

STORZ

KARL STORZ—ENDOSKOPE

**en Instructions for use
IMAGE1 S**



02-2024

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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

The products listed here may not yet be available in all countries due to differences in approval requirements.

These instructions for use apply to the following products up to and including software version 4.5:

Camera control units

Product name	Item number
IMAGE1 S CONNECT	TC200
IMAGE1 S CONNECT II	TC201
IMAGE1 S H3-LINK	TC300
IMAGE1 S X-LINK	TC301
IMAGE1 S D-LINK	TC302
IMAGE1 S 4U-LINK	TC304

Extension cables

Product name	Item number
IMAGE1 S D3-LINK Extension Cable	TC015

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

Camera control units

Camera control units are for use with camera heads or videoscopes and are used for visualizing and documenting endoscopic and microscopic procedures.

Camera control units do not have direct contact with the human body.

Extension cable

The extension cable is used for extending the camera head cable for connection to the IMAGE1S camera control unit.

The extension cable has no direct contact with the human body.

2.2 Indications

Camera Control Units

The camera control units do not come into direct contact with the patient; instead, they are used in conjunction with the corresponding accessories (videoscopes, 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.

Extension cable

Not applicable as there is no direct or indirect patient contact and the products considered have no clinical application.

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 Clinical benefits

The products support the presenting of important and crucial anatomic structures during the surgical procedure, permitting the endoscopic investigation and the performance of endoscopic procedures in minimally invasive surgery.

2.5 Residual risks

No residual risks directly related to the product were identified.

2.6 Target user populations

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

2.7 Patient population

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

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 Combination with other components

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

- ▶ Ensure that any additional devices connected to electrical medical devices comply with the relevant IEC or ISO standards.
- ▶ Ensure that all configurations comply with the requirements for medical electrical systems.
- ▶ Only combine the product with devices and components that the manufacturer has approved for combined use, see chapter *Possible combinations*.
- ▶ Only use devices and components that have standardized interfaces and do not breach the normal use of the product.
- ▶ Do not modify this equipment without authorization of the manufacturer.
- ▶ Do not use multiple socket outlets with this device.
- ▶ If the use of a multiple socket outlet cannot be avoided: Only use a multiple socket outlet with an isolation transformer in accordance with IEC 60601-1.

3.3 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.

3.4 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 all 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.
- ▶ Do not use more than one extension cable.
- ▶ The product's ground line should be installed by a qualified electrician.
- ▶ Ensure potential equalization according to the applicable national rules and regulations.
- ▶ 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.
- ▶ To avoid the risk of electric shock, this product must only be connected to a supply mains with protective earth.

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.

3.5 Damage due to ingress of liquid in electrical components

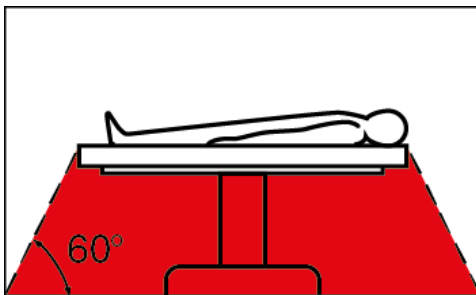
In the case of electrical products, individual components or the product itself may be live. Liquid ingress into an electrical product may result in a short circuit or an unintentional transfer of current. The product is damaged as a result and patients, users and third parties may be injured.

- ▶ 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.

3.6 Risk of explosion and fire

The product can generate sparks, which cause combustible or flammable gases and liquids to ignite or explode. This may cause injuries to patients, users, and third parties.

- ▶ When using explosive narcotic gases: Operate the product outside of the hazard zone.



- ▶ Do not use the product in the presence of flammable anesthetics.
- ▶ The product must not be operated in oxygenated environments.
- ▶ Only connect or disconnect the power plug to or from the power supply outside explosive atmospheres.

3.7 Electromagnetic interference

Medical electrical products are subject to special precautions regarding electromagnetic compatibility and must be installed and commissioned according to the tables on electromagnetic compatibility. If other products (e.g. for MRT, CT, diathermy, electrocautery or RFID) emit electromagnetic radiation, the function of the product may be impaired. High-frequency communication equipment can affect electrical medical products and impair their performance.

- ▶ During installation and operation of the product, please take note of the information on electromagnetic compatibility, see chapter *Electromagnetic compatibility*.

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.

3.8 Failure of products

The product may fail during use.

- ▶ Perform an equipment test before use, see chapter *Preparation* [p. 25].
- ▶ 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.

3.9 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.

4 Product description

4.1 Description of operation

The product offers the following functions:

- IMAGE1 S Visualization modes to support the user with contrast enhancement and/or consistent brightness perception.
- Light Source Control for automatic adjustment of the light source.
- Integrated image and video capture for simple documentation.

4.2 Product overview

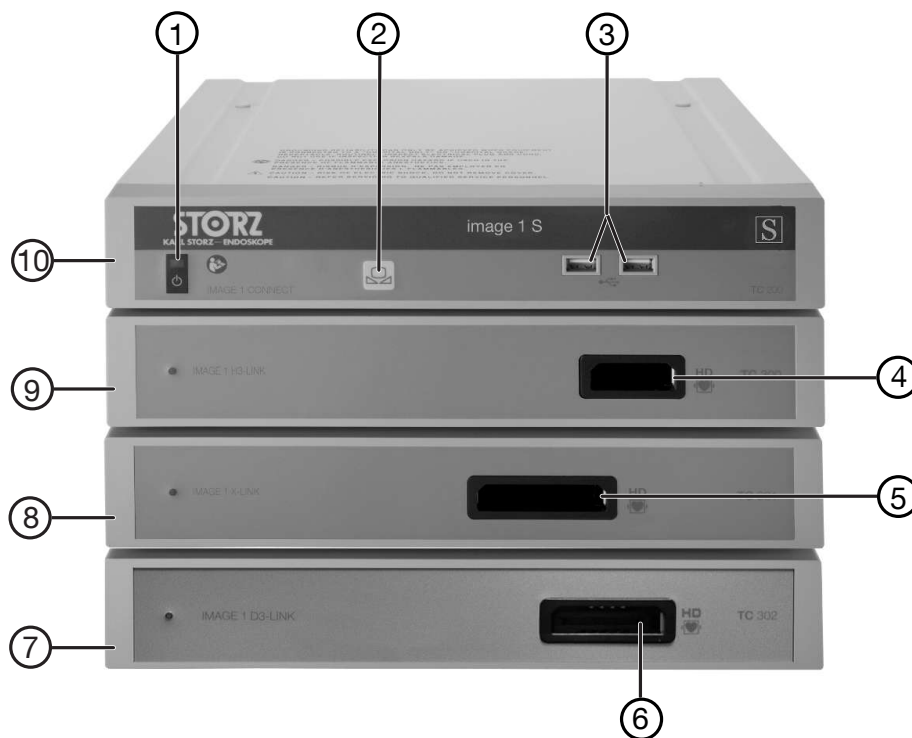
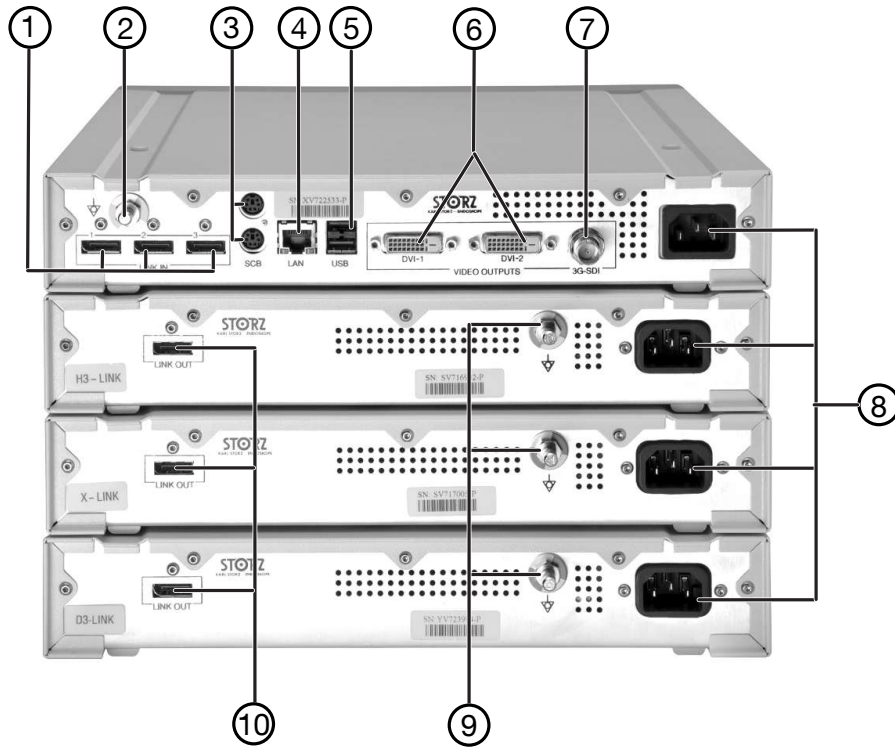


IMAGE1 S CONNECT, front

- | | | | |
|---|---------------------------|----|---------------------------|
| 1 | Power switch | 6 | D3-LINK camera connection |
| 2 | White balance | 7 | IMAGE1 S D3-LINK (TC302) |
| 3 | USB port | 8 | IMAGE1 S X-LINK (TC301) |
| 4 | H3-LINK camera connection | 9 | IMAGE1 S H3-LINK (TC 300) |
| 5 | X-LINK camera connection | 10 | IMAGE1 S CONNECT (TC200) |



Rear side of IMAGE1 S CONNECT

- | | | | |
|---|---|----|----------------------------------|
| 1 | LINK input ports | 6 | HD DVI-D video output sockets |
| 2 | Potential equalization connector | 7 | 3G-SDI video output |
| 3 | SCB input/output sockets (KARL STORZ Communication Bus) | 8 | Mains sockets |
| 4 | LAN interface, KS HIVE interface | 9 | Potential equalization connector |
| 5 | USB interface | 10 | LINK output |

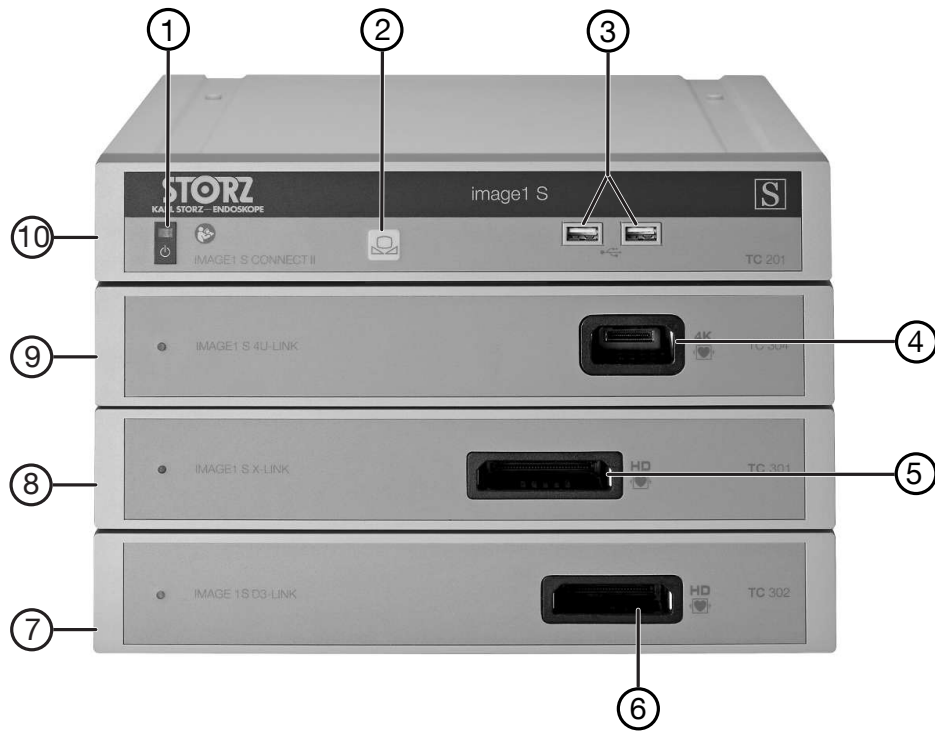
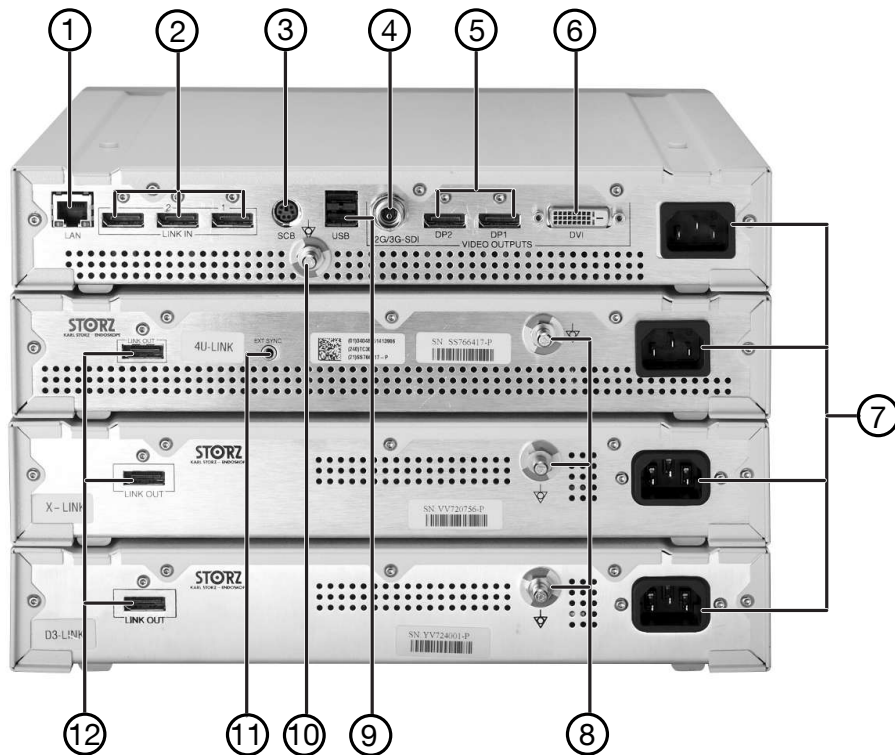


