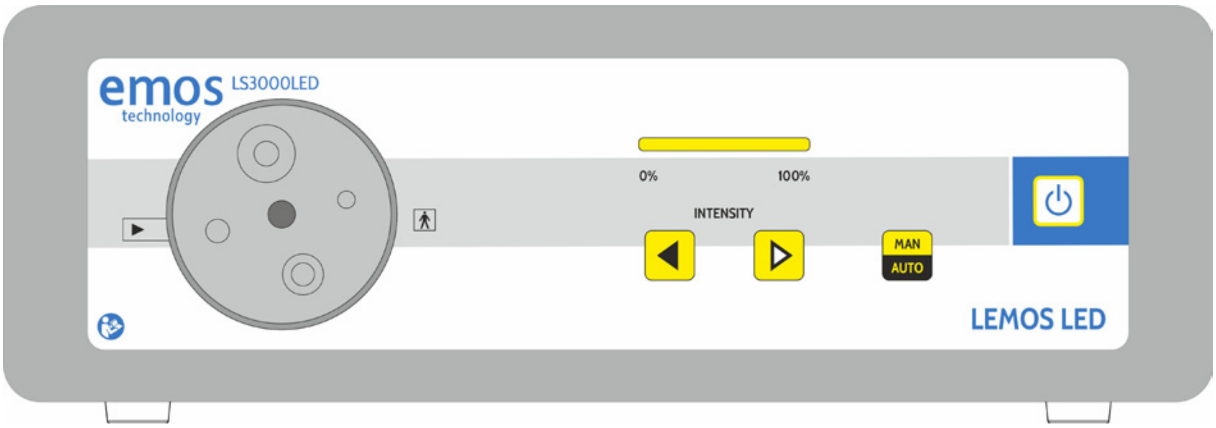
LEMOS LED
LS3000LED
Instruction manual

LED Light source for endoscopic applications



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General Information

These operating instructions contain important information on the function and safe and proper operation of the device in front of you. Before using the device for the first time, read the operating instructions carefully to ensure that there is no risk to the user or the patient. **Always keep these operating instructions together with the device.**

Data of the Device

On the type plate (back of the unit) you will find the information about the unit, which must always be given when ordering spare parts or if you have any other questions.

Warranty

⚠ **Important!** The warranty period is one year according to our warranty conditions. Unauthorized opening of the device and repairs, i.e. modifications by persons not authorized by the manufacturer release us from any liability for the operating reliability of the device. Any warranty entitlement therefore expires during the warranty period. Wear parts are excluded from the warranty.

Product service life

The service life of the medical devices manufactured by us is set at 10 years, provided they are used as intended and the recommended maintenance intervals/activities are observed (see chapter Service instructions/Service interval).

Responsibility

As the manufacturer of the device, we only consider us to be responsible for the impact on the safety, reliability and performance of the unit, if:

- Assembly, upgrade, resetting, modifications or repairs are carried out by persons authorized by us.
- the electrical installation of the particular area meets the requirements of the respective country.
- the device is used in accordance with the instruction manual.

Reporting requirement

The user must report all serious incidents occurring in connection with the product to the manufacturer and the competent authority of the Member State in which the user is established.

Rights

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Illustrations

Illustrations in the instructions serve to clarify the facts and are to be understood schematically. Due to the continuous development of our products, the illustrations may differ from the actual appearance of the product.

Disposal

According to the provisions of the European directive 2012/19/EU on used electrical and electronic equipment (WEEE), this symbol signifies that the product may not be disposed of as unsorted municipal waste, but must be collected separately. Contact your dealer regarding the return and / or the collection systems available in your country.

Safety reference / Place the equipment

Intended purpose / intended use

The device described in these instructions serves as a basic device for generating/providing light to illuminate the surgical site (surgical field) during minimally invasive surgical procedures (endoscopy).

Only use the device with accessories, consumables and disposable items that are marked as accessories by the manufacturer or whose safety-related and biologically harmless usability has been proven.

Qualifications of the user / operator

⚠ The unit may only be used by persons with the appropriate professional qualifications and who have been trained on this unit. Before using the unit, the user must be convinced of the reliability and the proper condition of the unit.

Storage and operating conditions

- Storage temperature: - 20°C to +60°C
- Operating temperature: +10°C to +40°C
- Atmospheric pressure - Storage: 600 mbar to 1300 mbar
- Atmospheric pressure - Operation: 700 mbar to 1060 mbar

- relative humidity – Storage: 10% to 90%
- relative humidity - Operation: 30% to 75%

Replacement device

Have a replacement device ready for incalculable emergencies (worst-case scenario).

