

STORZ

KARL STORZ—ENDOSKOPE

**en Instructions for use
TELECAM C3 TC100**



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Table of contents

1	General information	6
1.1	Read the instructions for use	6
1.2	Read the instructions for use of compatible products	6
1.3	Scope	6
1.4	General signs and symbols	6
1.5	Description of warning messages	7
2	Normal use	8
2.1	Intended use	8
2.2	Indications	8
2.3	Contraindications	8
2.4	Patient groups	8
2.5	Target user populations	8
3	Safety and warning	9
3.1	Serious incidents	9
3.2	Observing ambient condition	9
3.3	Combination with other components	9
3.4	Damage due to ingress of liquid in electrical components	9
3.5	Dangers from electrical current	9
3.6	Electromagnetic interference	10
3.7	Product not clean	10
3.8	Failure of devices	10
4	Product description	11
4.1	Product overview	11
4.2	Possible combinations	12
4.3	Technical data	15
4.4	Symbols employed	16
4.4.1	Symbols on the packaging	16
4.4.2	Symbols on the product	17
4.4.3	Symbols on the user interface	18
4.4.4	Symbols on the type plate	21
4.5	Ambient conditions	21
5	Preparation	22
5.1	Unpacking the product	22
5.2	Inspecting the product	22
5.3	Setting up the product	22
5.4	Connecting the product	22
5.4.1	Connecting the potential equalization	22
5.4.2	Connecting the monitor	23
5.4.3	Connecting USB devices	23
5.4.4	Connecting the camera head or videoendoscope	24
5.4.5	Connecting the power supply	24
5.5	Putting the product into operation	24
5.5.1	Switching the product on and off	25
5.5.2	Performing the white balance	25
5.5.3	Performing the function test	26

6	Application	27
6.1	Camera head buttons	27
6.2	User interface	28
6.3	Quick menu	28
6.3.1	Performing functions via the Quick menu	28
6.3.2	Quick menu configuration	28
6.4	Function Space	29
6.5	Setup menu	29
6.5.1	Accessing the Setup menu	29
6.5.2	Changing the general product settings	30
6.6	Information area	30
6.6.1	Opening the information area	30
6.6.2	Accessing information on the system status or on the connected accessories	30
6.6.3	Changing the camera head button assignment	31
6.7	Patient area	32
6.8	Patient management	32
6.8.1	Patient handling	32
6.8.2	Labeling	34
6.8.3	Export Mode	34
6.9	Access and security concept	35
6.9.1	Password encryption	35
6.9.2	Role-based access system with user accounts	35
6.9.3	Configuring a role-based access system	36
6.10	Storage functions	36
6.10.1	Storing recordings	36
6.10.2	Transferring recording from internal storage to USB storage device	36
7	Maintenance, servicing, repairs, and disposal	37
7.1	Maintaining the product	37
7.2	Maintenance	37
7.3	Safety inspection in accordance with IEC 62353	37
7.3.1	Visual inspection	37
7.3.2	Electric measurements	37
7.3.3	Functional test	37
7.4	Repairing the product	37
7.5	Disposing of the product	38
8	Accessories and spare parts	39
8.1	Accessories	39
9	Electromagnetic compatibility	40
9.1	General notes on the operating environment	40
9.2	Accessories and cables	40
9.3	Table 1 – Compliance level for immunity tests	41
9.4	Table 2 – Test levels for proximity fields from HF wireless communications equipment	42
9.5	Table 3 – Test levels for radiated and conducted immunity tests	43
9.6	Table 4 – Emission class and group	44
9.7	Table 5 – Recommended separation distances between portable and mobile HF communications devices and the product	45
10	Errors and messages	46
10.1	Troubleshooting	46

11 Subsidiaries	47
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1 General information

1.1 Read the instructions for use

If the instructions for use are not followed, patients, users, and third parties may be injured or the product may be damaged.

- ▶ Read the instructions for use carefully and follow all the safety notes and warnings.
- ▶ Read the reprocessing instructions carefully and follow all the safety notes and warnings. The reprocessing instructions can be downloaded from www.karlstorz.com/ifu by entering the item number.
- ▶ Keep the instructions for use and reprocessing instructions in a safe place.

1.2 Read the instructions for use of compatible products

If the instructions for use of compatible products are not followed, patients, users, and third parties may be injured or the product may be damaged.

- ▶ Read the instructions for use of the compatible products carefully and follow all the safety notes and warnings.
- ▶ Read the reprocessing instructions of the compatible products carefully and follow all the safety notes and warnings.

1.3 Scope

This instruction manual is valid for:

Product name	Item number
TELECAM C3	TC100

1.4 General signs and symbols

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

Practical tip

-  This sign refers to useful and important information.

Actions to be performed

Action to be carried out by several steps:

- ✓ Prerequisite that must be met before carrying out an action.
- 1. Step 1
 - ⇒ Interim result of an action
- 2. Step 2
 - ⇒ Result of a completed action

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

- ▶ Step 1

Lists

- 1. Numbered list
- Unnumbered list, 1st level

- Unnumbered list, 2nd level

1.5 Description of warning messages

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

WARNING

WARNING

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

CAUTION

CAUTION

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

NOTICE

NOTICE

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

2 Normal use

2.1 Intended use

The TELECAM C3 is a camera control unit for use with camera heads or videoendoscopes and is used for visualizing and documenting endoscopic and microscopic procedures. The TELECAM C3 has no direct contact with the human body.

2.2 Indications

The camera control units do not come into direct contact with the patient; instead, they are used in conjunction with the corresponding accessories (videoendoscopes, camera, light source, and monitor) and the applied parts for the purpose of visualizing and documenting endoscopic and exoscopic procedures. Use is not restricted to certain medical disciplines.

2.3 Contraindications

No contraindications relating directly to the medical device are currently known. The responsible physician must decide whether the foreseen application is admissible based on the general condition of the patient.

2.4 Patient groups

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

2.5 Target user populations

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

3 Safety and warning

⚠ WARNING

Danger due to non-observance of warnings and safety notes

This chapter contains warnings and safety notes structured according to hazards and risks.

- ▶ 1. Carefully read and observe all warnings and safety notes.
- ▶ 2. Follow the instructions.

3.1 Serious incidents

A 'serious incident' includes incidents which, directly or indirectly, had, could have had or could have any of the following consequences:

- Death of a patient, user, or another person
 - Temporary or permanent serious deterioration in the medical condition of a patient, user, or another person
 - A serious threat to public health
- ▶ The manufacturer and appropriate authority must be notified of all serious incidents.

3.2 Observing ambient condition

If the device is operated in an environment which is not suitable, patients, users and third parties may be injured.

- ▶ Always store and operate the product in the prescribed ambient conditions.

3.3 Combination with other components

The use of unauthorized devices and components or unauthorized changes to the product can result in injuries.