IMAGE1 S CONNECT II, front

- | | | | |
|---|---------------------------|----|-----------------------------|
| 1 | Power switch | 6 | D3-LINK camera connection |
| 2 | White balance | 7 | IMAGE1 S D-LINK (TC302) |
| 3 | USB port | 8 | IMAGE1 S X-LINK (TC301) |
| 4 | 4U-LINK camera connection | 9 | IMAGE1 S 4U-LINK (TC304) |
| 5 | X-LINK camera connection | 10 | IMAGE1 S CONNECT II (TC201) |



Rear side of IMAGE1 S CONNECT II

- | | | | |
|---|---|----|----------------------------------|
| 1 | LAN interface, KS HIVE interface | 7 | Mains sockets |
| 2 | LINK input ports | 8 | Potential equalization connector |
| 3 | SCB input/output sockets (KARL STORZ Communication Bus) | 9 | USB interface |
| 4 | 12G/3G SDI video output | 10 | Potential equalization connector |
| 5 | DisplayPort video output sockets | 11 | EXT SYNC connection |
| 6 | HD DVI-D video output socket | 12 | LINK output |

4.3 Technical data

IMAGE1 S CONNECT

Description	Value
HD video outputs	2x DVI-D 1x 3G-SDI
Signal output format	1,920 x 1,080p, 50/60 Hz
LINK input ports	3x
KS HIVE interface	RJ45
USB interface	4x USB
Image format	JPEG
Video format	MPEG 4
SCB interface	2x 6 pin Mini DIN

IMAGE1 S CONNECT II

Description	Value
4K and HD video outputs	2x DP 1x 12G/3G SDI 1x DVI-D
Signal output format	3,840 x 2,160p, 50/60 Hz for DP and 12G-SDI 1,920 x 1,080p, 50/60 Hz for 3G-SDI and DVI-D
LINK input ports	3x
KS HIVE interface	RJ45
USB interface	4x USB
Image format	JPEG
Video format	MPEG 4
SCB interface	1x 6 pin Mini DIN

Power supply (AC) and frequency requirements	Value
IMAGE1 S CONNECT	100–120 V, 50/60 Hz 200–240 V, 50/60 Hz
IMAGE1 S CONNECT II	100–240 V, 50/60 Hz
IMAGE1 S H3-LINK	100–240 V, 50/60 Hz
IMAGE1 S X-LINK	100–240 V, 50/60 Hz
IMAGE1 S D3-LINK	100–240 V, 50/60 Hz
IMAGE1 S 4U-LINK	100–240 V, 50/60 Hz

Dimensions	Value (W x H x D)
IMAGE1 S CONNECT	320 x 54 x 305 mm
IMAGE1 S CONNECT II	320 x 54 x 305 mm
IMAGE1 S H3-LINK	320 x 54 x 305 mm
IMAGE1 S X-LINK	320 x 54 x 305 mm
IMAGE1 S D3-LINK	320 x 54 x 305 mm
IMAGE1 S 4U-LINK	320 x 54 x 305 mm

Weight	Value
IMAGE1 S CONNECT	2.1 kg
IMAGE1 S CONNECT II	3.1 kg
IMAGE1 S H3-LINK	1.86 kg
IMAGE1 S X-LINK	1.86 kg
IMAGE1 S D3-LINK	1.86 kg
IMAGE1 S 4U-LINK	1.86 kg

Power input	Value
IMAGE1 S CONNECT	62 VA
IMAGE1 S CONNECT II	100–135 VA
IMAGE1 S H3-LINK	80 VA
IMAGE1 S X-LINK	80 VA
IMAGE1 S D3-LINK	80 VA
IMAGE1 S 4U-LINK	86 VA

4.4 Possible combinations

It is recommended that the suitability of the products for the intended procedure be checked prior to use. Please note that the described products in this medium may not be available in all countries due to different regulatory requirements.

The IMAGE1 S camera control unit (CCU) consists of the IMAGE1 S CONNECT (TC200) or IMAGE1 S CONNECT II (TC201) and 1–3 additional LINK modules. The various modules serve as interfaces to camera heads and videoendoscopes.

The following LINK modules are available:

- IMAGE1 S H3-LINK (TC300)
- IMAGE1 S X-LINK (TC301)
- IMAGE1 S D3-LINK (TC302)
- IMAGE1 S 4U-LINK (TC304)

i Only compatible products may be combined with the CONNECT modules and LINK modules, see chapter *Accessories* [p. 52].

The following products are required for navigation and input:

- Keyboard
- Mouse

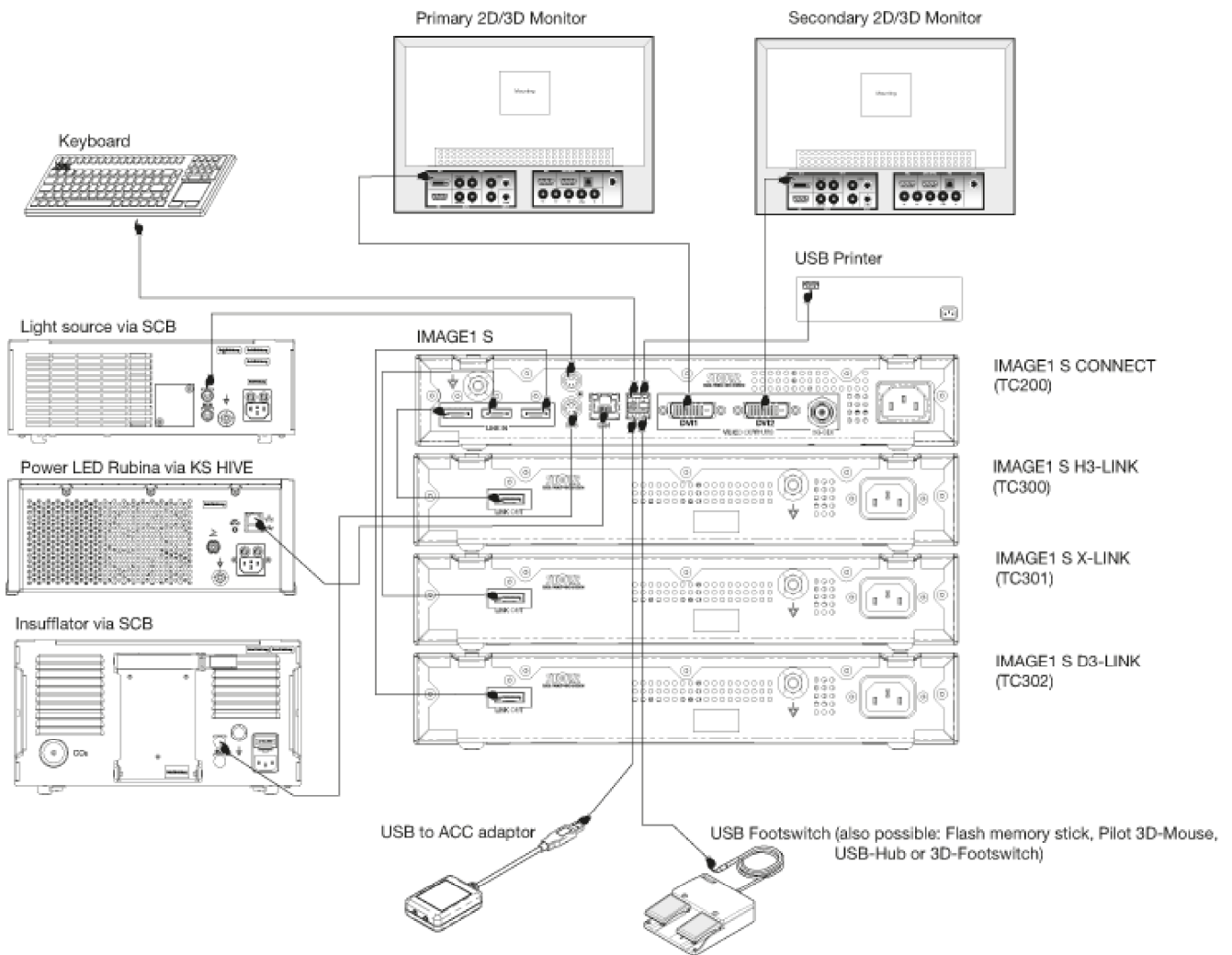
The following products are available as options for navigation:

- Compatible camera heads and videoendoscopes
- IMAGE1 PILOT (TC014)
- Microscope Footswitch (TC019)

i Do not connect network devices (Ethernet, Bluetooth, or WiFi dongles) to the USB port of the product. The connection may impair operation of the product.

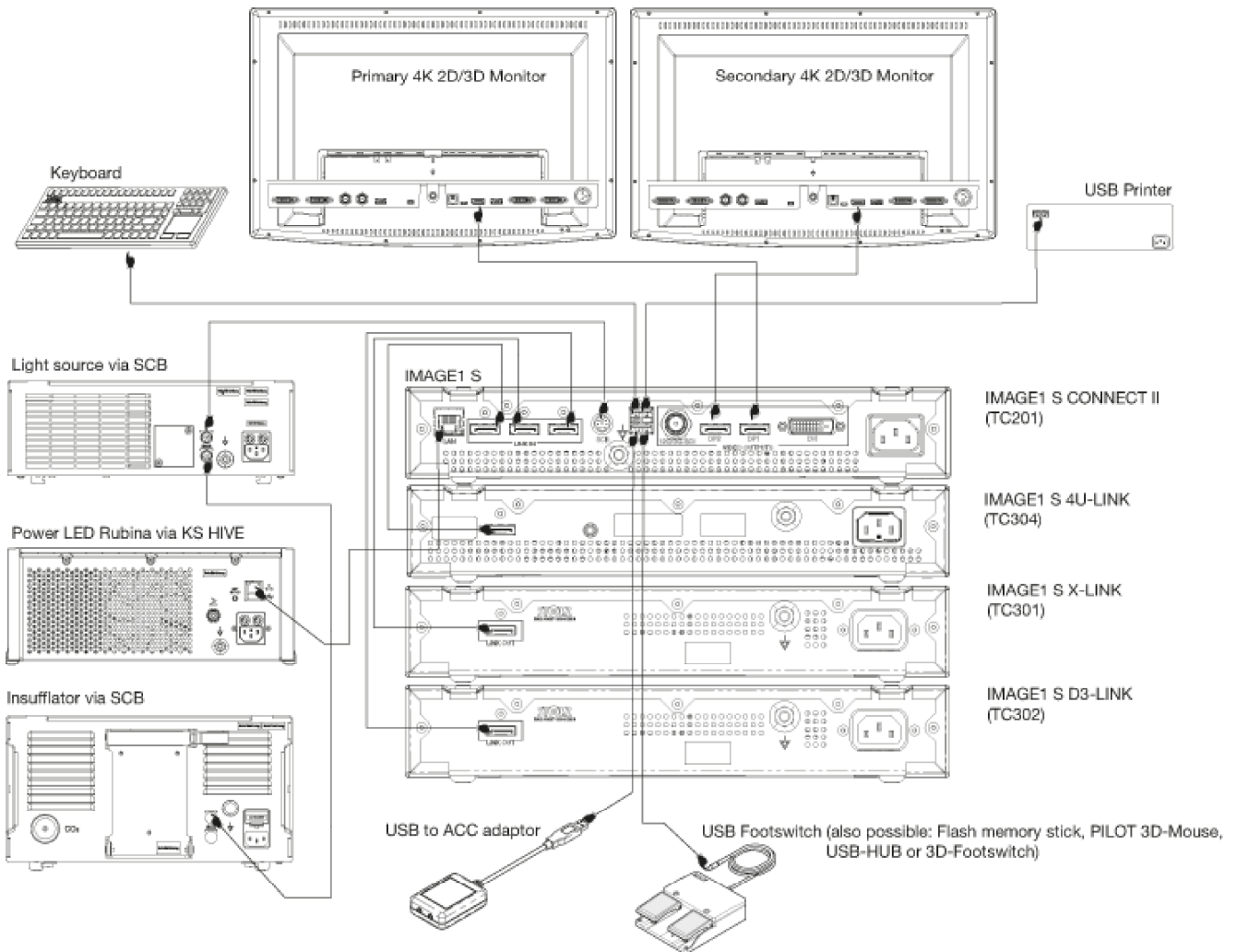
4.4.1 Installation overview of IMAGE1 S CONNECT

i If multiple KS HIVE-compatible peripheral devices are used, the OR1 HIVE router is required.



