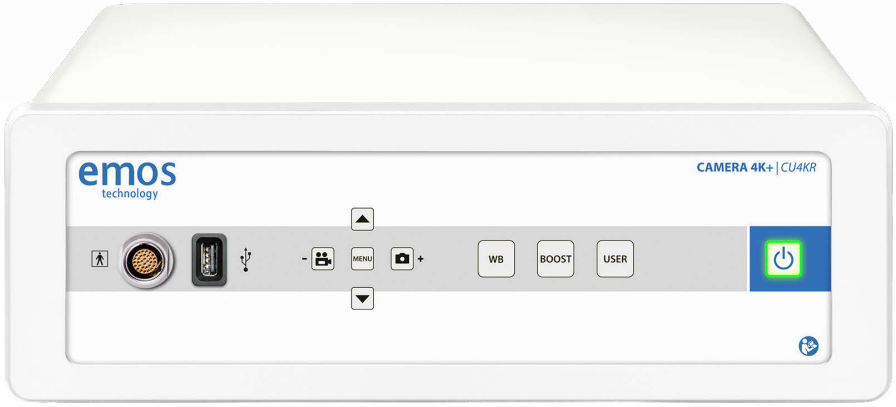
Instruction manual

Ultra high resolution digital 3chip-camera
for endoscopic applications
(MOS technology)



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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-

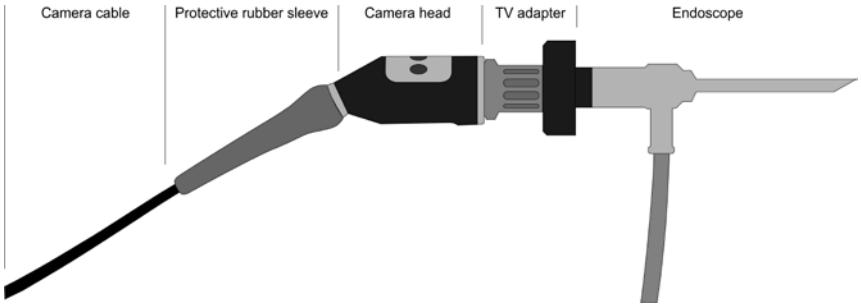
ment.

- 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.

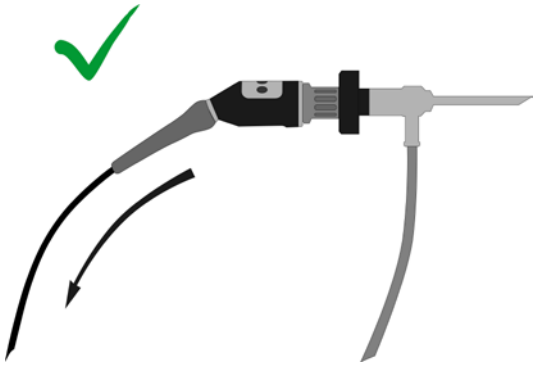
Camera head, cable and cable bend relief

⚠ 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.

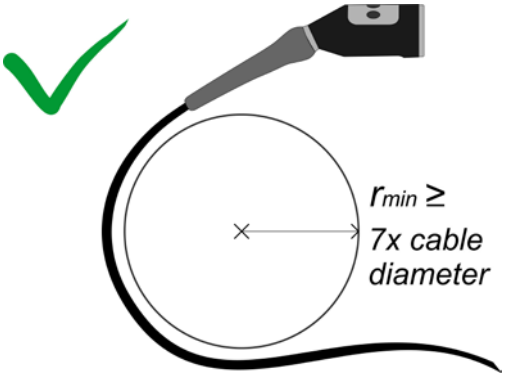
Assembly overview:



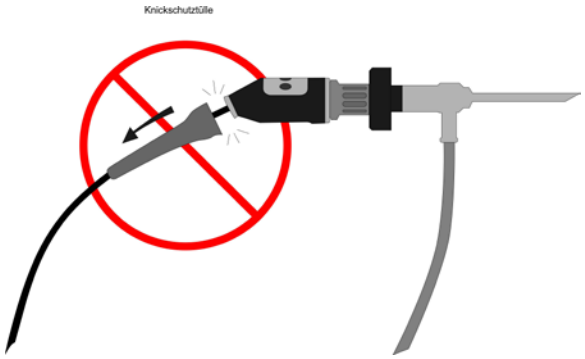
Correct cable routing: For all applications (including endoscopy as well as cleaning / sterilization), the manufacturer-defined natural run of the cable and the cable bend relief must be maintained. The direction of the cable is determined by design:



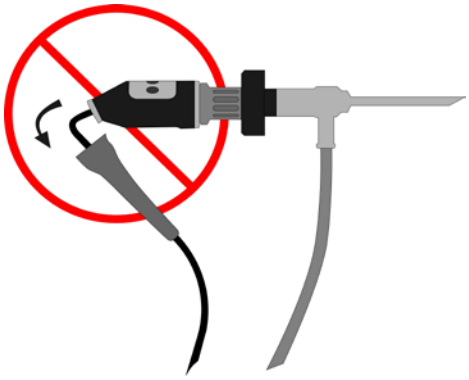
Smallest permissible bending radius: For all applications (including endoscopy as well as cleaning / sterilization), the cable and the cable bend relief must not be wound / laid / routed in a radius smaller than 7x cable diameter. This applies to every direction in which the cable is moved:



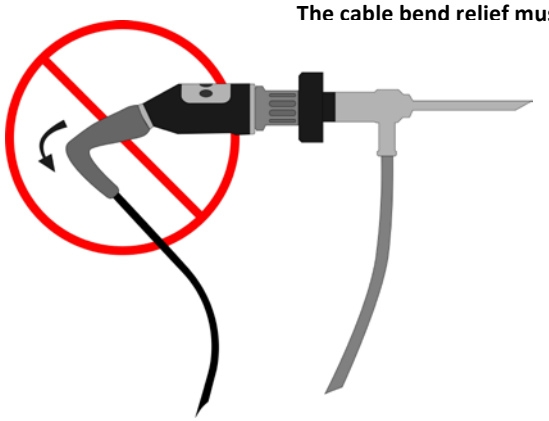
The cable bend relief must not be removed:

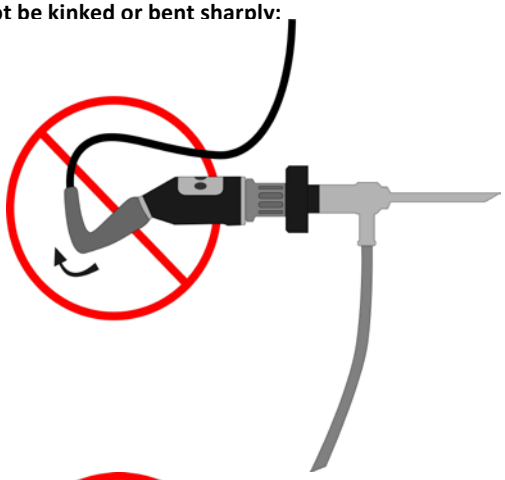


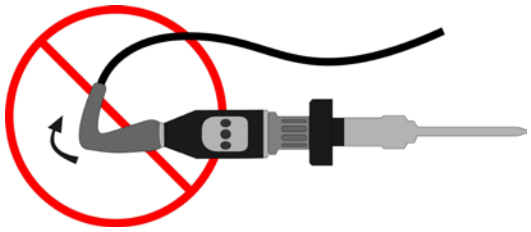
The cable must not be kinked or bent between the cable bend relief and the camera head housing:

