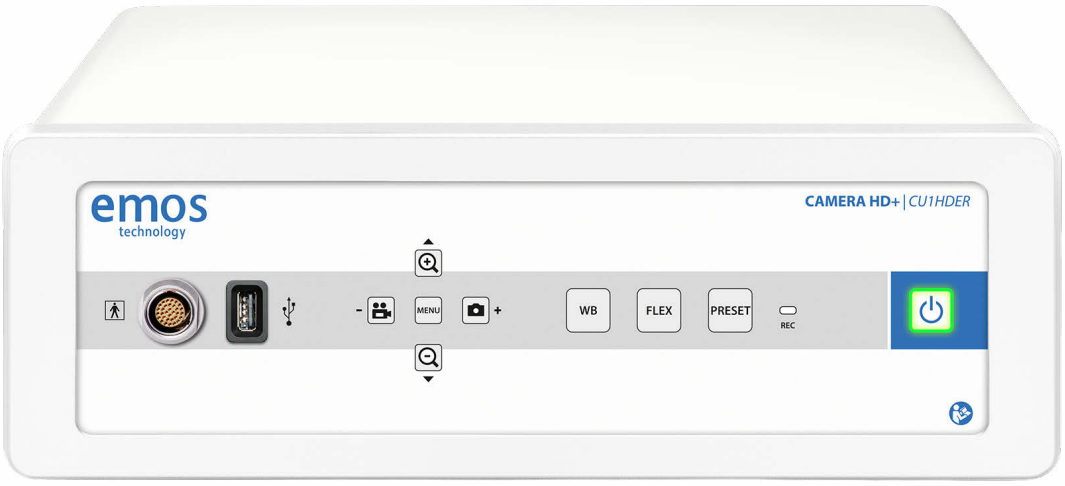
Instruction manual

High resolution digital 1chip
camera 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

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 digital camera system described in these instructions is intended for recording and displaying (on connected monitors) 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
- 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 environ-

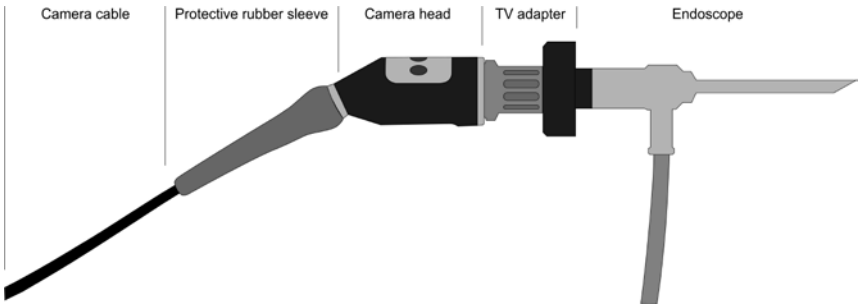
ment.

- The device is not intended for use in oxygen rich environments.
- 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.

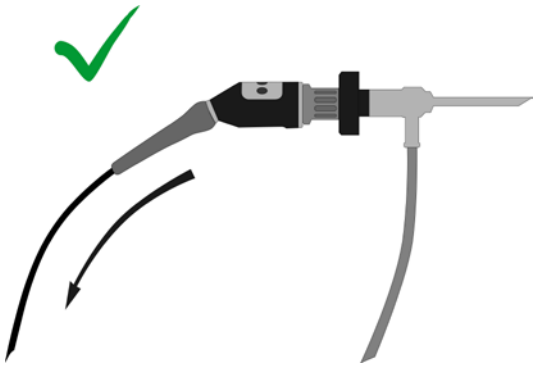
Camera head, cable and cable bend relief

⚠ 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.

