Instruction manual

Digital HD camera (1 MOS)
with integrated LED light source
for endoscopic applications

Manufacturer:

EMOS Technology GmbH
Gewerbestr. 10
88636 Illmensee / Germany

Phone: +49 (0) 7558/ 938 278 – 0
Fax: + 49 (0) 7558/ 938 278 – 55

www.emostechnology.de
info@emostechnology.de

Index

General Information **4**

Data of the Device 4
Warranty 4
Product service life 4
Responsibility 4
Reporting requirement 4
Rights 4
Disposal 4

Safety reference / Place the equipment **5**

Qualifications of the user / operator 5
Storage and operating conditions 5
Replacement device 5
Safety measures for setup and operation 5
Camera head, cable and cable bend relief 7

Description of the unit **9**

Installation and activation **10**

Receiving inspection 10
Unpacking / standard equipment 10
Installation 10
Connectivity options 11

Control elements / Connections **12**

Front view 12
Rear view 12
Camera head (Applied part BF) 12
Description of the control elements and connections 13

Operation **16**

Start up 16
Brightness control 16
White balance 16
Presets / User 16
Menu settings 17
Menu navigation 17
Foot switch 21
Shut down the device 21

Maintenance **22**

Preventive maintenance 22
Safety check / repeat test 22
Repair and maintenance 22
Replacing the mains fuses 22
Cleaning / Desinfection 24

Troubleshooting **25**

Malfunction / Troubleshooting 25
Error message 26

Specifications **27**

Technical data 27
Spare parts 28

Annex **29**

Electromagnetic compatibility 29
Maintenance log 32
Icons (Instruction manual) 33
Symbols (Medical device) 33

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

All rights to this instruction manual, especially the right of reproduction and distribution and translation, are reserved. No part of this operating manual may be reproduced (by photocopy, microfilm or other processes) without the prior written consent of the manufacturer or processed, copied or distributed by using electronic systems. The information contained in this operating manual may not be amended or expanded without prior notice and do not represent any obligation by the manufacturer. Errors and technical changes reserved.

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 combined system of camera and (LED) light source for lighting and recording/displaying the surgical site (surgical field) during minimally invasive surgical interventions (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

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

- Atmospheric pressure - Storage: 600 mbar to 1300 mbar
- Atmospheric pressure - Operation: 700 mbar to 1060 mbar

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.
- The following applies to cameras: Before each use or after changing the perspective or settings, it must be ensured that the view through the endoscope provides a real-time image (instead of a stored image) and the correct orientation of the image.
- 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.

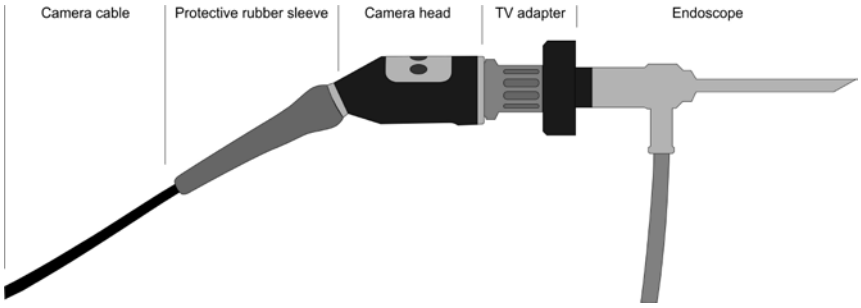
· **Risks:**
· Thermal injury to the patient's tissue (e.g. from prolonged exposure to intense illumination in cavities with small lumens, or if the telescope's distal end is placed into close proximity with the tissue.
· Burns to the patient's or user skin
· Burns or thermal damage to surgical equipment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

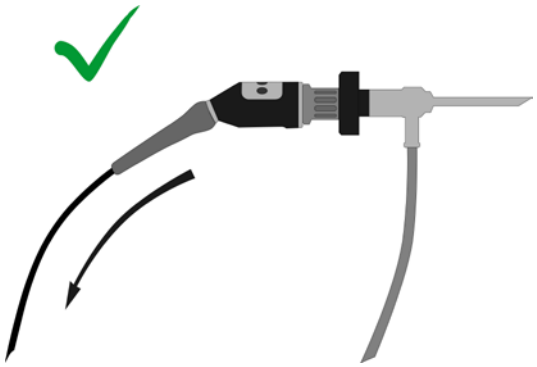
Camera head, cable and cable bend relief

⚠ The following instructions must be observed when handling the camera head. Failure to do so may damage the camera cable or the camera head. In the event of demonstrable application errors due to failure to follow these instructions, a manufacturer's warranty or liability is excluded.

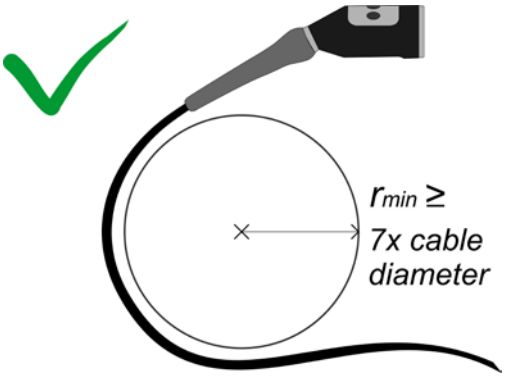
Assembly overview:



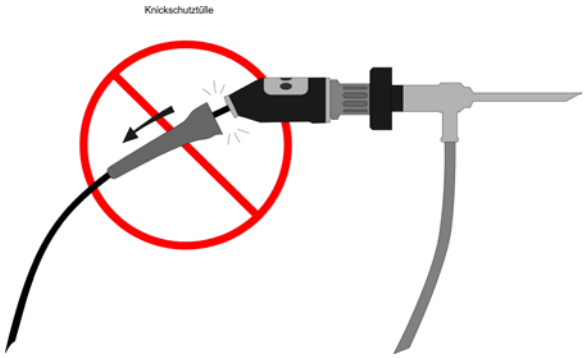
Correct cable routing: For all applications (including endoscopy as well as cleaning / sterilization), the manufacturer-defined natural run of the cable and the cable bend relief must be maintained. The direction of the cable is determined by design:



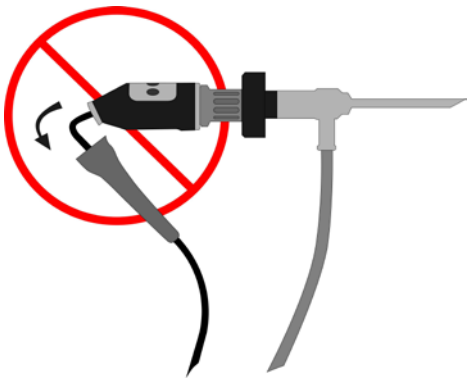
Smallest permissible bending radius: For all applications (including endoscopy as well as cleaning / sterilization), the cable and the cable bend relief must not be wound / laid / routed in a radius smaller than 7x cable diameter. This applies to every direction in which the cable is moved:



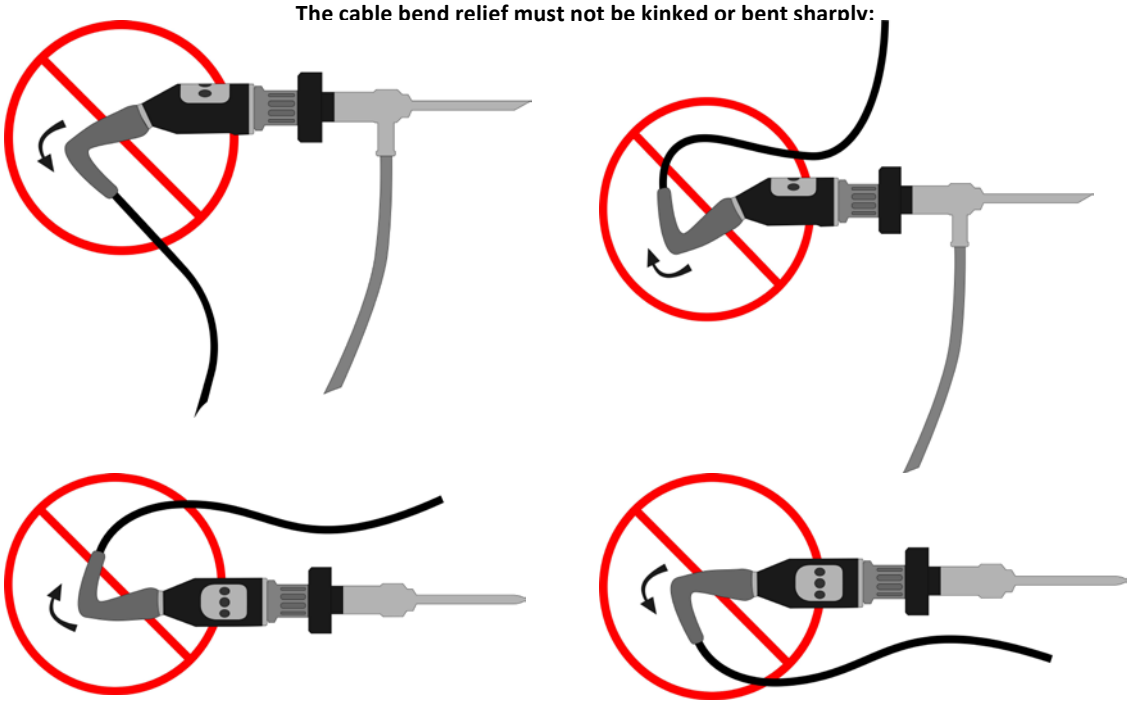
The cable bend relief must not be removed:



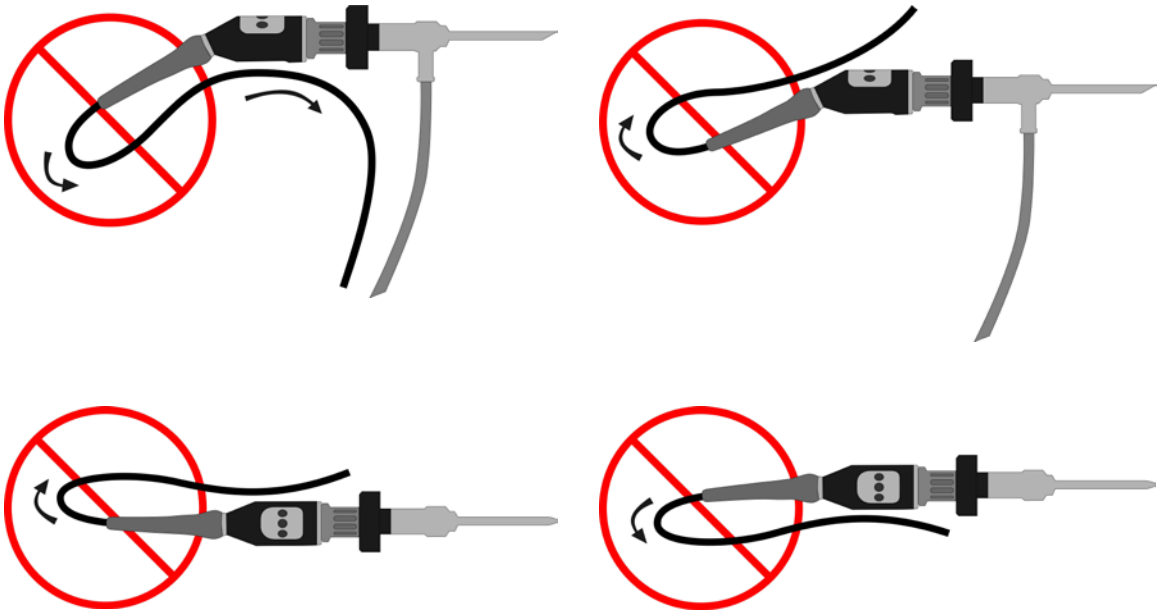
The cable must not be kinked or bent between the cable bend relief and the camera head housing:



The cable bend relief must not be kinked or bent sharply:



The cable itselve must not be kinked or bent sharply:



Description of the unit

The Combination-Device you have purchased features a state-of-the-art 1MOS HD camera, which was especially designed for use with endoscopic applications in connection to a built-in high-intensity LED illumination. The device offers the user a compact unit for optimal image quality in nearly every endoscopic discipline. The device is optionally equipped with image and video recording.

Standard:

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

1MOS HD camera:

This device containes a 1-MOS camera of the latest generation, with superior image quality in high definition (True HD Format 16:9) and natural color reproduction, which was especially adapted for endoscopic applications and meets specific quality standards.

- Equipment / functions

The camera consists of a control unit (CCU, Camera Control Unit) and a camera head with a C-mount thread, where standard lenses, zoom lenses, endoscope adapters and other adapters can be connected.

- OSD menu

This device can be set individually on the integrated on-screen menu. The settings are stored in an internal memory. Eight different user profiles can be created in order to use custom settings.

- Zoom

The camera is equipped with an electronic zoom function. Different zoom levels can be selected with the buttons on the front of the device (or optionally by pressing a button on the camera head).

- Recording system

Video clips and pictures can be stored on a USB flash drive.

- Freeze

The picture displayed on the screen can be frozen by pressing the foot switch (optional) (still picture).

- Connections

The video signal is available at the rear of the unit as a digital HDMI as well as DVI, VIDEO and SDI. A footswitch can be connected to the remote-In-jack.

- Other

The image brightness is adjusted automatically by the camera board to ensure an optimal display under all lighting conditions.

- Recommended accessories:

In order to make optimum use of the performance spectrum of this 1-MOS camera, we recommend using the latest HD endoscopes and HD TV couplers from the manufacturer of this device as well as SONY monitors (LMD-2450MD; LMD-X310MD; LMD-X550MD), AG-Neovo MX-24 monitor, FSN FS-P3102DS monitor for optimum image display.

LED light source:

This LED light source is a high quality and modern 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.

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 devlivers / Basic equipment:
  · Camera unit
  · Camera head with cable (3,05m) (10ft)
  · Mains cable (1,80m)
  · HDMI/DVI cable (2,00m)
  · Operating Manual

- Optional equipment:
  · Footswitch with cable (2,10m)

- Spare parts:
  · 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.

Make sure that the fan area and the ventilation slots of the appliance are not blocked. There must be at least 10 cm of free space behind the appliance and in the areas of the ventilation slots.

⚠ **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 camera cable!** Connect the plug of the camera cable to the appropriate jack. The plug has an anti-twist safeguard, so that the plug can only be plugged in one position (red dot on top). Plug the 32-pin connector with notch to the top in the socket. You can connect all the lenses and endoscope adapters that have a C-mount thread to the camera head.
- **Connect the light guide!** Insert the fibre optic into the supplied adaptor (Standard: STORZ). The fibre optic must snap in securely.