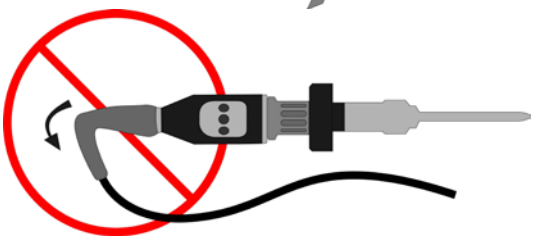


The cable bend relief must not be kinked or bent sharply:

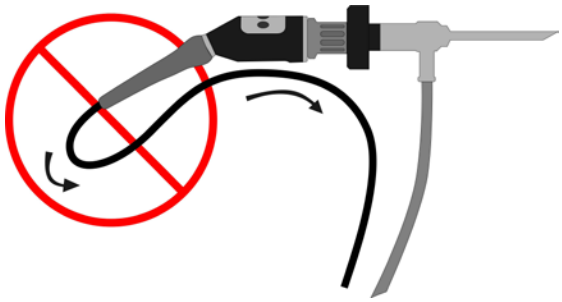


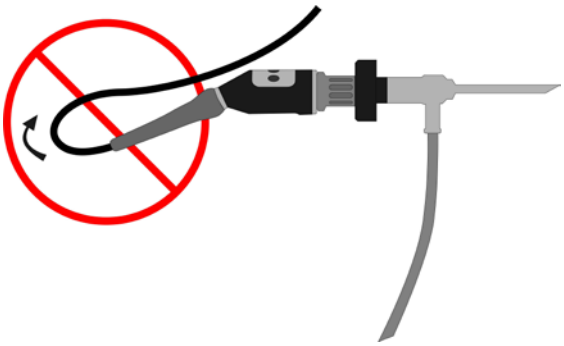


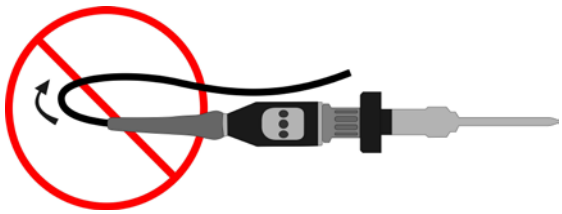


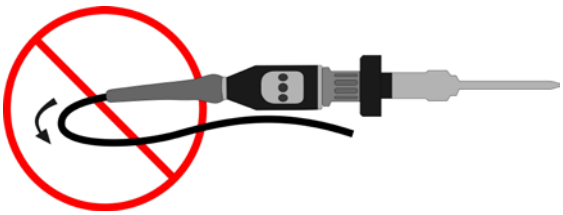


The cable itselve must not be kinked or bent sharply:









Description of the unit

This device is a 3-chip camera (MOS) of the latest generation, with superior image quality in 4K ultra high definition (Aspect ratio 16:9) and natural colour reproduction, which was especially adapted for endoscopic applications and meets specific quality standards. The camera delivers a significantly higher picture quality with very high detail accuracy with 4 times as many picture points as with Full HD. 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. At the front of the camera head is a C-mount thread, where standard lenses, zoom lenses, endoscope adapters and other adapters can be connected. The allocation of the buttons on the camera head is freely programmable, so that various camera functions can be activated or executed via the head buttons (e.g., White balance, Zoom, Freeze, ...)

• OSD menu

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

• Zoom

The camera is equipped with an electronic zoom function. Three different zoom levels (revolution x1.0 → x1.5 → x2.0 → x2.5) can be selected with the buttons on the camera head.

• Archiving system (optional)

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 buttons on the camera head or by pressing the foot switch (optional) (still picture).

• Connections

The video signal is available at the rear of the unit as a digital HDMI (4K UHD / HD) and SDI (4K UHD / HD). The remote-out jack is available for the connection of external output devices such as video printers or video recorders. A footswitch can be connected to the Remote In terminal.

• 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 sources by the manufacturer of this camera.

• Recommended accessories:

For optimum utilization of the performance spectrum of this 4K camera, we recommend the use of endoscopes and TV adapters specially designed for 4K from the manufacturer as well as 4K monitors. (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
  · Camera head with cable 3,05m (10ft)
  · Mains cable (1,80m)
  · HDMI cable (high speed) (2,00m), Jack cable 3,5 (1,55m)
  · Operating Manual

- Optional equipment:
  · Footswitch with cable (2,10m)
  · USB flash drive
  · USB keyboard with cable (1,80m)

- Spare parts:
  · Mains fuses, 5x20mm, delay acting 3,15A / 250V, with high breaking capacity (Ia = 1500 A)

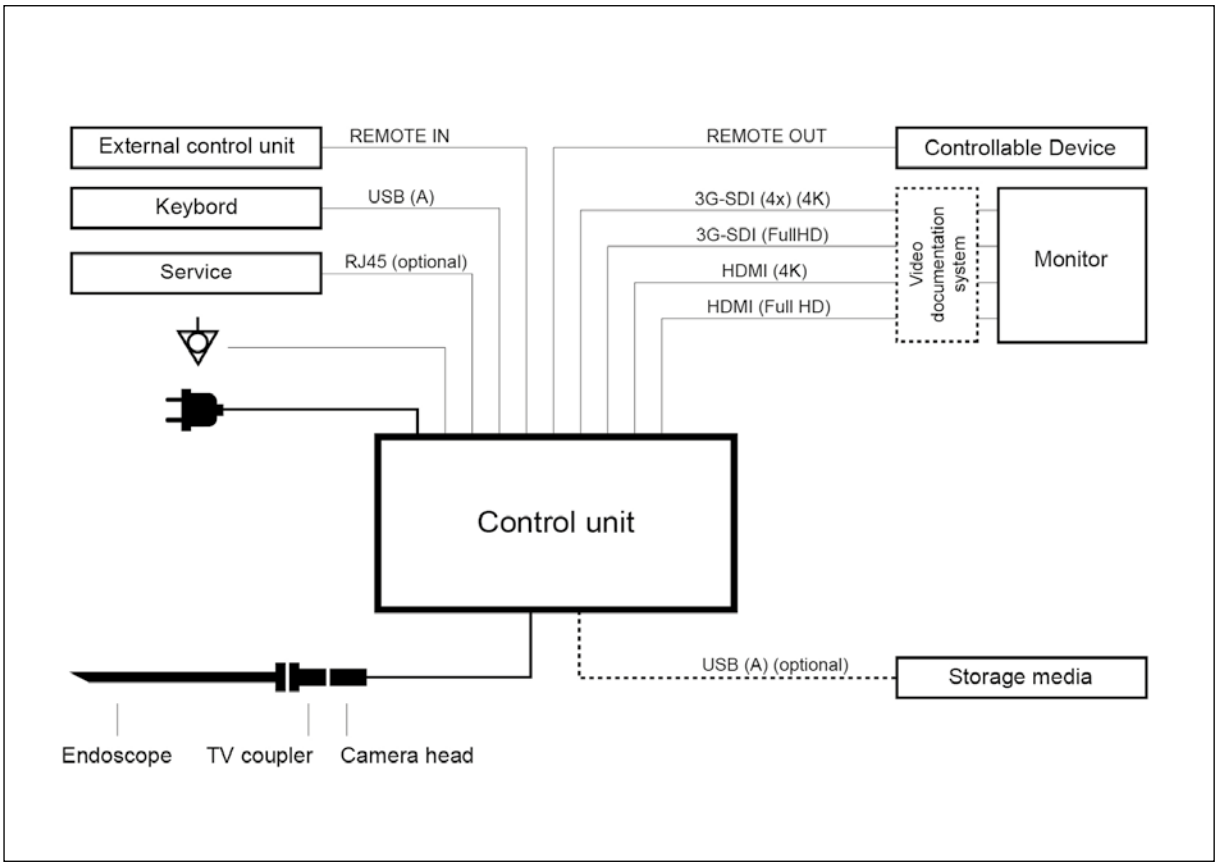
Installation

⚠ **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!** As described above, 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