4.4.2 Installation overview of IMAGE1 S CONNECT II











- i** To use OPAL1 fluorescence imaging, the IMAGE1 S 4U-LINK (TC304) and Power LED Rubina (TL400) must also be connected via a sync cable when using the TIPCAM1 Rubina.
- i** If multiple KS HIVE-compatible peripheral devices are used, the OR1 HIVE router is required.












4.5 Symbols employed

4.5.1 Symbols on the packaging





Symbol	Meaning
	Manufacturer
	Date of manufacture
	Medical device
	Article no.
	Serial number







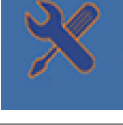



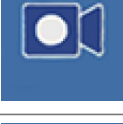

Symbol	Meaning
	Number of products in the product packaging
	Unique Device Identifier
	Consult the printed or electronic instructions for use
	Fragile, handle with care
	Keep dry
	Temperature limit
	Humidity limit
	Not MR safe
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	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




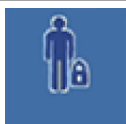


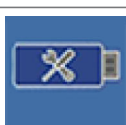




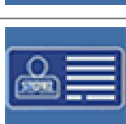
4.5.2 Symbols on the product





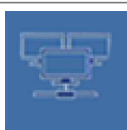
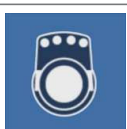



Symbol	Meaning
	Follow the instructions for use. The color may differ on the product. The symbol is black/white on the packaging label.
	ON/OFF (standby)
	USB
	White balance
	Applied part type CF defibrillation protection
	Potential equalization connector
	Prevention of pollution by electronic devices
	Separate collection of electrical and electronic devices. Do not dispose of in household refuse.
	Consult the printed or electronic instructions for use

4.5.3 Symbols on the user interface

Symbol	Meaning
	H3-LINK The button appears once the H3-LINK module is correctly connected.
	X-LINK The button appears once the X-LINK module is correctly connected.
	D3-LINK The button appears once the D3-LINK module is correctly connected.
	4U-LINK The button appears once the 4U-LINK module is correctly connected.

Symbol	Meaning
	Insufflator
	Printer
	Light source
	Storage/Eject
	Patient
	Presets
	Setup menu
	Info
	Brightness
	Print
	Video
	Image

Symbol	Meaning
	Image flip
	Enhance
	Parameter regions
	Patient data privacy
	Dashboard
	Live menu
	Image
	Software license
	Exit
	Frequency
	Display
	Contact information

Symbol	Meaning
	Date and time
	Camera buttons
	White balance
	OPAL1
	Network
	IMAGE1 PILOT
	Setup
	Update
	Remote Service

4.6 Ambient conditions

Transport and storage conditions	
Temperature	-10°C ... +60°C (14°F ... 140°F)
Relative humidity (non-condensing)	20–95%
Air pressure	500–1,060 hPa

Operating conditions	
Temperature	0°C ... 40°C (32°F ... 104°F)
Relative humidity (non-condensing)	20–85%
Air pressure	700–1,060 hPa
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 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.
4. When using 3D videoendoscopes, check to make sure the monitor's display is correct.
5. Be sure to use the correct polarized eyewear for the monitor.

5.3 Reprocessing the product

- ▶ Reprocess the product in line with the reprocessing instructions before using it.

5.4 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.
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.

5.5 Connecting the product

1. Connect the potential equalization cable.



2. Connect the potential equalization line to the connector of the treatment room.
3. Connect the numbered inputs in ascending order.
4. Use the LINK cable to connect the LINK module to the CONNECT module.



5. Pull back the protection device of the SCB connector and insert the connector into one of the SCB sockets.

- Connect the other end of the cable to a KARL STORZ SCB control device (KARL STORZ Communication Bus).



- Insert the OR1 patch cable into the KS HIVE/LAN interface.



- Connect the other end of the cable to a KS HIVE-compatible product, e.g., Power LED Rubina (TL400), Power LED Saphira (TL410), ARTIP CRUISE (UR500B, UR500C), AIDA (WD300, WD350), OR1 HIVE router (WO10240, WO10307).
- Connect the IMAGE1 S 4U-LINK (TC304) and Power LED Rubina (TL400) to a sync cable if the products are being used with the TIPCAM1 Rubina.
- Connect the monitor. For the IMAGE1 S CONNECT (TC200), connect the primary work screen to DVI 1.



- Ensure that the monitor supports a resolution of 1,920 x 1,080 pixels.
- If the D3-LINK module (TC302) is used in conjunction with a 3D videoendoscope, connect a compatible 3D monitor.

13. For the IMAGE1 S CONNECT II (TC201) connect the primary work screen to DP 1.
14. Ensure that the monitor supports a resolution of 3,840 x 2,160 pixels.
15. Connect the power cord. Push the power plug fully into the power socket.



16. Push the power plugs fully into the power sockets of the LINK modules.



17. Connect the power plugs to the power sockets.
 - i** Use the network device only in a protected network with firewall and router.

5.6 Putting the product into operation

⚠ WARNING

Hot surfaces! Risk of burns!

The surfaces can get hot due to locked ventilation fans or blocked air intakes. There is a possible risk of a burn if touched.

- ▶ If the surfaces get hot, switch off the product.

⚠ 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.

⚠ 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.

1. Turn the product on using the power switch.



⇒ The connected LINK modules start automatically.

2. Format the USB storage device as FAT 32.
3. Connect the USB storage device to the IMAGE1 S CONNECT to store still images or videos. Do not connect more than 1 USB storage device.



4. Check the values set for the primary source and the secondary source.
5. Check the layout.
6. Insert the camera head connector into the socket of the relevant LINK module.



5.7 Performing the white balance

- ① The white balance must be performed again after replacing the endoscope.
- ① Failure to perform proper white balance of system may result in color distortion.
 1. Ensure that the imaging instrument is connected and a live image appears 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 a white and clean surface, e.g., white gauze.
 4. Make sure that the light source emits enough light to sufficiently illuminate the surface.
 - ⇒ The monitor displays a completely white and well illuminated live image.
 5. Press the **White Balance** button on the IMAGE 1 CONNECT or the button in the Live menu.
 - ⇒ The white balance is performed.
 6. Check the monitor to see whether the white balance was successful.
 7. Repeat the white balance if required.

6 Application

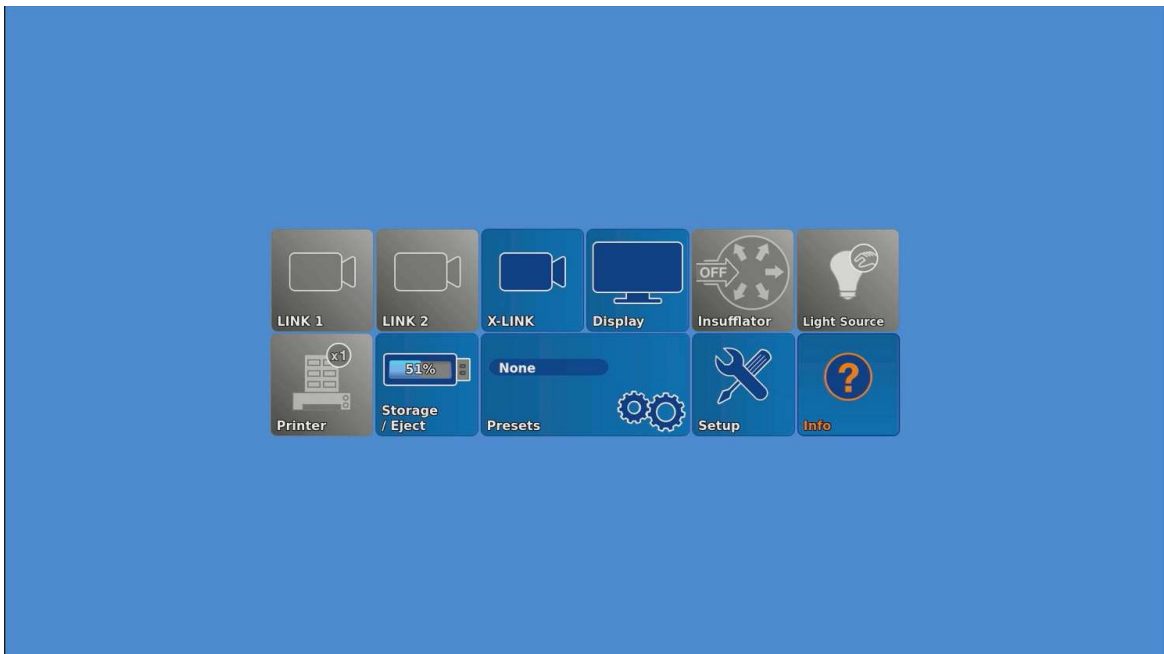
6.1 Dashboard

The dashboard displays the LINK modules, peripheral devices, and recommended accessories connected to the LINK module. Unconnected peripheral devices, recommended accessories, and the LINK modules are shown in gray.

If more than one LINK module is used, the IMAGE1 S with the Auto Source Detection function automatically recognizes the module to which a camera head is connected. Provided that the secondary source is configured with *None* or S-Technologies. If the secondary source is configured with a LINK module, the IMAGE1 S behaves according to the configuration.

Depending on the configuration, individual icons may be deactivated or unavailable. The configuration can be changed in the Setup menu, see chapter *Setup menu* [p. 37].

The dashboard is shown when no camera head or videoendoscope is connected.



1. Tap the **Display** button.
2. Set the primary source, secondary source, PiP layout, and grid.
3. Tap the **Insufflator** button.
4. In the **Insufflator** menu, adjust the settings for gas, flow, and pressure.
5. Tap the **Light Source** button.
6. Turn the light source on or off and set the light intensity and the mode.
 - ⇒ If two or more light sources, camera heads, videoendoscopes are connected at the same time, no light source settings can be made. Exception: The light source tile remains active if one OPAL1-compatible and one non OPAL1-compatible camera head are used.
7. Tap the **Printer** button.
8. The number of images per page and the number of copies can be set in the **Printer** menu.
9. On the **Storage/Eject** button, read off the amount of used storage space on the connected USB storage device.

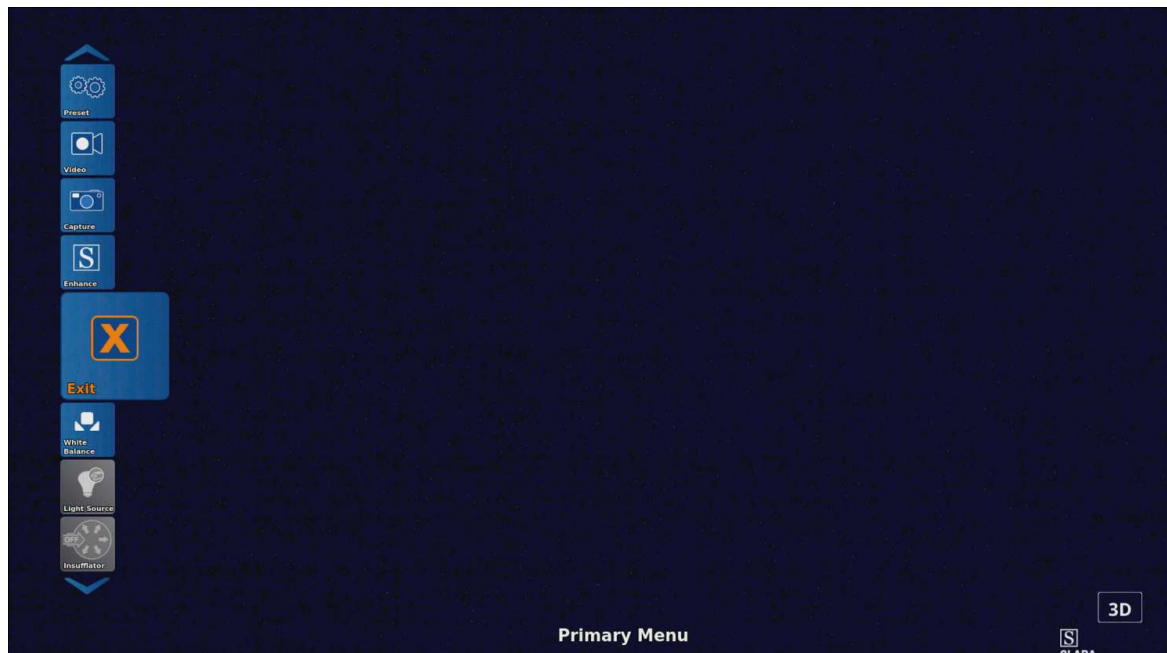
10. Tap the **Storage/Eject** button to eject the USB storage device. Data may be lost if the USB storage device is not ejected.
 - ⇒ The USB storage device can be removed.
11. Tap the **Presets** button.
12. If presets have been defined in the Setup menu, select a preset.
13. Tap the **Setup** button to open the Setup menu. Alternatively, you can press the SHIFT+ENTER keys.
14. Tap the **Info** button to see contact information.
15. Tap the **Patient** button.
16. Create, select, modify, or delete a patient information record. Up to 50 patient information records can be created.