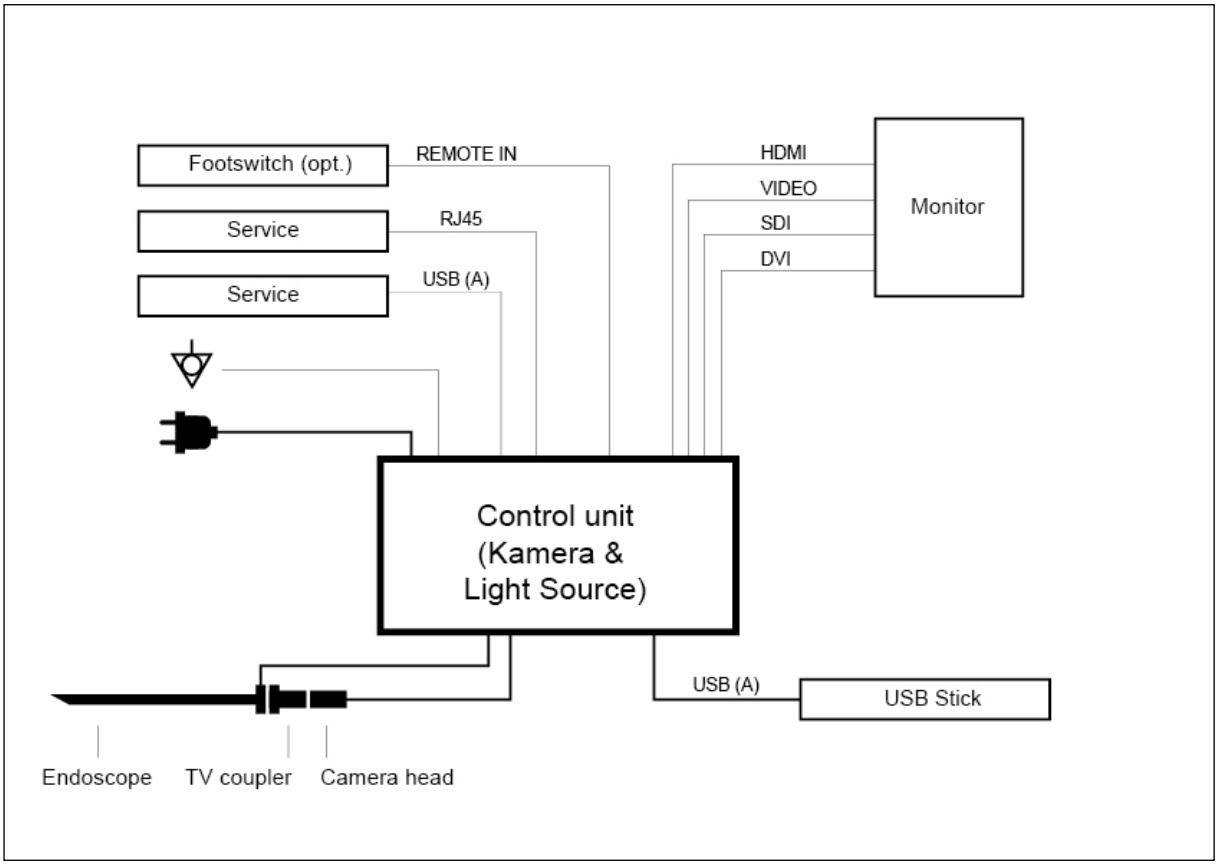
⚠ **Attention!** Use only high-performance light cables / high-temperature-resistant light guides!

⚠ **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.

- **Connect the monitor!** (rear of the device)
- **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!

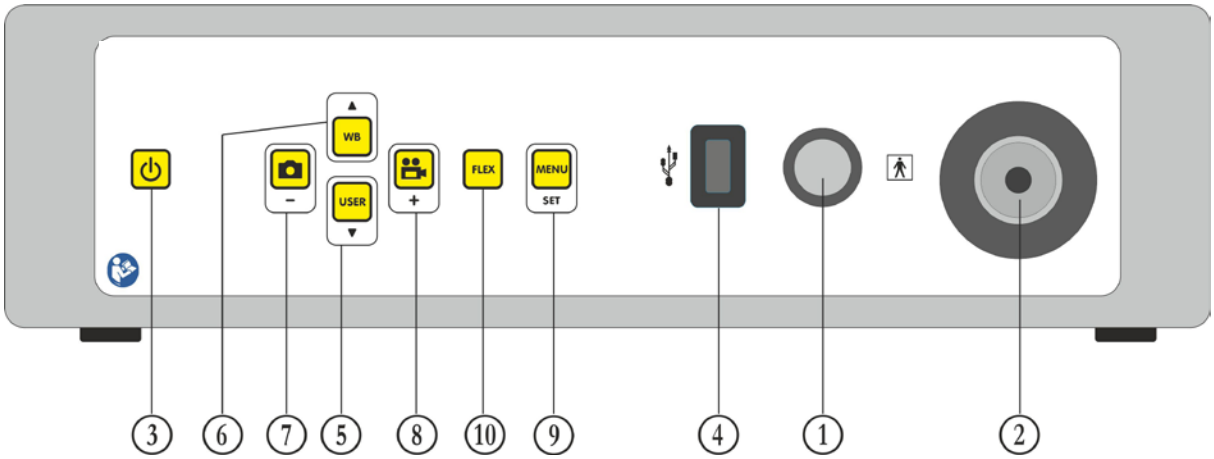
Connectivity options



Control elements / Connections

Front view

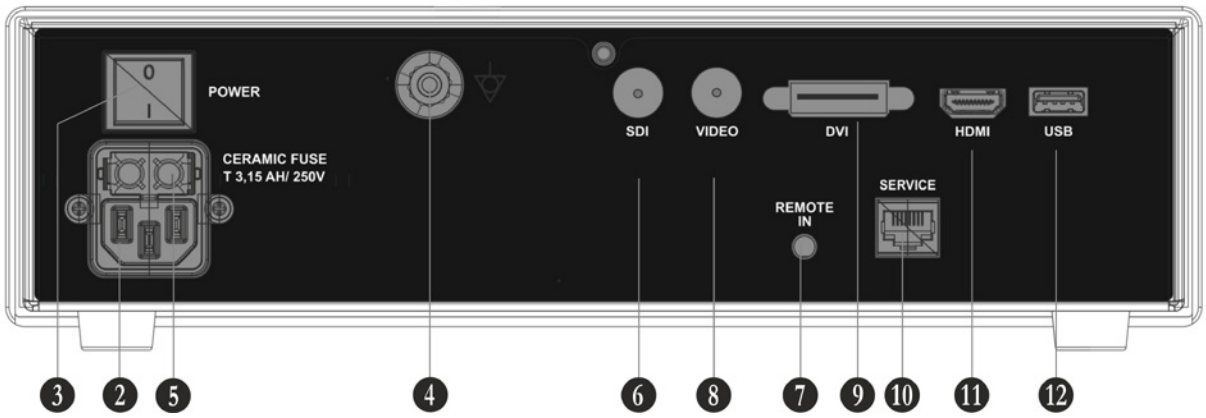
⚠ Note labeling style for the front view: „⓪“