- ▶ Only combine the product with devices and components that are approved for combined use by the manufacturer.
- ▶ Do not modify this equipment without authorization of the manufacturer.

3.4 Damage due to ingress of liquid in electrical components

In the case of electrical products, individual components or the product itself may be live. Liquid ingress into an electrical product may result in a short circuit or an unintentional transfer of current. The product is damaged as a result and patients, users and third parties may be injured.

- ▶ Do not store liquids near the product or on the product.
- ▶ If liquid has entered the product, pull out the plug and allow the product to dry completely.

3.5 Dangers from electrical current

An improper power supply may cause an electric shock and injure patients, users, or third parties. All electrical installations in the operating room in which the product is connected and used must meet applicable IEC standards.

- ▶ Do not touch the output jacks of the product and the patient at the same time during use
- ▶ Do not open the product.

- ▶ Use either the power cord supplied by KARL STORZ or a power cord which has the same properties and which bears a national mark of conformity.
- ▶ Make sure that the plug is completely clean and dry.
- ▶ To ensure reliable protective earth grounding, connect the product to a properly installed socket that is approved for use in the operation room. Routinely inspect the electrical plug and cord and do not use if the inspection reveals damage.
- ▶ Connect the product to a power supply with protective conductor.

If several products supplied with energy are used simultaneously, the patient leakage currents accumulate. These leakage currents can exceed the limit values and injure patients

- ▶ The patient applied parts of the simultaneously used products must be type BF or type CF.

3.6 Electromagnetic interference

The discharge of a defibrillator can cause image loss.

- ▶ If the image has not recovered after 4 seconds, switch the camera control unit off and on again.

3.7 Product not clean

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

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

3.8 Failure of devices

The product may fail during use.

- ▶ Perform an equipment test before use.
- ▶ If the image fails during the procedure, remove the camera from the endoscope and continue the procedure optically.
- ▶ If the surgery cannot be continued optically, determination of how to further the procedure is at the physician's discretion based on the surgical circumstances.
- ▶ Have a replacement system ready for each application.

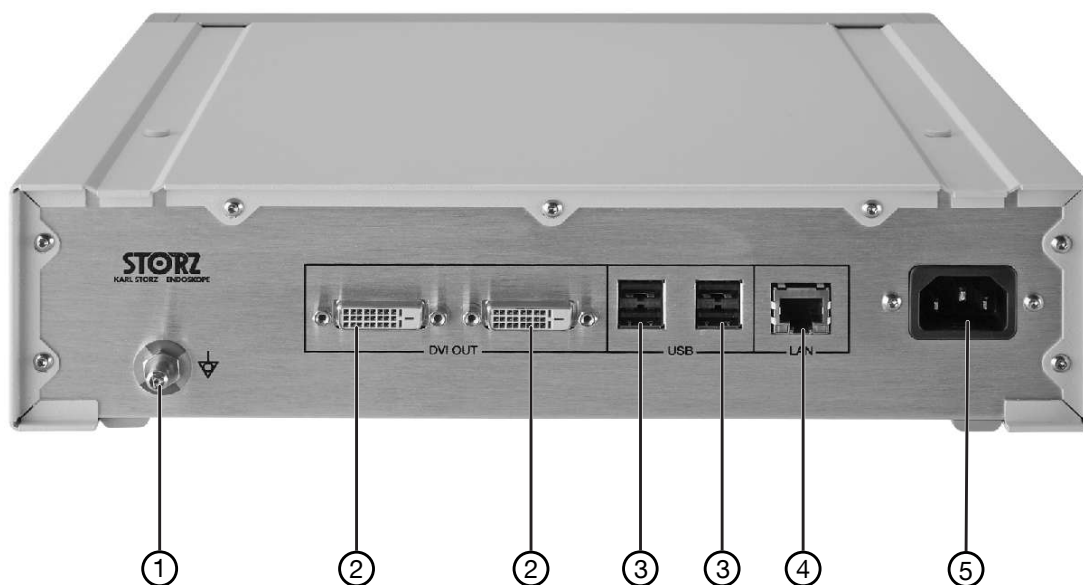
4 Product description

4.1 Product overview

The TELECAM C3 is a camera control unit for endoscopic image display and documentation. An intuitive user interface ensures simple and quick access as well as rapid understanding of menu navigation. Click here for a detailed description of the functions see chapter *User interface* [p. 28].



- | | | | |
|---|--------------------------|---|--------------------------|
| 1 | On/Off switch | 4 | X-Line camera connection |
| 2 | White balance | 5 | USB 2.0 (1x) |
| 3 | C-Line camera connection | | |



- | | | | |
|---|------------------------|---|-------------------|
| 1 | Potential equalization | 4 | LAN interface |
| 2 | DVI output (2x) | 5 | Power cord socket |
| 3 | USB 2.0 (4x) | | |

4.2 Possible combinations

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

Compatible camera heads for X-Line connection

Item	Order no.
IMAGE1 S HX	TH110
IMAGE1 S HX-P	TH111
IMAGE1 S D1	TH115
IMAGE1 S D1	TH116

Compatible camera heads for C-Line connection

Article	Order no.
H1 Camera head	TH130

Compatible videoendoscopes for X-Line connection

ENT

Article	Order no.
CCD Video Rhino-Laryngoscope	11101VP/VN
Strobo video rhino-laryngoscope	11101VPS, 11101VNS
HD Video Rhino-Laryngoscope	11101 HD

Urology

Item	Order no.
Video uretero-renoscope FLEX-XC	11278VSU, 11278VSUE
Video uretero-renoscope FLEX-XC	11278VS, 11278VSU
Flexible video urethro-cystoscope	11272VP, 11272VN
Flexible video urethro-cystoscope	11272VPU, 11272VNU
Flexible video cystoscope	11272VH, 11272VHU

Broncho

Item	Order no.
Video bronchoscope	11900BP, 11900BN
Video bronchoscope HD	11910T, 11910D
Video bronchoscope	11910P, 11910S
Video mediastinoscope	10973HD

Surgery

Item	Order no.
Flexible video choledochoscope	11292VP, 11292VPU
Flexible video choledochoscope	11292VS, 11292VSU

Gastroscopy

Item	Order no.
Slim gastroscope, 5.9/2/1100/PAL Slim gastroscope, 5.9/2/1100/NTSC	13820PKS, 13820NKS
Gastroscope 9.3/2.8/1100 PAL Gastroscope 9.3/2.8/1100 NTSC	13821PKS, 13821NKS
Duodenoscope 12.6/4.2/1260 PAL Duodenoscope 12.6/4.2/1260 NTSC	13885PKS, 13885NKS
Standard colonoscope 3.8/1400 PAL Standard colonoscope 3.8/1400 NTSC, set	13924PKS, 13924NKS
Standard colonoscope 3.8/1600 PAL Standard colonoscope 3.8/1600 NTSC	13925PKS, 13925NKS
Medium gastroscope 7.8/2.8/1100 PAL Medium gastroscope 7.8/2.8/1100 NTSC	13823PKS, 13823NKS
Slim colonoscope 11.2/3.4/1330 PAL Slim colonoscope 11.2/3.4/1330 NTSC	13926PKS/NKS