6.2 Live menu

The Live menu allows you to choose between different camera functions and change the settings of connected devices. Unconnected devices are shown in gray.

The Live menu can be opened using the following keys/buttons:

- The Enter key on the keyboard.
 - The menu button on the camera head or videoendoscope.
 - The left side button on the IMAGE1 PILOT.
- i** Be sure not to touch the 3D wheel or the buttons while the IMAGE1 PILOT is connecting to the IMAGE1 CONNECT.



1. Tap the **Brightness** button to set the brightness of the LINK module.
2. Tap the **Print** button to immediately print all images in the print queue.
 - i** Printouts with patient data remain in the queue until sufficient ink and paper are available. Switching off the product followed by switching off the printer will clear the print queues. Everything in the queues will be deleted.
3. Switch the IMAGE1 S off and back on again to clear the queue.

4. On the **Storage/Eject** button, read off the amount of used storage space on the connected USB storage device.
5. Tap the **Storage/Eject** button to eject the USB storage device. Data may be lost if the USB storage device is not ejected.
 - ⇒ The USB storage device can be removed.
6. Tap the **Presets** button.
7. To select a preset, define presets in the Setup menu.
8. When using presets in conjunction with 3D settings, switch manually between 2D and 3D if necessary.
9. Tap the **Video** button to start or stop a video recording.
10. Tap the **Capture** button to capture a still.
11. Connect a USB storage device to save the images and videos.
12. Connect a printer to print the images.
13. Connect AIDA to display and save the images and videos.
14. Tap the **OPAL1** button to set the fluorescence imaging, see chapter *OPAL1* [p. 35].
 - ⓘ Using an electrosurgical unit in ICG color light mode can cause image distortion.
15. Tap the **Enhance** button to set the S-Technologies, see chapter *Enhance (S-Technologies)* [p. 35].
16. Tap the **White Balance** button to perform the white balance.
17. Tap the **Light Source** button.
18. Turn the light source on or off and set the light intensity and the mode.
19. If the light sources are connected via KS HIVE, activate KS HIVE device integration, see chapter *Network* [p. 41].
 - ⇒ If two or more light sources, camera heads, or videoendoscopes are connected at the same time, no light source settings can be made.
 - ⇒ The light source tile remains active if one OPAL1-compatible and one non-OPAL1-compatible camera head are used.
20. Tap the **Insufflator** button.
21. In the **Insufflator** menu, adjust the settings for **Gas**, **Flow**, and **Pressure**.
22. Tap the **Display** button, see chapter *Display (Live menu)* [p. 36].

23. Tap the **Zoom** button to enlarge or reduce the display.



24. Select **Adaptive Zoom** in the *Zoom* menu. The menu is available if the following products are connected:
- IMAGE1 S CONNECT II (TC201) and a 4U-LINK in combination with 4U camera heads (TH120 or TH121)
 - IMAGE1 S CONNECT (TC200) or IMAGE1 S CONNECT II (TC201) and a D3-LINK in combination with a 4 mm TIPCAM1 S 3D
 - IMAGE1 S CONNECT (TC200) or IMAGE1 S CONNECT II (TC201) and an X-LINK in combination with the CMOS-based X-Line videoendoscopes
 - IMAGE1 S CONNECT (TC200) or IMAGE1 S CONNECT II (TC201) and an X-LINK in combination with HX camera heads (TH110, TH111, TH112, TH113)
25. Select *Enabled*.
- ⇒ The system detects the size of the endoscopic image. With small telescopes, the endoscopic image is zoomed to vertically fill the display. If the endoscopic image crosses the vertical boundaries, the display zooms to full screen.
 - ⇒ In the case of camera heads, the adaptive zoom function is used by means of the white balance function.
26. Tap the **Image Flip** button to flip the image vertically or horizontally or rotate it through 180°.
27. Tap the **Head Button** button to assign functions to the camera head or videoendoscope buttons.
28. Tap the **IMAGE1 PILOT** button to assign functions to the IMAGE1 PILOT buttons.
29. Tap the **Exit** button to exit the Live menu. Alternatively, press the ESC key or right side button on the IMAGE1 PILOT.

6.2.1 Enhance (S-Technologies)

- ▶ Tap the **Enhance** (S-Technologies) button.
 - ⇒ The following settings are possible:
 - CLARA: A specially optimized algorithm reduces disruptive shadows and ensures more even brightness perception of the endoscopic image.
 - CHROMA: Improves the perception of fine structures via contrast enhancements, particularly in the red area. The original colors are retained; the color intensity is changed.
 - SPECTRA A, SPECTRA B: Based on color inversions, a false color image with enhanced contrast is generated.
 - Fiber filters: The digital fiberscope filter can be set to two levels: Filter A: anti-moiré, Filter B: anti-grid. Interfering artifacts are reduced, such as the moiré effect or the display of the fiberscope grid. Filter A is suitable if the honeycombed grid structures are small. Filter B is suitable for larger honeycomb structures; for example, when an optical zoom is used.

6.2.2 OPAL1

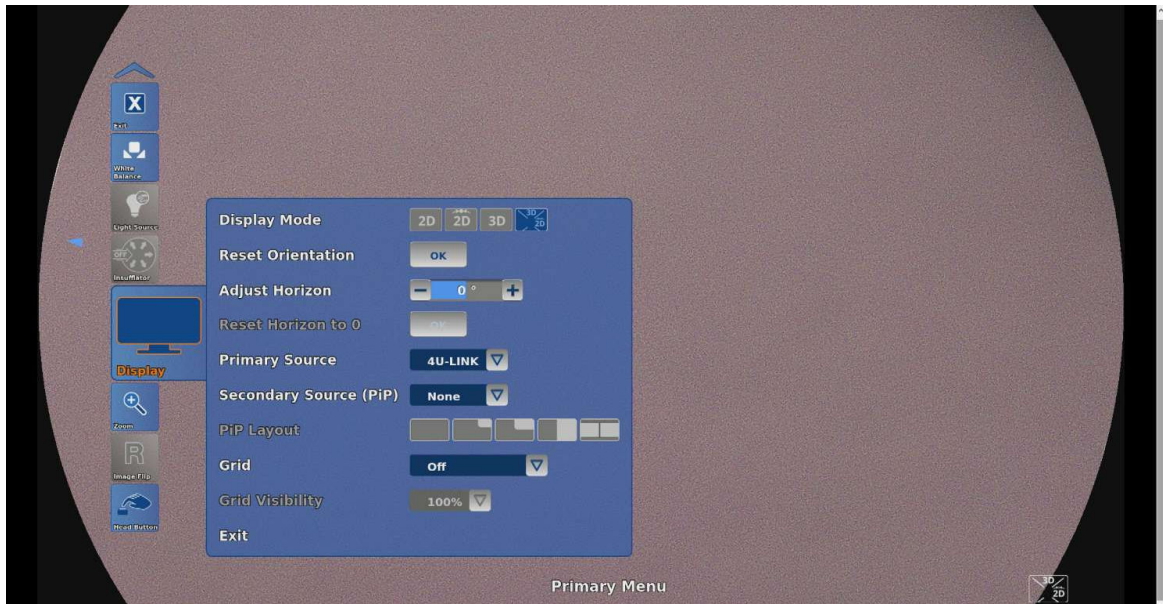
- ✓ The light source and camera head are connected to the FI support.
- ▶ Tap the **OPAL1** button to define the settings for the fluorescence imaging (FI).
 - ⇒ The following settings are possible:
 - FI switch: It is possible to switch between the FI application and white light in the menu, via the camera head buttons, or via a footswitch.
 - Overlay color: The NIR/ICG signal can be displayed in blue or green.
 - FI intensity (only available for PDD): Adjustable in 3 levels. When the FI intensity is increased, the exposure time is extended and the live image is delayed.



FI mode	Description
Overlay	The overlay image combines the white light image and the detected NIR signal. The NIR signal is displayed in either blue or green together with the white light signal.
Intensity Map	Intensity Map combines the white light image and the detected NIR signal. The NIR information is displayed in a color scale to differentiate between strong and weak NIR signals. The yellowish display represents stronger signals, the blue display weaker signals. The color scaling shown in the image depends on the position of the optics relative to the tissue. The display cannot be used to quantify the NIR signal.
Monochromatic	The monochromatic visualization displays the NIR signal in grayscale. No white light information is displayed.
Overlay Opacity (for TH121)	Set the overlay opacity of the NIR signal. The white light information remains unchanged.

6.2.3 Display (Live menu)

1. Tap the **Display** button in the Live menu.



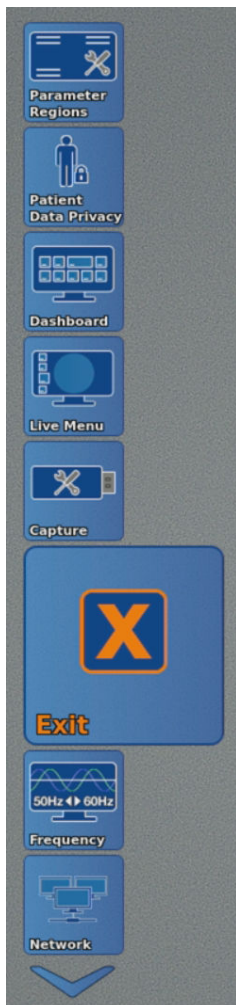
2. Select one of the 4 display modes for the TIPCAM1 Rubina in **Display Mode**:
 - 2D: 2D image without horizon control
 - 2D Autorotation: 2D image with digital horizon control
 - 3D: 3D image without horizon control
 - 3D/2D Autoswitch: Automatic switch between 3D image and upright 2D image, depending on the rotation angle of the TIPCAM1 Rubina. The angle for the image switch can be adjusted.
3. If the position of the horizon indicator is incorrect, tap the **Reset Orientation** button to restore the correct position.
4. In **Adjust Horizon**, tap the **Plus** or **Minus** button to rotate the digital image by the set angle.
5. Tap the **OK** button in **Reset Horizon to 0** to reset the horizon.
6. Open the **Primary Source** drop-down menu and select a LINK module.
 - ⇒ If the secondary source is configured with **None** or S-Technologies, the IMAGE1 S automatically recognizes the module to which a camera head is connected, even if the LINK used is not the primary source.
7. Open the **Secondary Source (PiP)** drop-down menu and select another LINK module or an S-Technology.
8. In **PIP Layout**, select a layout to adapt the picture-in-picture (PiP) function display.
 - ⇒ If **S-Technology** is selected and a visualization mode (CLARA or CHROMA) is selected, the standard white light image and the applicable visualization mode are displayed next to one another as PiP.
 - ⇒ If a D3-LINK or 4U-LINK is selected as the primary source and 3D equipment is connected, the secondary source is deactivated.
9. Activate the **Grid** option to fade a grid into the camera image.
10. Set the grid transparency in **Grid Visibility**.

6.3 Setup menu

In the Setup menu, the general settings and the LINK-specific settings can be changed and saved as a preset. If the 2D image is displayed, no menu structure appears in the image.

