

STORZ

KARL STORZ — ENDOSKOPE

en **Instructions for use**
AIDA C WD310
V1.0.0



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1 General information

1.1 Read the instructions for use

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

1. Read the instructions for use of the product carefully and follow them completely.
2. Keep the instructions for use clearly visible next to the product.
3. Observe the instructions for use of products used in combination.

It is recommended to check the suitability of the products for the planned procedure prior to use.

1.2 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 warning messages describe 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.

ATTENTION

ATTENTION

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

2 Normal use

2.1 Intended use

The KARL STORZ AIDA is intended for use by qualified personnel in the Doctor's Office or Operating Room. The AIDA is a dedicated appliance (consisting of hard- and software) intended for documentation of audio-visual and patient data during a diagnostic or therapeutic procedure. It allows for the capture and the annotation of the surgical procedure for documentation purposes. Audio-visual data recorded and distributed by AIDA are not intended for diagnostic or therapeutic purposes. Recorded audio-visual data is not intended for intraoperative display on the surgical monitor.

2.2 Indications

Receiving audio and video signals from signal sources and sending them to signal destinations in the case of medical procedures.

2.3 Contraindications

Use is contraindicated if, in the opinion of the responsible physician, the device is not compatible with successful completion of the planned procedure due to its technical design.

2.4 Target user populations

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

2.5 Patient groups

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

This product is intended for the following patient groups:

3 Safety

3.1 Serious incidents

According to the Medical Device Regulation (MDR), a “serious incident” includes incidents that directly or indirectly had, could have had, or could have any of the following consequences (MDR, Art. 2, No. 65 [1]):

- 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 Correct handling

If the product is not handled correctly, patients, users, and third parties may be injured.

- ▶ Only persons with the necessary medical qualification and who are acquainted with the application of the product may work with it.
- ▶ Check that the product is suitable for the procedure prior to use.
- ▶ Check the product for the following points before and after every use:
 - Completeness
 - Good working order
 - Rough surfaces left inadvertently
 - Sharp corners
 - Burred edges
 - Correct assembly of the components
 - Functionality
- ▶ Do not leave broken-off components inside the patient.
- ▶ Do not overload the product with mechanical stress.
- ▶ Do not bend bent products back to their original position.

3.3 Correct reprocessing

Incorrectly reprocessed products expose patients, users, and third parties to a risk of infection.

- ▶ Reprocess the product before use.
- ▶ A validated reprocessing procedure must be followed and the product must be reprocessed in line with the reprocessing instructions.

3.4 Contaminated products

Contaminated products pose a risk of infection for users, patients, and third parties.

- ▶ Comply with national laws and regulations.
- ▶ Observe the guidelines of the Employer’s Liability Insurance Association and equivalent organizations.

3.5 Combination with other components

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

Additional devices connected to electrical medical equipment must comply with the relevant IEC or ISO standards. Furthermore, all configurations must comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3rd edition of IEC 60601-1).

- ▶ Only combine the product with devices and components that are approved for joint use by the manufacturer.
- ▶ The product should not be used immediately adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the product should be observed to verify normal operation in the configuration in which it will be used.
- ▶ Observe the instruction manuals and interface specifications of the devices and components used in combination.
- ▶ Only use devices with display capability that are identified as "display".
- ▶ Comply with national and local regulations.
- ▶ Only make changes to the product if these changes are approved by KARL STORZ.

3.6 Damaged products

Damaged products can result in injury to patients, users, and third parties.

- ▶ Before every use, check all components of the product for damage.
- ▶ Do not use damaged products.
- ▶ Have defective products checked by KARL STORZ or by companies authorized by KARL STORZ.
- ▶ Have regular safety inspections performed by KARL STORZ or by companies authorized by KARL STORZ.

3.7 Dangers from electrical current

An improper power supply may cause an electric shock and injure patients, users, or third parties. All electrical installations of the operating room in which the product is connected and used must meet the applicable IEC standards. Input and output equipment connected to the product must comply with IEC 60601-1.

- ▶ Have the device installed and put into service by authorized and trained electricians of KARL STORZ SE & Co. KG or by companies authorized by KARL STORZ.
- ▶ 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.
- ▶ Position the product appropriately so that the power cord can be unplugged at any time. The product is only voltage-free when the mains plug has been disconnected.
- ▶ 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.
- ▶ Connect the product to a power supply with protective conductor.
- ▶ If several devices are connected to the product, note the maximum leakage current.

In the case of electrical products, individual components or the product itself may be live. Live parts can cause electric shocks in the event of contact and injure patients, users, and third parties.

- ▶ Do not open the product.
- ▶ Have servicing carried out by KARL STORZ or a company authorized by KARL STORZ. Failure to observe this will void the guarantee.
- ▶ Do not touch the output jacks of the product and the patient at the same time during use.
- ▶ Always pull out the mains plug before carrying out any cleaning and maintenance work.

- ▶ Disconnect the power plug before opening the housing.

3.8 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 HFID) emit electromagnetic radiation, the function of the product may be disturbed. High-frequency communication equipment can affect electrical medical products and impair their performance.

- ▶ Do not use the product in the vicinity of a magnetic resonance tomograph (MRT).
- ▶ Do not use the product next to or together with other devices. If such use is required, monitor the product and the other devices, and follow the relevant instructions for use in the event of malfunctions.
- ▶ Portable RF communications equipment including peripheral devices (e.g., antenna cables and external antennas) should be used no closer than 30 cm from the product, including cables specified by the manufacturer.
- ▶ Observe the information on electromagnetic compatibility; see chapter Electromagnetic compatibility [p. 87].
- ▶ In case of uncertainties, seek expert advice from KARL STORZ.
- ▶ Before use, a clinical/biomedical engineer or an EMC specialist should carry out an ad-hoc test of the electromagnetic radiation.
- ▶ To prevent increased electromagnetic emissions or reduced electromagnetic immunity of the product, only use accessories, transducers, and cables recommended or supplied by the manufacturer.
- ▶ In order to avoid exposing patients, users, or third parties to harmful electromagnetic interference, the product must not be operated outside of its intended EMC environment. Furthermore, the product must not be operated if the housing, cable, or electromagnetic shielding equipment is damaged.

3.9 Damage due to ingress of liquid in electrical components

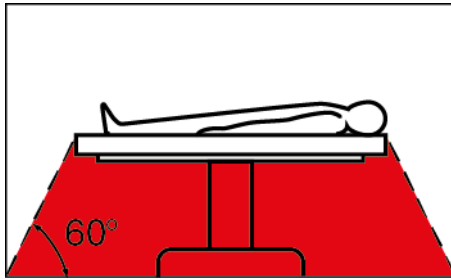
In the case of electrical products, individual components or the product itself may be live. Liquid ingress into an electrical product may result in a short circuit or an unintentional transfer of current. The product is damaged as a result and patients, users and third parties may be injured.

- ▶ 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.

3.10 Risk of explosion

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.