Safety measures for setup and operation

⚠ For proper operation of the unit and to avoid possible hazards you observe the following precautions:

- Only place the unit on a base secured against tipping.
- The device may only be used in rooms that are installed according to national valid standards. The environmental temperature and the relative humidity must correspond to the values listed above (see storage and operation conditions). If the instrument was exposed to extreme temperatures during transport it should be acclimatized to room temperature prior to operation.
- The plug-in device for a potential equalization should be properly connected. The control unit is basically grounded via the 3-pin type F plug, if it is connected to a grounded power cord as prescribed. When operating the device in rooms of application group 2 according to DIN VDE 0100 it is essential that the device is connected to the stationary potential equalization of the room or the equipment truck by an appropriate cable. The device has an appropriate plug-in connector (according to DIN 42801).
- Use only the power cord provided for the power connection.
- This device may only be connected to a supply network with a protective conductor
- Check if the local mains voltage corresponds to the voltage range of the instrument!
- The patient and the following parts must not be touched at the same time:
  - Touchable contacts of connectors
  - Contacts of fuse holders that are accessible during the replacement of fuses
- Install the instrument in a way that there is always a suitable flow of fresh air.
- Operating the unit in explosion-prone areas is prohibited.
- The safe operation of the device is guaranteed up to a height of 3000m.
- The connection of two or more devices can lead to a higher leakage current.
- Electro-medical devices are subject to specific precautions concerning electromagnetic compatibility (EMC). Observe the following information prior to operation:
  - Mobile communication devices can interfere with the function of other electronic devices. Switch off your mobile phone or similar devices close to medical devices or medical facilities.
  - Use solely the enclosed cables and original spare parts (see chapter Unpacking / Standard equipment).. The use of other cables and spare parts may lead to a reduced interference resistance and to an increased emitted interference.
  - If the present medical device is stacked or placed directly next to other electronic devices the whole configuration and the present medical device has to be tested for correct function.

- The device must not be operated near flammable gases or flammable substances, and within the direct patient environment.
- Caution! Only connect medical devices to the interfaces (Signal-In-Put / Signal-Out-Put) on the back of the device!
- When using other medical devices in conjunction with the application part (BF or CF) of this device, please note that all devices within the configuration must be adapted to the corresponding application with regard to the type (BF or CF).
- The device must be set up/positioned in such a way that disconnection from the mains / disconnecting device is not made more difficult or prevented by pulling out the mains plug.
- Do not look into the light beam, light guide output or endoscope light beam during operation! This can be injurious to the eyes!
- Light with high radiant energy coming out of the light exit window of the endoscope can lead to a raising temperature in the tissue in front of the light exit window and can thus damage the tissue or it can lead to coagulations.
- Never cover the fiber optic connector (fire hazard)!
- The failure of the illumination during an operation can endanger the patient indirectly. It is recommended to provide a ready spare instrument.

⚠ **Attention!** Please use only high-performance light cables / high-temperature resistant light guides (Preferably: HLC type of the manufacturer of this unit)!

⚠ **Attention!** The use of light guides with a smaller diameter than 4.8mm of the active part is not recommended, as this leads to increased temperature!

⚠ **Caution!** Injuries and damage caused by exposure to heat!

· **Effect:**
· The light-guide connector and the telescope's distal end may become extremely hot.
· The light energy is concentrated in a relatively small area.

· **Risks:**
· Thermal injury to the patient's tissue (e.g. from prolonged exposure to intense illumination in cavities with small lumens, or if the telescope's distal end is placed into close proximity with the tissue.
· Burns to the patient's or user skin
· Burns or thermal damage to surgical equipment (e.g. surgical drapes, plastic materials, etc.).

· **Countermeasures:**
· Avoid prolonged exposure to intense illumination.
· Use the minimum level of illumination necessary to satisfactory illuminate the target area.
· Do not place the telescope's distal end or the light-guide connector on the patient's skin, on flammable materials, or on heat-sensitive materials.
· Do not touch the telescope's distal end or the light-guide connector.
· Turn the light source off after use.
· Allow the telescope and the light-guide cable to cool down after use.

Description of the unit

This LED light source is a high quality light source that offers you high light intensity with low heat conduction by improved LED technology. This light source is designed for use in every endoscopic discipline.

The colour temperature equals daylight quality. This allows an accurate color representation.

The brightness is controlled manually by means of buttons on the front of the device or via the automatic function. In the standard version, the light source is equipped with a Storz adapter; a device version with a multi-adapter is optionally available.

The device is designed according to the latest findings concerning safety of medical devices and complies with the requirement set out in (EU) 2017/745.

CE

Installation and activation

Receiving inspection

The device and the delivered accessories have to be examined for completeness and apparent damages on receipt. To assert your rights, transport damages must be reported immediately (within 24 hours) to the deliverer. Please always use the original packing if you return the device and the additional instruments. Describe the error / misfunction and attach the address of a contact person for possible requests.

Unpacking / standard equipment

Carefully remove the unit and the included accessories from the packaging. Check the delivery for completeness and for possible damage from transportation. If the delivery should provide a cause for complaint, please contact the manufacturer or supplier immediately. Store the original packaging, as these can be reused for any possible future shipping.