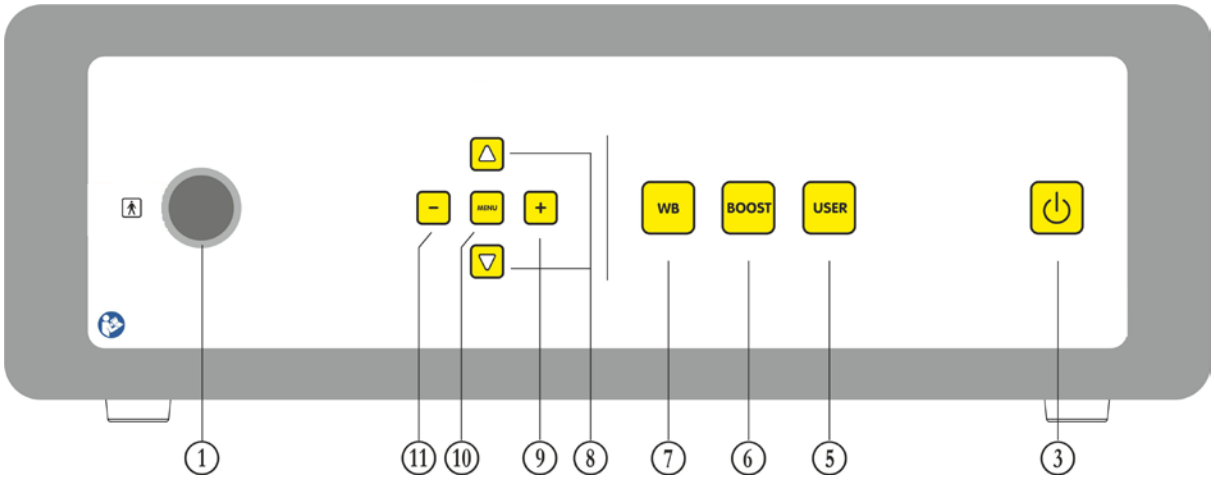


Control elements / Connections

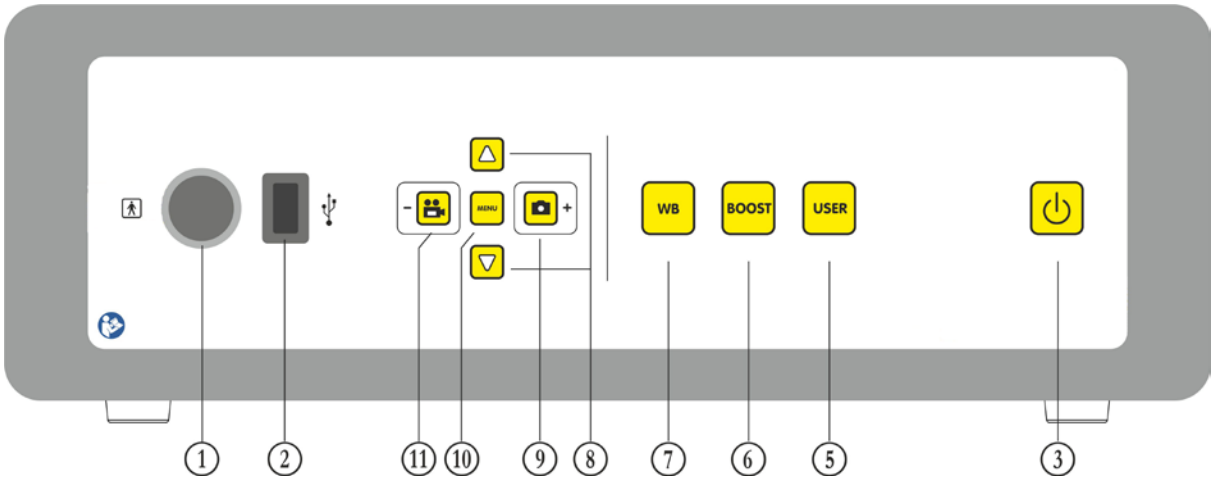
Front view

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

- Device without archiving option



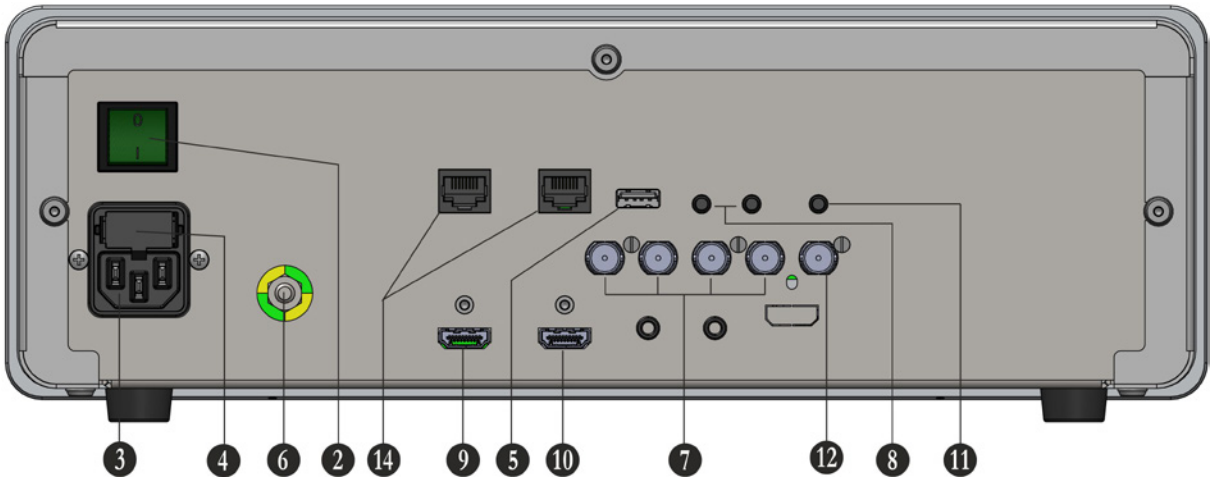
- Device with archiving option

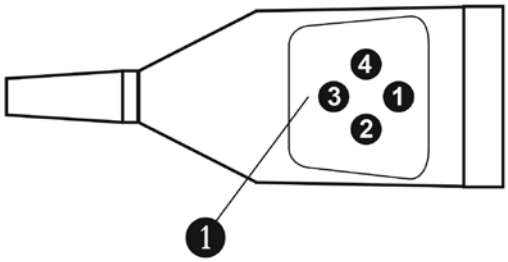


Rear view

⚠ 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!