- ▶ The product must not be operated in oxygenated environments.
- ▶ Do not operate the product in explosive atmospheres.
- ▶ Do not operate the product in environments with combustible gases such as inhalation anesthetics and mixtures thereof. Observe the hazard zones:



- ▶ Only connect or disconnect the power plug to or from the power supply outside explosive atmospheres.
- ▶ Combustible and flammable gases must be allowed to escape, be extracted, or be displaced with CO₂ before use.
- ▶ Only start the application when combustible or flammable gases and liquids are no longer present.

3.11 Observing ambient conditions

If the device is stored, transported, operated or reprocessed under unsuitable conditions, patients, users or third parties may be injured and the device can be damaged.

- ▶ Observe the ambient conditions listed in the instructions for use and reprocessing.

3.12 Failure of systems

The system may fail during use.

- ▶ Have a replacement system ready for each application.

3.13 Data loss

Data may be lost when working on the software and hardware or on the hard disk, e.g., during a system recovery.

- ▶ Back up existing data before formatting the hard disk.
- ▶ Only transfer encrypted data.
- ▶ Ensure that data storage is finished and only then remove an external storage medium.
- ▶ Perform a system test which verifies perfect functioning after adding new software or hardware.
- ▶ Shut down the software via the user interface or by briefly pressing the rocker switch.

4 Product description

4.1 Description of operation

The device enables diagnostic and therapeutic interventions to be recorded as still images, video and audio sequences.

The recorded data can be saved, edited and annotated, forwarded and printed for documentation purposes.

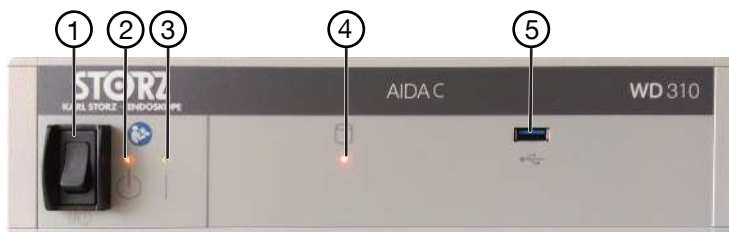
4.2 Product overview

⚠ WARNING

Electric shock!

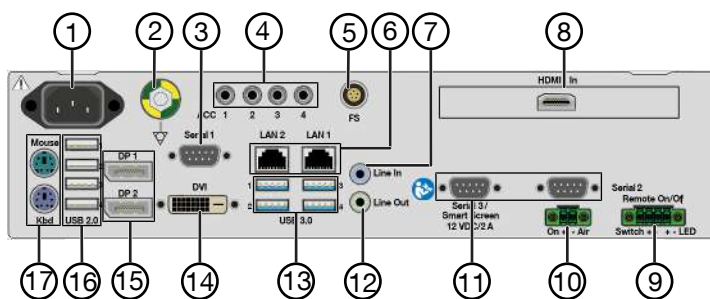
There is a voltage of 12 V / 2 A at the 'Smart Screen' socket.

- ▶ Do not touch the socket during operation.
- ▶ Only connect or remove the cable when the device is switched off.



Front panel

- | | | | |
|---|---|---|------------------------------|
| 1 | Rocker switch ON/OFF Standby and operating mode | 4 | Access to hard disk LED, red |
| 2 | Standby LED, yellow | 5 | USB 3.0 |
| 3 | ON LED, green | | |



Back panel

- | | | | |
|---|---------------------------------------|----|--|
| 1 | Power connection | 10 | Phoenix 2-pin (On Air Lamp) |
| 2 | Potential equalization connection | 11 | Serial interfaces, smart screen (D-Sub DE 9) |
| 3 | Serial interface (D-Sub DE 9) | 12 | Mini jack (audio OUT) |
| 4 | 4x 3.5 mini jack (camera head button) | 13 | 4x USB 3.0 |
| 5 | Foot pedal connection (Lemo 5-pin) | 14 | Monitor (DVI) |
| 6 | 2x LAN (RJ-45) | 15 | 2x monitor (digital port) |

| | | | |
|---|--|----|-----------------------|
| 7 | Mini jack (audio IN) | 16 | 4x USB 2.0 |
| 8 | HDMI ON | 17 | Mouse/keyboard (PS/2) |
| 9 | Remote switch KARL STORZ OR1 FUSION® (Phoenix 4-pin) | | |

4.3 Technical data

| Designation | Value |
|---|---|
| Power supply | |
| Operating voltage | 100–240 V |
| Operating frequency | 50–60 Hz |
| Power input | 5–2 A |
| Electrical protection class | I |
| Degree of protection acc. to IEC 60259 | IP 20 |
| Housing | |
| Dimensions (L x H x W) | 355 x 74.5 x 305 mm |
| Weight | 6.0 kg |
| System | |
| WLAN adaptor | in accordance with IEEE 802.11ac |
| Channel width (bidirectional) | 20 MHz / 40 MHz / 80 MHz |
| Preferred frequencies (bidirectional) | Channel used is determined by external infrastructure (access point). |
| Bandwidth (receiver) | 2.4 GHz / 5 GHz |
| Frequencies and frequency bands (receiver) | 2.4 GHz 2.399–2.4845 GHz (channel 1 to 13) |
| | 5 GHz 5.15–5.35 GHz (channel 36 to 64) 5.47–5.725 GHz (channel 100 to 140) |
| | 2.4 GHz 2.399–2.4845 GHz (channel 1 to 13) |
| Frequencies and frequency bands (transmitter) | 2.4 GHz 2.399–2.4845 GHz (channel 1 to 13) |
| | 5 GHz 5.15–5.35 GHz (channel 36 to 64) 5.47–5.725 GHz (channel 100 to 140) |
| | 2.4 GHz 2.399–2.4845 GHz (channel 1 to 13) |
| Modulation characteristics | in accordance with IEEE 802.11ac |
| Transmission power (effective) | 2.4 GHz 100 mW |
| | 5.15–5.35 GHz 200 mW |
| | 5.47–5.725 200 mW |

| Designation | Value |
|----------------------------|---------------------------|
| Hard disk capacity | 1 TB |
| Random Access Memory (RAM) | 8 GB |
| CPU | Intel® Core™ i5-9500TE |
| Operating system | Windows 10 IoT Enterprise |
| Operating mode | Continuous operation |

4.4 Possible combinations

Supported touchscreen models

Use the supplied DisplayPort cable to connect touchscreens. Alternatively, you can use a DVI-D Single Link cable, 18+1 with a maximum length of 3 m and two ferrite cores.

| Item | Order no. |
|-------------------------------|-----------|
| KARL STORZ touchscreen, 21.5" | WM100 |
| KARL STORZ touchscreen, 21.5" | 20090621 |
| KARL STORZ touchscreen, 21.5" | 20090521 |
| KARL STORZ touchscreen, 24.5" | WM101 |
| KARL STORZ touchscreen, 24.5" | 20090624 |
| KARL STORZ touchscreen, 24.5" | 20090524 |