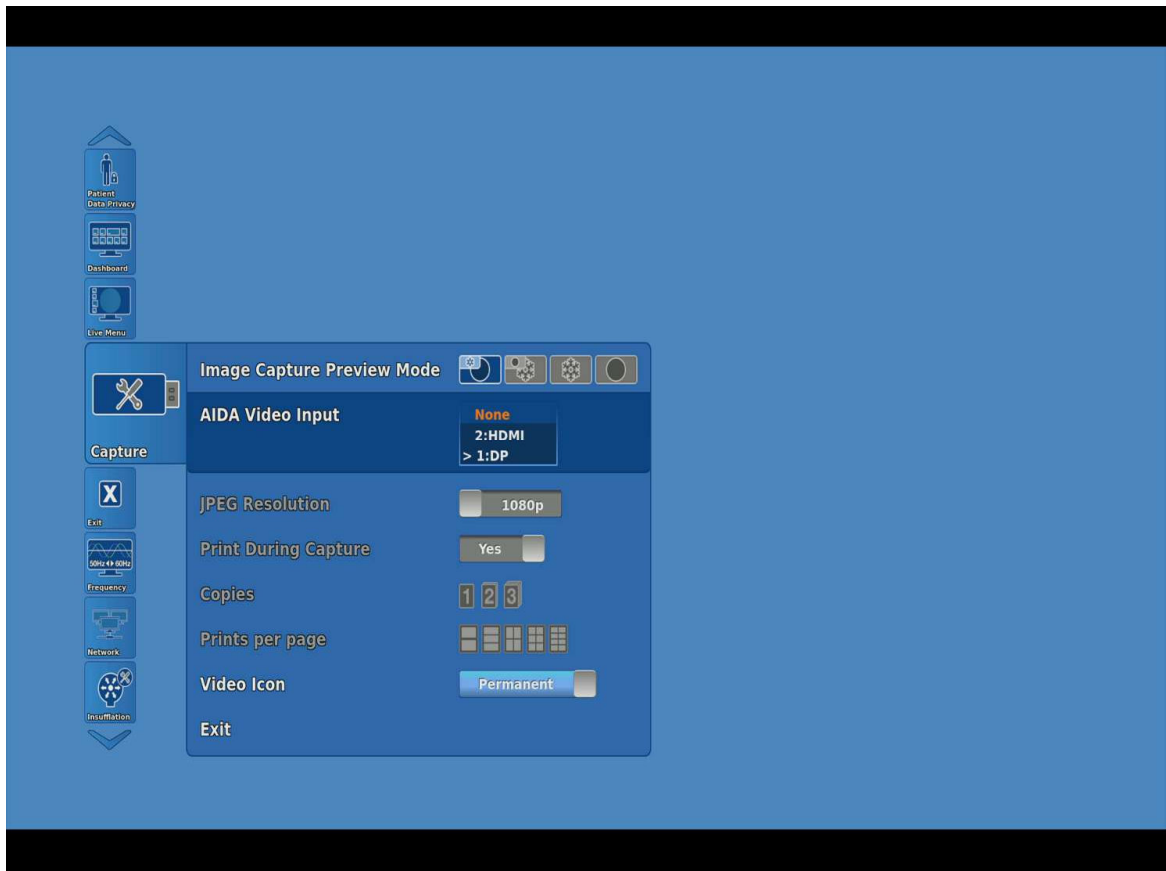
1. Open the Setup menu using one of the following options:
2. Press the Setup button on the dashboard.
3. Press and hold the center camera head button in the Live menu for 7 seconds.
4. Press the SHIFT+ENTER shortcut on the keyboard.
5. Press and hold the left side button on the IMAGE1 PILOT in the Live menu for 7 seconds.
6. Tap the **Presets** button to perform the following actions:
 - Store the current settings as presets
 - Load stored presets
 - Delete stored presets
 - Apply default settings
7. To amend the LINK-specific settings, tap a displayed LINK module.
8. Tap the **Head Button** button to assign functions to the camera head or videoendoscope buttons.
9. Tap the **Setup** button and set which visualization modes are to appear in the S-menu.

- Tap the **Module Information** button to call up information about the CONNECT module, the connected LINK modules, and the camera heads or videoendoscopes.



- Tap the **General** button to apply the general settings.
- Tap the **Parameter Regions** button to adjust the display of additional information from connected SCB devices and KS HIVE devices.
- Tap the **Patient Data Privacy** button to configure the settings for the **Patient Data Privacy**, see chapter *Patient data privacy* [p. 43].
- Tap the **Dashboard** button and select the icons to be displayed on the dashboard here.
- Tap the **Live Menu** button and select the icons to be displayed in the Live menu.

16. Tap the **Capture** button to apply settings for capturing the live image.

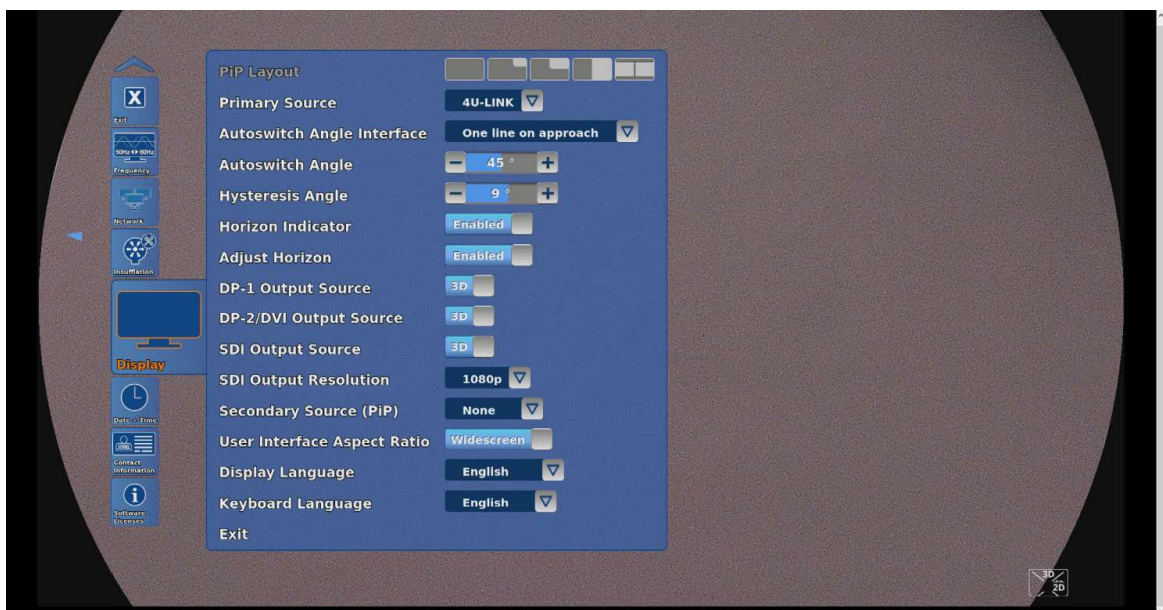


17. Use **Image Capture Preview Mode** to set how the frozen image or live image is to be displayed.
18. If AIDA is connected, select full screen.
19. If AIDA is connected via KS HIVE, select the video input being used in **AIDA Video Input** (available with AIDA software version 1.7 and higher). To do this, turn on KS HIVE device integration, see chapter *Network* [p. 41].
20. Set the resolution of the captured image in **JPEG Resolution**.
21. In **Freeze/Capture Preview Time**, set whether and how long the image is to remain frozen.
22. In **Print During Capture**, set whether to create a printout during capture.
23. In **Copies**, set the number of printouts.
24. In **Prints per page**, set the number of images to be printed per page.
25. In **Video Icon**, set a permanent or temporary display of a video icon during video recording.
26. Tap the **Frequency** button to select the image refresh rate between 50 and 60 Hz.
27. If the image refresh rate has been changed, restart the system.
28. Tap the **Network** button to call up the network parameters and configure the network settings, see chapter *Network* [p. 41].
29. Tap the **Remote Service** button to adjust software update settings and to perform software updates.
30. Tap the **Insufflation** button and, in the dashboard, select the insufflator functions that can be set in the Live menu.

31. Tap the **Display** button to configure the display settings, see chapter *Display (Setup menu)* [p. 40].
32. Tap the **Date + Time** button to set the date, time, and display format.
33. Tap the **Contact Information** button to store the institution name and contact information. The contact information can be accessed via the Help function on the dashboard.
34. Tap the **Software Licenses** button to view a list of the open source software included in the product, and the open source software license terms.

6.3.1 Display (Setup menu)

1. Tap the **Display** button in the Setup menu.
⇒ The following menu appears:



2. In **PIP Layout**, select a layout to adapt the picture-in-picture (PiP) function display.
3. Open the **Primary Source** drop-down menu and select a LINK module.
⇒ If the secondary source is configured with **None** or S-Technologies, the IMAGE1 S automatically recognizes the module to which a camera head is connected, even if the LINK module used is not the primary source.
4. If the IMAGE1 S CONNECT (TC200) is being used, select one of the following modes for emitting the 3D signal:
 - DVI 1
 - DVI 1 / DVI 2
 - DVI 1 / 3G-SDI
 - DVI 1, DVI 2 / 3G-SDI

All outputs that are not selected transmit a 2D image. The 3D signal is always present at the DVI 1 (see label on the IMAGE1 S CONNECT (TC200)).

5. If the IMAGE1 S CONNECT II (TC201) is used with connected D3-LINK, 4U-LINK, and 3D equipment, select outputs DP-1, DP-2/DVI, and SDI as 2D or 3D mode.
6. Open the **SDI Output Resolution** drop-down menu and select the resolution of the signal outputs (available only with IMAGE1 S CONNECT II (TC201)).

7. Open the **Secondary Source (PiP)** drop-down menu and select another LINK module or an S-Technology.
 - ⇒ If **S-Technology** is selected and a visualization mode (CLARA, CHROMA, or SPECTRA) is selected, the standard white light image and the applicable visualization mode are displayed next to one another as PiP.
 - ⇒ If a D3-LINK or 4U-LINK is selected as the primary source and 3D equipment is connected, the secondary source is deactivated.
8. In **User Interface Aspect Ratio**, select Widescreen (16:9) or 4:3.
9. Select the **Display Language** and the **Keyboard Language**.
10. Open the **Autoswitch Angle Interface** drop-down menu and select one of the following settings for the autoswitch limits display behavior when a TIPCAM1 Rubina is connected:
 - One line on approach
 - Four lines on approach
 - Four lines permanently
11. In **Autoswitch Angle**, tap the **Plus** or **Minus** button to set the angle between +/- 30° and +/- 60° in 5° increments. The autoswitch angle specifies the TIPCAM1 Rubina rotation angle at which the image changes from 3D to the upright 2D mode.
12. In **Hysteresis Angle**, tap the **Plus** or **Minus** button to set the angle between +/- 0° and +/- 15° in 3° increments.
 - ⇒ The autoswitch limit of the active area moves by the specified number of degrees. Performing work at the autoswitch limit prevents frequent switching.
13. Activate or deactivate the horizon indicator.
14. In **Adjust Horizon**, select whether the adjustment option for the Live menu is activated or deactivated.

6.3.2 Network

⚠ CAUTION

Image and function malfunctions!

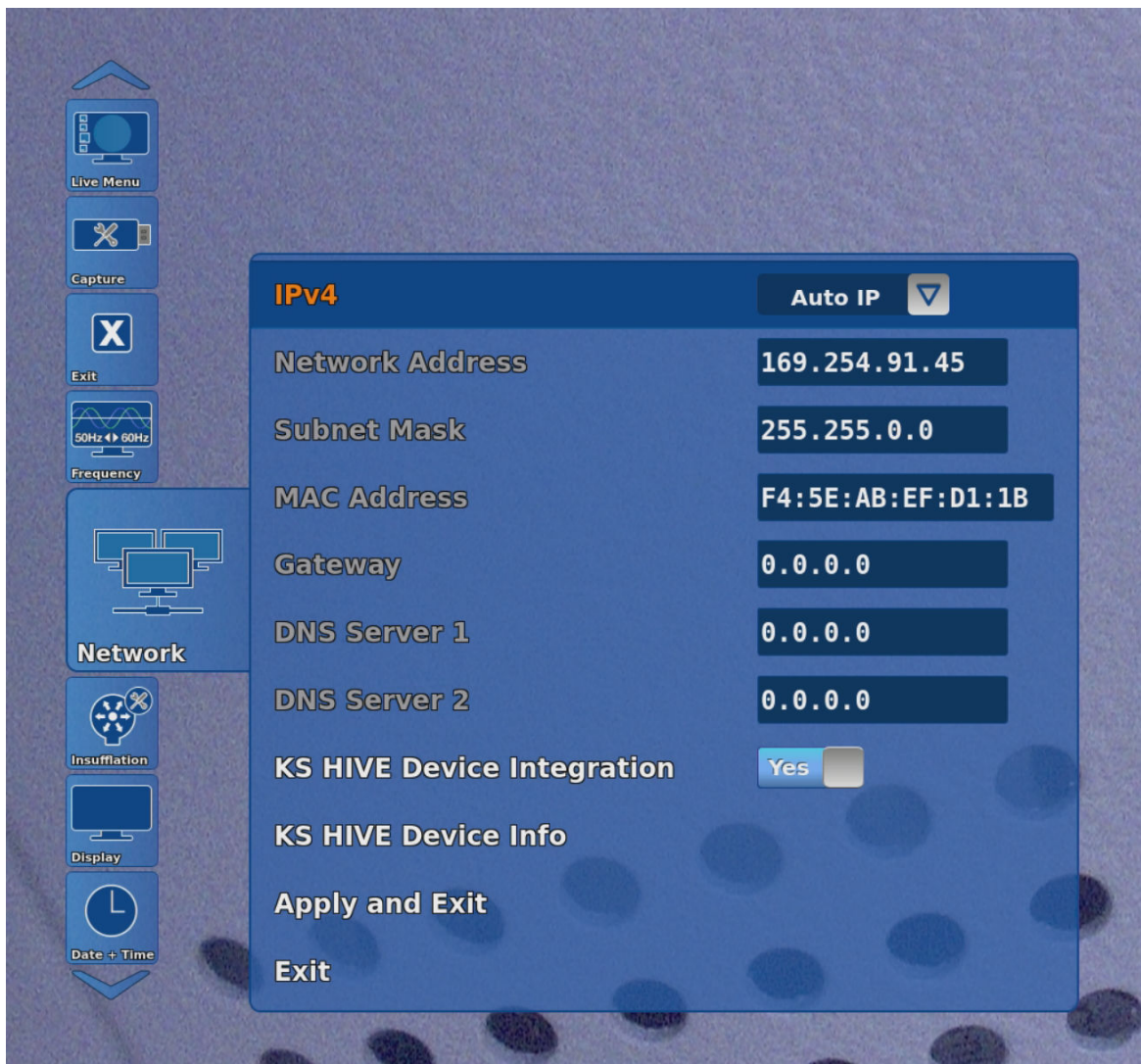
Malicious attacks on the organizational network may cause image and function malfunctions and impair performance of the product.