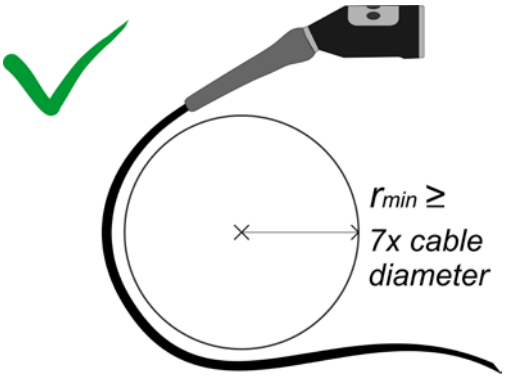
Assembly overview:



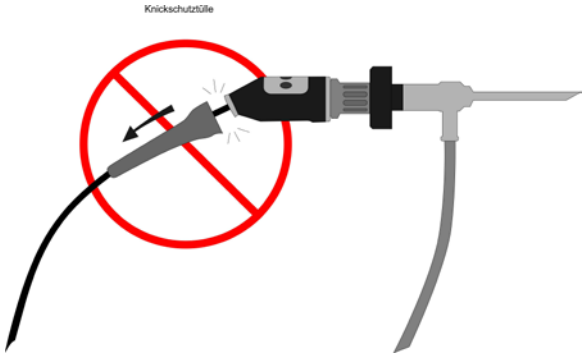
Correct cable routing: For all applications (including endoscopy as well as cleaning / sterilization), the manufacturer-defined natural run of the cable and the cable bend relief must be maintained. The direction of the cable is determined by design:



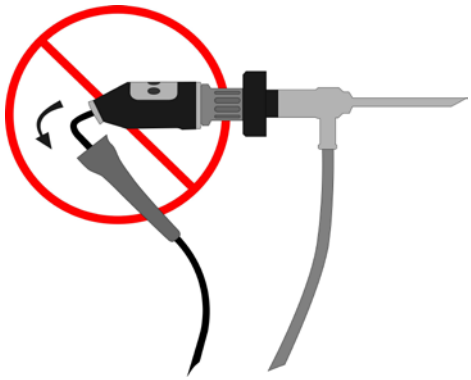
Smallest permissible bending radius: For all applications (including endoscopy as well as cleaning / sterilization), the cable and the cable bend relief must not be wound / laid / routed in a radius smaller than 7x cable diameter. This applies to every direction in which the cable is moved:



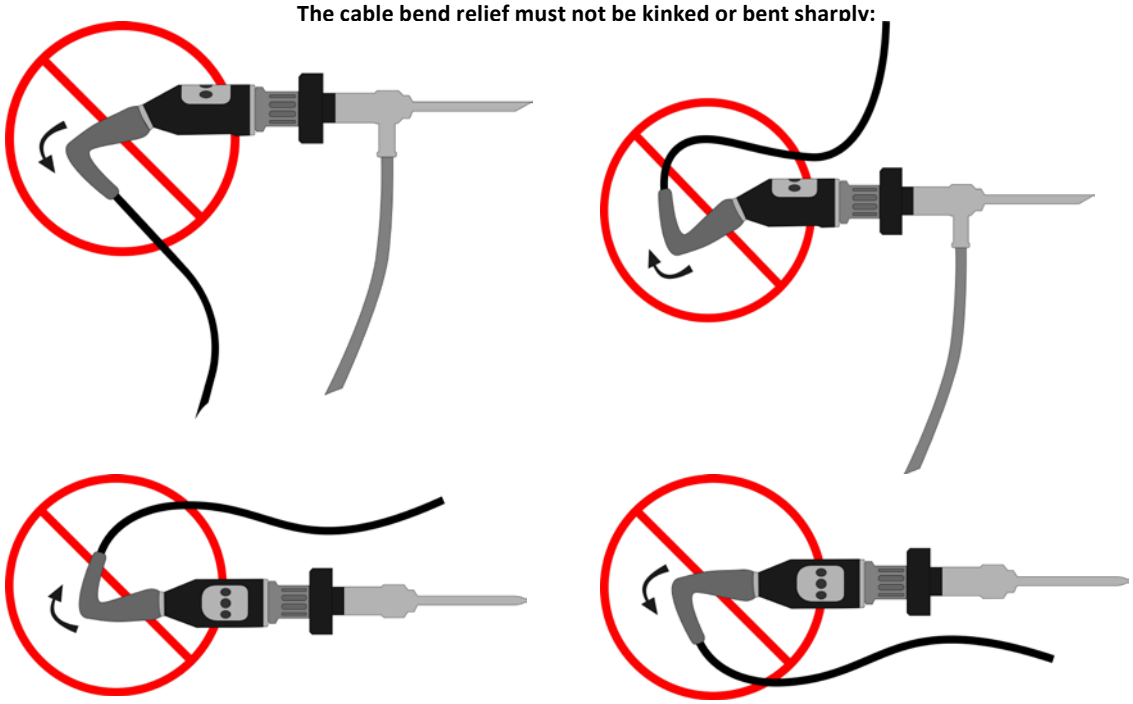
The cable bend relief must not be removed:



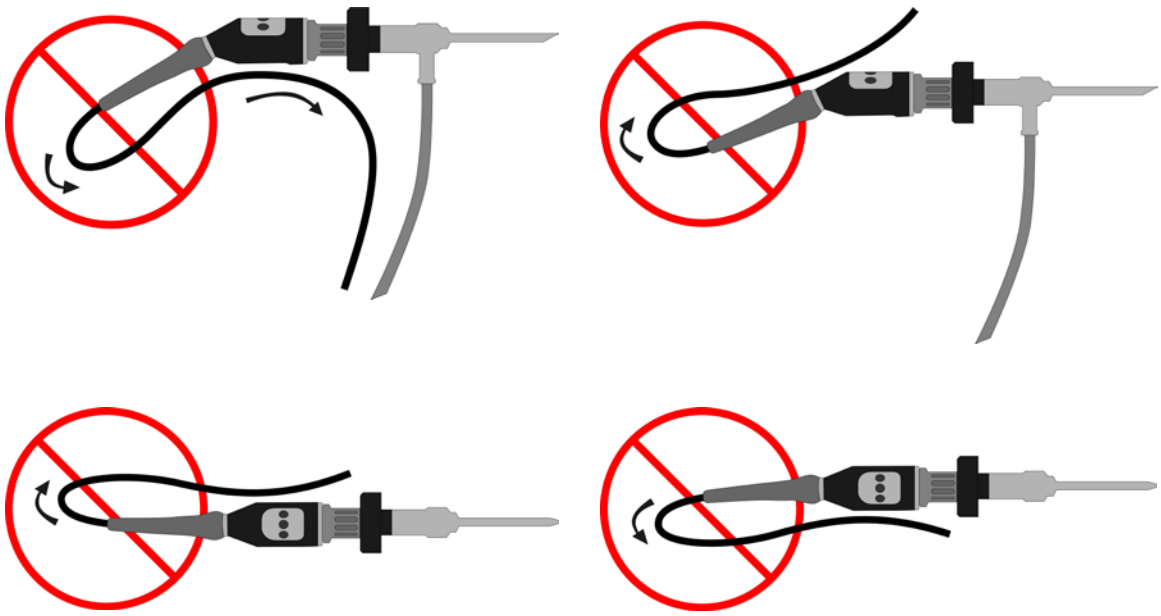
The cable must not be kinked or bent between the cable bend relief and the camera head housing:



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

This device is 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. The high-end image quality is provided by fully digital, high-speed image processing, separated for red, green and blue channels. This result in a significantly higher image quality and virtually all movements are eliminated. 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

• 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 equipment combinations:

LED light by the manufacturer of this camera.

• Recommended accessories:

For optimum utilization of the performance spectrum of this HD camera, we recommend using the latest HD endoscopes and TV adapters C-mount ISO/TS 18339 from the manufacturer as well as Sony monitors. (SONY LMD 2450MD, SONY LMD-X310MD, SONY LMD-X550MD, AG-Neovo MX-24, FSN FS-P3102DS)

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
  - Removable part - Camera head with cable (3,05m) (10ft)
  - Mains cable (1,80m)
  - HDMI/DVI cable (2,00m), HDMI/HDMI cable (2,00m)
  - USB Stick
  - Operating Manual

- **Optional accessories:**

  The following items are available as optional accessories:

  - Foot switch with cable (2.10m)