Item	Order no.
Slim colonoscope 11.2/3.4/1530 PAL Slim colonoscope 11.2/3.4/1530 NTSC	13927PKS, 13927NKS
Sigmoidoscope 11.2/3.4/800 PAL Sigmoidoscope 11.2/3.4/800 NTSC	13920PKS, 13920NKS
Gastroscope 12/2.8–3.8/1100 PAL Gastroscope 12/2.8–3.8/1100 NTSC	13826PKS, 13826NKS
FRIMBERGER duodenoscope, PAL FRIMBERGER duodenoscope, NTSC	13885FPKS, 13885FNKS
Colonoscope 12.9/3.8/1400 PAL Colonoscope 12.9/3.8/1400 NTSC	13924HPKS, 13924HNKS
Colonoscope 12.9/3.8/1600 PAL Colonoscope 12.9/3.8/1600 NTSC	13925HPKS, 13925HNKS

Proctology

Item	Order no.
TROIDL rectoscope, flexible, PAL TROIDL rectoscope, flexible, NTSC	13912PKS, 13912NKS

Veterinary

Item	Order no.
FLEX-XC Veterinary	60278VS, 60278VSU
Veterinary videoendoscope PV-SG 28-140	60714PKS, 60714NKS
Veterinary videoendoscope PV-G 28-140	60914PKS, 60914NKS
Veterinary videoendoscope PV-G 28-180	60118PKS, 60118NKS
Veterinary videoendoscope PV-G 28-250	60125PKS, 60125NKS
Veterinary videoendoscope PV-G 28-300	60130PKS, 60130NKS
Veterinary videoendoscope PV-G 34-325	60332PKS, 60332NKS
Veterinary videoendoscope PV-SG 20-110	60511PKS, 60511NKS

Compatible videoendoscopes for C-Line connection
Anesthesia

Item	Order no.
C-MAC S Imager	8403XS
C-MAC S Imager	8403XSI
C-MAC S Pediatric Imager	8403XSP
C-MAC Video laryngoscope MAC #0	8403EXC
C-MAC Video laryngoscope MAC #2	8403KXC
C-MAC Video laryngoscope MAC #3	8403AX
C-MAC Video laryngoscope MAC #3	8403AXC

Item	Order no.
C-MAC Video laryngoscope MAC #4	8403BX
C-MAC Video laryngoscope MAC #4	8403BXC
C-MAC Video laryngoscope D-BLADE	8403HX
C-MAC Video laryngoscope D-BLADE, Ped.	8403HXP
C-MAC Video laryngoscope MIL #0	8403DXC
C-MAC Video laryngoscope MIL #1	8403GXC
C-MAC Video laryngoscope MIL #2	8403MXC
Flex. Intubation Videoscope	11301ABX
Flex. Intubation Videoscope	11302BDX
Flex. Intubation Videoscope	11303BNX
Flex. Intubation Videoscope	11304BCX
C-MAC VS	10331BX

ENT

Article	Order no.
CMOS Video Rhino-Laryngoscope	11102CM
Video Esophagoscope	13303E

Urology

Article	Order no.
CMOS Video Cystoscope-Urethroscope	11272VE/VUE

Compatible disposable videoendoscopes for C-Line connection

Item	Order no.
FIVE S 3.5x65, sterile, for single use	091361-01
CMOS Video Esophagoscope SSU	091370-01
CMOS Video Rhino-Laryngoscope SSU	091330-01
FIVE S 5.3x65, sterile for single use	0915612-01
Video-uretero-renoscope FLEX-X ^{C1}	091271-01
Video-uretero-renoscope FLEX-X ^{C1}	091279-01

4.3 Technical data

TELECAM C3 TC100	
Power supply (AC)	100–240 V
Operating frequency	50/60 Hz
Power input	100–135 VA
Electrical protection class	I

TELECAM C3 TC100	
Applied part type according to IEC 60601-1	CF (X-Line) BF (C-Line)
Dimensions (W x H x D):	305 mm x 77 mm x 339 mm
Weight	2.75 kg
Memory device	
Memory interface	USB
Image format	JPEG
(Audio)/video format	MPEG-4
Internal memory size	50 GB
Interfaces	
Service port	RJ45
Video interface	2x DVI-D output
Footswitch connection	USB

4.4 Symbols employed

4.4.1 Symbols on the packaging

Symbol	Meaning
	Manufacturer
	Date of manufacture
	Medical device
	Article no.
	Serial number
	Number of products in the product packaging
	Unique Device Identifier
	Consult the printed or electronic instructions for use

Symbol	Meaning
	Note for the user to consult the instructions for use for important cautionary information such as warnings and precautions.
	Fragile, handle with care
	Keep dry
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	CE marking With this marking, the manufacturer declares the conformity of the product with the applicable EU directives. A code number after the CE mark indicates the responsible notified body. The EU directives relevant to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ.
	This side up

4.4.2 Symbols on the product

Symbol	Meaning
	Follow the instructions for use. The color may differ on the product. The symbol is black/white on the packaging label.
	Ready/standby button
	USB
	Applied part type BF
	White balance
	Applied part type CF defibrillation protection
	Potential equalization connector

Symbol	Meaning
	Prevention of pollution by electronic devices
	Separate collection of electrical and electronic devices. Do not dispose of in household refuse.
	Consult the printed or electronic instructions for use

4.4.3 Symbols on the user interface

Symbol	Meaning
	White Balance Performs the white balance.
	Freeze Freezes the image. During this time, the live image is shown in the top right-hand corner of the monitor.
	Zoom Digitally magnifies the display.
	Orientation Flips the displayed image vertically or horizontally or rotates it through 180°.
	Enhance Sets the digital fiberscope filter (anti-moiré filter or anti-grid filter) to two levels (A, B). These filters reduce interfering artifacts, such as the moiré effect and display of the fiberscope grid. Use filter A to reduce small honeycomb-like grids. Use filter B to reduce larger honeycomb-like grids.
	Light Turns the light source on or off.
	Close Exits the Quick menu. Alternatively, exit the menu using the ESC button on the keyboard. The Close button appears only if a keyboard is used or the product is operated via the camera head buttons.
	Still Captures a still image.

Symbol	Meaning
	Video Starts or stops a video recording.
	Training Mode Displays a circle in the center of the image. The training mode can be used specifically for endoscopy training.
	Brightness Sets the brightness of the camera.
	Print Immediately prints all images in the print queue. This button appears only if a printer is connected.
	Swap Cameras Toggles between two connected cameras.
	Function Space Selects various camera functions or changes the product settings.
	Setup Changes general product settings.
	Display Language Selects the language for the user interface.
	Keyboard Language Selects the language for the on-screen keyboard. The selected keyboard language is used for an external keyboard.
	DVI Signal Output Selects the image refresh rate between 50 and 60 Hz for the DVI output. The product has to be restarted after the frequency is changed.
	Date and time Sets the date, time, and display format.
	Patient Management Manages the settings for handling patient data.