- ▶ Monitor internal network activity to identify attack attempts.

The following network parameters can be called up:

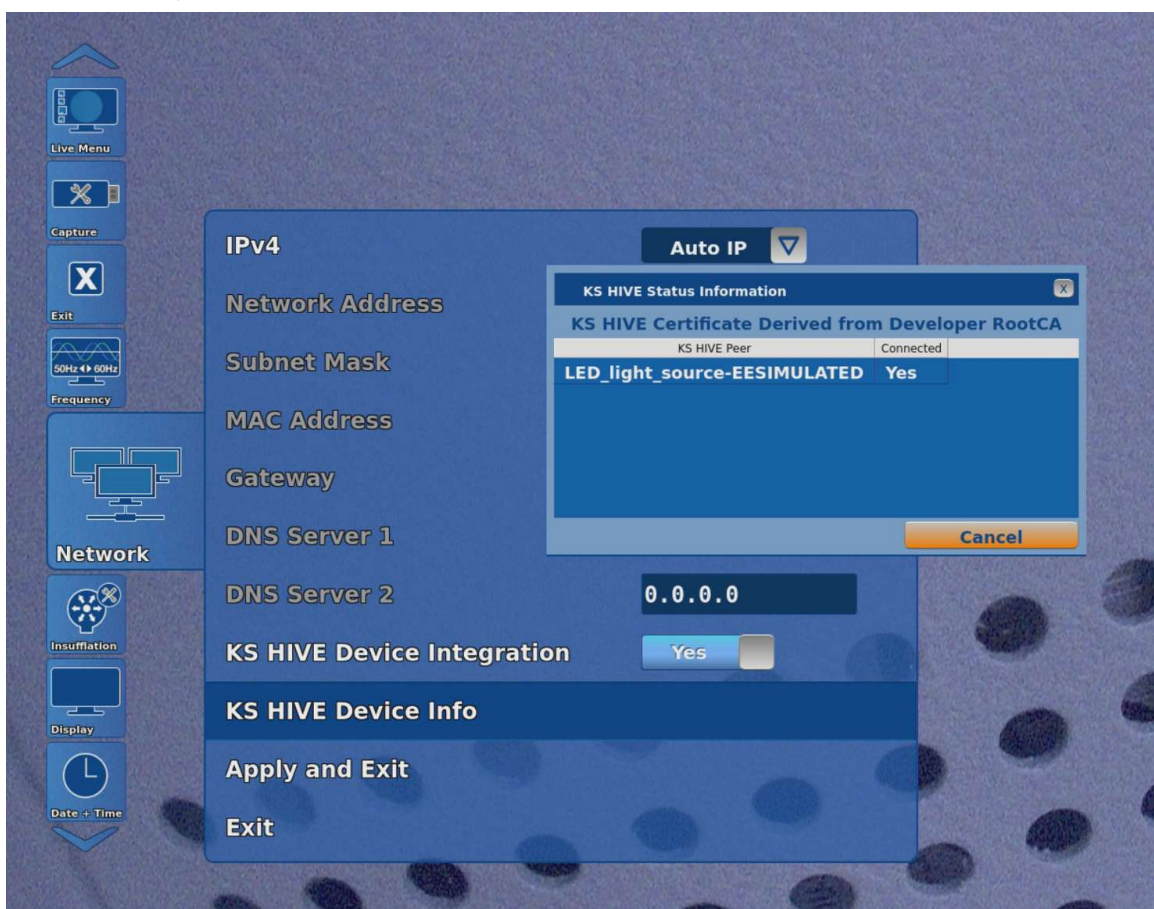
- Internet Protocol Version 4
- Network address
- Netmask
- MAC address
- DNS server

1. Tap the **Network** button.
⇒ The following information appears:



2. In **Patient Data Privacy**, enter the password to access the **Network** menu, see chapter *Patient data privacy* [p. 43].
3. Alternatively, enter the password when opening the **Network** menu for the first time.
4. In **KS HIVE Device Integration**, switch the KS HIVE communication interface on or off as required. KS HIVE device integration enables bidirectional communication between the IMAGE1 S and KS HIVE-compatible peripheral devices.
5. To change the KS HIVE settings, switch the CONNECT module off and back on again.

- In **KS HIVE Device Info**, call up information about KS HIVE with the connected devices, their availability and their status.



6.4 Patient data privacy

- i** Do not record sensitive patient information including patient's face, name, social security number, etc.
- i** 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 product.
- i** The patient data administration functions (e.g. entry, access, display, storage and transfer) must be activated manually. Upon activating the patient data administration functions, the user assumes responsibility for all patient-related data which are managed using the product as per the applicable national data protection laws.

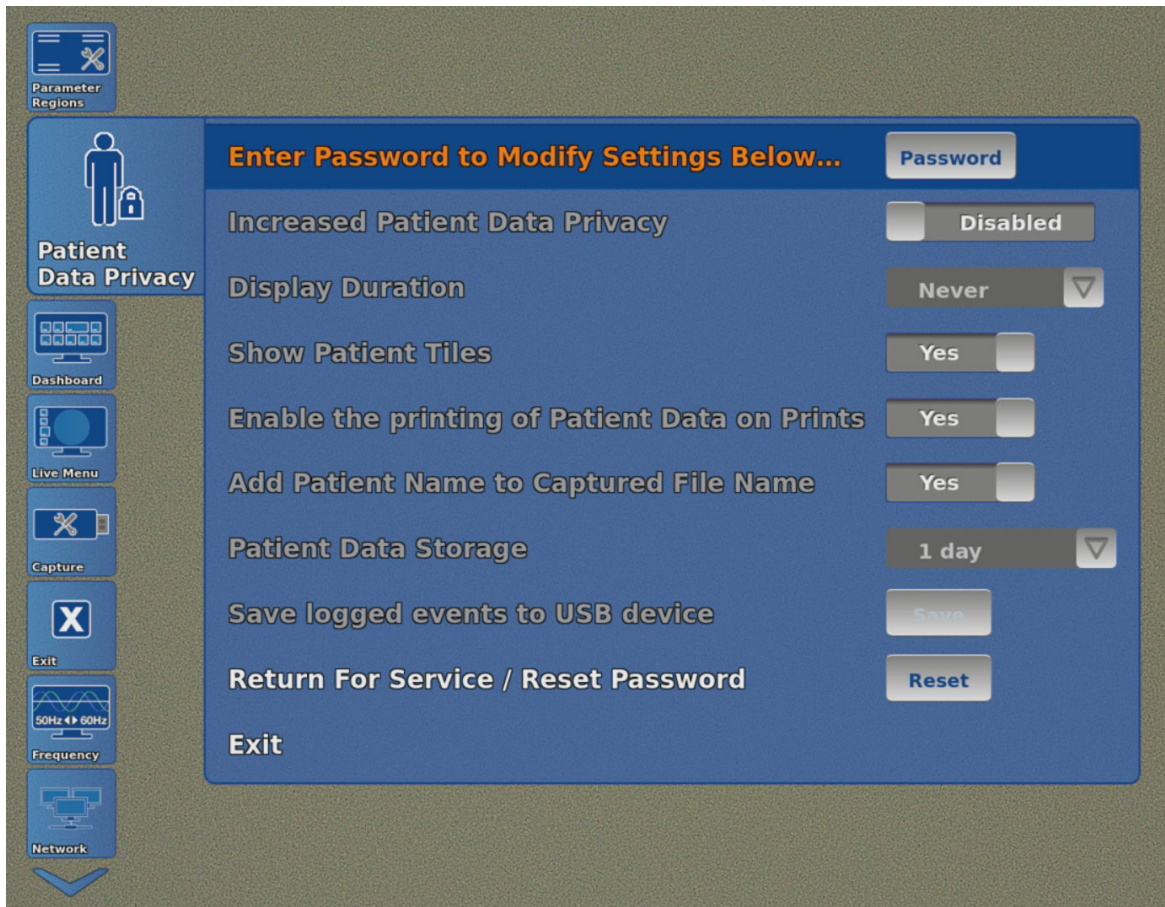
In the **Patient Data Privacy** settings, you can edit all settings related to patient information. Patient information is available only if the corresponding settings have been made. The system does not contain patient data as standard.

- Tap the **Patient Data Privacy** button.
- The **Patient Data Privacy** menu is password-protected as standard. Enter a personal password that fulfils the following criteria:
 - At least 8 characters
 - At least 1 uppercase letter

- At least 1 lowercase letter
 - At least 1 numeral
 - At least 1 special character
3. Repeat the password in the second line and confirm it.

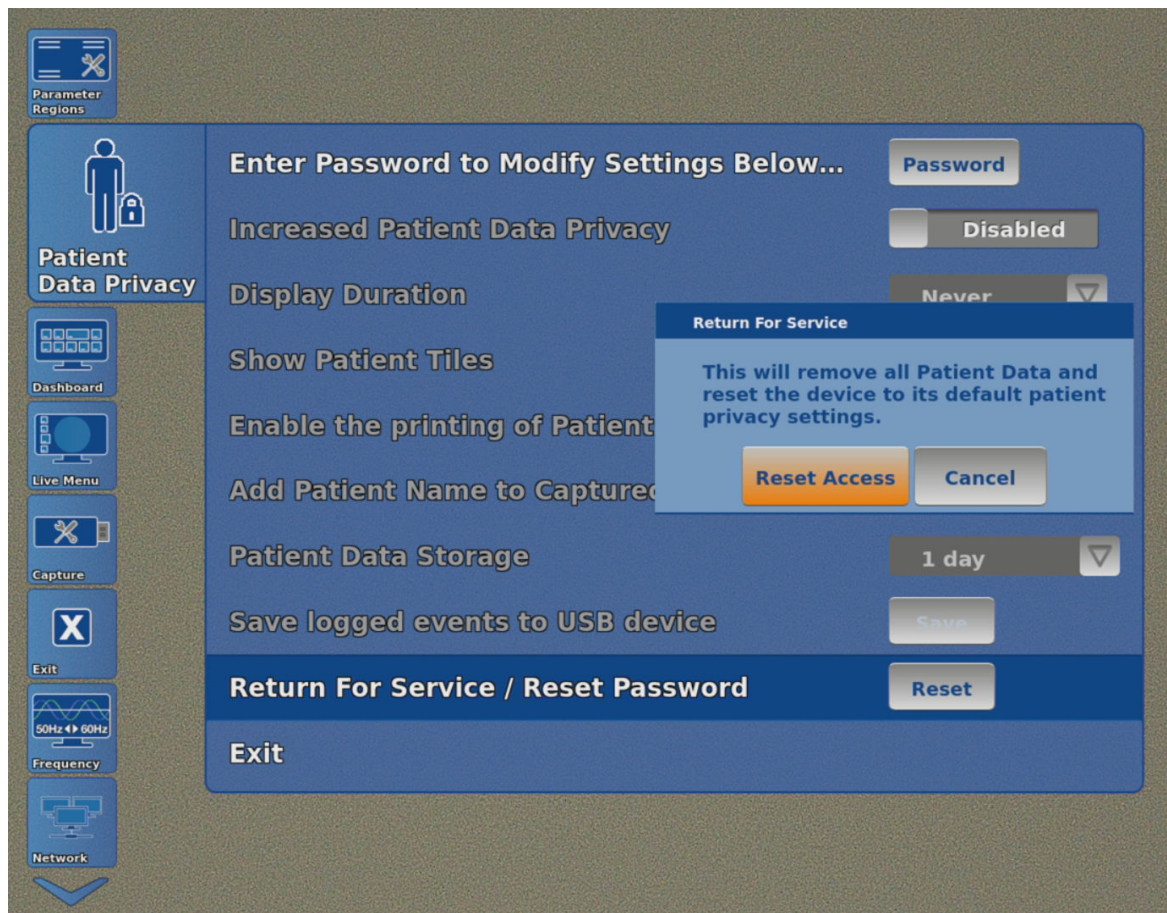


- ⇒ A prompt appears.
 - ⇒ The menu can be used once the password has been entered again.
4. Activate the **Increased Patient Data Privacy** setting to apply the cybersecurity presets.
- ⇒ If this setting is activated, all sub-settings for **Patient Data Privacy** will be deactivated and the default settings restored.