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 **USB (A) (optional)**	This USB-interface it‟s for connecting the device with USB flash drives to record data. When a USB flash drive is connected to this interface, the notice “USB” appears on 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 **not applicable**	
⑤ **User:**	User profiles can be activated by pressing this button. The individual profiles can be selected by repeatedly pressing this button. The profiles can be set in the menu (see “Setting USER profiles”), the desired profile must be selected. If a USER - change is selected the button “USER” is fully illuminated when reloading the profile and a “U” flashes in the lowest line (right).
⑥ **Brightness amplification** **(Boost)**	The camera is equipped with a BOOST function to raise the image brightness in low light conditions. Press the corresponding button to activate the feature. You will hardly recognize an effect on the monitor with adequate lighting. The current setting is indicated by a notice (“B”) on the screen. Note: This function can be activated optionally via remote keys (camera head or footswitch) (see “Menu settings”).
⑦ **White balance (WB):**	The white balance of the camera is made with the “WB” button (see “Operation→White balance”). If the function “White balance” is selected, the key “WB” is fully illuminated. “WB” flashes in the lowest line (right) of the OSD while executing the function. An “OK” appears when successful or “NG” when failed after completing the function.
⑧ **Scoll buttons:**	Menu items can be selected and settings can be executed by using these buttons.
⑨ **Image capture (optional)** **/ Scroll:**	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 “USB” display in the lower left corner of the screen disappears briefly and reappears when the saving process is complete. • 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 (optional)** **/ Scroll:**	By pressing this button videos can be stored (MPEG-4) on the connected USB flash drive or within the menu settings can be made. • If you want to record a portion of the video, press this button once to start recording. The storage process is signaled with a flashing “REC” in the lower left corner of the screen. 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 segment, 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. The memory function can optionally be triggered via a button on the camera head or a foot switch (see “Menu settings”). Within the menu, menu items can be selected.
❶ **Remote control function**	With these keys, the functions of the camera can be remotely controlled by the camera head. The head keys are distinguished between pressing the key briefly and a long, so that a total of 8 functions are possible. The allocation of the head buttons can be defined via the OSD menu (see Menu settings – Option “Remote keys“).
❷ **Main 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 connection is used for mains disconnection / mains connection. The plug of the power connection cable is connected to this cold equipment power connection. Use only the provided power cord.
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 keyboard**	This USB port (Type A) is used to connect an USB keyboard. Any text can be placed on the video image via a connected keyboard. The text remains on the screen or video recordings. A more detailed functional description, see the chapter “Using an USB keyboard“.
❻ **Equipotential terminal**	This connector is used to connect the device to the central potential equalization of the OP, or the trolley.
❼❾❿⓬ **Video ports**	External devices (such as a monitor or recording device) can be connected to the VIDEO OUT jacks. The video signal is available in different standards. · HDMI 1 ❾ · HDMI 2 ❿ · SDI 1 / 4x 3G SDI ❼ · SDI 2 ⓬
❽⓫ **Remote Input / Output**	Remote IN: For connecting a footswitch (optional). Remote OUT: For connecting external devices.
⓮ **Service**	Connection for diagnosis / 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.

Note: When the “POWER OnSTART” function is activated, the device switches directly to the operating mode. (See also chapter: “Menu settings - Options - POWER OnStart”) Otherwise, the device is now in standby mode.

The standby mode is indicated by yellow lightning of the push button “POWER” ③ . By pressing the ③ 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 LEDs on the front panel.

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

Note: When the “USER OnSTART” function is activated and If the connected monitor is switched on, an image appears on the monitor and a selection menu with the preset basic settings of the 10 USER presets appears. The selection option when starting the device only appears if the “User On Start” function is set in the menu. Select a preset that suits your working conditions.

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

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.

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“ is fully illuminated. “WB” flashes in the lowest line (right) of the OSD while executing the function. An “OK” appears when successful or “NG” when failed after completing the function.

Note: This function can be activated optionally via remote keys (camera head or footswitch) (see “Menu settings”).

User profiles

The 4k camera unit can handle 10 USER profiles. The user can be changed through the front button „USER“ ⑤ or the F5 key (with keyboard connected). The profile can be selected using the scroll buttons ⑧ and activated with the menu button ⑩. Profile settings can be made in the menu, while the desired profile must first be selected. The currently active profile is displayed in the menu header in brackets.

Changes of menu settings are saved. The above items are written in the currently active user-memory. They are available immediately.

The following user profiles are available as standard settings (factory default settings):

- **Lap 10mm:** Standard setting for laparoscopy with 10mm endoscopes
- **Lap 10mm enh R Y:** Standard setting for laparoscopy with 10mm endoscopes, enhancement function for contrast spreading in the red / yellow area, improved contrast for visualizing the vessels
- **Lap 5mm:** Standard setting for laparoscopy with 5mm endoscopes
- **Lap 5mm enh R Y:** Standard setting for laparoscopy with 5mm endoscopes, enhancement function for contrast spreading in the red / yellow area, improved contrast for visualization of the vessels
- **Arthro:** Standard setting for arthroscopy
- **Arthro enh exp:** Standard setting for arthroscopy with reduction of overexposure
- **Arthro enh R:** Standard setting for arthroscopy with enhancement function for contrast spreading in the red area
- **Uro Gyn:** Standard setting for urology and gynecology
- **Uro Gyn enh R Y:** Standard setting for urology and gynecology, enhancement function for contrast spreading in the red / yellow area, improved contrast for visualizing the vessels
- **Flex:** Standard setting for flexible and semi-flexible endoscopes with fiber image guides

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.

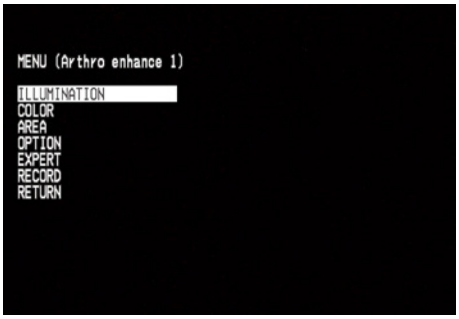
The menu can be controlled if a USB keyboard is connected ❺ . Settings can be made by using the cursor keys. The settings are confirmed with the Enter key.

The changed parameters are automatically saved in the selected USER-profile of the camera. If you have accidentally changed parameters and you are unsatisfied with the picture quality, factory settings can be reset at any time. On that point, select and perform the menu item “factory settings”.

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

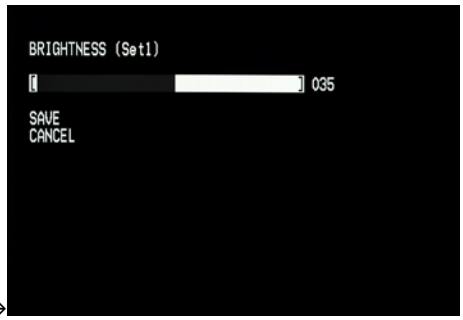
Main menu:



Submenus:

Illumination (Main menu item 1)

This menu item offers the user the possibility to individually adjust the illumination of the camera image.