- Scope of delivery / basic equipment: Control Unit (Light source), Power cord (1,80m), Operating Manual
- Optional equipment: Video cable (1,80m)
- Spare part: Mains fuses, 5x20mm, delay acting 3,15A / 250V, with high breaking capacity (Ia = 1500 A)

Installation

Perform a visually inspection before using the product. Make sure that the mechanical condition of the product does not impair safe use. Make sure that the product has been properly cleaned / disinfected and tested before use. Guarantee that the fan area, as well as the ventilation louver not blocked. Behind the light source must be at least 10 cm of free space.

⚠ **Attention!** Establish all cable connections prior to switching the unit on!

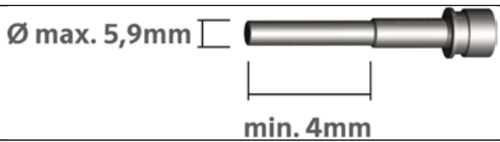
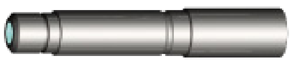
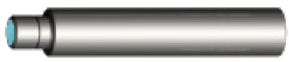
- **Connect the power cord!** Use the supplied power cord to connect the device to the line voltage. Verify that the line voltage displayed on the device is correct. Plug the device only into a grounded protective contact socket.

- **Connect the light guide!** Plug the light guide into the adapter.

⚠ **Attention!** Use only high-performance light cables / high-temperature-resistant light guides!

⚠ **Attention!** Before connecting a light cable into a light source adapter of the equipment, please ensure that you have the correct plug and adapter. A wrong light guide could result in damage of the optic inside. It can also be a significant loss of light, because the proximal end of the fiber optics can’t be positioned correctly to the adapter.

- Insert the fibre optic into the supplied adaptor (Standard: STORZ). The fibre optic must snap in securely.
- Optionally the light source is delivered with TURRET adaptor. You can connect fibre optics of different makes to the TURRET adaptor. The following fibre optics can be used for the connection to the TURRET adaptor:

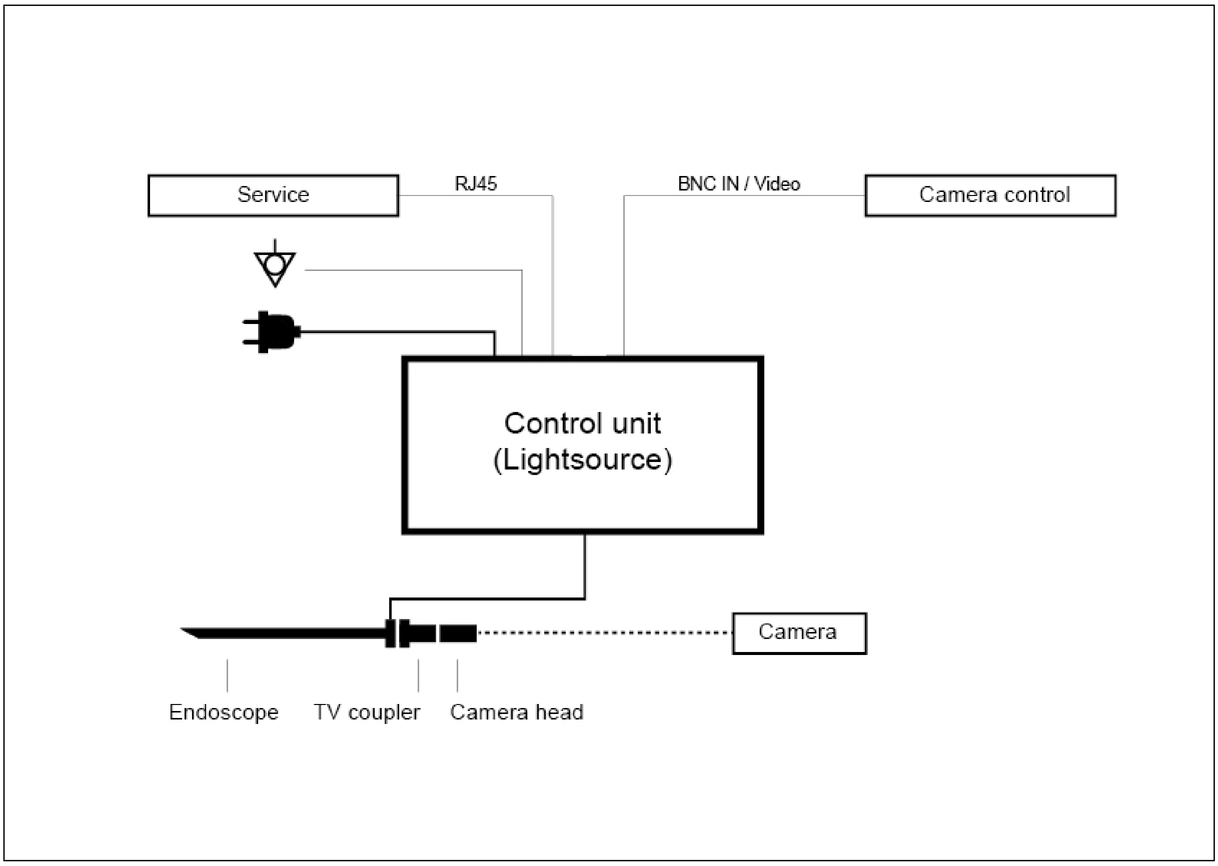
STORZ	
WOLF	
ACMI	
OLYMPUS	

⚠ **Attention!** In order to avoid unwanted light emission, the light guide output of the TURRET adapter may only be selected when the device is switched off.

- **Connect the equipotential terminal!** Connect the unit to the stationary potential equalization of the room or the equipment truck by an appropriate cable. Observe the local safety rules!

⚠ **Attention!** If use the potential equalization, please note the requirements of IEC 60601-1 (current edition). Don't use this terminal as protective ground connection!

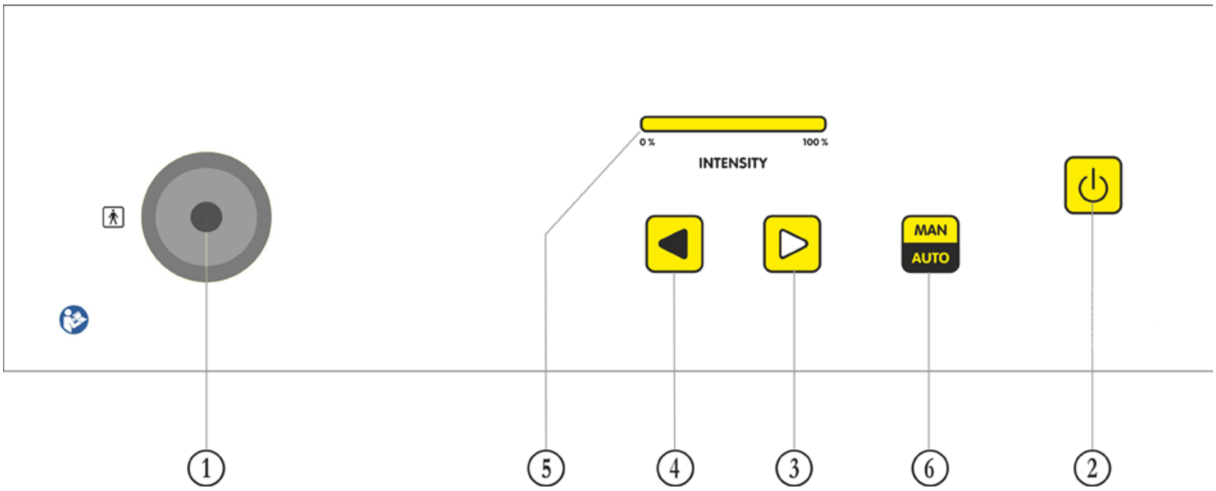
Connectivity options



Control elements / Connections

Front view

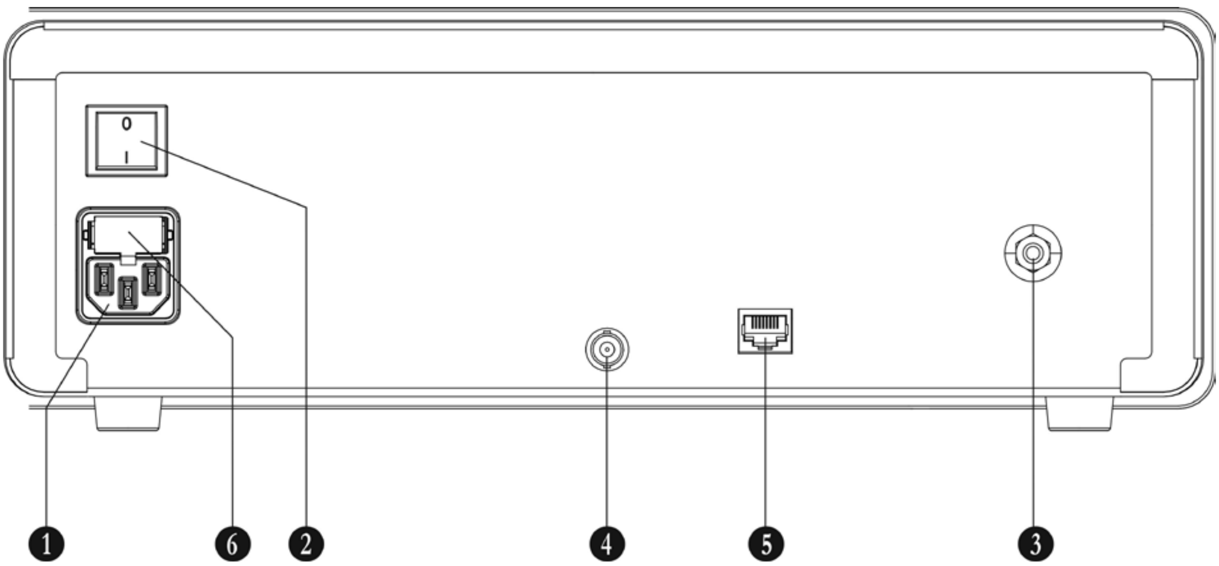
⚠ Note labeling style for the front view: „⓪"