Symbol	Meaning
	Module information Calls up all the necessary information on the system and the connected camera heads or videoendoscopes.
	Quick menu settings Configures the Quick menu.
	Software Update Updates the software of the product and of the connected camera heads and videoendoscopes.
	Software Licenses A list of the open source software included in the product, and the open source software license terms can be viewed here.
	Logged Events Displays the system log and exports it via USB. Via <i>Audit Logs</i> , you can view the audit log and export it via USB.
	Reset Resets the product to its factory settings.
	Access and Security Manages access to sensitive areas of the system.
	Camera Calls up the item number, name, and camera head button assignment of a connected compatible camera head.
	Foot Switch Calls up the item number, name, and button assignment of a connected compatible footswitch.
	Printer Calls up the printer configuration of a connected compatible printer.
	USB Storage Calls up the storage space currently used as well as the free storage space.
	Internal Storage Calls up the storage space currently used as well as the free storage space. Transfers stored data to a USB storage device.

4.4.4 Symbols on the type plate

Symbol	Meaning
	Manufacturer
	Separate collection of electrical and electronic devices. Do not dispose of in household refuse.
	Prevention of pollution by electronic devices

4.5 Ambient conditions

Storage/transport conditions	
Temperature	-20 °C ... +60 °C (-4 °F ... +140 °F)
Relative humidity (non-condensing)	5 – 95 %
Air pressure	500 – 1,080 hPa
Operating conditions	
Temperature	0 °C ... 40 °C (32 °F ... 104 °F)
Relative humidity (non-condensing)	20 – 95 %
Max. operating altitude	3,000 m

5 Preparation

5.1 Unpacking the product

1. Carefully remove the product and accessories from the packaging.
2. Check the delivery for missing items and any possible damage.
3. In the case of damage, hidden defects, and short deliveries, document their nature and extent and contact the manufacturer or supplier immediately.
4. Keep packaging for further transport.

5.2 Inspecting the product

1. Check the product and the camera head or videoendoscope for external damage.
2. Ensure that the camera head cable or videoendoscope cable is not damaged or kinked.
3. Point the camera head or the videoendoscope toward an object to check the display quality on the monitor.

5.3 Setting up the product

⚠ WARNING

Blocked air inlets and air outlets! Risk of fire!

If the air inlets and outlets are blocked, the product may overheat. This can cause the product to fail and start a fire. Users, patients, and third parties may be injured.

- Remove any blockages in the air inlets and outlets when setting up the product.

The product can be operated free-standing, on a video cart, or in a rack.

1. Set the product down on a horizontal, flat surface or in a video cart. Make sure that the power cord can be unplugged at any time.
2. Ensure adequate air circulation.
3. For best thermal performance position the product at the top of the device stack.

5.4 Connecting the product

5.4.1 Connecting the potential equalization

1. The product's ground line should be installed by a qualified electrician.
2. Connect the potential equalization cable to the plug connection for potential equalization on the device.



3. Connect the potential equalization cable to the outlet in the treatment room.

5.4.2 Connecting the monitor

- ✓ The connected monitor supports a resolution of 1920 x 1080 pixels.
1. Connect the monitor to the TELECAM C3 via one of the DVI outputs on the rear of the device. Connect the primary work screen to DVI1.



5.4.3 Connecting USB devices

Peripheral devices are required to navigate in the menu and trigger menu functions.

Action	Possible peripheral device
Entering patient data	Keyboard
Navigating in menus	Keyboard, mouse, camera head buttons, footswitch
Triggering menu functions	Keyboard, mouse, camera head buttons, footswitch

The TELECAM C3 USB ports are suitable for connecting the following peripheral devices:

- Keyboard or mouse
 - Printer
 - Footswitch
 - USB stick, FAT32 formatted
 - USB to ACC adaptor
1. Connect the peripheral device to the USB interface on the product.



5.4.4 Connecting the camera head or videoendoscope

- ✓ The plug must be clean and free of debris. Dry a damp plug with a sterile cloth before connecting it.
- 1. Insert the C-Line camera plug into the socket for the C-Line camera connection.



- 2. Insert the X-Line camera plug into the socket for the X-Line camera connection.

5.4.5 Connecting the power supply

- ✓ Only use power cords that are approved for use in hospitals for this camera.
- 1. The product may only be operated with the line voltage stated on the rating plate.
- 2. Before connecting the devices to the power supply, check that the values on the power sockets match the values on the device's type plate.
- 3. Insert the device plug of the power cord into the TELECAM C3 power socket.
- 4. Connect the power plug of the TELECAM C3 to a power socket.

5.5 Putting the product into operation

⚠ CAUTION

Image and function malfunctions!

Incorrectly connected camera connections can cause image interference and malfunctioning.

- ▶ Ensure that the camera connector is always attached properly and securely before starting the procedure.

⚠ WARNING

HF electrodes and laser probes! Risk of injury!

If HF electrodes and laser probes are activated in the instrument channel, the patient may be seriously injured.

- ▶ Only apply power to the HF electrodes and laser probe once the active parts have left the instrument channel and are in the user's field of vision, and the site of the operation is clearly recognizable

5.5.1 Switching the product on and off

1. Press the **On/Off** switch.
⇒ The product is switched on.



2. Press the **On/Off** switch.
⇒ The product is switched off.

5.5.2 Performing the white balance

- ❗ The white balance must be performed again after replacing the endoscope.
 - ✓ Perform a white balance before each use.
 - ✓ Perform a white balance each time the endoscope is replaced.
1. Ensure that the imaging instrument (e.g., a camera head with a connected endoscope, videoendoscope, or exoscope) is connected to the TELECAM C3 and displays a live image on the monitor.
 2. Connect the light source to the imaging instrument via the light cable.
 3. Point the tip of the imaging instrument at any clean white surface (e.g., white gauze).
⇒ The light source emits enough light to sufficiently illuminate the white surface. The monitor displays a completely white and well illuminated live image.
 4. Press the **White Balance** button on the front of the TELECAM C3 or the **White Balance** button in the live menu to perform the white balance.



5. Look at the monitor to determine whether the white balance was successful or not.

5.5.3 Performing the function test

- ✓ Perform the function test before each use.
- 1. Check the TELECAM C3 and the camera head or videoendoscope for external damage.
- 2. Ensure that the camera head cable or videoendoscope cable is not damaged or kinked.
- 3. Point the camera head or the videoendoscope toward an object and check the quality of the display on the monitor.

6 Application

6.1 Camera head buttons

All compatible camera heads and X-Line videoendoscopes feature three buttons for retrieving programmed functions and for menu control.