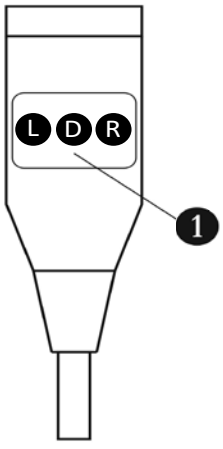
Rear view

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

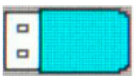
⚠ Caution! Only connect medical devices to the interfaces (Signal-In-Put / Signal-Out-Put) on the back of the device!



Camera head (Applied part BF)



Description of the control elements and connections

① **Camera connector:**	The plug of the camera cable is connected to this socket. The plug has an anti-twist safeguard, so that the plug can only be plugged in one position. ⚠ **Attention!** Use only the supplied camera head and cable!
② **Connector: Light guide**	This connector is used to connect and adjust the light guide to the light source. The light source is delivered as with STORZ® adaptor. ⚠ **Attention!** Using the wrong light guide can damage the light source and the accessories and threats the patient!
③ **Standby:**	In standby mode, the button lights up yellow. The device is switched on by pressing this button. • Short press of the power button turns the control unit on. The operation mode is indicated by a green illumination of the “POWER” button. • By pressing the “POWER” button (approx. 3 sec.) again, the unit is turned off (Standby mode). • Note: The mains switch at the rear panel must be switched on, before you can use this button.
④ **USB:**	The USB interface is used to connect the device to external USB storage media (USB flash drives) for recording data If a USB flash drive is connected to this interface, the following message appears in the bottom right-hand corner of the screen:  If a USB flash drive is disconnected from this interface, the following message appears in the bottom right-hand corner of the screen:
⑤ **User / Scroll:**	8 different presets can be selected by pressing this button. The currently activated preset is displayed when the button is pressed in the upper left corner of the monitor. The preset loading process takes 4 seconds. More information under “Operation of the device / presets” ––– When the menu is activated: Various menu items can be selected using these keys.
⑥ **White balance (WB) / Scroll**	The white balance of the camera is made with the “WB” button (see “Operation→White balance”). “AWB HOLD” appears in the upper left corner of the OSD while executing the function. An “AWB DONE” appears when successful after completing the function. ––– When the menu is activated: Various menu items can be selected using these keys.

⑦ **1. Image recording /** **2. Changing values /** **3. Decrease Light Intensity**	**1.** By pressing this button, images can be saved in JPEG format (1920x1080) or settings can be made within the menu. • To save the current camera image, hold the endoscope steady. The current video image is saved by pressing the button. During saving (approx. 3 seconds), the button flashes and the image saving information appears in the top right-hand corner of the screen Note: To be able to use the storage function, a USB storage medium must be connected to the corresponding port ④ on the front of the device ––– **2.** When the menu is activated: These keys can be used to change the values of selected menu items within the menu. ––– **3.** Decrease light intensity: see chapter “Operating - Brightness control”
⑧ **1. Video recording /** **2. Changing values /** **3. Increase Light Intensity**	**1.** Press this button to save videos to the USB storage medium connected to the device (MPEG-4) or to make settings within the menu. • If you want to record a video clip, press this button once to start recording. The saving process is signaled by a flashing „REC“ at the top corner of the screen and the button flashes . Press the button again to stop recording. Wait a few seconds while the video is being saved. You can press this button again to start recording a new video section, etc. • Note: To use the memory function, a USB storage medium must be connected to the corresponding port ④ on the front of the device. ––– **2.** When the menu is activated: These keys can be used to change the values of selected menu items within the menu. ––– **3.** Increase light intensity: see chapter “Operating - Brightness control”
⑨ **Menu/ Set**	User settings can be made via a menu. Pressing this button activates the camera’s menu. The button lights up when the menu is activated. Values set within the menu can be saved using the “SET” function
⑩ **Flex (FIBERSCOPE)**	The preset for the use of flexible endoscopes can be called up via this quick selection button. A confirmation will appear in the upper left corner of the screen (FIBERSCOPE). The button remains lit as long as the Fiberscope preset is active. If you press the button again, the previously active preset is automatically reactivated.

❶ **Camera buttons (optional):** **(Remote control)**	These buttons can be used to remotely control the camera's functions from the camera head. The assignment of 3 functions is possible. The assignment of the head buttons can be defined via the menu (see "Menu settings – "Shortcut key " option).
❷ **Mains connection**	The plug of the power connection cable is connected to this cold equipment power connection. Use only the provided power cord.
❸ **Power switch**	The unit is switched on by pressing the power button. The power switch has two switching positions: • I (ON – switched on) • O (OFF – swichtes off) The switch lights up green when the unit is turned on.
❹ **Equipotential terminal**	This connector is used to connect the device to the central potential equalization of the OP, or the trolley.
❺ **Fuse holder**	The equipment fuses are located in the fuse holder. Only use the fuses listed on the model tag! Replacing the fuses is described in the service section of these operating instructions (see "Replacement of the power fuses").
❻ **Video port**	SDI
❼ **Remote Input**	The remote IN jack is for connecting a footswitch (optional).
❽ **Video port**	VIDEO
❾ **Video port**	DVI
❿ **Service**	Service/ diagnostic/ maintenance
⓫ **Videoausgang**	HDMI
⓬ **USB**	Service/ diagnostic/ maintenance

Operation

Start up

After all cable connections have been made, the camera can be put into operation. Switch on the camera by using the mains switch ❸ on the rear. The green light in the switch lights up. The device is now in standby mode.