Supported display types

| Item | Order no. |
|------------|-----------|
| 2D monitor | 9524NB |
| 2D monitor | 9726NB |
| 2D monitor | 9626NB |
| 2D monitor | 9627NB |
| 2D monitor | 9526NBL |
| 2D monitor | 9619NB |
| 2D monitor | 9626NB-2 |
| 2D monitor | 9826NB |
| 2D monitor | TM220 |
| 2D monitor | TM263 |
| 2D monitor | TM340 |
| 2D monitor | TM341 |
| 2D monitor | TM342 |
| 2D monitor | TM440 |

Supported camera types

To connect other HDMI image sources, KARL STORZ recommends using Premium High Speed HDMI cables with a maximum length of 2 m (e.g., PureLink PS3000-020).

| Item | Order no. |
|----------------------|-----------|
| IMAGE1 S CONNECT® | TC200 |
| IMAGE1 S CONNECT® II | TC201 |
| IMAGE1 HD | 22202020x |
| IMAGE1 HUB HD | 22201020x |
| TELECAM C3 | TC100 |

Remote switch

| Item | Order no. |
|---------------|-----------|
| Remote switch | W23174 |

Footswitch

| Item | Order no. |
|------------|-----------|
| Footswitch | 20014430 |






Connecting cable











| Item | Order no. |
|------------------------|-----------|
| Connecting cable 2.5 m | 4802051 |

-  This accessory must be used if the product is installed in a housing, rack, or in-wall configuration.





4.5 Symbols employed



4.5.1 Symbols on the packaging

| Symbol | Meaning |
|---|------------------------------|
|  | Manufacturer |
|  | Date of manufacture |
|  | Consult instructions for use |
|  | Fragile, handle with care |
|  | Keep dry |











| Symbol | Meaning |
|---|---|
|  | Air pressure limit |
|  | Humidity limit |
|  | Temperature limit |
|  | Article no. |
|  | Serial number |
|  | Number of products in the product packaging |
|  | Medical device |
|  | Unique Device Identifier |
|  | In accordance with US federal law (21 CFR 801.109), this product may only be sold to or on prescription from a licensed physician. |
|  | CE conformity mark With this mark, the manufacturer declares the compliance of the products with the applicable regulation (EU) 2017/745. A code number after the CE mark indicates the responsible notified body. |

4.5.2 Symbols on the product









| Symbol | Meaning |
|---|---|
|  | Follow instructions for use |
|  | Dangerous voltage Danger of an electric shock! |
|  | The potential equalization is responsible for equalizing the potentials of different metal parts that can be touched at the same time, or for reducing potential differences that could occur between the body, electromedical devices, and external live parts during use. |
|  | 'Standby' When the yellow indicator light is on, the device is in standby mode. |

| Symbol | Meaning |
|---|---|
| | 'ON' When the green indicator light is on, the device is switched on. |
|  | 'Access to hard disk' When the red indicator light is on, the hard disk is being accessed. |
|  | USB |

4.5.3 Symbols on the rating plate

| Symbol | Meaning |
|---|---|
|  | Manufacturer |
|  | Date of manufacture |
|  | Environmental protection use period of 10 years (China RoHS) |
|  | Separate collection of electrical and electronic devices. Do not dispose of in household refuse. |
|  | CSA certification mark for the USA and Canada With this mark, the manufacturer declares compliance with the certification requirements. |
|  | Alternating current |
| SN | Serial number |
|  | Medical device |
|  FCC ID: PD9260NG IC: 1000M-5260NG | Non-ionizing radiation The IC identification code refers to the internal Wi-Fi adaptor |
| FCC ID: | FCC identification number of the internal WLAN adapter |
| IC: | IC identification number of the internal WLAN adapter |
|  | In accordance with US federal law (21 CFR 801.109), this product may only be sold to or on prescription from a licensed physician. |
|  | CE conformity mark With this mark, the manufacturer declares the compliance of the products with the applicable regulation (EU) 2017/745. A code number after the CE mark indicates the responsible notified body. |

4.5.4 Symbols on the user interface

| Symbol | Meaning |
|---|---|
|  | User Call up the user login. |
|  | Filing Cabinet Display documentation which has already been created. The symbol is only available if the home screen has been deactivated. |
|  | Microphone Mute the microphone. The microphone is muted as standard and must be activated manually. |
|  | Volume Set the output level of the active speakers or headphones. |
|  | Settings Select the functional scope and application-specific settings. This area is password protected. |
|  | System information Display product data and license information and save it on a USB stick. |
|  | Exit Exit or shut down AIDA® or log out the user. |
|  | Printer Display the status of the connected printer. The symbol is only available if a SONY printer is connected. |

4.6 Ambient conditions

| Storage/transport conditions | |
|------------------------------|-------------------|
| Ambient temperature | -10 °C ... +60 °C |
| Relative humidity | 5–95% |
| Air pressure | 500–1,080 hPa |
| Operating conditions | |
| Ambient temperature | 5 °C ... 35 °C |
| Relative humidity | 10–90% |
| Air pressure | 700–1,080 hPa |
| Maximum 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 evidence of shipping 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.

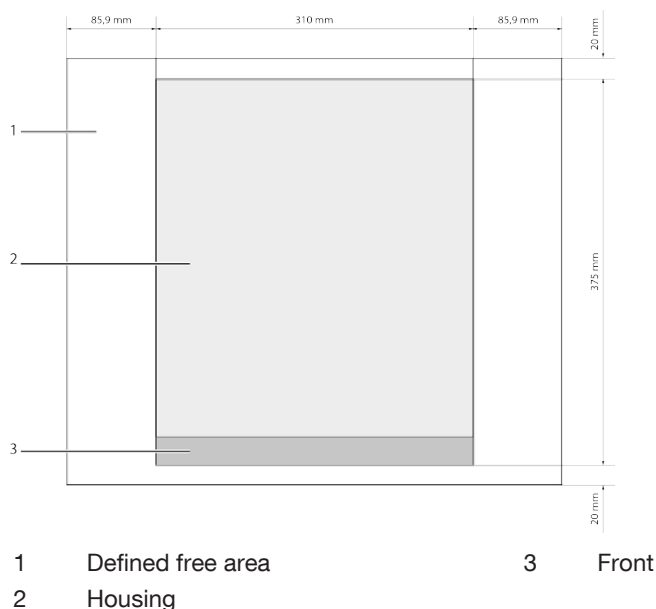
5.2 Testing the product

1. Inspect the product for visible contamination. Do not use if contaminated.
2. Inspect the product for the following characteristics:
 - Good working order
 - Functionality
 - Correct assembly of the components
 - Completeness

5.3 Setting up the device

The product can be operated free-standing, in a rack or as a wall-mounted solution in either a vertical or horizontal position.