  The following items are available as spare parts for the customer/operator:

  - Mains fuse, 5x20mm, slow-acting, 3.15 AH

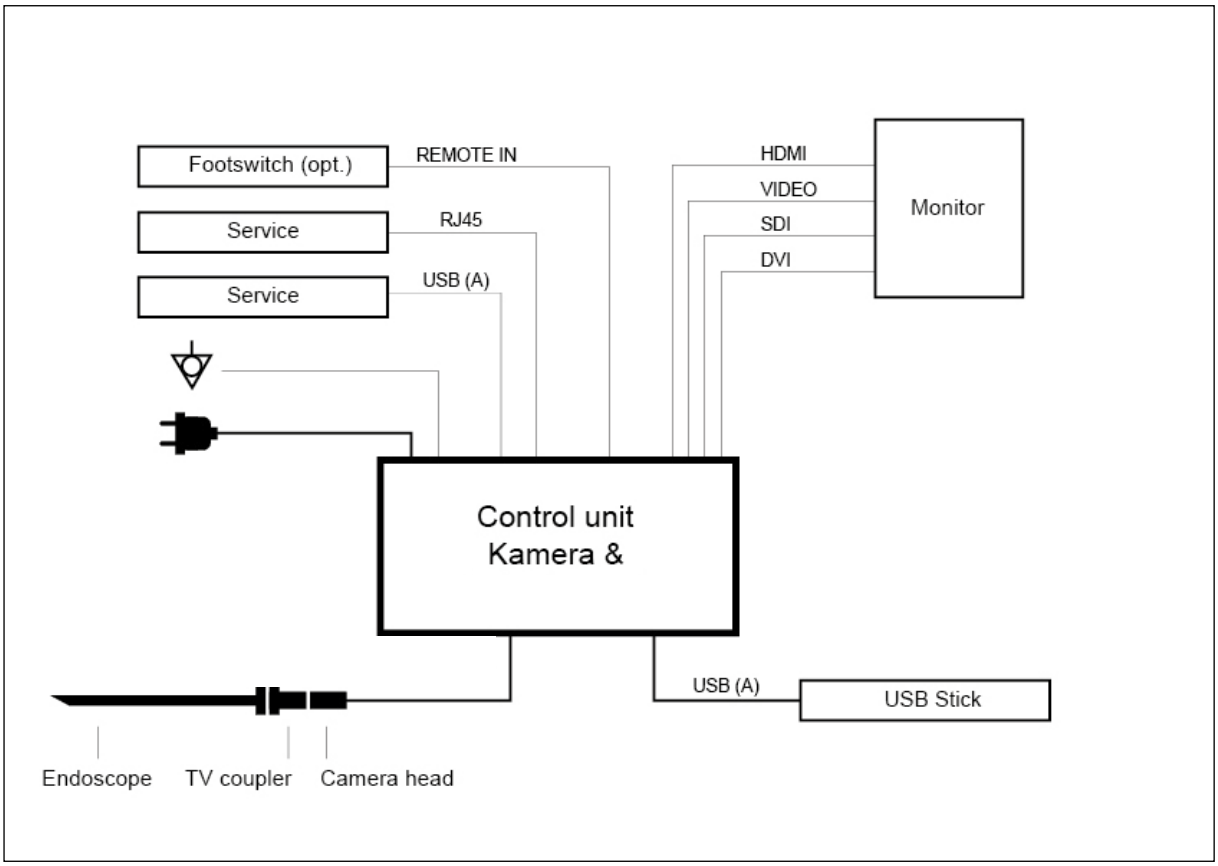
Installation

⚠ **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 external output devices!** The camera provides the video signal in various standards. Here you can connect all external output devices such as monitors, video recorders and video printers.
- **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!