The standby mode is indicated by yellow lightning of the push button “Standby” ③ . By pressing the Standby button the device turns into the operating mode.

The device performs power-up diagnostics at the start-up. This is indicated by an illumination sequence of the control elements on the front panel.

The operating mode is indicated by green lightning of the standby-button ③.

⚠ **Caution!** Before each use or after changing the perspective or settings, it must be ensured that the view through the endoscope provides a real-time image (instead of a stored image) and the correct orientation of the image.

Note: The camera head can exceed a temperature of 41 ° C during operation and heat up to 60 ° C under unfavorable operating conditions.

Brightness control

The integrated light source has a manual brightness control. When delivered, the preset illumination is approx. 80%.

The light intensity can be adjusted as follows:

- Press and hold the Menu ⑨ button for more than 2 seconds.
- The two keys ⑦ and ⑧ are now in the brightness adjustment mode.
- You can now gradually decrease the brightness by pressing the ⑦ button and gradually increase it by pressing the ⑧ button. The brightness levels can be changed more quickly by pressing and holding the buttons for more than 2 seconds.
- Exit the setting mode by pressing the ⑨ button again.

White balance

The white balance of the camera is made with the “WB” button ⑥ . To do this, hold the camera head (TV adapter and endoscope screwed on) on an evenly illuminated white surface (for example sheet of paper) and simultaneously press the ⑥ button. Make sure that the white surface is not overexposed nor eclipsed. You can recognize this, for example, by the fact that the fibre structure of the paper is visible on the monitor. Correct color reproduction is only guaranteed if the white balance has been carried out correctly.

The current setting is stored in the camera and is retained even after switching off. If the function “White balance” is selected, the button „WB“ flashes. “AWB HOLD” appears in the upper left corner of the OSD while executing the function. An “AWB DONE” appears when successful after completing the function.

Presets / User

This HD camera can manage 8 user presets. Saved presets can be selected by pressing the “USER” button ⑤ . The activated preset is displayed in the upper left corner of the monitor when the button is pressed. The preset loading process takes 4 seconds. The settings of the individual presets can be made in the menu under “Menu / Endoscope” the desired preset must be selected.

The following presets are available as factory defaults

- **Custom 1:** User-defined presetting
- **Laparoscopy:** Preset for laparoscopy
- **GYN/URO:** Preset for urology and gynecology
- **Arthroscopy:** Preset for arthroscopy
- **OTO/NEURO:** Preset for otoscopy
- **Laryngoscopy:** Preset for laryngoscopy
- **P TED:** Percutaneous transforaminal endoscopic discectomy

Menu settings

Various functions and parameters can be changed according to individual requirements in the OSD mode.

Note: According the respective software revision, the menu items can deviate from the menu items as described in this manual..

In order to reach the menu mode, press the appropriate button ⑨. In menu mode, the buttons on the front panel have the following functions:

- ⑤ ⑥ Selecting menu items
- ⑦ ⑧ Changing the settings
- ⑨ Activate the functions and submenus

The front panel buttons ⑤ ⑥ and ⑦ ⑧ are used to navigate within the menu and sub-menues. All processes are completed by pressing the “MENU” button ⑨. Each of the next menu items is selected or activated by repeatedly pressing the MENU button.

To exit the menu, the menu item “RETURN” must be used.

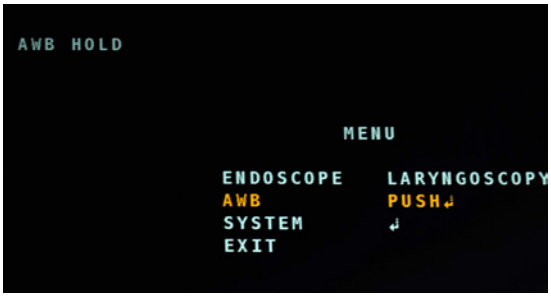
Menu navigation

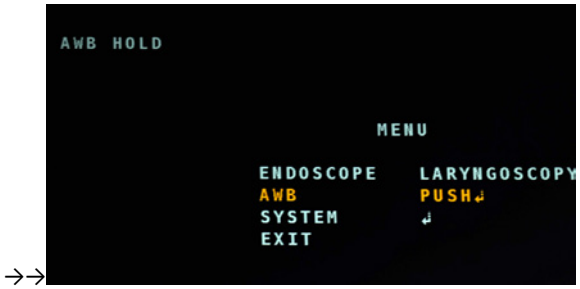
Endoscope

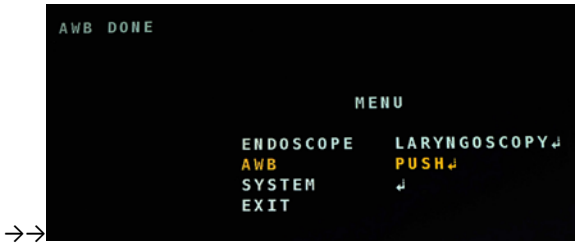
The parameters of the currently selected preset can be set under this menu item.