Setting	Description	Default setting
Display Duration	Specify the display duration for the patient data.	Never
Show Patient Tiles	Specify whether the Patient tile is to appear on the dashboard and in the Live menu.	No
Enable the printing of Patient Data on Prints	Specify whether prints will be labeled with patient information or not.	No
Add patient name to the name of the recorded file	Specify whether media files stored will be labeled with the patient information.	No
Patient Data Storage	Set the data storage period on the device.	1 day
Save Logged Events to USB storage device	The audit log can be viewed via Open Log . Audit logs can be exported via Save As .	-

The **Return for Service / Reset Password** option is not affected by the **Increased Patient Data Privacy** setting. The option is available at any time and provides access to the settings of the **Patient Data Privacy** menu when the password is reset. All patient data is cleared and the default settings are restored. This function is recommended before returning the device for service.

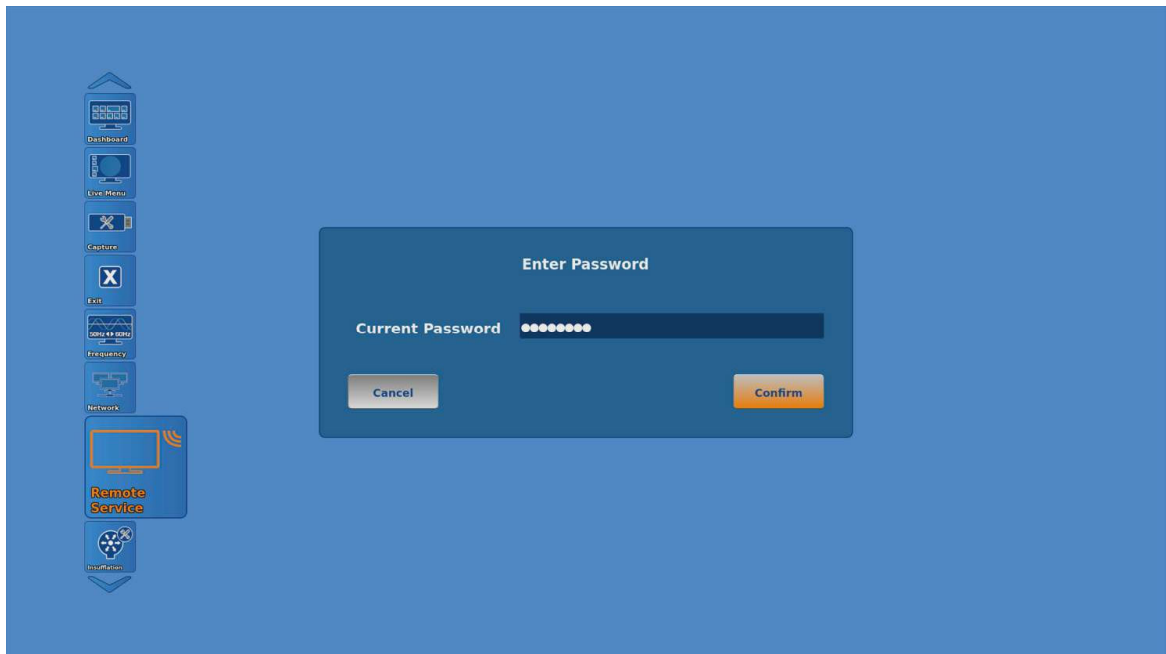


6.5 Remote Service

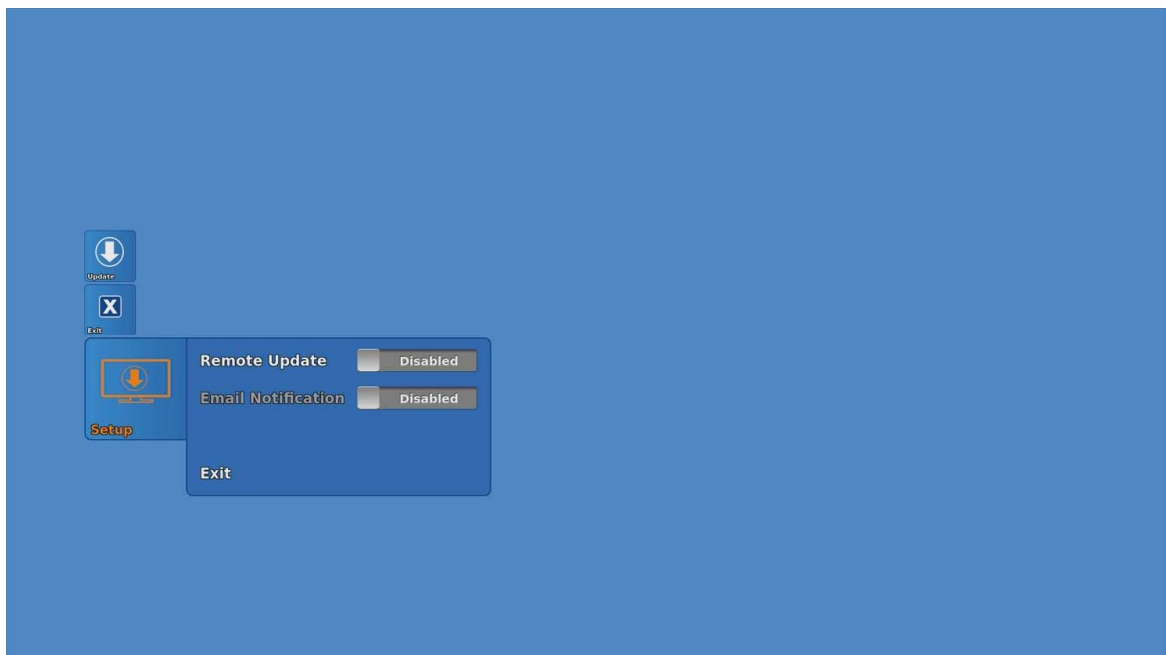
1. Make sure that the product is registered for Remote Service. If necessary, contact the local contact person.
2. Make sure that software version 4.4 or higher is installed.
3. Make sure that IPv4 is set to DHCP in the network settings, see chapter *Network* [p. 41].
4. Check whether the date and time are set correctly, Setup menu.
5. Using an OR1 patch cable, connect the product (TC200, TC201) to a network connection to connect to the Internet. If necessary, use an OR1 HIVE router.

6.5.1 Setup

1. Tap the **Remote Service** button in the **Setup** menu.
⇒ The following window appears:



2. Enter the password to access the **Patient Data Privacy** and **Network** menu, see chapter *Patient data privacy* [p. 43].
3. Tap the **Setup** button.



4. If necessary, activate the **Remote Update** option to enable online software updates, see chapter *Performing an update* [p. 48].
5. If necessary, activate the **E-mail Notification** option to receive notifications about available software updates via e-mail.

6.5.2 Performing an update

- ⓘ The installation process may not be interrupted.
 - ⓘ The product cannot be used during the update.
1. Touch the **Update** button.
 - ⇒ Both the installed and currently available software are displayed.
 2. Tap the **Description** button for information on the software.
 3. When updating the CONNECT modules and LINK modules, make sure that no camera heads or videoendoscopes are connected.
 4. Tap the **Update** button to install the software which is currently available. Make sure that the update is performed first for the CONNECT module (TC200, TC201).
 5. Follow the instructions on the screen.



6. Update the LINK module software.
7. If the update fails, restart the system and repeat the update.

6.6 Switching off the product

1. Switch the product off with the power switch.



7 Maintenance, servicing, repairs, and disposal

7.1 Maintenance

The following maintenance intervals are recommended:

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

7.2 Safety inspection in accordance with IEC 62353

⚠ WARNING

Risk of injury due to product degradation!

Patients, users and third parties may be injured as a result of product and accessory degradation.

- ▶ 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.

7.2.1 Visual inspection

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

7.2.2 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 Repairing the product

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

- ▶ Please contact your local [Product/Brand variable] 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.

7.4 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

Basic equipment

Article	Order no.
Videoendoscope adaptor 0°	TC001
Videoendoscope adaptor 90°	TC013
IMAGE 1 FULL HD extension cable, length 520 cm, for use with all IMAGE 1 HD camera heads – except H3-M	22220072
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
OR1 patch cable CAT6a 2.0 m UL	WO10275
USB silicone keyboard with touchpad, CH	20040240CH
USB silicone keyboard with touchpad, DE	20040240DE
USB silicone keyboard with touchpad, ES	20040240ES
USB silicone keyboard with touchpad, FR	20040240FR
USB silicone keyboard with touchpad, IT	20040240IT
USB silicone keyboard with touchpad, PT	20040240PT
USB silicone keyboard with touchpad, RU	20040240RU
USB silicone keyboard with touchpad, SE	20040240SE
USB silicone keyboard with touchpad, US	20040240US
USB flash drive, 32 GB	20040282
DVI connecting cable, length 200 cm	20040086
DVI connecting cable, length 300 cm	20040089
DisplayPort cable, length 3 m	TC003
Synch connecting cable, 3.5mm, 100 cm	TL006
12G-/3G-SDI cable, length 3 m	TC007
12G-/3G-SDI cable, length 10 m	TC008
LINK cable, length 30 cm	TC011
IMAGE1 PILOT	TC014
Extension cable IMAGE1 S D3-LINK	TC015
OR1 HIVE router	WO10240
HIVE router US	WO10307
USB silicone keyboard with touchpad, DE	20040241DE
USB silicone keyboard with touchpad, CH	20040241CH

Article	Order no.
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
Microscope footswitch	TC019
E-Box for X-LINK	TC028

Compatible camera heads for IMAGE1 S H3-LINK with S-Technologies

Item	Order no.
IMAGE1 S H3-Z three-chip FULL HD camera head	TH100
IMAGE1 S H3-Z three-chip FULL HD camera head	TH101
IMAGE1 S H3-Z FI three-chip FULL HD camera head	TH102
IMAGE1 S H3-P three-chip FULL HD pendulum camera head	TH103
IMAGE1 S H3-ZA three-chip FULL HD camera head	TH104
IMAGE1 S H3-M COVIEW three-chip FULL HD camera head	TH106

Compatible camera heads for IMAGE1 S H3-LINK without S-Technologies

Item	Order no.
IMAGE 1 H3-Z three-chip FULL HD camera head	22220055-3
IMAGE1 H3-ZI three-chip FULL HD inline camera head	22220053-3
IMAGE1 H3-Z FI three-chip ICG FULL HD camera head	22220085-3
IMAGE1 H3-P three-chip FULL HD pendulum camera head	22220056-3
IMAGE1 H3-ZA three-chip FULL HD camera head	22220061-3
IMAGE1 H3-FA three-chip FULL HD camera head	22220060-3

Compatible camera heads for IMAGE1 S X-LINK with S-Technologies

Item	Order no.
IMAGE1 S D1, 50 Hz	TH115
IMAGE1 S D1, 60 Hz	TH116
IMAGE1 S HX-FI	TH112
IMAGE1 S HX-P-FI	TH113

 The IMAGE1 S HX-FI (TH112) and IMAGE1 S HX-P-FI (TH113) camera heads do not support the CLARA mode.

Compatible camera heads for IMAGE1 S X-LINK without S-Technologies

Item	Order no.
IMAGE1 S HX	TH110
IMAGE1 S HX-P	TH111

Compatible videoendoscopes for IMAGE1 S X-LINK with S-Technologies

Item	Order no.
Video bronchoscope	11900BP
Video bronchoscope	11900BN
Video bronchoscope HD	11910T
Video bronchoscope HD	11910D
Video Mediastinoscope	10973HD
Video rhino-laryngoscope	11101VP
Video rhino-laryngoscope	11101VN
Video rhino-laryngoscope	11101VPS
Video rhino-laryngoscope	11101VNS
HD Video rhino-laryngoscope	11101HD
Video-gastroscope 9.3/2.8/1,100	13821PKS
Video-gastroscope 9.3/2.8/1,100	13821NKS
Slim gastroscope 5.9/2.0/1,100	13820PKS
Slim gastroscope 5.9/2.0/1,100	13820NKS
Video-gastroscope 12/4.2/1,100	13807PKS
Video-gastroscope 12/4.2/1,100	13807NKS
Video-gastroscope 12/2.8–3.4/1,100	13806PKS
Video-gastroscope 12/2.8–3.4/1,100	13806NKS
Video-gastroscope 9.7/2.8/1,100	13801PKS
Video-gastroscope 9.7/2.8/1,100	13801NKS
Video duodenoscope 12.6/4.2/1,260	13885PKS
Video duodenoscope 12.6/4.2/1,260	13885NKS
FRIMBERGER Video duodenoscope	13883PKS
Video duodenoscope 12.6/4.2/1,250	13882PKS
Video duodenoscope 12.6/4.2/1,250	13882NKS
Video colonoscope 12.9/3.8/1,600	13925HPKS
Video colonoscope 12.9/3.8/1,600	13925HNKS
Video colonoscope 12.9/3.8/1,600	13925PKS
Video colonoscope 12.9/3.8/1,600	13925NKS
Video colonoscope 12.9/3.8/1,400	13924HPKS