Rear view

⚠ Note labeling style for the front view: „⓿"

⚠ Caution! Only connect medical devices to the interfaces (Signal-In-Put / Signal-Out-Put) on the back of the device!



Description of the control elements and connections

① Connector fibre optics:

This connector is used to connect the fibre optics to the light source (application part type BF). The light source is delivered as standard with STORZ adaptor and optional with TURRET adaptor. You can connect light guides of different makes to the TURRET adaptor

⚠ **Attention!** Using the wrong light guide or adaptor can damage the light source and the accessories and threats the patient.

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② Standby:

Pressing this button switches the appliance to operating mode. (The mains switch ❷ on the back of the appliance must be switched on beforehand)

Pressing the button once (briefly) switches the appliance on. The operating status is indicated by the button lighting up green.

- Pressing the button repeatedly (approx. 3 seconds) switches the appliance off (standby mode).

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③④ Intensity control:

These buttons are used to adjust the intensity of the output in manual mode. The left button decrease the intensity, the right button raises the intensity. The two end positions are indicated by the corresponding pushbuttons lighting up.

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⑤ Display: Light intensity:

This display shows the adjusted brightness level in %.

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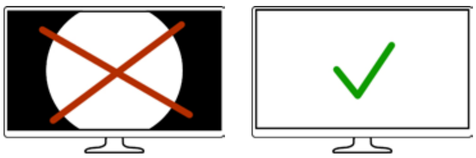
⑥ Manual / Automatic Mode

The push button is used to switch the light source between 2 different modes:

- Manual: Use of the light source without a camera connected or in conjunction with a camera without a shutter function. The intensity can be adjusted by using the buttons “Intensity” ③
- Automatic: With connected cameras with shutter function and analog BNC output. A full screen and not a circle screen is required:



- The intensity of the light source can be adjusted automatically by the diaphragm (light source) and the shutter of the camera. This mode is activated by pressing the button „Man/Auto“ ⑤ and indicated by illumination of the button

Note: The light source is always in manual mode after switching on. You can re-adjust the intensity in the automatic mode by using the buttons “Intensity” ③.

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❶ Mains connection

The connection is used for mains disconnection / mains connection.

The plug of the power connection cable is connected to this cold equipment power connection. Use only the provided power cord.

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❷ **Power switch**	The appliance is switched on or off by pressing the power switch. The power switch has two switch positions: I (ON – switched on) O (OFF – swichtes off) If the mains switch is switched on, a green indicator lamp lights up in the switch. The appliance is now in standby mode, which is indicated by the standby button ② lighting up yellow ⚠ Actuating the mains switch does not disconnect the appliance from the mains.
❸ **Equipotential terminal**	Basically, the control unit is protectively earthed by the 3-pin power supply cord when it is connect to a protectively earthed wall socket, as prescribed. When running the equipment in rooms which comply to group 2 acc. DIN VDE 0100, the control unit must be joined to the central potential equalisation of the operating theatre or of the equipment trolley by means of a grounding cable. In addition, the equipment possesses an appropriate socket outlet and plug (acc. DIN 42801).
❹ **Video input terminal**	The video input terminal can be used to connect a camera for automatic brightness control. This terminal provides the video standard via BNC jack.
❺ **Service**	This port is used to service personnel for diagnostic / maintenance purposes. .
❻ **Mains fuses**	It contains the mains fuses. Only use the declared fuses! The exchange of the fuses is described in the service part of this manual (see “Replacing of the power fuses”).

Operating

Power-up

Before connecting a light cable into a light source adapter of the equipment, please ensure that you have the correct plug and adapter. A plug that is too long or too thin can for example be pushed too far into the equipment, and can damage the sensitive diaphragm or lens inside. This will result moreover in considerable loss of light, in the same way as a plug that is too short, or a plug of the wrong diameter, because of the wrong position of the contacts at the light entry.

After having installed all connections, switch the unit on by using the mains switch ❷ at the rear. The green lamp inside the switch lights up. At power-up, the light source performs a self check. After that, the light source is in standby mode, indicated by yellow lightning of the push button “Standby” ②. By pressing the standby button the device turns into the operating mode. The operating mode is indicated by green lightning of the standby button and a brief bleep.