1. Clean and disinfect the product thoroughly before using for the first time.
2. Observe the ambient conditions, see section Ambient conditions [p. 18].
3. Observe the technical data, see section Technical data [p. 13].
4. Install the product out of reach of patients.
5. Note the free area dimensions based on the graphic to guarantee that the product is sufficiently ventilated.



-  Nothing may be mounted in the defined free areas.

5.4 Connecting the product

The product may only be connected to other components by KARL STORZ service personnel or personnel authorized by KARL STORZ.

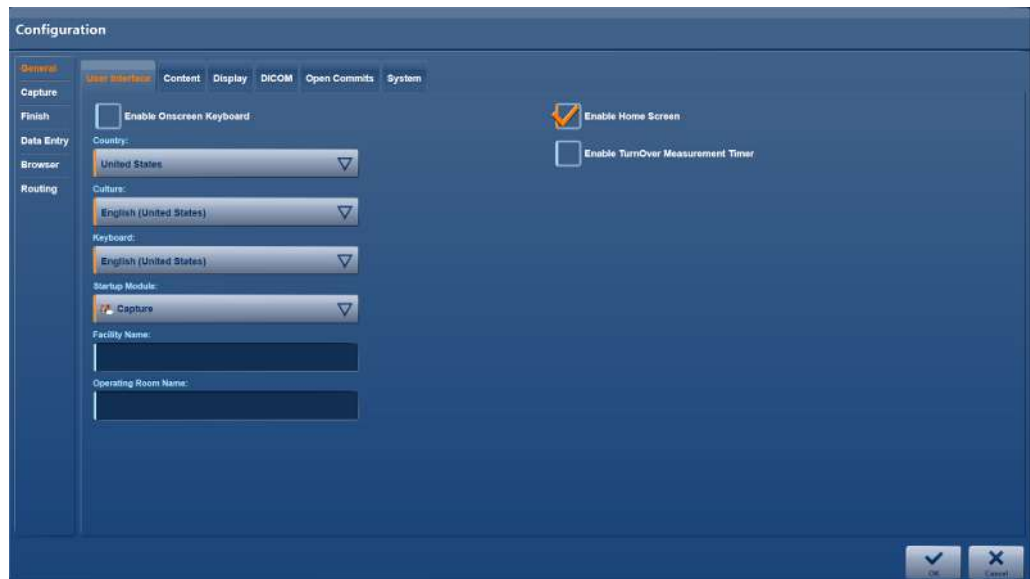
6 Installation and commissioning

6.1 Overview of configuration area

 The configuration must be checked after each software update.

The configuration area displays all menus and tabs on which you can make settings. Which menus and tabs are available depends on the administration role you have logged in with.

The menus and tabs of the user interface are explained in the subsequent sub-sections.



6.1.1 Opening the configuration area

1. Tap the **Settings** button.
⇒ The following window appears:

2. Enter the username and password.
3. Confirm with **OK** or by pressing Enter.
⇒ The *Manage Profiles* window, in which the currently assigned default or group profile is displayed, appears.

4. Edit the assigned profile or reset all settings.
 - ⇒ Edit the profile: The configuration area appears.
 - ⇒ Reset the profile: The group profile assigned by the administrator or the default profile is reset.

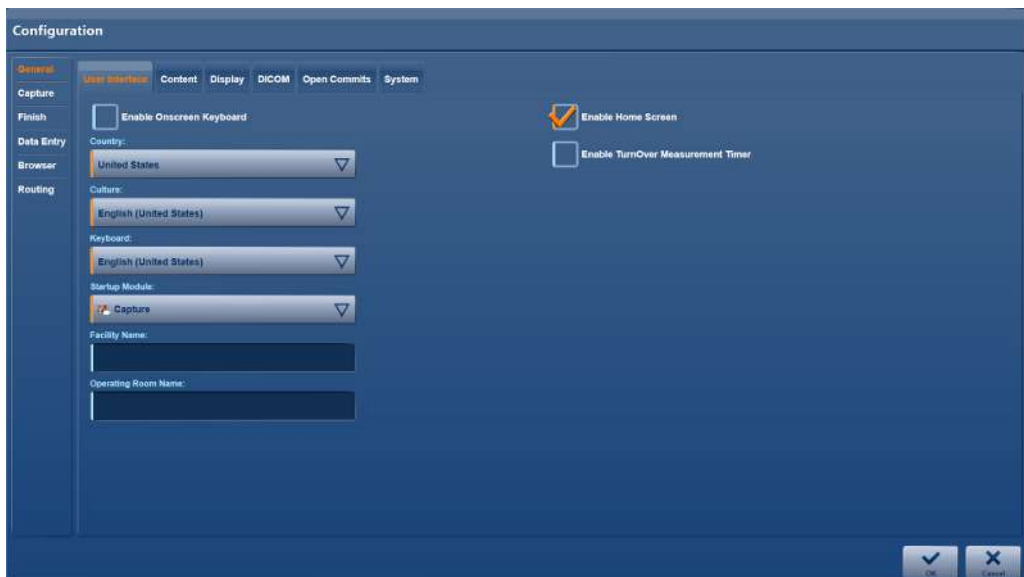
6.1.2 General

6.1.2.1 User interface

The following can be defined and enabled on the *User Interface* tab:

- System language
- Keyboard layout
- Start screen
- Onscreen keyboard

1. Tap the *General* menu.
 - ⇒ The *User Interface* tab is displayed:

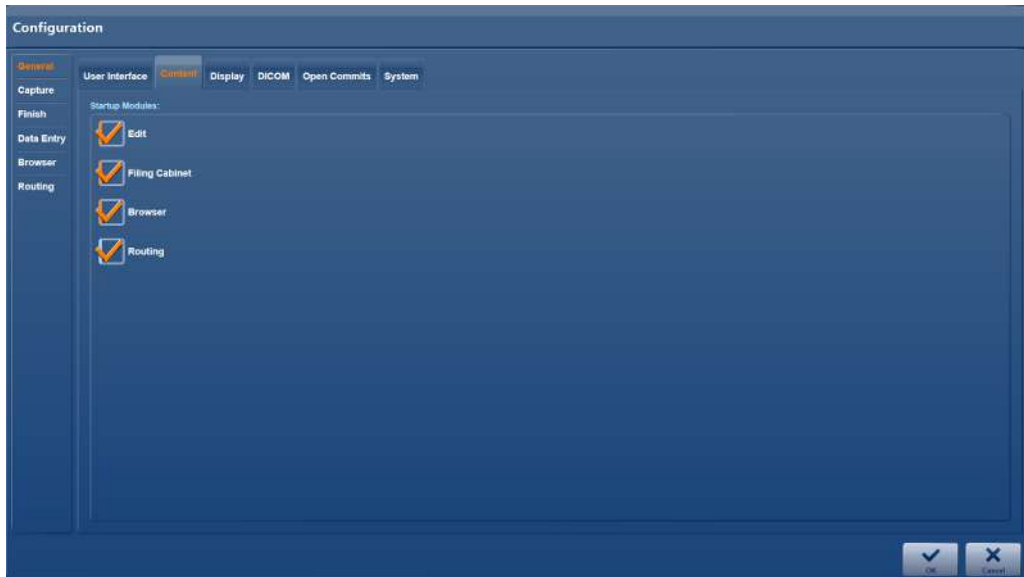


2. Place a check mark next to *Enable Onscreen Keyboard* if the virtual keyboard is to be available for entering text on the touchscreen.
3. Open the drop-down menus and define the following:
 - Country:* location
 - Culture:* system language
 - Keyboard:* keyboard layout
 - Startup Module:* module displayed once the system has started
4. Enter the facility name.
5. Enter the name of the operation room if the room is to be available for a room-to-room connection.
6. Place a check mark next to *Enable Home Screen* to enable the home screen.