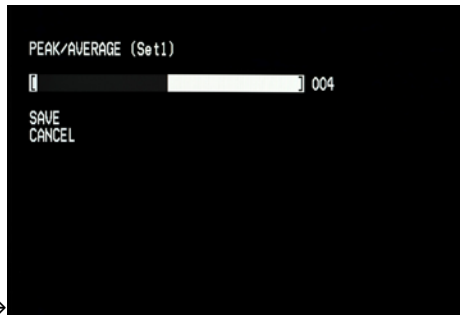


BRIGHTNESS

The brightness of the overall image can be regulated under this menu item.

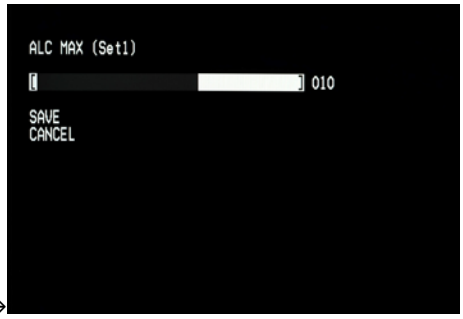
As shown in the picture above, the current value is visualized by a slider and a numerical value. The value is changed by using the buttons ⑨ and ⑪ Using the buttons ⑩ the user can select the items “SAVE” or “CANCEL”. In case of “SAVE”, the current setting will be saved and is also available after restarting. In the case of “CANCEL”, the set value is discarded and reset to the initial value.

Note: All of the following menu items are set in the same manner.



PEAK / AVERAGE

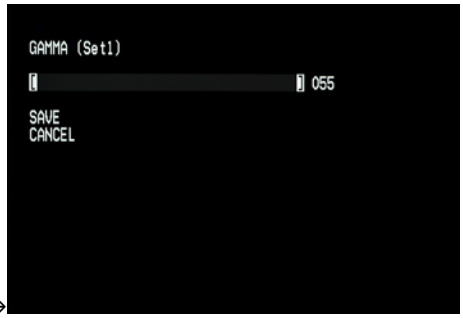
Sets the ratio of average brightness values to peak values (Average/Peak) to reduce fading.



ALC MAX

Setting the maximum brightness intensity

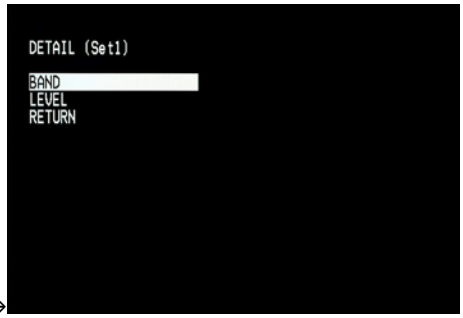
→→



GAMMA

Changing the GAMMA value

→→



DETAIL

The detail contrast can be defined under this menu item.

→→→

BAND

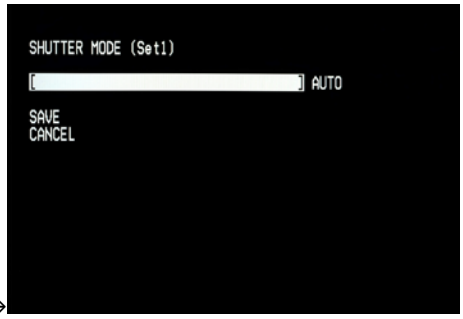
Determining the emphasis between coarser and finer image stuctures

→→→

LEVEL

Edge enhancement to enhance the sharpness of the image

→→

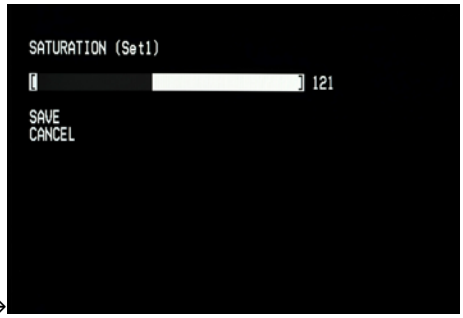


SHUTTER MODE

Setting Shutter-Mode: Manual (1/60…1/10.000) / Automatic

Color (Main menu item 2)

In this menu, the total color saturation and the intensity of the individual colors can be set. A color bar pattern can also be inserted (4 COLOR BAR) for test purposes.



Saturation

Use this control to adjust the color saturation.

Red

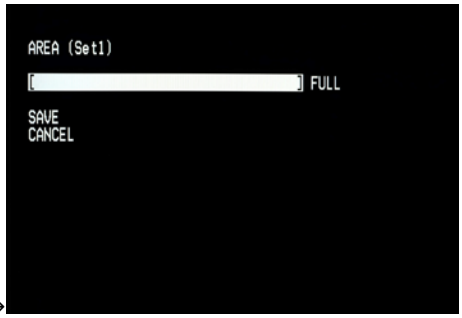
Moving the slider changes the red portion of the image. (Adjusting the camera to the monitor)

Blue

Moving the slider changes the blue portion of the image. (Adjusting the camera to the monitor)

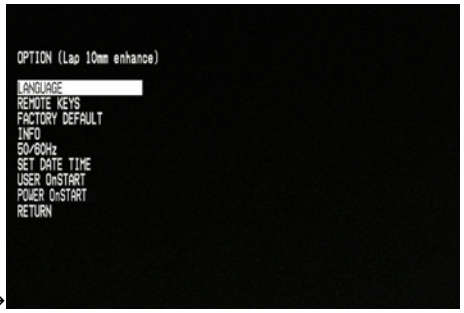
Color bar

View to test the monitor signal

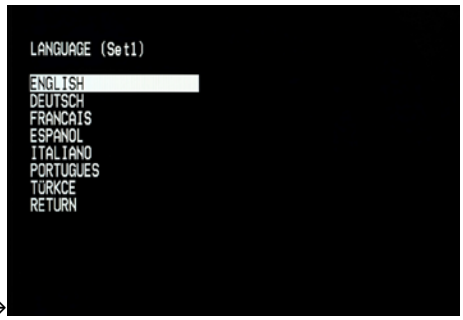


Area (Main menu item 3)

Under this menu item, the measurement field for the brightness control can be set.

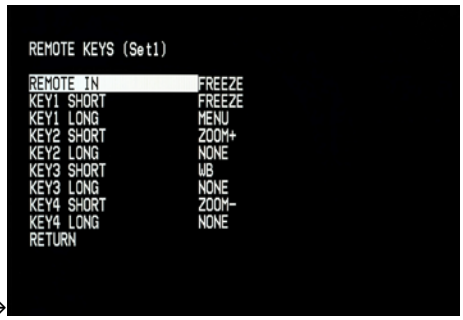


Option (Main menu item 4)



LANGUAGE

In this menu the desired language of the menu can be selected.

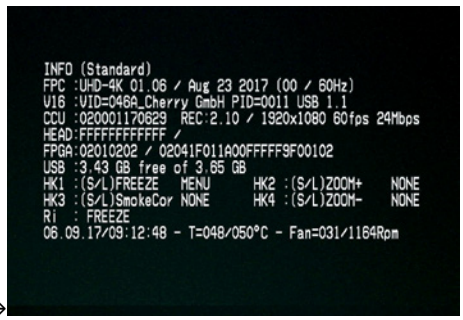


REMOTE KEYS (Camera head keys)

In this menu item, it is possible to assign different functions to the buttons of the camera head ❶. In the case of the head buttons, a distinction is made between a short and a long key press, so that a total of 8 functions are possible.

