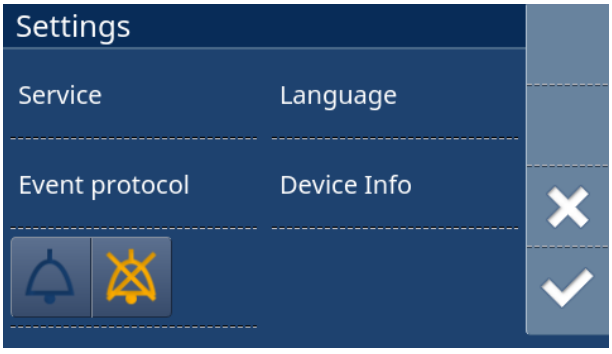
6.4 Activating fluorescence mode

1. Press the footswitch to change from white-light mode to fluorescence mode.
2. Press the footswitch again to return to white-light mode.

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:

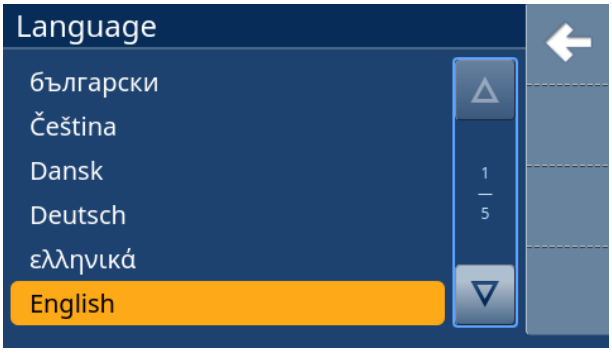


6.5.1 Service

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**.

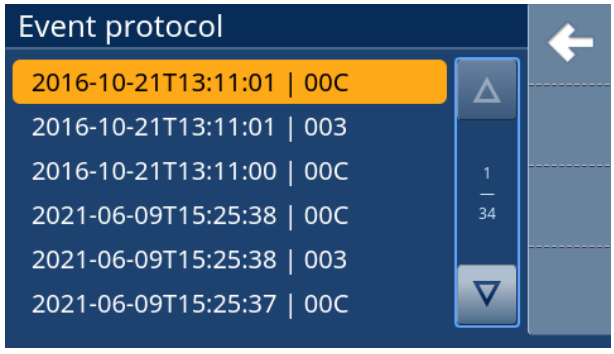
6.5.3 Event protocol

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.



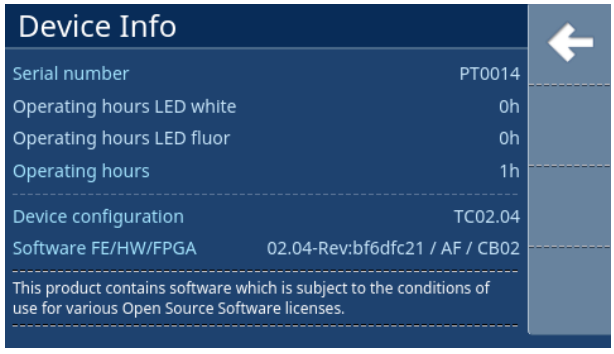
   ⇨ The **Event log** screen appears.

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.

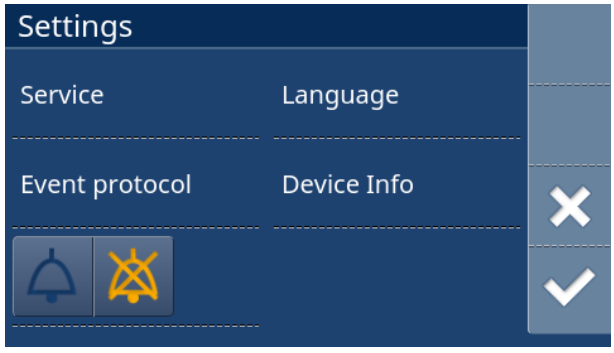


   ⇨ The **Device info** screen appears.

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.

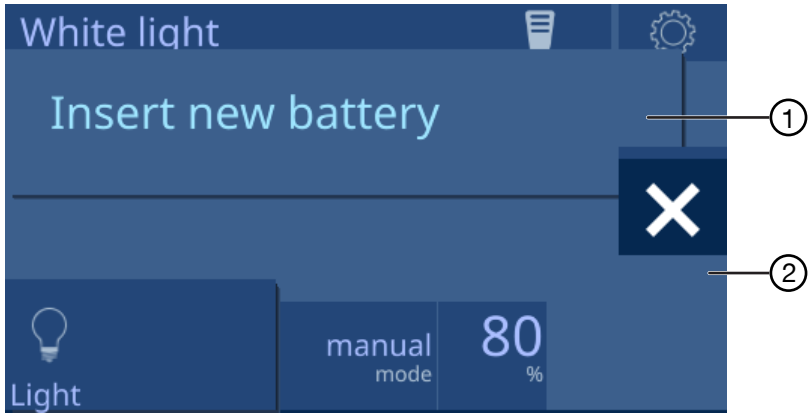
6.7 Information signals

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.