6.1.2.2 Content

The *Content* tab is used to set up the system's range of functions.

1. Tap the *Content* tab.

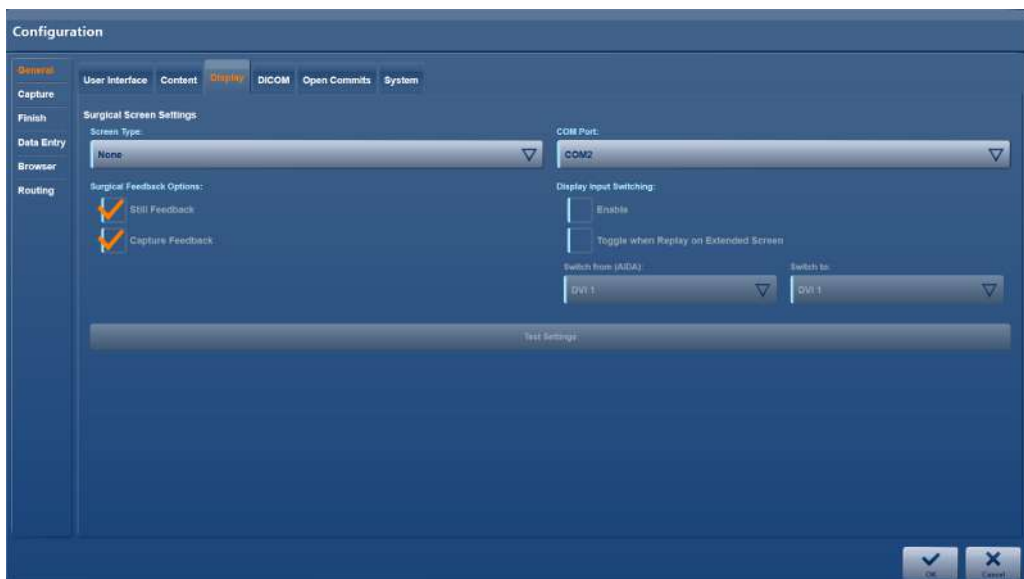


2. Enable or disable the required modules.

6.1.2.3 Display

The *Display* tab is used to make the settings for the operation monitor.

1. Tap the *Display* tab.

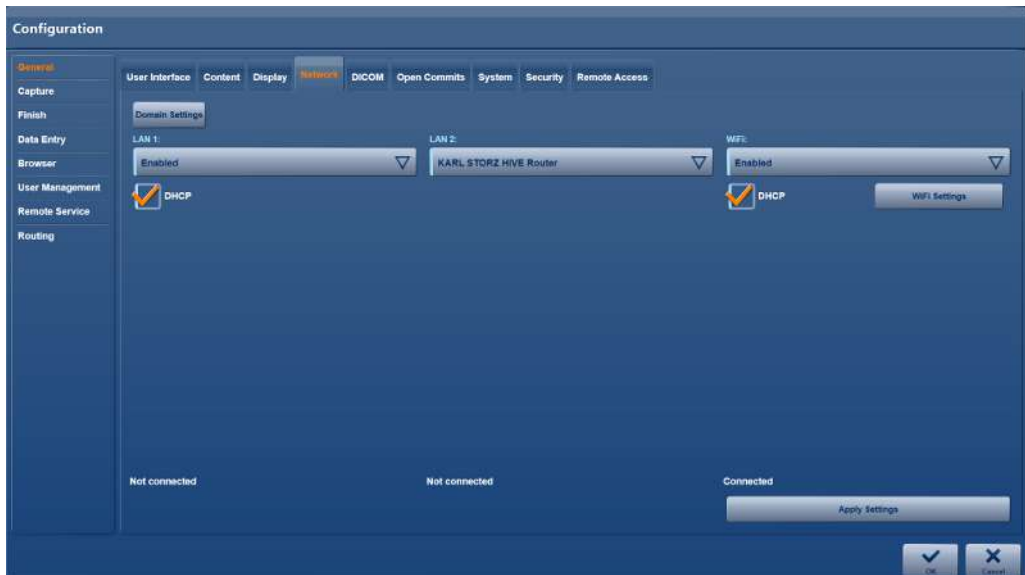


2. Select the *Screen Type*.
3. Select the *COM Port*.
4. Check the required checkboxes.
5. To switch to a different screen, select a connection, e.g., *DVI 1*.
6. Test the settings if necessary.
7. Press **OK** to confirm.
8. Restart the computer to enable the settings.

6.1.2.4 Network

The settings for the local and wireless network are made on the *Network* tab.

1. Tap the *Network* tab.



2. Make the required settings.
3. Tap **Apply Settings**.
4. Press **OK** to confirm.

6.1.2.5 DICOM

⚠ CAUTION

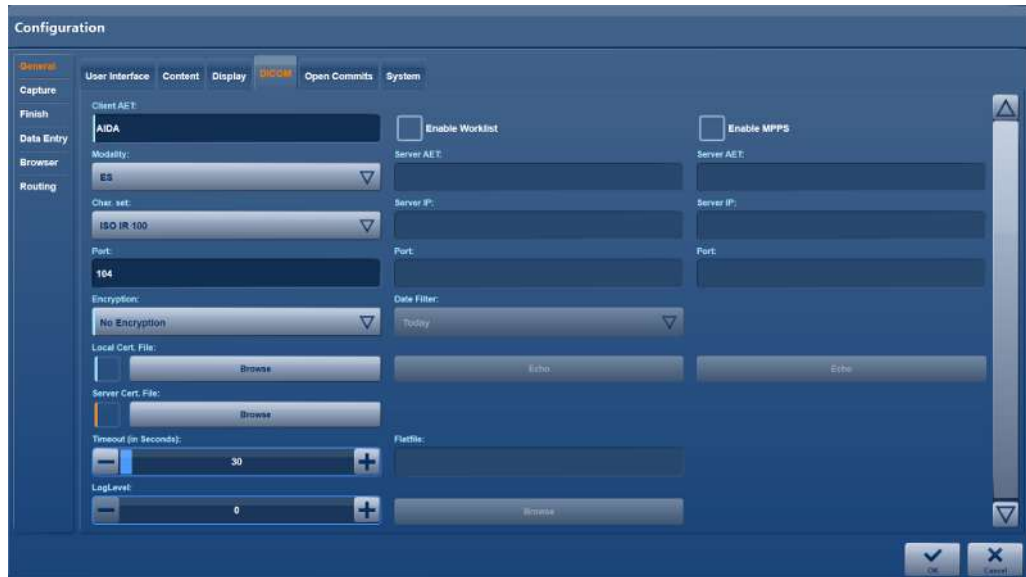
Data privacy!