The following functions are possible:

- NONE: no function
- WB: white balance
- SC: Smoke correction
- BOOST: Image brightening
- MENU: OSD Menu
- MOV: Video capturing
- PIC: Image capturing
- ZOOM+: Modification Circulation x1,0 > x1,5 > x2.0 > x2,5
- ZOOM - :Modifikation Scaling x1,0 > x2,5 > x2.0 > x1,5
- REMOTE 1: Triggering a switching pulse (currently 300ms)
- REMOTE 2: Triggering a switching pulse (currently 300ms)
- Freezing the image, characterized by “F” Pos = 12 x 26
- Change of user data



→→

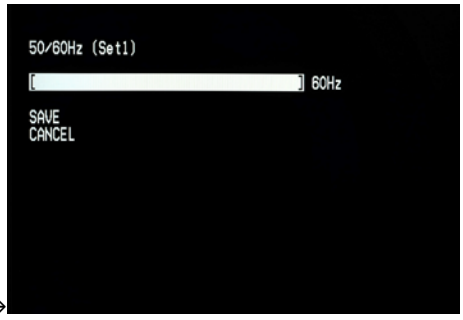
INFOSCREEN

The Infoscreen displays current status information

→→

FACTORY DEFAULT

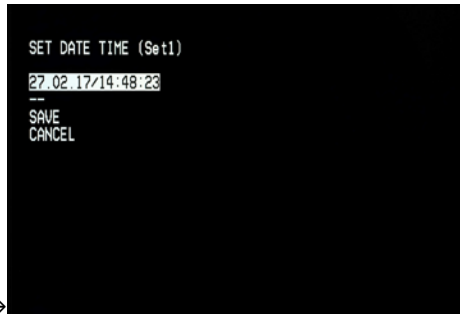
By activating the “Reset” point, all parameters are reset to the factory settings and the system is “rebooted”. This is characterized by a uniform flashing of the button lighting and lasts approx. 7s.



→→

50/60Hz

Switching / setting of the mains frequency (country-specific)

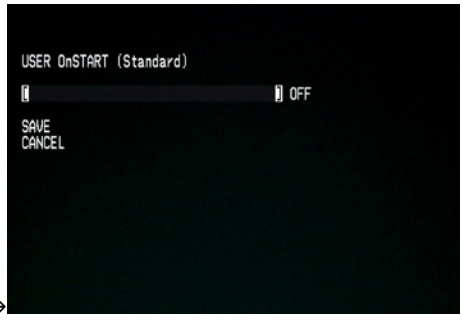


→→

SET DATE TIME

Setting the date and time

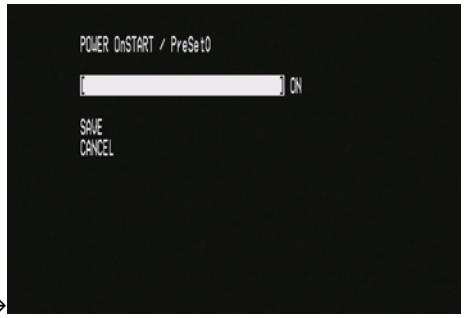
Note: These data are not displayed in image or video recordings.



→→

USER ON START

In the “UserOnStart” menu, you can specify whether the user profile selection should first be carried out when the device is restarted, or whether the device starts automatically with the last user profile selected.



POWER OnSTART

In the „POWER OnStart“ menu you can specify whether the device starts directly in the operating mode when it is switched on with the mains switch ❷.

Function: “ON” - the device starts directly in the operating mode when the mains switch is switched on

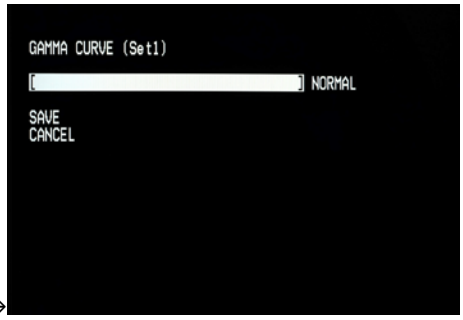
Function: “OFF” – the device starts in standby mode when the mains switch is switched on

Note: The function can optionally be activated (“ON”) in the delivery status according to customer requirements.

Expert (Main menu item 5)

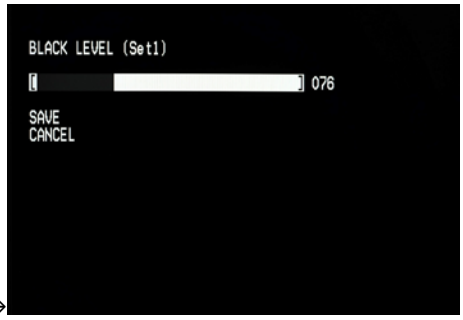
DNR (Digital Noise Reduction)

With “DNR” a noise reduction can be achieved



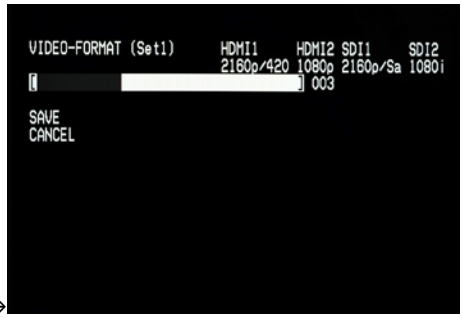
GAMMA CURVE

This menu item can be used to influence the S-curve of the gamma curve. This causes a contrast increase.



BLACK LEVEL

Black level controls the black level.



VIDEO FORMAT

Depending on the monitor, the setting of the video resolution can be made here.

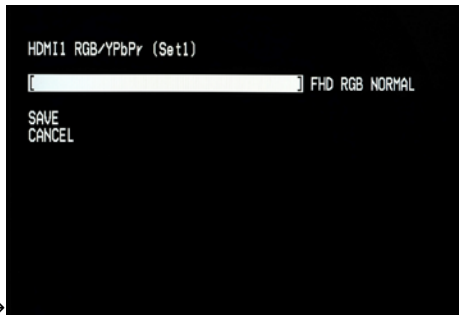
- HDMI 1: 4K resolution
- HDMI 2: FullHD resolution
- SDI 1: 4K resolution
- SDI 2: FullHD resolution

Abbreviations / method of image composition:

p: progessive i: interlaced

Sa: Sample interleave Sq: Square division

Note! If an incorrect setting is selected in the video format, no image may appear on the monitor. A reset of the video outputs could help. Please refer to the troubleshooting chapter.



HDMI 1 – output: Setting the video signal

HDMI 2 – output: Setting the video signal

HDMI 1: Selecting the color space between BT.2020 or BT.709.5

SDI 1: Selecting the color space between BT.2020 or BT.709.5

Head Center: Adjusting the image orientation

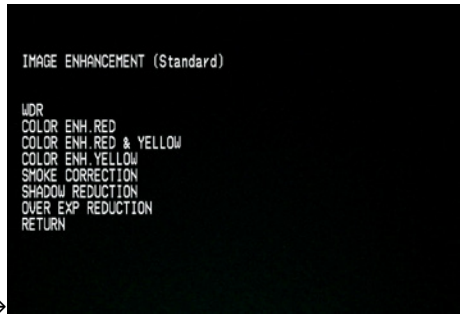


IMAGE ENHANCEMENT

In various modes image enhancements can be made. The mode that is active in the userpreset flashes. If a mode is changed, it is automatically activated.

WIDE DIGITAL RANGE

Increasing the dynamic absorption.