- 1 Scroll down
- 2 Scroll up

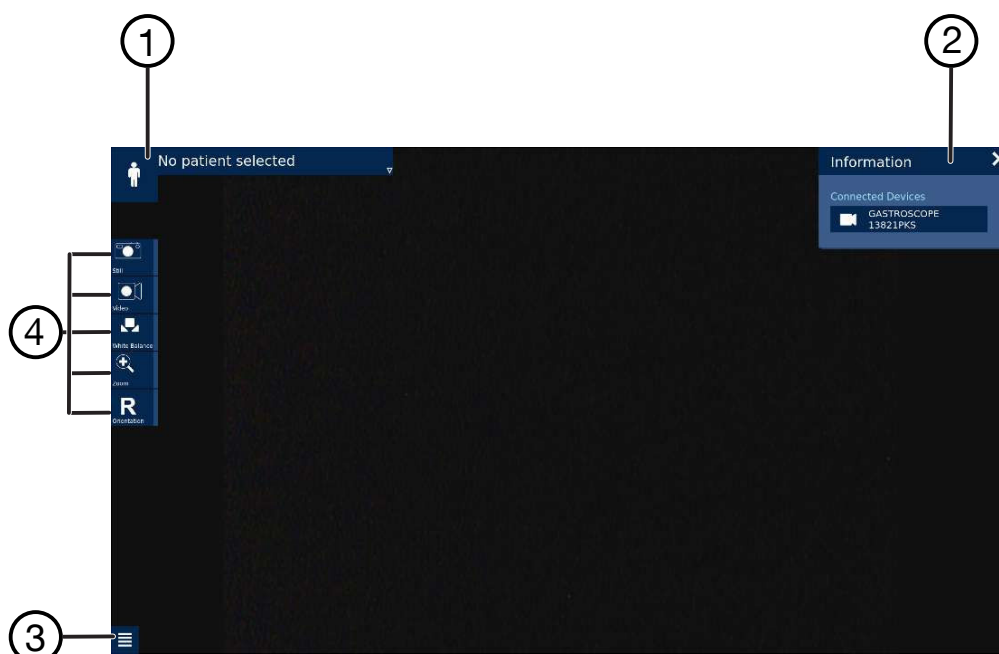
- 3 **Menu** button

Camera head button functions

Button	Function
Scroll down	Scrolls down the menus or options
Scroll up	Scrolls up the menus or options
Menu button	Activates a highlighted option Selects the Quick menu

6.2 User interface

Main screen



- | | |
|---|---|
| 1 Patient area | 3 Function Space (access to the Setup menu) |
| 2 Information area with information bar and information panel | 4 Quick menu |

6.3 Quick menu

The Quick menu shows the symbols for frequently used camera functions or device settings on the left-hand side of the main screen. The Quick menu can be configured individually. Up to 8 functions can be added. Functions that are unavailable are grayed out.

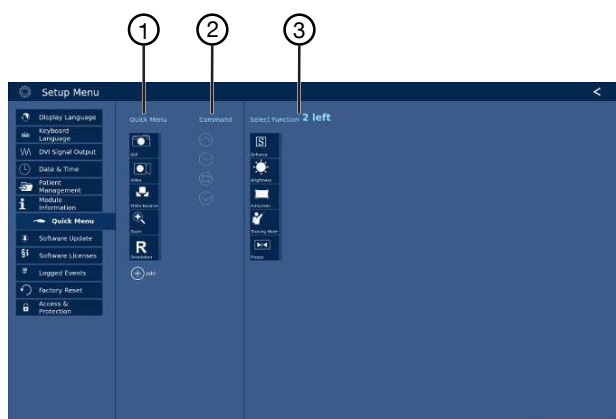
6.3.1 Performing functions via the Quick menu

Performing functions via the Quick menu

- ✓ The main screen will be displayed.
- 1. Press the corresponding symbol for the desired function.
- 2. Activate the desired function.

6.3.2 Quick menu configuration

The Quick menu configuration window is divided into three columns. The functions can be moved, replaced, added or removed.



1. To change the configurations, press the **Quick Menu** button in the Setup menu.
2. Restart the product to activate the configuration.

Symbol	Meaning
Quick Menu column	Displays the functions that are set up for quick access.
	Press the button to add a new function to the Quick menu.
Command column	Edits a selected function.
	Press the button to move a selected function upward in the Quick menu.
	Press the button to remove a selected function from the Quick menu.
	Press the button to replace a selected function with one from the <i>Select Function</i> column.
	Press the button to move a selected function downward in the Quick menu.
Select Function column	Displays the functions that are not currently configured in the Quick menu.

6.4 Function Space

The function space contains all functions that were not configured in the Quick menu. Some icons in the function space are grayed out until a camera head is connected.

6.5 Setup menu

The general settings can be changed in the Setup menu.

6.5.1 Accessing the Setup menu

1. Press the **Function Space** button.

2. Press the **Setup** button.
⇒ The Setup menu opens.

6.5.2 Changing the general product settings

1. Press the corresponding symbol for the setting.
2. Select the desired setting.

6.6 Information area

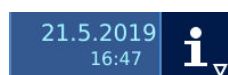
The information area consists of the following elements:

Information bar	Overview of the system status
Information panel	System status information Information on the connected accessories

6.6.1 Opening the information area

Opening the information area

1. Press the **i** button in the information bar.



⇒ This opens the information panel.



6.6.2 Accessing information on the system status or on the connected accessories

- Press the corresponding symbol for the system status or the connected accessories.

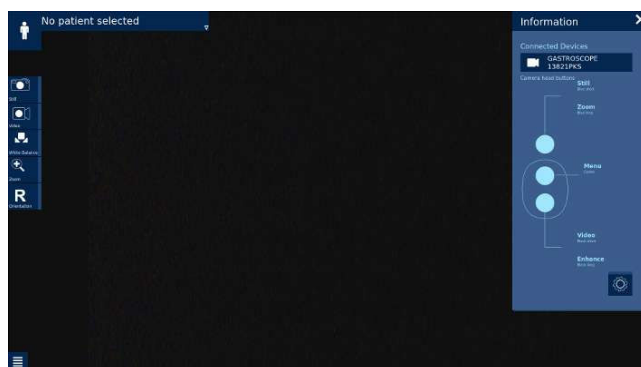
Symbol	Meaning
	Calls up all the necessary information on the system and the connected camera heads or videoendoscopes.
	Calls up information about a connected compatible camera head or a connected compatible videoendoscope: – Item number – Item name

Symbol	Meaning
	– Camera head button assignment
	Calls up information about the footswitch: – Item number – Item name – Button assignment
	Calls up the printer configuration of a connected compatible printer. Configures functions if a printer is connected: – Number of images per page – Number of copies – Print images during the current treatment
	Calls up the storage space currently used as well as the free storage space.
	Calls up the storage space currently used as well as the free storage space. Transfers stored data to a USB storage device. Internally stored data is deleted automatically after successful transfer in order to create space for new recordings.