If an encryption protocol is not selected, data is transmitted in an unencrypted format and data may not be transmitted securely.

- ▶ Only transmit data in encrypted format.

The *DICOM* tab is used to set up the DICOM interface.

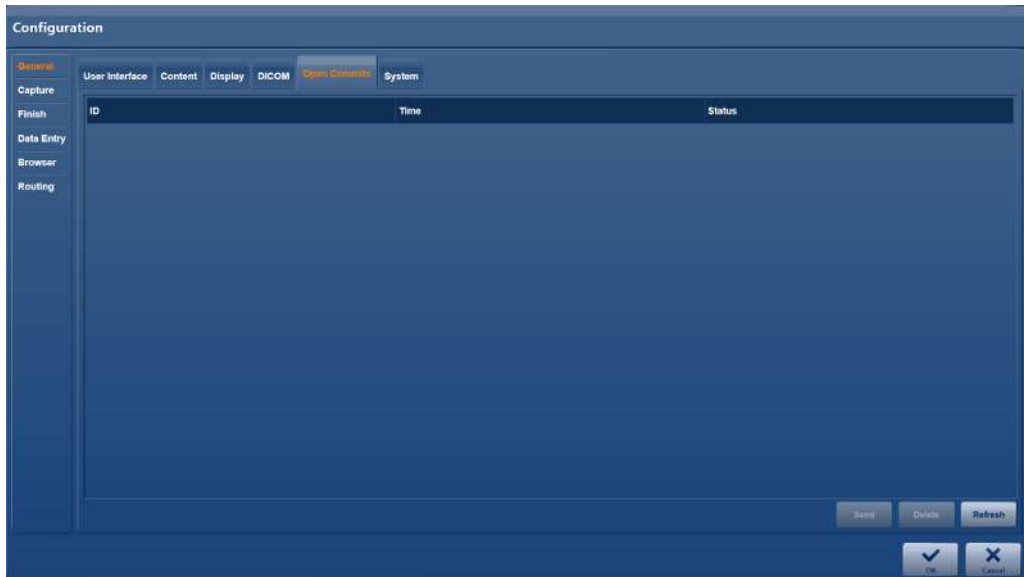
The MPPS service (Modality Performed Procedure Step) can be enabled and set up on the tab. This service enables notification of a performed action.



1. In the *Client AET* field, enter the AE title which was assigned to the AIDA® system by the IT department.
2. Open the *Modality* drop-down menu and select a type:
ES: endoscopy
US: ultrasound
OT: other
3. In consultation with the IT department, select a *Char. set*.
4. Leave the *LogLevel* as the factory setting.
5. Place a check mark next to *Enable Worklist* to allow access to a DICOM worklist.
 ⇒ The **Import DICOM Worklist** button is displayed on the user interface.
6. Enter the following in the fields:
Server AET: AE title of the DICOM worklist server
Server IP: IP address of the DICOM worklist server
Port: port of the DICOM worklist server
7. Open the *Date Filter* drop-down menu and limit the date range displayed when searching for patient data in the DICOM worklist:
None: date range not limited
Today: only display the patients in today's worklist
One Day: plus/minus 1 day
Two Days: plus/minus 2 days
Three Days: plus/minus 3 days
8. Leave the *Timeout* as the factory setting unless it needs to be changed.
9. Tap the **Echo** button to test the connection to the DICOM server.
10. In the event of connection problems, contact the IT department.

6.1.2.6 Open commits

1. Tap the *Open Commits* tab.
ID: unique ID of the media data
Time: time of the upcoming storage process
Status: current status of the query



2. Tap the **Send** button to request a storage commitment again.
3. Tap the **Delete** button to delete an incomplete open commit from the list.
4. Tap the **Update** button to update the list. The list is updated automatically every 30 seconds.

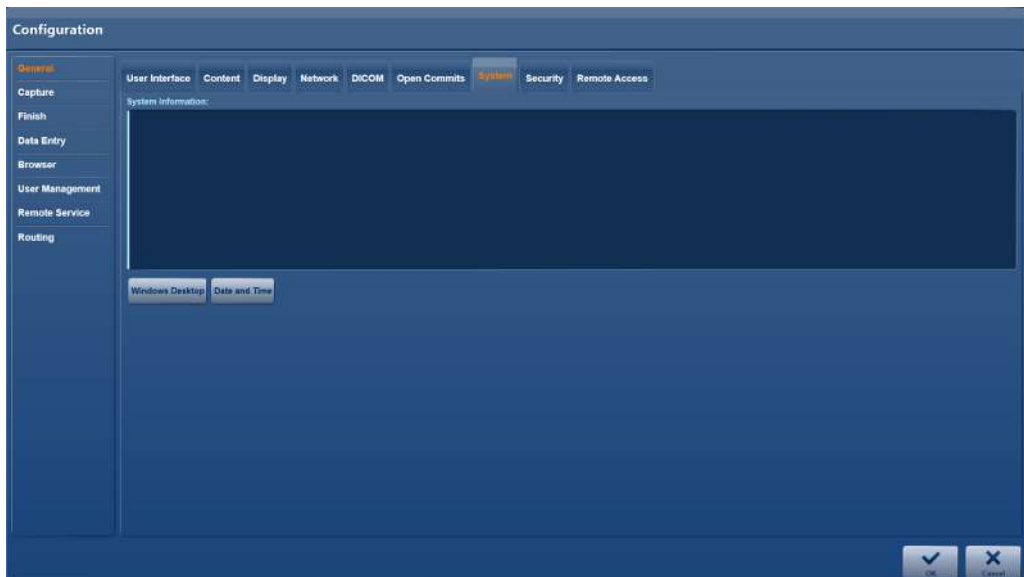
Messages during transmission

| Message | Status | Description | Action |
|----------------|---------|--|---|
| Unknown | Error | Unknown error/error in retrieving the methods, no return value for the status. | <ul style="list-style-type: none"> ▶ Re-send the Commit request. ▶ Contact the DICOM administrator. |
| Failed | Error | The Commitment server has sent the response "Failed" for at least one object. | <ul style="list-style-type: none"> ▶ Re-send the Commit request. ▶ Contact the DICOM administrator. |
| CommitTime-out | Warning | Commit requests were sent, but no answer has yet been received from the Commitment server for at least one object. The first request was made at least as long ago as the configured timeout. If failed and timed-out objects are present, "Timeout" is set. | <ul style="list-style-type: none"> ▶ Re-send the Commit request. |
| CommitPending | Normal | Commit requests were sent, but no answer has yet been received from the Commitment server. The first request was made within the configured timeout period. | <ul style="list-style-type: none"> ▶ Wait for transmission to take place. |

| Message | Status | Description | Action |
|-----------------------|--------|---|---|
| CommitIn-complete | Normal | No Commit request was sent for at least one object. | ► Observe the timeout period, then re-send the Commit request. |
| StorageIn-complete | Normal | At least one object was not stored. | ► Observe the timeout period, then re-send the Commit request. |
| StorageNot-Done | Error | Error when storing the objects on the store server; no Commit request was sent. | ► Re-send the Commit request. ► Contact the DICOM administrator. |
| StorageNot-Configured | Error | No store server configured; Commit request not possible. | ► Check the DICOM server settings. |