Parameters of the current preset

- Brightness
- Color Gain
- Color
- Sharpness
- Gain
- DNR
- Contrast
- Exposure
- Enhance







Automatic White Balance

For the white balance, the camera head (with the lens screwed on) must be held onto an evenly lit white surface. Simultaneously press the (ENTER) button for white balance ⑨. Be careful not to cover the white area. Correct color reproduction is only guaranteed if the white balance is carried out correctly.

The current setting is stored in the camera and is retained even after it is switched off. If the „White balance“ function is selected, the „WB“ button flashes. “AWB HOLD” appears in the upper left corner of the OSD while the function is in progress. An „AWB DONE“ appears when the function has been successfully completed

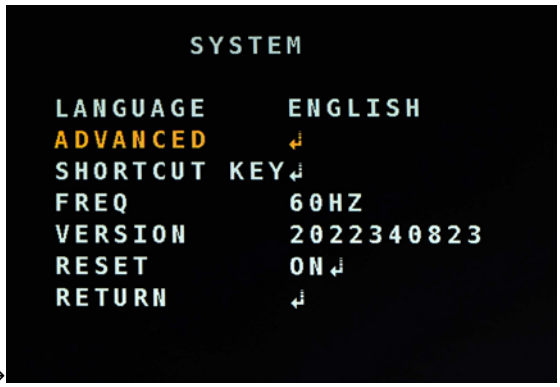
As described, the function can also be executed using the ⑥ key

System

The system settings of the camera can be made under this menu item.

Language

Choose the language.



Advanced

Advanced camera settings can be made under this menu item:

- shutter
- zoom
- vertical and horizontal image alignment

Shortcut key

The settings for the assignment of the buttons on the camera head are made under this menu item.

Button assignment on the camera head

The individual keys ❶ can be assigned different functions based on the designation under:

Off → no function assignment

AWB → Automatic Wite Balance

Freeze → Freeze frame

Brightness + → Increase brightness

Brightness - → Decrease brightness

Zoom+ → Zoom in

Zoom- → Zoom out

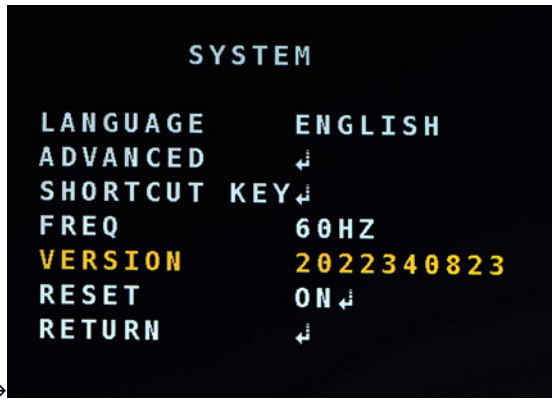
ATM → AntiMoirée

Video → Recording Video

Photo → Recording Bild

FREQ

Setting the frame rate



VERSION

Reading the software version

→→

RESET

Factory reset

Foot switch

When delivered, the foot switch is assigned the „Freeze“ function by default. The foot switch can be assigned a total of 3 functions: “Image capture” “Video recording” “Freeze”

• Connect the footswitch to ❼.

• Keep the foot switch pressed for at least 3 seconds

• The two keys ⑤ and ⑥ light up. You are in the configuration mode for the foot switch.

- Pressing the ⑦ button: Assignment of the foot switch to the „Image capture“ function
- Pressing the ⑧ button: Assignment of the foot switch to the „Video recording“ function
- Pressing the ⑨ button: Assignment of the foot switch to the „Freeze“ function

• The respective key lights up according to the selected assignment. The setting remains in effect beyond a restart.

• Pressing the foot switch again confirms the setting and exits the configuration mode.

Shut down the device

Press the “Standby” button ③ for about 2 seconds to turn off the device. The shutdown is signaled acoustically by a three times beep. Then the device is in standby mode and the LED inside the key lights yellow.

The device completely turns off by pressing the power switch ❸ on the rear.

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:**

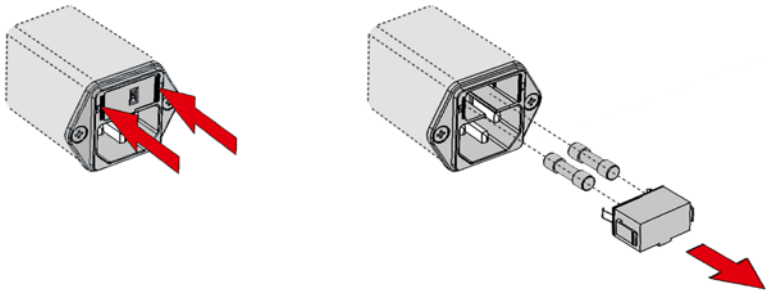
   Ensure that the fuse is correctly seated and avoid using force

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

- **Housing and camera head**:

⚠ Attention! Disconnect the main power plug prior to beginning the cleaning/disinfection!
All external surfaces of the device and camera head 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.

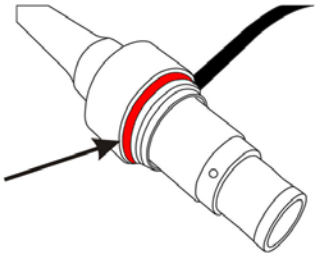
⚠ **Attention!** Do not autoclave any part of the equipment!