6.6.3 Changing the camera head button assignment

It is only possible to change the camera head button assignment for videoendoscopes where the camera head buttons are not permanently assigned on the videoendoscope.

- ✓ A compatible camera head or videoendoscope is connected.
- 1. Select the connected product from **Connected Devices** in the **Information** panel.
 - ⇒ The camera head button assignment is shown true to original.

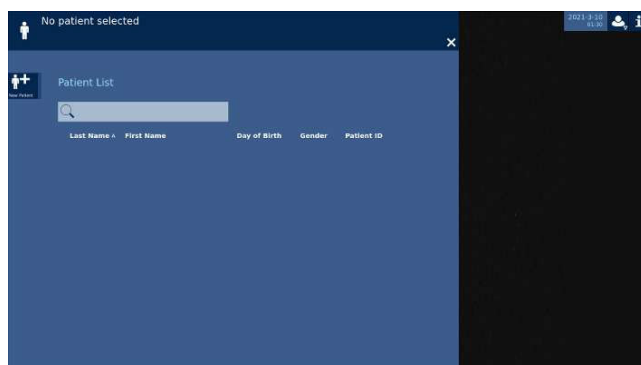


- 2. Press the **Settings** button.
- 3. Change the button assignment as required.

6.7 Patient area

Depending on the configuration, the following entries or queries are possible in the patient area:

- Manual entry of one or more patient records
- Accessing and selecting patient records from a patient workload



6.8 Patient management

The system does not contain patient data as standard.

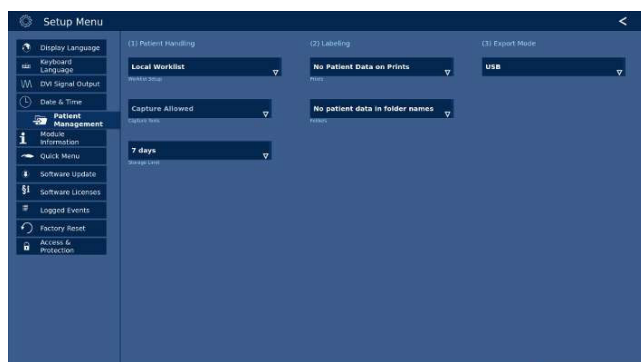
The functions for managing patient data must be activated by the user in the patient data privacy settings. Patient information is available only if the corresponding settings have been made. Upon activating the functions, the user assumes responsibility for all patient-related data that is managed in accordance with the applicable national data protection laws.

All safety-relevant actions are recorded and saved by the system. KARL STORZ assumes no legal liability or responsibility for the loss, accuracy, damage, or disclosure of patient data that has been managed using the TELECAM C3.

The configuration of the **Patient Management** (Patient Data Privacy) menu is password-protected.

The **Patient Management** menu is divided into 3 areas:

- (1) Patient Handling
- (2) Labeling
- (3) Export Mode



6.8.1 Patient handling

The following sub-menus for processing patient data are available for selection in the **Patient Handling** sub-menu:

Sub-menu	Function
Worklist Setup	Specifies the settings for working with patient data
Capture Tools	Specifies the settings for capturing images and recording videos
Storage limit	Specifies the settings for data storage

6.8.1.1 Editing the Worklist Setup

1. Call up the **Worklist Setup** sub-menu.
2. Specify the desired setting for working with patient data.

Option	Function
No Worklist / Patient Entry (selected by default)	Working with patient data is not allowed. The data is not stored on the product. The data can be exported via the USB interface.
Local Worklist	Patient data is stored and can be edited in a patient worklist.

6.8.1.2 Editing tools

1. Call up the **Capture Tools** sub-menu.
2. Specify the desired setting for capturing images and recording videos.

Option	Function
No Capture	Images or video recordings are not stored.
Capture Allowed (default setting)	Images or video recordings are stored with patient information.
Anonymous recording of media files	Images or video recordings are stored anonymously.

6.8.1.3 Editing the storage limit

1. Call up the **Storage Limit** sub-menu.
2. Specify the desired setting for data storage.

Option	Function
Infinite	Patient records, images or video recordings are stored indefinitely.
Power cycle	Patient records, images or video recordings are deleted in chronological order when the storage capacity is exhausted. Deleted data cannot be recovered.
1 day	Patient records, images or video recordings are stored for 1 day.
7 days (default setting)	Patient records, images or video recordings are stored for 7 days.
30 days	Patient records, images or video recordings are stored for 30 days.
90 days	Patient records, images or video recordings are stored for 90 days.

6.8.2 Labeling

The **Labeling** sub-menu is used to set the labeling of prints.

Editing the labeling

1. Call up the **Labeling** sub-menu.
2. Specify the desired setting for labeling prints.
3. Specify the desired setting for labeling folders.

Option	Function
No patient data on print-outs (default setting)	Patient data is suppressed on print-outs.
Patient data on print-outs	Patient data is specified on print-outs.
No patient data in folder names (selected as standard)	Patient data is not included in folder names.
Patient data in folder names	Patient data is included in folder names.

6.8.3 Export Mode

Data export is set in the **Export Mode** sub-menu.

Editing Export Mode

1. Call up the **Export Mode** sub-menu.
2. Specify the desired setting for data export.

Option	Function
USB (default setting)	Exporting data to a USB storage device is allowed.
No Export	Exporting data to a USB storage device is not allowed.

6.9 Access and security concept

Certain settings are protected by an access system to prevent the product and the sensitive areas of the menu from being accessed by unauthorized parties.

There are two variants of access control:

- Password encryption
- Role-based access system via user accounts

Specifying the access system

- When configuring the product, select password encryption or the role-based access system via user accounts.

6.9.1 Password encryption

Certain settings are password-protected to prevent the product and the sensitive areas of the menu from being accessed by unauthorized parties.

The default password when the product is delivered is: *90290245*. The default password must be changed the first time it is used.

Changing the password

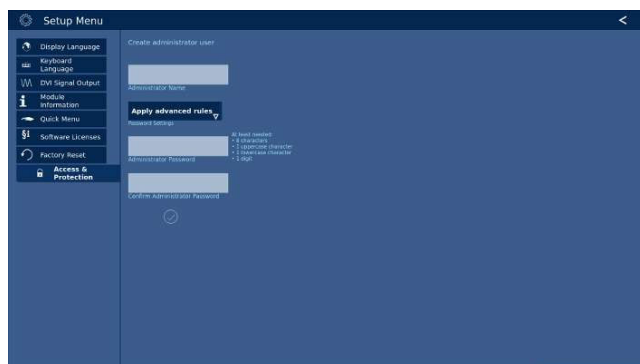
- ✓ The Setup menu is open.
- 1. Open the **Access & Protection** sub-menu.
- 2. Choose a personal password.