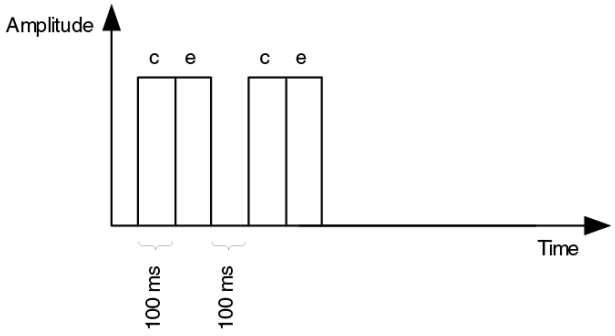


1 Text display of an information signal 2 Close information signal

6.7.2 Acoustic information signal

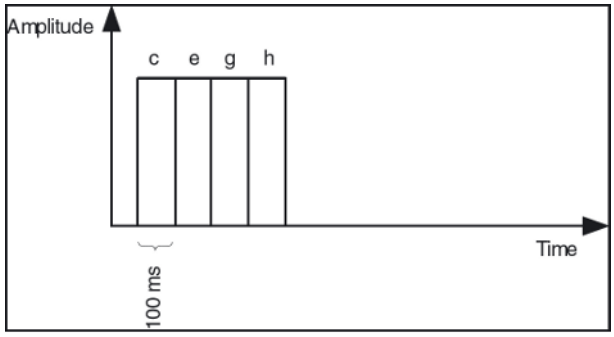
The acoustic information signal is issued for as long as the signal conditions apply. However, at least one complete signal sequence sounds. Acoustic signals can be temporarily switched on or off in Settings and are are always active when the product is restarted.

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 device can cause severe injuries due to electric shock.

- ▶ Do not open the housing.
- ▶ Make sure that the connection to the power supply is disconnected.

✓ The product is switched off.

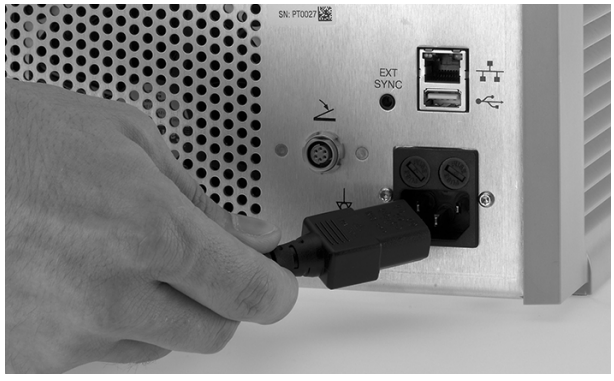
✓ The power cord is disconnected from the product.

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

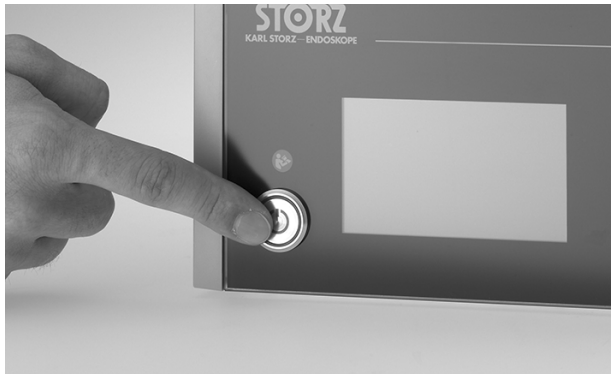
2. Remove the defective fuse.

3. Insert a 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 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

Item	Order no.
Light cable	495NAC
Power cord (grounded)	400A
“Hospital grade” power cord (USA)	400B
One-pedal footswitch, one-stage	UF101
OR1 patch cable CAT6a 2.0 m UL	WO10275

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

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 and 17	Pulse modulation 217 Hz	9	9
745					
780					
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation 18 Hz	28	28
870					
930					
1720	1700 – 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE band 1, 3, 4, 25, UMTS	Pulse modulation 217 Hz	28	28
1845					
1970					
2450	2400 – 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
5500					
5785					

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

Guidelines and manufacturer's declaration – Electromagnetic immunity

The product is intended for use in the electromagnetic environment specified below. The user 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 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 emitted, Standby button lights up (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”
Endoscopic image too dark in PDD mode	The patch cable is not correctly connected between the camera control unit and light source (KS HIVE not connected)	▶ Check the patch cable connection
	Patch cable defective	▶ Check the patch cable for damage and replace if necessary
Touchscreen does not react	Touchscreen was actuated during the start process	▶ Switch the product off and on

Fault	Possible causes	Actions
	Touchscreen is wet	▶ Wipe with a clean, dry cloth
Device certificate expired	Certificate not up to date	▶ Contact Service
Incorrect time stamp	Date and time are not set	▶ Check and set the date and time

11 Overview of mitigating warnings

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

12 Subsidiaries

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