Item	Order no.
Video colonoscope 12.9/3.8/1,400	13924HNKS
Video colonoscope 12.9/3.8/1,400	13924PKS
Video colonoscope 12.9/3.8/1,400	13924NKS
Video colonoscope 10.6/2.8/1,600	13907PKS
Video colonoscope 10.6/2.8/1,600	13907NKS
Video colonoscope 10.6/2.8/1,400	13906PKS
Video colonoscope 10.6/2.8/1,400	13906NKS
Video colonoscope 13/3.8/1,600	13905PKS
Video colonoscope 13/3.8/1,600	13905NKS
Video colonoscope 13/3.8/1,400	13904PKS
Video colonoscope 13/3.8/1,400	13904NKS
Medium gastroscope	13823PKS
Medium gastroscope	13823NKS
Sigmoidoscope	13920PKS
Sigmoidoscope	13920NKS
Slim colonoscope	13926PKS
Slim colonoscope	13926NKS
Slim colonoscope	13927PKS
Slim colonoscope	13927NKS
Interventional gastroscope	13826PKS
Interventional gastroscope	13826NKS
Video uretero-renoscope FLEX-X C	11278VSU
Video uretero-renoscope FLEX-X C	11278VSUA
Video uretero-renoscope FLEX-X C	11278VSUE
Video uretero-renoscope FLEX-X C	11278VS
Video uretero-renoscope FLEX-X C	11278VSA
Video uretero-renoscope FLEX-X C	11278VSE
Flexible video urethro-cystoscope	11272VP
Flexible video urethro-cystoscope	11272VPU
Flexible video urethro-cystoscope	11272VN
Flexible video urethro-cystoscope	11272VNU
Flexible HD video cystoscope	11272VH
Flexible HD video cystoscope	11272VHU
TROIDL flexible rectoscope	13912PKS
TROIDL flexible rectoscope	13912NKS
Video choledochoscope	11292VP

Item	Order no.
Video choledochoscope	11292VPU
Video choledochoscope	11292VS
Video choledochoscope	11292VSU
Flexible video choledochoscope	11292VSA
Flexible video choledochoscope	11292VSUA
Flexible HD Video Choledochoscope	11292VH

Compatible single-use videoendoscopes for IMAGE1 S X-LINK with E-Box

Item	Order no.
FIVE S 3.5x65	091361-06
FIVE S 5.3x65	0915612-06
Video rhino-laryngoscope	091330-06
Video esophagoscope	091370-06
Video-uretero-renoscope FLEX-X ^{C1}	091271-06
Video-uretero-renoscope FLEX-X ^{C1}	091279-06

Compatible videoendoscopes and camera heads for IMAGE1 S D3-LINK with S-Technologies

Item	Order no.
TIPCAM1 S 3D, 0°, dia. 10 mm,	26605AA
TIPCAM1 S 3D, 30°, dia. 10 mm	26605BA
TIPCAM1 S 3D, 0°, dia. 4 mm	7240AA3D
TIPCAM1 S 3D, 30°, dia. 4 mm	7240BA3D
TIPCAM1 S 3D, 0°, dia. 4 mm	28164AA3D
TIPCAM1 S 3D, 30°, dia. 4 mm	28164BA3D
TIPCAM1 S 3D, 45°, dia. 4 mm	7240FA3D
TIPCAM1 S 3D, 45°, dia. 4 mm	28164FA3D
VITOM 3D, dia. 4 mm	TH200

Compatible camera heads and videoendoscopes for IMAGE1 S 4U-LINK with S-Technologies in combination with IMAGE1 S CONNECT II

Item	Order no.
IMAGE1 S 4U	TH120
IMAGE1 S 4U Rubina	TH121
VITOM EAGLE	TH201
TIPCAM1 Rubina, 0°	26606ACA
TIPCAM1 Rubina, 30°	26606BCA

The IMAGE1 S 4U camera head can also be used together with the IMAGE1 S CONNECT.

Operable SCB light sources

Item	Order no.
XENON 300 SCB	20133120-1
XENON 175 SCB	20132120-1
POWER LED 175 SCB	20161420-1
XENON 100 SCB	20132620-1
Cold light fountain CO2mbi LED SCB	TL100
Cold light fountain power LED 300	TL300
D-LIGHT C	20133620-1
D-LIGHT C/AF	20133620-133
D-LIGHT P	20133720-1

Operable KS HIVE light sources

Item	Order no.
Power LED Rubina	TL400
Power LED Saphira	TL410

Operable SCB insufflators

Item	Order no.
THERMOFLATOR SCB	26432020-1
ENDOFLATOR SCB	26430520-1
ENDOFLATOR 40	UI400
ENDOFLATOR 50	UI500

3D monitors

Item	Order no.
3D monitor (FHD), 26"	9826NB-3D
3D monitor (FHD), 32"	9832NB-3D
3D monitor (FHD), 32"	TM323
3D monitor (FHD), 32"	TM330
3D monitor (FHD), 26"	TM263
4K 3D monitor, 32"	TM350
32" 4K/3D Monitor	TM351
4K/3D monitor, 55"	TM450

2D monitors

Item	Order no.
2D monitor (FHD), 19"	9619NB
2D monitor (FHD), 26"	9626NB
2D monitor (FHD), 27"	9627NB
2D Monitor (FHD), 21.5"	WM100
2D monitor (FHD), 27"	TM220
4K 2D monitor, 32"	TM324
4K/2D monitor, 32"	TM340
4K 2D monitor, 31"	TM341
4K 2D monitor, 31"	TM342
4K 2D monitor, 58"	TM440
4K 2D monitor, 32"	TM343
4K 2D Monitor, 43"	TM441

KS HIVE compatible motorized support arms

Item	Order no.
ARTIP CRUISE	UR500B
ARTIP CRUISE	UR500C

Compatible veterinary videoendoscopes for IMAGE1 S X-LINK with S-Technologies

Item	Order no.
Veterinary videoendoscope	60914NKS
Veterinary videoendoscope	60914PKS
Veterinary videoendoscope	60714NKS
Veterinary videoendoscope	60714PKS
Veterinary videoendoscope	60511NKS
Veterinary videoendoscope	60511PKS
Veterinary videoendoscope	60332NKS
Veterinary videoendoscope	60332PKS
Veterinary videoendoscope	60130NKS
Veterinary videoendoscope	60130PKS
Veterinary videoendoscope	60125NKS
Veterinary videoendoscope	60125PKS
Veterinary videoendoscope	60118NKS
Veterinary videoendoscope	60118PKS
Veterinary videoendoscope	60278VS
Veterinary videoendoscope	60278VSU


9 Electromagnetic compatibility

9.1 General notes on the operating environment

Special environment

The product is suitable for use in close proximity to an active HF electrosurgical device in professional healthcare facility environments. Professional healthcare facility includes 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 RF shielded room of an ME system for MRT).

 This product has been evaluated for compatibility with high-frequency surgical equipment.

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

WARNING

Electromagnetic interferences! Malfunction!

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

- ▶ This situation should be avoided.
- ▶ If such use is necessary: Verify that this equipment and the other equipment are operating normally.



CAUTION

MR unsafe!

This product is MR unsafe.

- ▶ Keep the product away from the Magnetic Resonance Imaging (MRI) Scanner Room and mobile MRI scanner.

9.2 Accessories, transducers, and cables

WARNING

Reduced immunity! Malfunction!

The use of an accessory, transducers and cables with the product other than those specified in this manual may result in increased emissions or decreased immunity.

- ▶ Preferably use the accessories specified in the manual.
- ▶ When using other than those specified in this manual, it becomes the responsibility of the user to determine compliance with IEC 60601-1-2.

⚠ 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.

- ▶ Use portable communications equipment no closer than 30 cm (12 inches) to any part of the product, including cables.

The following accessories and cables are defined for EMC compliance.

Type	Shielded	Maximum length (m)	Contains ferrite	Use
LINK cable (IML cable)	Yes	2	No	Interconnection of inter-module LINK signals
BNC to BNC (12G SDI cable)	Yes	10	No	Connection of 3G/12G SDI video signals
DVI	Yes	3	Yes	Connection of DVI signals
DisplayPort cable	Yes	3	No	Connection of DisplayPort signals (TC201 only)
4 pin mini-DIN	Yes	1	No	Connection of SCB signals
Power cord	No	2	No	Device power supply connection
Ethernet – CAT6A	Yes	2	No	Connection of HIVE signals

9.3 Test-Tables

9.3.1 Table 1 – Compliance level for immunity tests

Interference immunity tests	EN/IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
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	The relative humidity should 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/± 1 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 line(s) to line(s) ± 2 kV line(s) to ground	± 1 kV line(s) to line(s) ± 2 kV line(s) to ground	The power supply quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and fluctuations of the power supply acc. to IEC 61000-4-11	<u>Voltage dip:</u> Dip to 0% for 1 cycle @ 0° phase angle	<u>Voltage dip:</u> Dip to 0% for 1 cycle @ 0° phase angle	The power supply quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation in the event of interruptions to the

Interference immunity tests	EN/IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
	<p>Dip to 70% for 25/30 cycles @ 0° phase angle</p> <p>Dropout to 0% for 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° phase angles</p> <p><u>Voltage interruption:</u> 100% for 250/300 cycles</p>	<p>Dip to 70% for 25/30 cycles @ 0° phase angle</p> <p>Dropout to 0% for 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° phase angles</p> <p><u>Voltage interruption:</u> 100% for 250/300 cycles</p>	<p>power supply network, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.</p>
<p>Magnetic field at the supply frequency (50 Hz/60 Hz) acc. to IEC 61000-4-8</p>	<p>30 A/m at 50 Hz/60 Hz</p>	<p>30 A/m at 50 Hz/60 Hz</p>	<p>If image distortion occurs, it may be necessary to position the equipment further from sources of power frequency magnetic fields or to install magnetic shielding. Before installing the device, the electromagnetic field should be measured to ensure that it is sufficiently low.</p>
<p>Immunity test acc. to IEC 61000-4-3 for high-frequency electromagnetic fields</p>	<p>3 V/m 80 MHz to 2.7 GHz</p> <p>see chapter <i>Table 2 – Test levels for proximity fields from RF wireless communications equipment</i> [p. 62] for wireless HF near field test levels</p>	<p>3 V/m 80 MHz to 2.7 GHz</p>	-
<p>Immunity to conducted disturbances, induced by radio-frequency fields acc. to IEC 61000-4-6</p>	<p>3 V_{rms} on 150 kHz to 80 MHz</p> <p>1 kHz 80% AM modulation</p> <p>6 V_{rms} in ISM frequency bands between 0.15 MHz and 80 MHz</p>	<p>3 V_{rms} on 150 kHz to 80 MHz</p> <p>1 kHz 80% AM modulation</p> <p>6 V_{rms} in ISM frequency bands between 0.15 MHz and 80 MHz</p>	-
<p>Magnetic field in close proximity, IEC 61000-4-39</p>	<p>8 A/m @ 30 kHz (CW modulation)</p> <p>65 A/m @ 134.2 kHz (pulse modulation)</p> <p>7.5 A/m @ 13.56 kHz (pulse modulation)</p>	<p>8 A/m @ 30 kHz (CW modulation)</p> <p>65 A/m @ 134.2 kHz (pulse modulation)</p> <p>7.5 A/m @ 13.56 kHz (pulse modulation)</p>	-

9.3.2 Table 2 – Test levels for proximity fields from RF wireless communications equipment

Test frequency MHz	Frequency band ^{a)} MHz	Radio service ^{a)}	Modulation	Immunity test level V/m	Compliance level V/m
385	380–390	TETRA 400	Pulse modulation ^{b)} 18 Hz	27	27
450	430–470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz deviation 1 kHz sine wave	28	28
710	704–787	LTE band 13 & 17	Pulse modulation ^{b)} 217 Hz	9	9
745					
780					
810	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation ^{b)} 18 Hz	28	28
870					
930					
1720	1700–1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE band 1, 3, 4, 25, UMTS	Pulse modulation ^{b)} 217 Hz	28	28
1845					
1970					
2450	2400–2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modulation ^{b)} 217 Hz	28	28
5240	5100–5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	9	9
5500					
5785					

If necessary to achieve the immunity test level, the distance between the transmitting antenna and the product may be reduced to 1 meter. The 1 meter test distance is permitted by IEC 61000-4-3.

^{a)} For some radio services, only the uplink frequencies are included.

^{b)} The carrier shall be modulated using a 50% duty cycle square wave signal.

^{c)} As an alternative to FM modulation, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.

9.3.3 Table 3 – Emission class and group

Emission measurements	Compliance	Electromagnetic environment – guidance
RF emissions as per CISPR 11	Group 1	The product uses RF energy only for its internal function. The customer or user of the product should make sure that it is used in such an environment. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic product.
RF emissions as per CISPR 11	Class A	The product 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.
Harmonic emissions as per IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions as per IEC 61000-3-3	Complies	

9.3.4 Table 4 – Recommended separation distances between portable and mobile HF communications equipment 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.

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