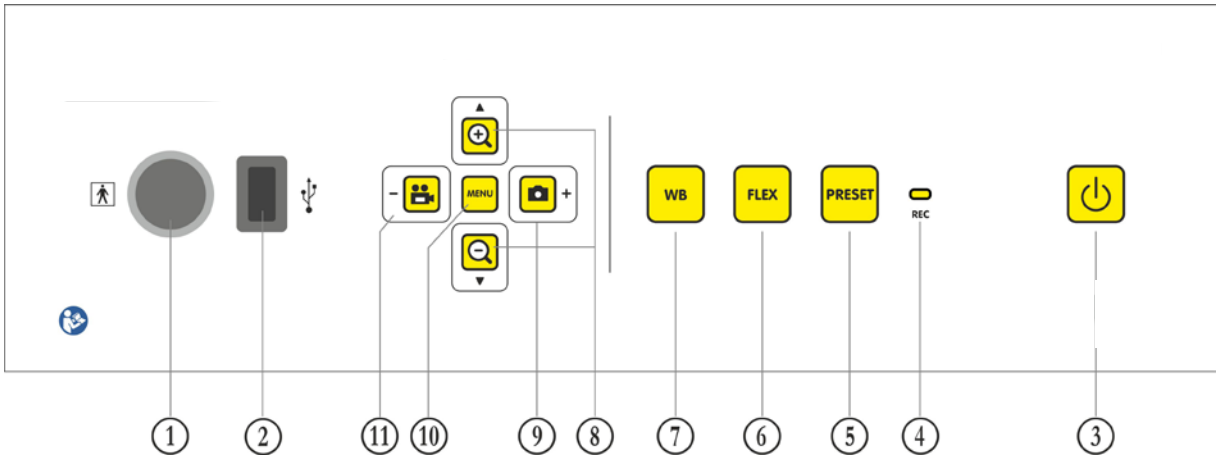
Connectivity options



Control elements / Connections

Front view

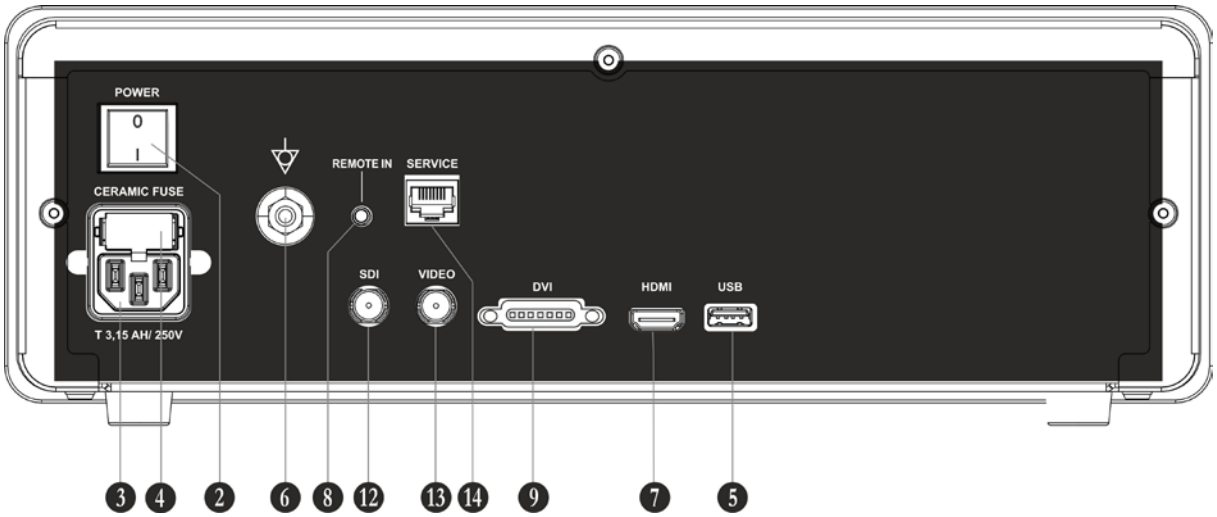
⚠ Note labeling style for the front view: „⓪“



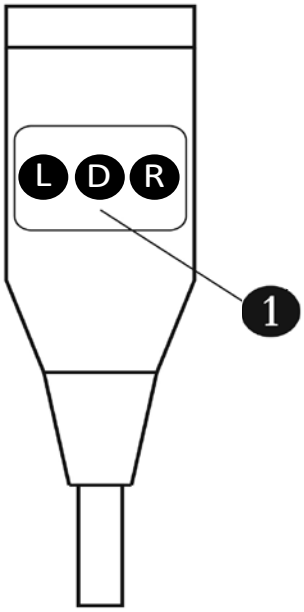
Rear view

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

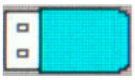
⚠ Caution! Only connect medical devices to the interfaces (Signal-In-Put / Signal-Out-Put) on the back of the device!