Operating

When you switch the operation mode the intensity is gone to the minimal position and the button ④ lights up.

The output brightness can be adjusted by using the “Intensity” buttons ③④. By pressing the ③ or ④, the brightness will be adjusted in predefined steps. The luminous energy changes thereby accordingly.

If the display has reached final positions, the buttons ④ (min. position) resp. ③ (max. position) lights up permanently.

The brightness is displayed on a light bar ⑤ (20 steps).

At overheating the unit will automatically switch off. In this case you have to switch off the unit by the mains switch. Let the light source cool down before you carry on.

⚠ **Attention!** Risk of eye injury. Do not look directly into the distal end of the light-guide cable!

Shut down the device

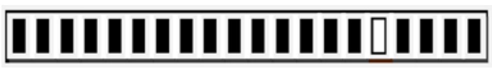
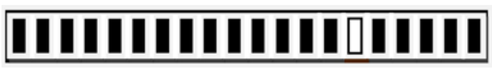
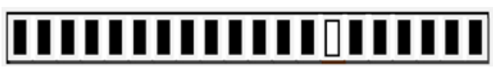
Hold down the button “Standby” ② longer (you will hear 3 beeps) to turn the unit into standby mode. Then the device can be shut down by the power switch ❷ on the back.

⚠ The mains is only disconnected by pulling out the mains plug ❶.

Notice and warning messages

The error codes are displayed at the „Intensity“ bar graph 5. During operation, the display changes in 1 sec. / 2 sec. intervals between the display of the light intensity and the error codes. The error code is received after switching off (standby mode).

The following errors will be displayed:

Display		Error
 ERR_FAN_1	Error Code 0x01	Main fan fault
 ERR_FAN_2	Error Code 0x02	Light guide fan fault
 ERR_H_LED_TEMP	Error Code 0x04	T Led > 57°C
 ERR_L_TEMP	Error Code 0x08	Temp too low <2 ° C or temperature sensor defective
 ERR_H_TEMP	Error Code 0x10	T Led or PCB> 65 ° C max. 60 sec. + Beep
 LED_NOT_WORKING	Error Code 0x20	LED without function
 ERR_LWL_DET	Error Code 0x40	Fiber optic detection defective or malfunction

Maintenance

⚠ Neither the device nor any accessories or removable parts may be serviced or maintained while in use on the patient.

⚠ Maintenance and periodic inspections may only be carried out by persons who have the appropriate technical knowledge and qualifications and are familiar with the product. To carry out these measures, the person must have the necessary test equipment and original spare parts (mains fuse).

Carry out an inspection (safety check) every 36 months in accordance with the manufacturer's instructions. The appliance does not require any further maintenance.

Preventive maintenance

Preventive maintenance is not required, but can increase the safety and service life of the medical device. Any maintenance services can be requested from the manufacturer.

Safety check / repeat test

The test intervals for a repeat test are set at 36 months for light sources and cameras as defined in IEC 62353. It is assumed from the initial assessment that the medical device complies with the IEC 60601-1 series. The safety check/repeat test must be carried out by a qualified electrician in accordance with IEC 62353. The following points/measurements must be observed/carried out:

- Visual inspection for mechanical damage
- Check labels for legibility
- Check the appliance fuses
- Protective conductor resistance in accordance with IEC 62353
- Insulation resistance in accordance with IEC 62353
- Device leakage current in accordance with IEC 62353
- Leakage current of the applied part in accordance with IEC 62353

The tests must be documented in the maintenance log of the instruction for use with details of the next test.

Repair and maintenance

Defective ME devices may only be serviced and repaired by the manufacturer. In the event of a repair, please contact the manufacturer. The replacement of a defective mains fuse is excluded from this point.

Software updates are also only installed on the ME device by the manufacturer.

In the event of a repair, please contact the manufacturer. To simplify the repair process, please provide a description of the fault, the article number and serial number of the ME device.

Replacing the mains fuses

Specification of the mains fuse:

Material:	Tube Ceramics
Type:	SPT 5x20
Voltage:	250VAC
Characteristic:	Time-Lag T
UL:	115v-300VDC
Current:	3,15A

Procedure:

1. **preparation and safety:** ⚠ Switch off the power supply. Pull out the mains plug!

2. **localize the fuse:**

   The mains fuses are located on the back of the appliance, above the IEC connection in a small fuse drawer.

3. **remove the defective fuse:**

   Release the fuse drawer by unlocking the two clips on the side of the drawer and pull the drawer out.

   Remove the defective fuse.

4. **check the defective fuse:**

   Identify the defective fuse.

   Check whether the fuse is actually defective (check for continuity with a multimeter or check for visible damage).