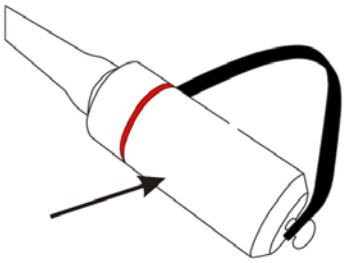
- **Camera head:**

The disinfection or sterilization of the camera head can be carried out by the following practices: *STERRAD® 100NX; Steris System 1*

1. Preparation:

· Carefully disconnect the camera cable from the camera!
· Check the silicone seal!
· Screw the safety cap on the plug!





2. Pre-cleaning: Remove fouling from all external surfaces with a soft disposable cloth. Then rinse all visible dirt under running water.

3. Disinfection: Insert the camera heads for 30 min in an immersion bath of 2.0% Gigasept Instru AF: Temperature: 25 ± 5 ° C.

4. Rinsing / Drying: Rinse t he camera heads with sterile de-ionized water. Then allow the heads to dry at room temperature.

5. Maintenance, inspection and testing: Prior to beginning the sterilization check (visually) the camera head in terms of damage and wear.

6. Sterilization: Follow the instructions for each method of sterilization!

· *H2O2 plasma sterilization (STERRAD ® 100NX)*→ Temperature: 50°C / Cycle time: 47 min

· ⚠ Attention! Wrap the camera head into Tyvek film prior to beginning the plasma sterilization!

· *35% sterilization with peracetic acid (Steris 20), Steris System 1*→ Temperature: 50-60°C / Cycle time: 12 min

7. Storage: The storage is depending on the sterilization practice. Follow the instruction for each practice of sterilization!

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

Troubleshooting

Malfunction / 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
No image on the monitor	Power cord not connected	Connect power cord
	Device is not turned on	Switch on the device
	Mains fuses defective	Check / replace the mains fuses
	Camera cable is not connected	Connect the camera cable
	No line voltage available	Check the line voltage
	Video output cable defective / not connected	Check / replace / connect the video output cable
	Monitor not turned on	Switch the monitor on
Image too dark	Parameter brightness set at minimum	Increase brightness parameter
	Lighting insufficient	Improve lighting
	Monitor settings not optimal	Verify / correct the monitor settings
Picture too bright	Parameter brightness set at maximum	Decrease parameter brightness
	Monitor settings not optimal	Verify / correct the monitor settings
Image blurred	Lens fogged	Clean / replace lens
	Lens poorly set	Set sharpness of the lens correctly
Poor picture quality	Lighting insufficient	Improve lighting / increase brightness
	No white balance	Perform white balance
	Monitor settings not optimal	Verify / correct the monitor settings

Error message

Error message	**Cause / defect**
Standby blinks **1 time** with simultaneous beep	Lamp defective
Standby blinks **2 time** with simultaneous beep	Fan 1 defective
Standby blinks **3 time** with simultaneous beep	Fan 2 defective
Standby blinks **4 time** with simultaneous beep	Error camera module
Standby blinks **5 time** with simultaneous beep	Error, LED temperature too high
Standby blinks **6 time** with simultaneous beep	Error, board temperature too high
Standby blinks **7 time** with simultaneous beep	Error, LED temperature too low
Standby blinks **8 time** with simultaneous beep	Error, board temperature too low
Standby blinks **9 time** with simultaneous beep	errors, general
Standby flashes **green and blue alternately** with a simultaneous beep	No camera head plugged in

Specifications

Technical data

General data	
Line voltage:	100-240 VAC
Power requirements:	95 VA
Mains fuses:	Fuses, 5x20mm, inert 3,15 AH, 250V with high switching capacity (Ia = 1500 A)
Dimensions (WxHxD):	Control unit: 295 x 128 x 278 mm Camera head with buttons: approx. Ø38 x 79 mm (without grommet)
Weight:	Control unit: approx. 3kg Camera head with buttons: approx. 180g
Light source	
LED	LED unit; comparable 50W (lifetime 30.000 h)
Camera	
Image sensor:	1/2“ CMOS
TV-System:	Interlaced at 50 / 60 Hz (Rolling shutter)
Image resolution:	1920x1080 Pixel (Full HD) (camera incl. sensor)
TV resolution:	>900 TV-Lines; horizontal
USB interface, device front	Max. 256 GB (USB stick only)
Index ratio:	16:9
Min. sensitivity:	< 3 lux (1/1.4)
Connections	
Video outputs:	1 x HDMI 1 x DVI 1 x SDI 1 x VIDEO

Other connections:	1 x USB (Service) 1 x Remote IN (footswitch) 1 x RJ45 (service interface)
Classification / Conformity	
Safety class (EN 60601-1)	1
Application part (Typ)	BF (Camera head, Light guide connector)
Degree of protection:	IP20
Classification (MDD)	I

Spare parts

Items	Description	Order No.
Mains fuses	Fuses, 5x20mm, inert 3,15 AH, 250V with high switching capacity (Ia = 1500 A)	113-0025
Camera head (complete)	Camera head 1CMOS HD, fully assembled	

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>Fulfilled</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 √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	The quality of the supply voltage should correspond to that of a typical professional healthcare facility (non-public supply network).
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	
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)
	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)
	Medical device (EN ISO 15223-1, 5.7.7)
	Catalog/article number (EN ISO 15223-1, 5.1.6)
	Serial number (EN ISO 15223-1, 5.1.7)
	Pull out the mains plug (Mains disconnection)! (ISO 7010 M006)

EMOS Technology GmbH
Gewerbestr. 10
88636 Illmensee / Germany

Phone: +49 (0) 7558/ 938 278 – 0
Fax: + 49 (0) 7558/ 938 278 – 55

www.emostechnology.de
info@emostechnology.de