6.1.2.7 System

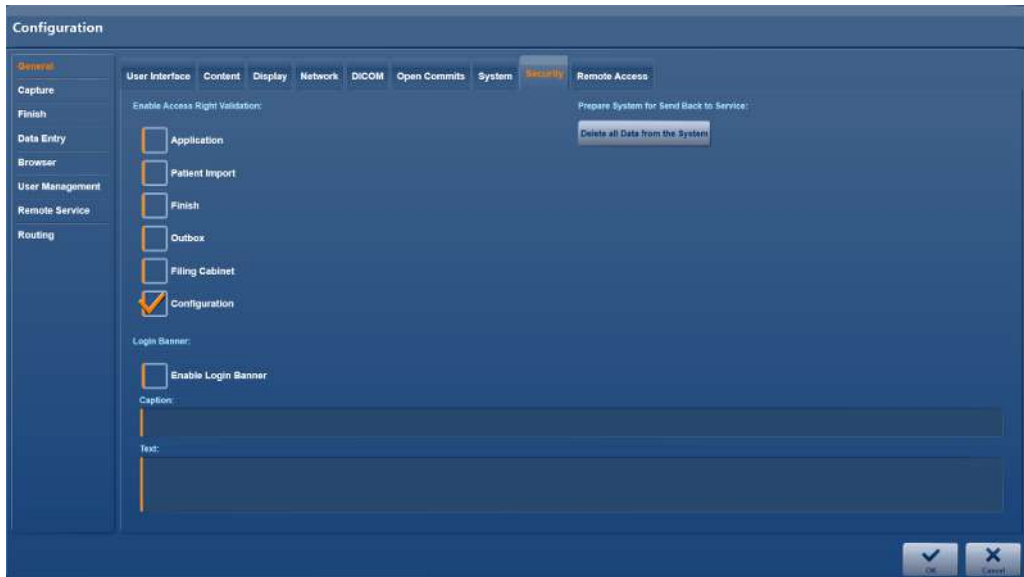
The *System* tab is used to make various settings at operating system level, such as network or WLAN settings. Local users can be created and free text can be stored via the Windows desktop.



6.1.2.8 Security

The *Security* tab is used to set up access control.

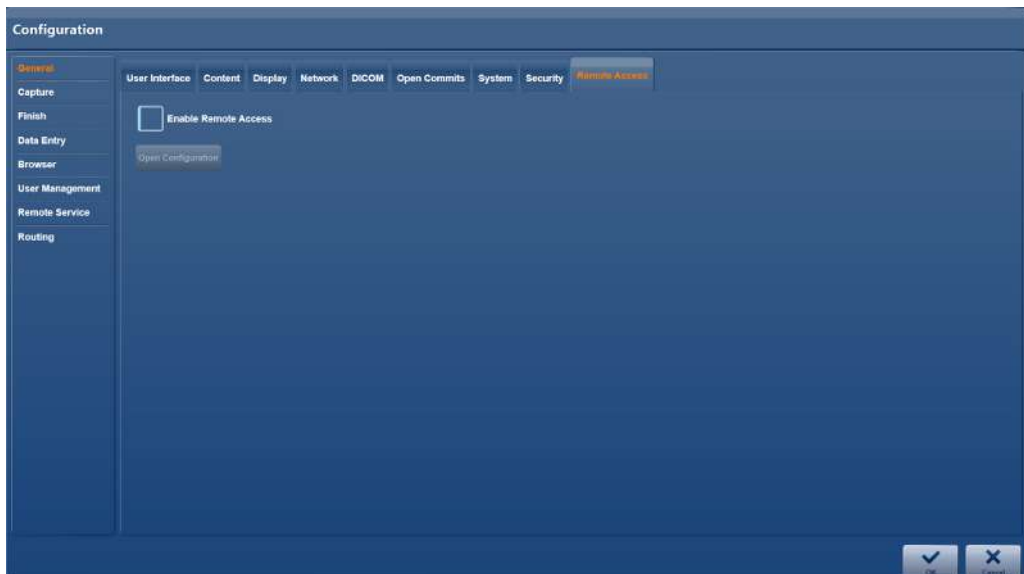
1. Tap the *Security* tab.



2. Check the required checkboxes.
3. Complete the *Heading* and *Text* fields. This text is displayed to every user when they log in.
4. If the system is to be sent to the Service team, tap the **Delete All Data from the System** button.
5. Press **OK** to confirm.

6.1.2.9 Remote Access

1. Tap the *Remote Access* tab.



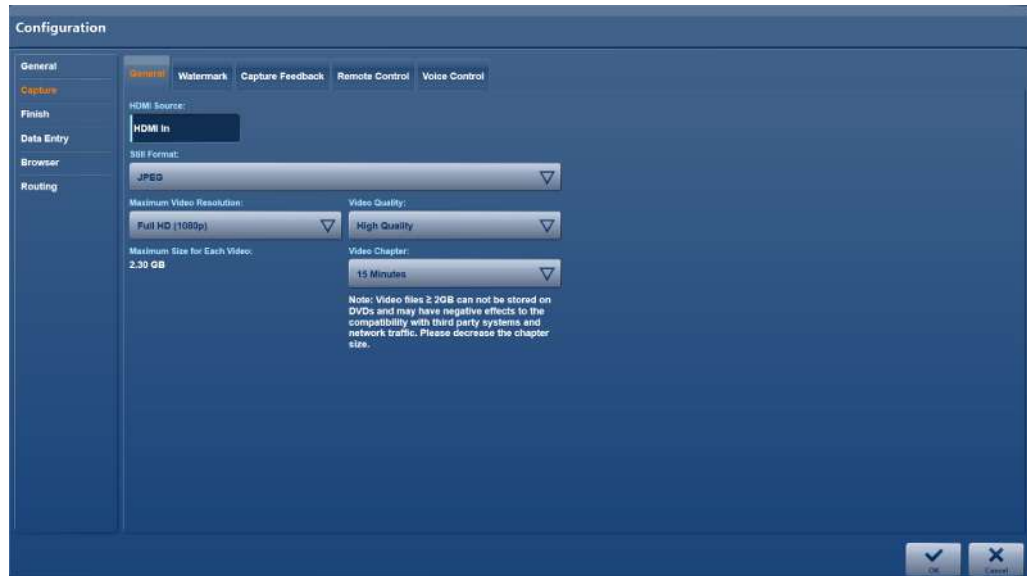
2. Place a check mark next to *Enable Remote Access*.
3. Press **OK** to confirm.