Camera head (Applied part BF)



Description of the control elements and connections

① **Camera connection:**	The plug of the camera cable is connected to this socket.The plug has an anti-twist safe-guard, so that the plug can only be plugged in one position. ⚠ **Attention!** Use only the supplied camera head and cable!
② **USB (A):**	This USB-interface it is for connecting the device with USB flash drives to record data. When a USB flash drive is connected to this interface, the following notice appears on the lower right corner of the screen:  When a USB flash drive is disconnected from this interface, the following notice appears on the lower right corner of the screen:
③ **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).
④ **REC**	The diode confirms the connection of an USB stick by shining The diode confirms the recording process (video or image) by flashing
⑤ **Preset:**	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”
⑥ **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.
⑦ **White balance (WB):**	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.
⑧ **Zoom IN/OUT;** **Sroll buttons:**	By briefly pressing the button (<1 sec.) The image is zoomed in gradually. By briefly pressing the button (< 1 sec.) the image is zoomed out. (after previous zoom in) ––– Within the menu: These buttons can be used to select and change menu items.

⑨ **Image capture** **/ select value:**	By pressing this button images in JPEG format (1920x1080) can be stored or within the menu settings can be made. • To save the current camera image, hold the endoscope steady. The current video image is saved by pressing the button. During the saving process (approx. 3 seconds), the LED ④ flashes and information about image storage appears in the upper right corner of the screen • Note: In order to be able to use the storage function, a USB storage medium must be connected to the corresponding port ② on the front of the device. ___ Within the menu values of selected menu items can be changed.
⑩ **Menü:**	User settings can be conveniently carried in a menu. The menu of the camera is activated by pressing this button. The button lights up when the menu is activated.
⑪ **Video capture** **/ select value:**	By pressing this button videos can be recorded stored (MPEG-4) on the connected USB flash drive or within the menu settings can be made. • If you want to capture a video clip, press this button once to start recording. The saving process is signaled with a flashing “REC” at the top corner of the screen and the LED ④ flashes . Press the button again to stop recording. Wait a few seconds while the video is saved. You can press this button again to start recording a new video clip, etc. • Note: In order to be able to use the storage function, a USB storage medium must be connected to the corresponding connection ② on the front of the device. ___ Within the menu, menu items can be selected.
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 the head buttons can be defined via the menu (see “Menu settings – “Ext. buttons” option).
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 ③ lighting up yellow
❸ **Mains connection**	The plug of the power connection cable is connected to this cold equipment power connection. Use only the provided power cord.
❹ **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“).
❺ **USB connection**	This port is reserved for service personnel for diagnostic / maintenance purposes.

❻ **Equipotential terminal**	This connector is used to connect the device to the central potential equalization of the OP, or the trolley.
❼ **Video port**	HDMI
❽ **Remote Input / Output**	The remote IN jack is for connecting a footswitch. This output is assigned the “FREEZE” function by default.
❾ **Videoport**	DVI
⓬ **Videoport**	SDI
⓭ **Videoport**	VIDEO
⓮ **Service**	This port is reserved for service personnel for diagnostic / maintenance purposes.

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 ❷ 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 controls on the front panel.

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

Now switch on the light source connected to the endoscope and set a medium brightness.

⚠ **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.

Using the camera connected with a light source

- Light source without automatic intensity control:

If you are using a light source, that does not provide an automatic intensity control via video level, set the intensity to an average brightness. The powerful shutter guarantees a correct exposure. If there is not enough illumination available, the video signal is automatically enhanced by the Automatic Gain Control. This will add noise to the monitor picture. In this case you should increase the output intensity of the light source.