COLOR ENHANCEMENT RED

Color adjustment in the red area

→→→

COLOR ENHANCEMENT RED & YELLOW

Color adjustment in the red & yellow area

→→→

COLOR ENHANCEMENT YELLOW

Color adjustment in the yellow area

→→→

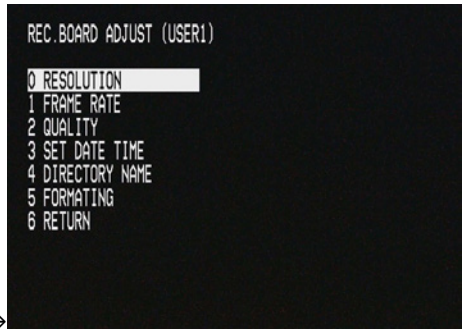
SMOKE CORRECTION

→→→

SHADOW REDUCTION

→→→

OVER EXPOSURE REDUCTION

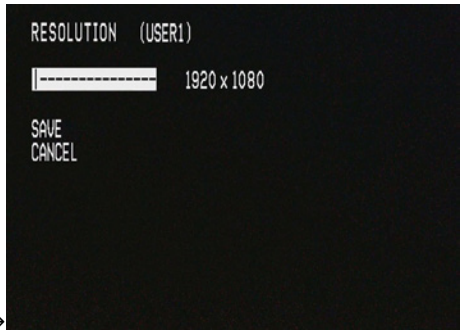


→→

Record Board Adjustment (optional)

This menu item various parameters associated with the storage of images or videos can be adjusted.

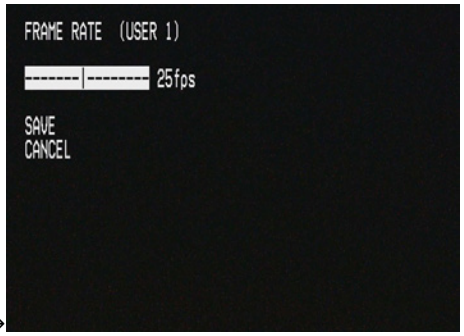
The detailed settings can then be made in the menus below.



→→→

RESOLUTION

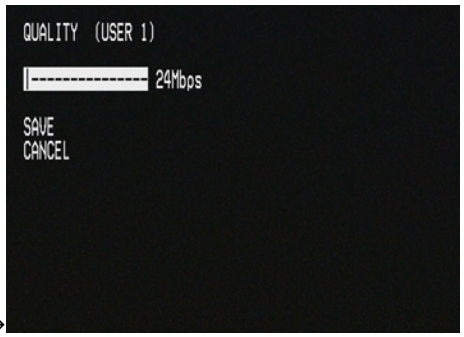
Image resolution in recording mode (1920x1080; 1280x720; 640x360; 320x180)



→→→

FRAME RATE

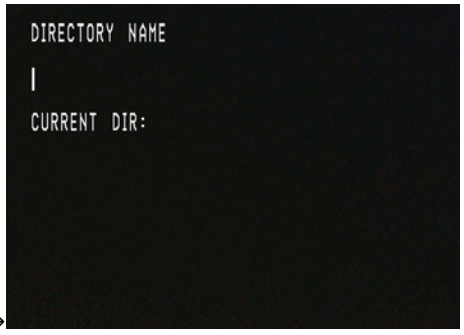
image repetition frequency (60fps; 30fps; 15fps)



→→→

QUALITY

Compression (data rate to the USB memory medium) (24Mbps; 16Mbps; 12Mbps; 8Mbps; 4Mbps)

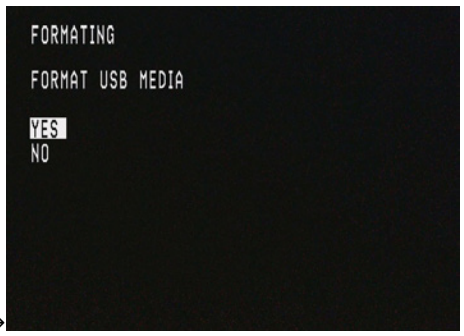


→→→

DIRECTORY NAME

An individual name of the location (folder) can be set under this menu item.

Note: To use this function, a USB keyboard must be connected to the device.

→→→ 

FORMATING

Format the connected USB storage media. The “Format” message flashes during the formatting process. If the formatting is completed successfully, the message “OK” appears.

Optional Features

• Connecting USB flash drives

Use the USB port ② (Type A) on the front side of the device for connecting external USB storage devices (flash drives). When a USB device is connected to this interface, the message “USB” appears on the monitor and information on the size and availability (free space) of the storage medium will be displayed momentarily.

Note: The (optional) supplied 64 GB stick has been tested and verified. The device supports up to **16GB FAT**, up to **32GB FAT32** and up to **256GB exFAT**. Commercially available sticks may not be supported by the device due to the formatting. In this case, the file format must be changed using a computer. Note the stick’s write speed of 24 Mb/s (USB 2.0)! We only use high-quality USB 3.0 sticks.

Note: Press the button “Scroll down” ⑧ for 2 seconds before removing the USB flash drive. The message “Remove USB Media” and an acoustic signal (beep) indicate that the USB memory stick can be separated from the device.

• Remote functions (head buttons and footswitch
Available with camera head with integrated head buttons ❶ or connected foot switch ❽ (further information under chapter “Menu navigation – REMOTE”

• Recording function – Image

Hold the endoscope steady to save the current camera image. The current video image is saved by pressing the ⑨ button. During the saving process (approx. 3 seconds), the „USB“ display in the lower left corner of the screen disappears briefly and reappears when the saving process is complete. 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.

• Recording function – Video

If you want to record a portion of the video, press the ⑪ button once to start recording. The storage process is signaled with a flashing „REC“ in the lower left corner of the screen. 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 section, etc. 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. The memory function can optionally be triggered via a button on the camera head or a foot switch (see „Menu settings“).

• Using an USB keyboard

All camera functions can be controlled and settings in the menu can be made by using an USB keyboard. The user is also able to place an individual text on the screen with the aid of the keyboard (see “On Screen Display“).

BUTTON ALLOCATION

The following keys have fixed functions:

- F1: Help
- F2: INFO
- F3: WB (White balance)
- F4: BOOST (Brightness amplification)
- F5: USER (User settings)
- F6: Menu
- F7: OSD (input of patient information„)
- F10: CLR SCR (Clear Screen)

· F11: Recording image
· F12: Recording video (Start/Stop)
· BREAK: FREEZE (freeze frame)
· PRTSC: REMOTE (ext. switching contact)
· ESC: QUIT → Menu or OSD
· PG-UP: ZOOM+
· PG-DW: ZOOM-
· STRG+ALT+S: WHITE SHADING
· STRG+ALT+P/B: BLEMISH DAT/COM:
· Automatic Pixel Compensation
· STRG+ALT+P: Display
· STRG+ALT+B: Performing the function
· Note: The lens must be connected when performing the BLEMISH function.