   Ensure that you are using the correct type of replacement fuse. (See specifications data sheet fuse)

5. **insert the new fuse:**

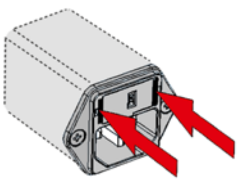
   Ensure that the fuse is correctly seated and avoid using force

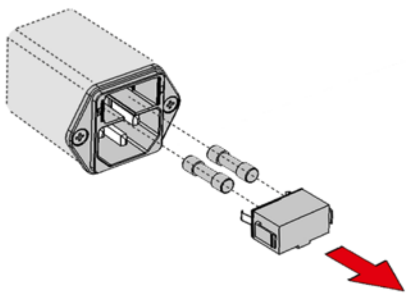
6. **restore the power supply / voltage supply:** By plugging in the mains plug.

7. **functional test:**

   Switch on the medical device.

   Observe whether the new fuse works properly and does not blow again immediately.





⚠ **Important notes**

- Always use a fuse with the stated specifications. Using a fuse with the wrong current rating or characteristics can damage appliances or cause a fire hazard.
- If the new fuse blows again, there is an underlying problem (e.g. a short circuit or overload). In this case, consult a specialist or contact the manufacturer.
- Always comply with the applicable safety regulations and standards

Cleaning / Desinfection

⚠ **Attention!** Disconnect the main power plug prior to beginning the cleaning / disinfection!

All external surfaces of the device are resistant to all common cleaners and disinfectants, so that these may be used without restrictions.

For the application of cleaning and disinfecting liquids, a soft cloth or blotting paper should be used to avoid scratching the surface and to better dispense and distribute the liquid. The dosing must be accomplished with a cloth, especially with flammable liquids such as alcohol. Do not let any -liquids leak into the unit! Let the unit dry for at least 1 hour after cleaning with flammable liquids before switching it on again. Otherwise the risk exists that an explosive mixture of air and cleaning agent ignites when switching on the unit.

⚠ **Attention!** Do not autoclave any part of the equipment!

⚠ **Attention!** Incorrect or incomplete cleaning or disinfection may jeopardize the patient or medical staff!

Troubleshooting

In the case of a malfunction of the device, please try localizing the error source and repairing it yourself by using the table below, before you return the unit to the manufacturer for repair.

Error Description	Possible Causes	Remedy
Equipment doesn´t work, main switch doesn´t shine	Power cord not connected	Connect power cord
	Main switch switched off	Switch on the device
	Mains fuses defective	Check / replace the mains fuses

Specifications

Technical Data

General data	
Mains voltage:	100-240 VAC
Power consumption:	130 VA
Mains fuses:	Fine fuses, 5x20mm, delay acting 3,15A / 250V with high breaking capacity (Ia = 1500 A)
Dimensions (WxHxD):	Device: 360 x 125 x 351 mm
LED module:	· LED approx. CRI 90, Daylight quality, approx. 5600 K, Lifetime: > 20.000 hr
Connections	
Video-In terminal	1 x Video, BNC
Light guide:	Storz, Turret (optional)
Service / Network (optional):	1 x RJ 45
Remote-IN	1x Connection of external control units
Classification / Confomrity	
Safety class (EN 60601-1)	1
Application part (Typ)	BF (Fiber optic connection)
Degree of protection:	IP20
Classification (EU) 2017/745, Annex VIII	I

Spare parts

Item	**Description**	**Order-Nr.**
Mains fuses	Fine fuses, 5x20mm, delay acting 3,15A / 250V with high breaking capacity (Ia = 1500 A)	113-0023

Annex

Electromagnetic compatibility

- This unit complies with the standard: IEC 60601-1-2

- Precautionary measures
  Medical electrical devices are subject to special precautionary measures with regard to electromagnetic compatibility (EMC). This device must be installed, set up and operated in accordance with the intended use described in the operating instructions and in accordance with the EMC guidelines.

- Effects of mobile and portable RF communications devices
  High frequency emissions from mobile communication devices can have an impact on the function of medical electrical devices. The operation of such mobile communication devices (e.g. mobile phones, GSM telephones) in the vicinity of medical electrical equipment is prohibited.

- Electrical connections
  Connections between plugs and sockets must not be made without prior implementation of ESD precautionary measures.

- ESD precautionary measures
  Connect all electrical devices connected to the device to a potential equalisation (via PE). Only use the equipment and accessories mentioned in the operating instructions.
  Employees should be informed and trained on ESD precautionary measures.

- Attention! This endoscopic device is intended for use in the environment specified below. The user should assure that it is used in such an environment.