- Light source with automatic intensity control:

If you are using a light source with automatic intensity control via video level, the co-operation of both controls - shutter control of the camera and light level control of the light source - can produce excellent results. If there appear variations on the monitor resulting from counteractions of both controls, switch off the light level control on the light source.
Continue with the white balance.

White balance

The white balance of the camera is made with the “WB” button ⑦ . 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 ⑦ 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

This HD camera can manage 8 user presets. Saved presets can be selected by pressing the Presets 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:** Custom Preset
- **Laparoscopy:** Setting for Laparoscopy
- **URO/GYN:** Setting for urology and Gynecology
- **Arthroscopy:** Setting for Arthroscopy
- **OTO/NEURO:** Setting for Otoscopy
- **ENT 2,9mm:** Setting for Entheroscopy
- **Laryngoscopy:** Setting for Laryngoscopy
- **Fiberscope:** Setting for flexible endoscopes
- **P TED:**

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 ⑩. In menu mode, the buttons on the front panel have the following functions:

- ⑧ Selecting menu items
- ⑨ ⑪ Changing the settings
- ⑩ Activate the functions and submenus

The front panel buttons ⑧, ⑨ and ⑪ are used to navigate within the menu and sub-menues. All processes are completed by pressing the “MENU” button ⑩. Each of the next menu items is selected or activated by repeatedly pressing the MENU button.

The menu can be controlled if a USB keyboard is connected ❺. Settings can be made by using the cursor keys. The settings are confirmed with the Enter key.

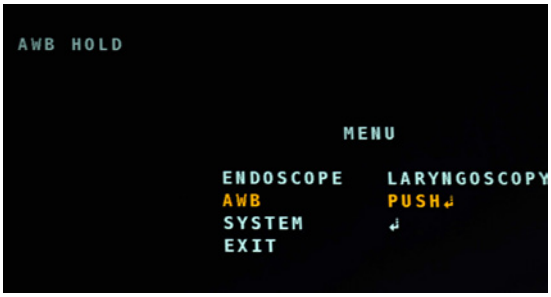
To exit the menu, the menu item “RETURN” must be used. Optionally, use the “ESC” key to leave the menu if a USB keyboard is connected.

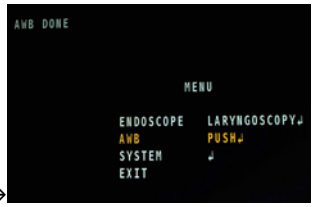
Menu navigation

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 ⑩. Be careful not to cover the white area. Correct color reproduction is only guaranteed if the white balance is carried out correctly.

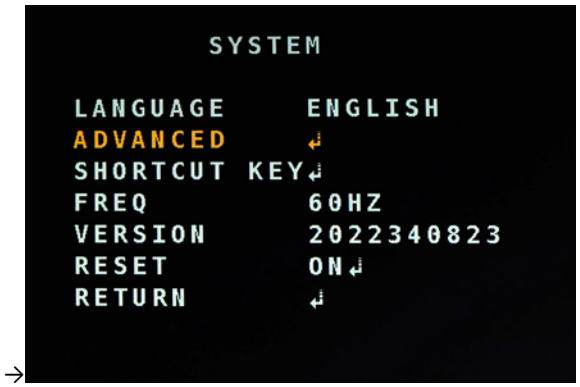
The current setting is stored in the camera and is retained even after it is switched off. If the “White balance” function is selected, the “WB” button flashes. “AWB HOLD” appears in the upper left corner of the OSD while the function is in progress. An “AWB DONE” appears when the function has been successfully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

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

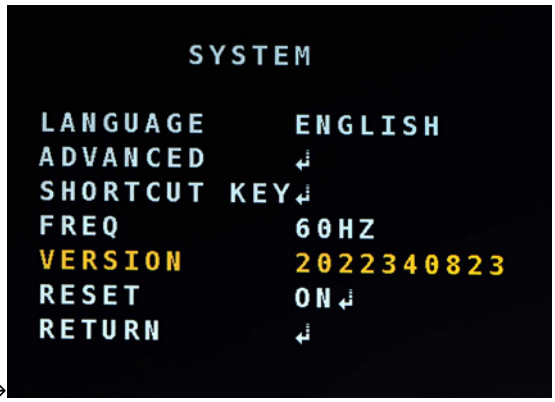
ATM → AntiMoirée

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 footswitch can be assigned one of the following 3 functions: image capture, video capture, freeze

Function assignment of the foot switch:

• Connect the footswitch to ❽.