If the personal password is lost, the product's factory settings have to be restored. In addition to all settings, the patient data is also deleted from the product.

6.9.2 Role-based access system with user accounts

When this option is selected, the user account has only limited access to sensitive areas.

1. Create an Administrator account.
2. Define the password rules.
 - ⇒ The password rules apply to all further passwords.
3. Create a new password.
4. Configure all further settings.



The following roles can be selected:

- Administrator: Full access to all functions and settings
- Operating room personnel: Access to patient data. No access to patient data security or storage medium

- Technician: Access to device settings, e.g. updates. No access to patient data or other sensitive areas.

All safety-relevant actions are recorded and saved by the system. KARL STORZ assumes no legal liability or responsibility for the loss, accuracy, damage, or disclosure of patient data that has been managed using TELECAM C3.

6.9.3 Configuring a role-based access system

Additional user accounts can be created and existing ones can be edited or deleted. The maximum number of user accounts is limited.

1. A name, the corresponding role, and a password have to be defined for each user account.
2. Under **Login Message**, enter a customized message to be shown in the login area before the system grants access to sensitive areas.
3. Under **Password Rules**, specify whether and which rules are to be applied when passwords are assigned.
4. Under **Automatic Logout**, specify whether the system is to log out a user after an individually definable period of inactivity has expired.
 - ⇒ Once the role-based access system has been activated, a further menu item with the name **Login** appears in the main screen next to the information area.
5. Select **Deactivation** to deactivate the role-based access system.
 - ⇒ The encryption of sensitive menus via password is activated automatically.

Under **Login**, all system users can log in using their user account and password. If no users are logged in, certain areas such as the patient area and the settings for patient data security and storage cannot be called up.

6.10 Storage functions

The product comprises the following storage options:

- Internal storage
- USB storage

6.10.1 Storing recordings

- ✓ The function for storing recordings in the **Capture Tools** sub-menu is enabled.
- ✓ The patient area is open.
- ✓ Approx. 50 GB of storage space are available for internal storage.
- ▶ Press the **End Treatment** button.
 - ⇒ USB storage device connected: The data is saved and transferred to the USB storage device.
 - ⇒ No USB storage device connected: The data is stored internally and can be transferred manually to a storage device at a later time.

6.10.2 Transferring recording from internal storage to USB storage device

1. Open the information area.
2. Press the **Internal Storage** button.
3. Activate the data export to the USB storage device.
 - ⇒ The data is transferred to the USB storage device and deleted from the internal storage. The transfer status is displayed in the information area.

7 Maintenance, servicing, repairs, and disposal

7.1 Maintaining the product

If they are not described in more detail here, maintenance activities may only be performed by KARL STORZ or by a company authorized by KARL STORZ.

7.2 Maintenance

The following maintenance intervals are recommended:

Interval	Activity	To be performed by
annually	Safety test	KARL STORZ service technicians

7.3 Safety inspection in accordance with IEC 62353

⚠ WARNING

Risk of injury due to product deficiencies!

Patients, users, and third parties may be injured as a result of deficiencies with the product and accessories.

- ▶ Shut down the product.
- ▶ Have the deficiencies repaired by persons authorized by KARL STORZ.

Regardless of the national accident prevention regulations and testing intervals for medical devices, for this device safety checks must be performed as repeat inspections according to IEC 62353 and recorded by a qualified electrician at least once a year. Detailed specifications regarding the scope and execution of the safety inspection can be found in the service manual.

7.3.1 Visual inspection

1. Check the product and accessories for any mechanical damage.
2. Check labels for readability.

7.3.2 Electric measurements

i Limit values for electrical measurements can be found in the current IEC 62353.

1. Measure the protective ground resistance.
2. Measure the earth leakage current.
3. Measure the touch current.
4. Measure the patient leakage current.

7.3.3 Functional test

1. Perform a functional test in line with the instructions for use.
2. Document the results of the safety inspection.

7.4 Repairing the product

Repair work may only be performed by KARL STORZ or by a company authorized by KARL STORZ. The interventions described in this instruction manual are exempt from this rule.

- Please contact your local KARL STORZ subsidiary or authorized dealer (see the list of subsidiaries).

Contaminated devices may not be shipped. To prevent contact infections and airborne infections, products must first be decontaminated. KARL STORZ reserves the right to send back contaminated products.

7.5 Disposing of the product

The product meets the requirements of the Directive on Waste Electrical and Electronic Equipment (WEEE).

Within the scope of application of this directive, KARL STORZ SE & Co. KG is responsible for the proper disposal of this product.

1. The product must be disposed of in accordance with the applicable national laws and regulations at a suitable collection point for the reprocessing of electrical and electronic equipment.
2. Contact KARL STORZ SE & Co. KG, a KARL STORZ branch or an authorized dealer to find out the address of the collection point in your area.

8 Accessories and spare parts

8.1 Accessories

Article	Order no.
Videoendoscope adaptor 0°	TC001
Videoendoscope adaptor 90°	TC013
USB to ACC adaptor	TC009
ACC connecting cable, to control peripheral devices, length 180 cm	20221070
Power cord, length 300 cm	400A
Power cord, US version, 200 cm	400B
USB flash drive, 32 GB	20040282
DVI connecting cable, length 200 cm	20040086
DVI connecting cable, length 300 cm	20040089
USB color printer	549M
USB silicone keyboard with touchpad, DE	20040241DE
USB silicone keyboard with touchpad, CH	20040241CH
USB silicone keyboard with touchpad, ES	20040241ES
USB silicone keyboard with touchpad, FR	20040241FR
USB silicone keyboard with touchpad, IT	20040241IT
USB silicone keyboard with touchpad, PT	20040241PT
USB silicone keyboard with touchpad, RU	20040241RU
USB silicone keyboard with touchpad, SE	20040241SE
USB silicone keyboard with touchpad, US	20040241US

9 Electromagnetic compatibility

9.1 General notes on the operating environment

The product is suitable for use in professional healthcare settings. Professional healthcare facilities include physician offices, dental offices, limited care facilities, freestanding surgical centers, freestanding birth centers, multiple treatment facilities, hospitals (emergency rooms, patient rooms, intensive care, surgical rooms, outside the HF-shielded room of an ME system for MRT).

- ❗ The emission characteristics of this product make it suitable for use in industrial areas as well as in hospitals (CISPR 11 Class A) and other professional healthcare environments. If it is used in a residential environment (for which CISPR 11 Class B is normally required), the product may not offer sufficient protection for radio transmission operation. The user might need to take mitigation measures, such as relocating or re-orienting the product.

⚠ WARNING

MR unsafe!

This product is MR unsafe.

- ▶ Keep the product away from magnetic resonance Imaging scanner room

⚠ WARNING

Electromagnetic interferences! Malfunction!

Use of this equipment adjacent to or stacked with other equipment could result in improper operation.