- Manufacturer’s declaration – Electromagnetic emissions:

Interference emission measurement	**Compliance**	**Electromagnetic environment – guide**
Conducted interference emissions according to IEC/CISPR 11	Class A	This device uses RF technology only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic devices. This device is suitable for use in professional healthcare facilities (e.g. doctor’s practices, clinics, operating rooms, intensive care units, hospital rooms, emergency rooms and accident clinics). Comment: If it is used in a residential environment (for which CISPR class B is normally required) this device might not offer adequate protection from radio services. If necessary, the user must take corrective measures such as relocating or realigning the device.
Radiated interference emissions according to IEC/CISPR 11	Class A	
Harmonics according to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker according to IEC 61000-3-3	Yes	

- Manufacturer’s declaration – electromagnetic interference immunity:

<table>
<tr><th>Interference immunity tests</th><th>Testing level</th><th>Ful-filled</th><th>Electromagnetic environment – Guidelines</th></tr>
<tr><td>Discharge of static electricity (ESD) according to IEC 61000-4-2</td><td>8 kV
Contact discharge

± 2; 4; 8; 15 kV
Air discharge</td><td>Yes</td><td>Floors should be made of concrete or wood or have ceramic tiles. If floors are covered with synthetic material and do not provide ESD protection, the relative humidity should be at least 30%.</td></tr>
<tr><td>High frequency electromagnetic fields according to IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.7 GHz
80% AM 1 kHZ Output wires</td><td>Yes</td><td rowspan="5">Recommended protective distance:
0.3 m (12 inches)
at the typically assumed transmission power in the corresponding frequency band
Using the following formula with “P” as the rated power of the transmitter in watts (W) as specified by the transmitter manufacturer, “d” as the minimum distance in metres (m) and “E” as the interference immunity test level, possible minimum distances can be calculated and corrected if necessary if the rated power of the transmitter is known precisely:
$d = 6 \sqrt{P} : E$
Interference may occur in the vicinity of devices that bear the following symbol.
</td></tr>
<tr><td rowspan="4">High-frequency electromagnetic fields according to IEC 61000-4-3 in close proximity to wireless communications equipment</td><td>28 V/m
450, 810, 870, 930 MHz
50% PM 18 Hz</td><td>Yes</td></tr>
<tr><td>28 V/m
1720, 1845, 1970, 2450 MHz
50% PM 217 Hz</td><td>Yes</td></tr>
<tr><td>27 V/m
385 MHz
50% PM 18 Hz</td><td>Yes</td></tr>
<tr><td>9 V/m
710, 745, 780, 5240, 5500, 5785 MHz
50% PM 217 Hz</td><td>Yes</td></tr>
</table>

Magnetic field at the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	30 A/m 50 Hz, 60 Hz	Yes	Magnetic fields at the mains frequency should correspond to the typical values found in the hospital environment.
Fast transient electrical disturbances variables/bursts in accordance with IEC 61000-4-4	± 2 kV 100 kHz supply lines ± 1 kV 100 kHz signal and data lines	Yes	
Surges according to IEC 61000-4-5	± 0,5 kV, ± 1 kV 100 kHz (line to line) ± 0,5 kV, ± 1 kV, ± 2 kV 100 kHz (line to earth)	Yes	
Conducted RF disturbance variables according to IEC 61000-4-6	6 V_{eff} 150 KHz to 80 MHz 80% AM 1 kHZ (Power line, POAG earthing cable)	Yes	The quality of the supply voltage should correspond to that of a typical professional healthcare facility (non-public supply network).
Voltage dips according to IEC 61000-4-11	0% U_T; ½ period (at 0, 45, 90, 135, 180, 225, 270 and 315°) 0% U_T; 1 period and 70% U_T; 25/30 Periods (50Hz/60Hz) Single phase at 0°	Yes	
Voltage interruption according to IEC 61000-4-11	0% U_T; 250/300 periods (50Hz/60Hz)	Yes	If the user of this device requires continued operation even in the event of interruptions to the power supply, it is recommended that this device be supplied from an uninterruptible power supply!

Maintenance log

Operator	
Address	
Serial-No.:	

Maintenance measures	**Name**	**Date**	**Signature**

Icons (Instruction manual)

⚠	Attention, important information!
	Service information

Symbols (Medical device)

	Follow instructions for use (EN ISO 7010-M002)
	Follow instructions for use (EN ISO 15223-1, 5.4.2)
	Type BF application part (IEC 60417-5333) - Connection
	Potential equalization (IEC 60417-5021) - Connection
	Earthing (IEC 60417-5021)
CE	Conformity labelling in accordance with EU 2017/745, Appendix V
	Do not dispose of with household waste (ElektroG / WEEE 2012/19/EU)
	Manufacturer (EN ISO 15223-1, 5.1.1)
	Date of manufacture EN ISO 15223-1, 5.1.3)
	Distribution partner (EN ISO 15223-1, 5.1.9)
MD	Medical device (EN ISO 15223-1, 5.7.7)
REF	Catalog/article number (EN ISO 15223-1, 5.1.6)
SN	Serial number (EN ISO 15223-1, 5.1.7)
	Pull out the mains plug (Mains disconnection)! (ISO 7010 M006)

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