• Keep the foot switch pressed for at least 3 seconds

• The two keys ⑧ light up. You are in the configuration mode for the foot switch.

- Pressing the ⑥ button: Assignment of the foot switch to the „Image capture“ function
- Pressing the ⑤ button: Assignment of the foot switch to the „Video recording“ function
- Pressing the ⑦ 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 ❷ 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:**

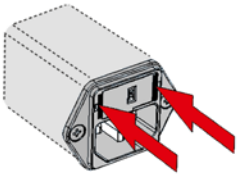
   Ensure that the fuse is correctly seated and avoid using force

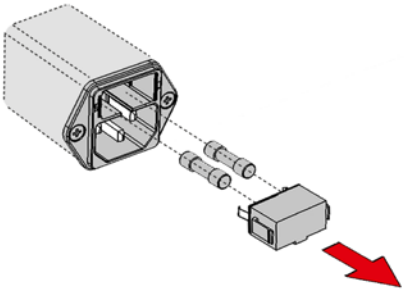
6. **restore the power supply / voltage supply:** By plugging in the mains plug.

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**:

⚠ 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, ¬es-pecially 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.

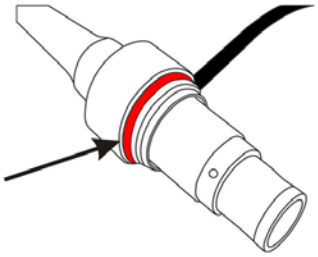
⚠ **Attention!** Do not autoclave any part of the equipment!

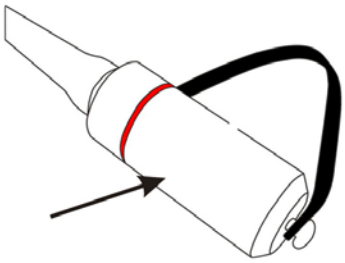
- **Camera head:**

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	Lighting insufficient	Improve lighting
	Monitor settings not optimal	Verify / correct the monitor settings
Picture too bright	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
Bad colors	Color settings not optimal	Correct color settings (monitor)
	Monitor settings not optimal	Verify / correct the monitor settings
	Color settings not optimal	Correct color settings (monitor)

Error message

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:	25 VA
Mains fuses:	Fuses, 5x20mm, inert 3,15 AH, 250V with high switching capacity (Ia = 1500 A)
Dimensions (WxHxD):	Control unit: 360 x 125 x 351 mm Camera head: approx. Ø38mm, lenght: 79 mm (without cable bend relief)
Weight:	Control unit: approx. 4,7kg Camera head: approx. 180g
Camera	
Image sensor:	1/2“ CMOS
TV-System:	Progressive at 50 / 60 Hz (Rolling Shutter)
TV resolution:	1920x1080 Pixel (Full HD) (camera system incl. sensor)
Image resolution:	>900 TV-Lines; horizontal
Index ratio:	16:9
Min. sensitivity:	< 3lx
Connections	
Video outputs:	1 x HDMI, 1 x DVI, 1 x SDI, 1 x Video
Other connections:	1 x USB (A) Front (USB-Stick) (max. 256 GB, USB Stick only) 1 x USB (A) Back (Service) 1 x Remote IN (Footswitch) 2 x RJ45 (Service)

Classification / Conformity	
Safety class (EN 60601-1)	1
Applied part (Typ)	BF (camera head)
Degree of protection:	IP20
Classification (EU) 2017/745, Anhang VIII	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 1MOS HD, fully assembled	740-2018

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)

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