- ▶ Avoid this situation.
- ▶ If such use is necessary: Ensure that this equipment and the other equipment are operating normally.

⚠ WARNING

Reduced immunity or increased emissions! Malfunction!

Use of the product with accessories, transducers and cables other than those specified in this manual may result in increased emissions or decreased immunity.

- ▶ Only use the accessories specified in the manual.

9.2 Accessories and cables

⚠ WARNING

Degradation of performance! Malfunction!

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) could result in degradation of the performance of the product.

- ▶ Do not use portable communications equipment closer than 30 cm (12 inches) to any part of the product, including cables.

System cables and maximum lengths used for EMC compliance.				
Type	Shield	Length [m]	Ferrite	Use
Mains cord	No	3	No	Power supply
Two-pedal footswitch	Yes	2	No	Device control, socket rear
USB keyboard with touchpad	Yes	2	No	Data input
Camera	Yes	3	No	Image transmission
DVI cable	Yes	3	Yes	Signal transmission

9.3 Table 1 – Compliance level for immunity tests

Guidelines and manufacturer's declaration – electromagnetic immunity

The product is intended for use in the electromagnetic environment specified below. The user of the product should make sure that it is used in such an environment.

Interference immunity tests	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should be made of wood, concrete, or covered with ceramic tiles. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transients/bursts acc. to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines 100 kHz repetition	± 2 kV for power lines ± 1 kV for input and output lines 100 kHz repetition	The power supply quality should be that of a typical commercial or hospital environment.
Surges acc. to IEC 61000-4-5	± 1 kV voltage outer conductor – outer conductor ± 2 kV voltage outer conductor – ground	± 1 kV voltage outer conductor – outer conductor ± 2 kV voltage outer conductor – ground	The power supply quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations acc. to IEC 61000-4-11	<u>Voltage dip:</u> Dip to 0% for 1 cycle at 0° phase angle Dip to 70% for 25/30 cycles at 0° phase angle Dropout to 0% for 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° phase angles <u>Voltage interruption:</u>	<u>Voltage dip:</u> Dip to 0% for 1 cycle at 0° phase angle Dip to 70% for 25/30 cycles at 0° phase angle Dropout to 0% for 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° phase angles <u>Voltage interruption:</u>	The power supply quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation in the event of interruptions to the power supply network, it is recommended that the product be oper-

Interference immunity tests	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
	100% for 250/300 cycles	100% for 250/300 cycles	ated with an uninterruptible power supply or a battery.
Magnetic field at the power frequency (50/60 Hz) acc. to IEC 61000-4-8	30 A/m at 50 Hz / 60 Hz	30 A/m at 50 Hz / 60 Hz	If image distortion occurs, it may be necessary to install the product further from sources of electromagnetic fields or to install magnetic shielding. Before the product is installed, the electromagnetic field should be measured to ensure that it is sufficiently low.
Immunity test acc. to IEC 61000-4-3 for radiated, radio-frequency electromagnetic fields	3 V/m 80 MHz to 2.7 GHz * Refer to Table 2 for wireless proximity RF field test levels	3 V/m 80 MHz to 2.7 GHz	
Immunity to conducted disturbances, induced by radio-frequency fields acc. to IEC 61000-4-6	3 V _{rms} on 150 kHz to 80 MHz 1 kHz 80% AM modulation 6 V _{rms} in ISM band	3 V _{rms} on 150 kHz to 80 MHz 1 kHz 80% AM modulation 6 V _{rms} in ISM band	

9.4 Table 2 – Test levels for proximity fields from HF wireless communications equipment

Test frequency MHz	Frequency band MHz	Radio service	Modulation	Immunity test level V/m	Compliance level V/m
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	27	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine wave	28	28
710	704 – 787	LTE band 13 and 17	Pulse modulation 217 Hz	9	9
745					
780					
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation 18 Hz	28	28
870					
930					

Test frequency MHz	Frequency band MHz	Radio service	Modulation	Immunity test level V/m	Compliance level V/m
1720	1700 – 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE band 1, 3, 4, 25, UMTS	Pulse modulation 217 Hz	28	28
1845					
1970					
2450	2400 – 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
5500					
5785					

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

Guidance and manufacturer's declaration – Electromagnetic immunity

The product is intended for use in the electromagnetic environment specified below. The user should make sure that it is used in such an environment.

Immunity tests	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – Guidance
Conducted RF disturbances acc. to IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz 6 V _{eff} in ISM and between 0.15 MHz and 80 MHz	3 V _{rms} 150 kHz to 80 MHz 6 V _{eff} in ISM and between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended safety distance calculated from the equation applicable to the frequency of the transmitter. Recommended safety distances: $d = 1.2 \sqrt{P}$ Where P is the rated power of the transmitter in watts [W] according to the information provided by the transmitter manufacturer and d is the recommended safety distance in meters [m].
Radiated RF disturbances acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	

Immunity tests	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – Guidance
			The field strengths of fixed transmitters as determined by an electromagnetic site survey ^a should be less than the compliance level ^b in all frequency ranges. $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz Interference may occur in the vicinity of devices marked with the following symbol: 
Note: At 80 MHz and 800 MHz, the higher frequency range applies. Note: These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by absorptions and reflections of buildings, objects, and people. ^a Field strengths from fixed transmitters, e.g., base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment with regard to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location where the product is being used exceeds the compliance levels above, the product should be monitored to ensure that it is functioning as intended. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the product. ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

9.6 Table 4 – Emission class and group

Guidelines and manufacturer's declaration – Electromagnetic emissions

The product is intended for use in such an environment as specified below. The customer or user of the product should ensure that it is used in such an environment.

Interference emission measurements	Compliance	Electromagnetic environment – guidelines
RF emissions acc. to CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions acc. to CISPR 11	Class A	The device is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Emission of harmonic oscillations acc. to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions acc. to IEC 61000-3-3	Complies	

9.7 Table 5 – Recommended separation distances between portable and mobile HF communications devices and the product

The product is intended for use in an electromagnetic environment in which HF disturbances are controlled. The customer or user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communications equipment (transmitters) and the product as recommended below, according to the output energy of the communications equipment.

Rated maximum output power of the transmitter [W]	Separation distance d [m] according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose maximum rated power is not listed in the table above, the recommended separation distance d in meters (m) can be estimated using the equation from the respective column, whereby P is the maximum rated power of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for higher frequency range applies.

Note: These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by absorptions and reflections of buildings, objects, and people.

- ❗ The product was tested for compatibility with HF surgical devices in accordance with IEC 60601-2-2 Appendix BB.

10 Errors and messages

10.1 Troubleshooting

Symptom	Possible causes	Actions
Loss of image for longer than 4 seconds	Defibrillator discharged.	▶ Switch the device off and back on again.
Update failed		▶ Restart the device ▶ Repeat the procedure ▶ Contact Service
Incompatible camera head		▶ Replace the camera head

11 Subsidiaries

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