During the functions of “FREEZE”, “ZOOM” and “USER”, status information is displayed in the bottom line. The function “FREEZE” is marked by an “F”. In the case of a zoom level greater than 1.0, this becomes visible by the display:

· *1,5 / *2,0 / *2,5

• On Screen Display (OSD)
It is possible to place an individual text on the screen by using the USB keyboard. This mode is activated by the F7 key only when the menu is not activated. A cursor flashes in the top left corner in the form of a “|” character at the initial use after power up. Now the user can modify his input. The following buttons are available for editing tasks:

· HOME: places the cursor in the upper left corner
· END: places the cursor in the lower left corner
· DEL: deletes current character
· BACKSPACE: deletes left character
· CURSOR LEFT: \
· CURSOR RIGHT: Cursor
· CURSOR UP: move
· CURSOR DOWN: /
· ENTER: Cursor is placed at the beginning of the next line
· SHIFT+ Taste: + button - Second allocation
· TAB: Cursor position +3 shifted
· F10: Delete screen
If an input is not carried out within 20 seconds, the cursor disappears. After resuming the input, the cursor appears at the current position.

The title generator function can be canceled at any time by pressing the “ESC” button. The menu is then also available to the user again. If the title generator function is activated again, the last contents of the screen appear. The user has to actively delete the screen information (F10). The information is lost even after a restart (line voltage Off / On).

Note: The bottom line of the screen is not writable.

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.

Notice / warning signals

• No camera head detected
· the buttons ⑧ flash in a 500ms cycle with a simultaneous “Beep”.

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:**

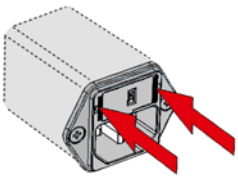
   Ensure that the fuse is correctly seated and avoid using force

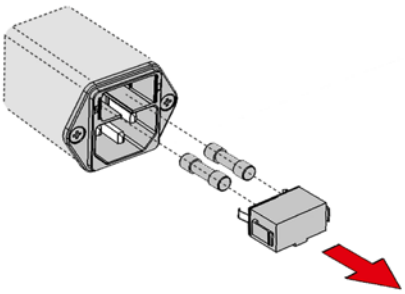
6. **restore the power supply / voltage supply:** By plugging in the mains plug.

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.

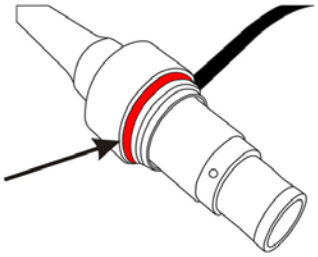
⚠ **Attention!** Do not autoclave any part of the equipment!

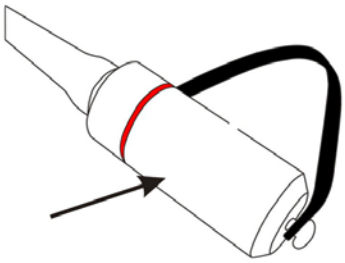
- **Camera head:**

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 tempe-rature.

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

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
	Video outputs may not be configured correctly	Reset the video outputs: When the device is restarted, press and hold the standby button for more than 5 seconds. The video outputs are reset.
	Monitor not turned on	Switch the monitor on
Menu not visible	BNC connections incorrectly inserted	Check the assignment of the BNC cables to the individual jacks
	Video output incorrectly configured	Check the menu item EXPERT / OUTPUT the setting of the video format (especially Sa / Sq)
Only parts of the image are visible on the monitor or the image is displayed incorrectly	BNC connections incorrectly inserted	Check the assignment of the BNC cables to the individual jacks
	Video output incorrectly configured	Check the menu item EXPERT / OUTPUT the setting of the video format (especially Sa / Sq
Image too dark	Parameter brightness (OSD) set at minimum	Increase brightness parameter
	Measuring range for brightness control is too large	Adjust parameter Area (OSD)
	Lighting insufficient	Improve lighting
	Monitor settings not optimal	Verify / correct the monitor settings

Picture too bright	Parameter brightness (OSD) set at maximum	Decrease parameter brightness
	Measuring range for brightness control is too small	Adjust parameter Area (OSD)
	Monitor settings not optimal	Verify / correct the monitor settings
	Shutter defective	Send unit for repair
Image blurred	Lens fogged	Clean / replace lens
	Lens poorly set	Set sharpness of the lens correctly
Poor picture quality	BNC or Y / C video output in use	Use HD SDI, HDMI DVI or RGB video output
	Lighting insufficient	Improve lighting / increase brightness (OSD)
Bad colors	No white balance	Perform white balance
	Color settings not optimal	Correct color settings (OSD or monitor)
	Monitor settings not optimal	Verify / correct the monitor settings
No colors	Color settings not optimal	Correct color settings (OSD or monitor)
	Video output jack or cable defective	Check / replace the video output jack or the cable
	Monitor settings not optimal	Verify / correct the monitor settings
Image / video storage is canceled (only with recording option)	Data rate is too high	Reduce data rate (quality) in the menu (Options/Rec. Board adjust)

Specifications

Technical data

General data	
Line voltage:	100-240 VAC | 50-60 Hz
Power requirements:	60 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 (WxHxD) Camera head: Ø 43mm, Length: 85,7mm (without grommet)
Weight:	Control unit: 6,2 kg Camera head: approx. 200g
Camera	
Image sensor:	3 x 1/3“ MOS
TV-System:	Progressiv Scan at 50 / 60 Hz
TV resolution:	3840 x 2160 Pixel (UHD)
Image resolution:	1600 TV-Linien; horizontal
Index ratio:	16:9
S/N:	54 dB
Archiving (optional)	
Picture format:	JPG (1920 x 1080)
Video format:	Full HD 1920 x 1080; Mpeg-4 (H.264 Codec); Frame rate: 60fps
Connections	
Video outputs Digital:	1 x HDMI 4K (3840 x 2160) 1 x HDMI Full HD (1920 x 1080) 1 x SDI 4K (4 x BNC) (3840 x 2160) 1 x SDI Full HD (1 x BNC) (1920 x 1080)

Video format:	HDMI output: 3840x2160/59.94p, 3840x2160/50p, 1920x1080/59.94p, 1920x1080/59.94i, 1920x1080/50p, 1920x1080/50i SDI output: 3840x2160/59.94p, 3840x2160/50p, 1080/59.94p, 1080/59.94i, 1080/50p, 1080/50i
Archiving:	1 x USB (A)
Other connections:	1 x USB (A) (USB-keyboard) 1 x Remote IN (footswitch) 2 x Remote OUT (video printer, video recorder,…) 2 x RJ45 (service interface)
Classification / Conformity	
Safety class (EN 60601-1)	1
Application part (Typ)	BF (Camera head)
Degree of protection:	IP20
Classification (EU) 2017/745, annex 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 4K UHD, fully assembled	740-2401

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:

Interference immunity tests	**Testing level**	**Fulfilled**	**Electromagnetic environment – Guidelines**
Discharge of static electricity (ESD) according to IEC 61000-4-2	8 kV Contact discharge ± 2; 4; 8; 15 kV Air discharge	Yes	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%.
High frequency electromagnetic fields according to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM 1 kHZ Output wires	Yes	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.
High-frequency electromagnetic fields according to IEC 61000-4-3 in close proximity to wireless communications equipment	28 V/m 450, 810, 870, 930 MHz 50% PM 18 Hz	Yes	
	28 V/m 1720, 1845, 1970, 2450 MHz 50% PM 217 Hz	Yes	
	27 V/m 385 MHz 50% PM 18 Hz	Yes	
	9 V/m 710, 745, 780, 5240, 5500, 5785 MHz 50% PM 217 Hz	Yes	

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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