6.1.3 Capture

6.1.3.1 General

The *General* tab is used to configure the capture source.

1. Tap the *General* tab.



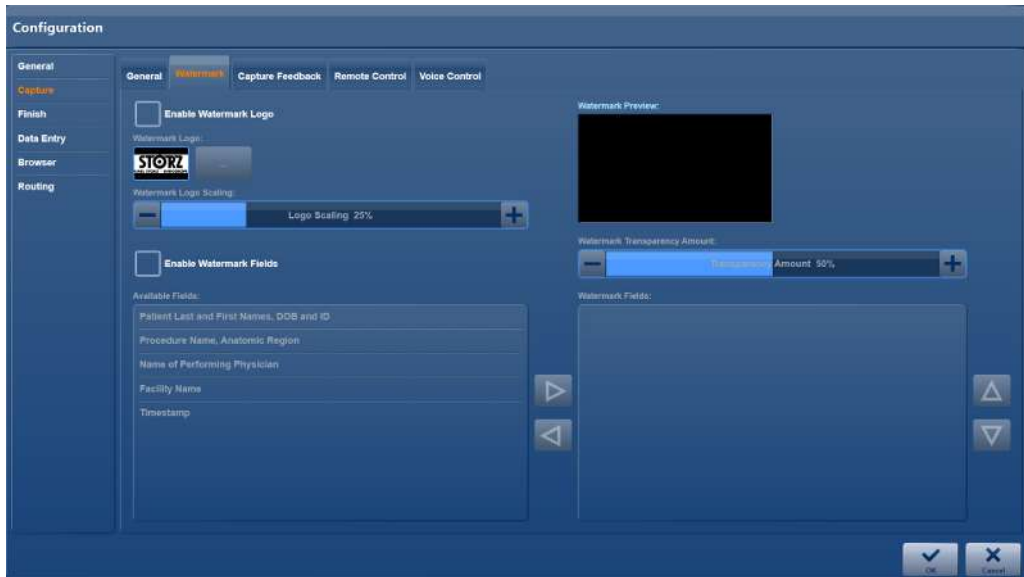
2. Enter a name for the *HDMI source*.
3. Select the required format, quality, and resolution settings.
4. Press **OK** to confirm.

KARL STORZ recommends setting up different capture qualities to minimize transmission rates and storage requirements.

6.1.3.2 Watermark

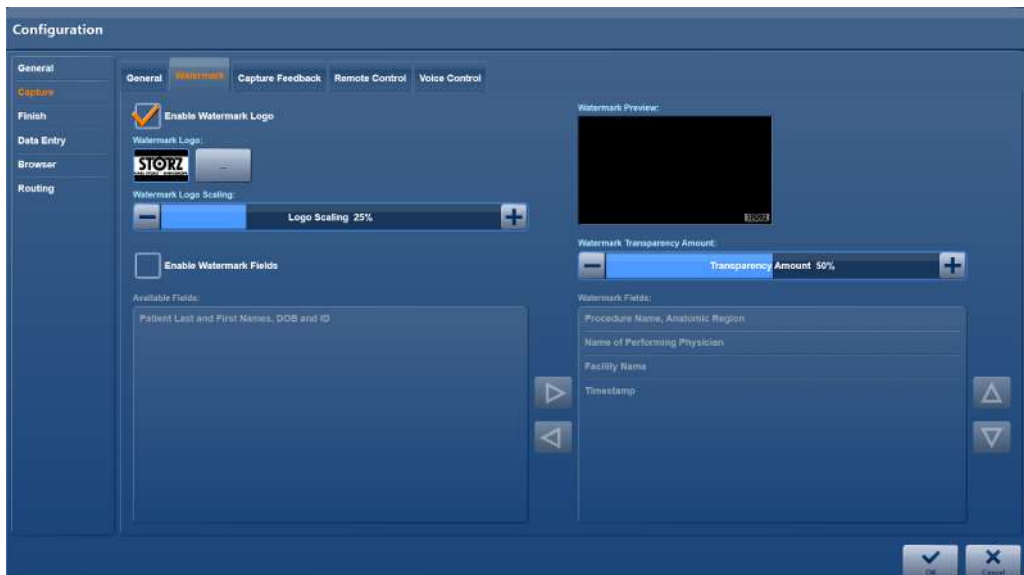
The *Watermark* tab is used to specify whether the captured stills and video recordings should be stored with a watermark. Watermarks cannot be changed or removed once they have been added.

- ▶ Tap the *Watermark* tab.



Setting up the watermark

1. Place a check mark next to *Enable Watermark Logo*.



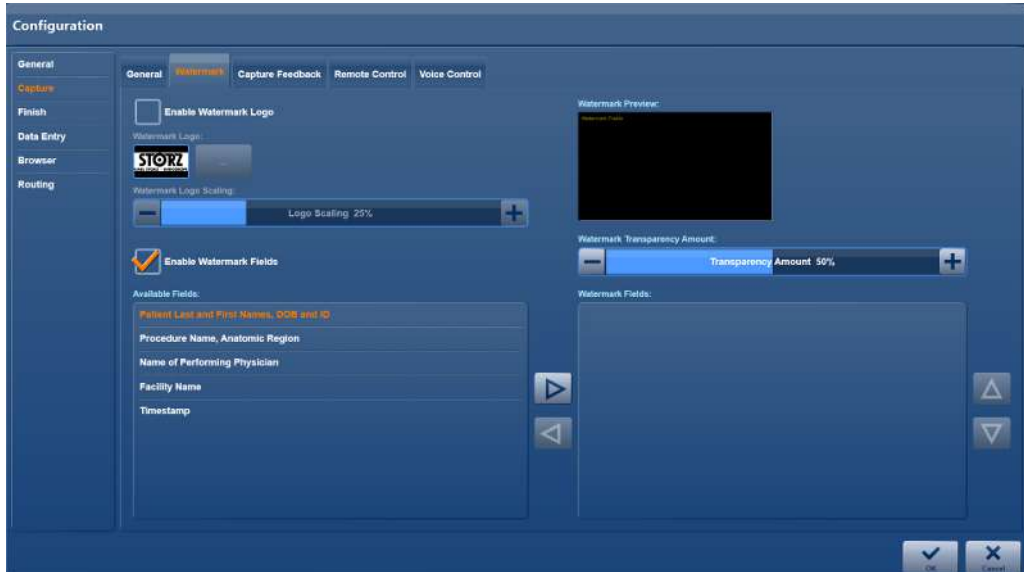
2. Tap the "..." button.
3. Select the logo in the file directory and confirm with **Open**.

The place where the watermark logo is stored must be on the local hard disk. If necessary, a relevant archive must be created by a service technician.

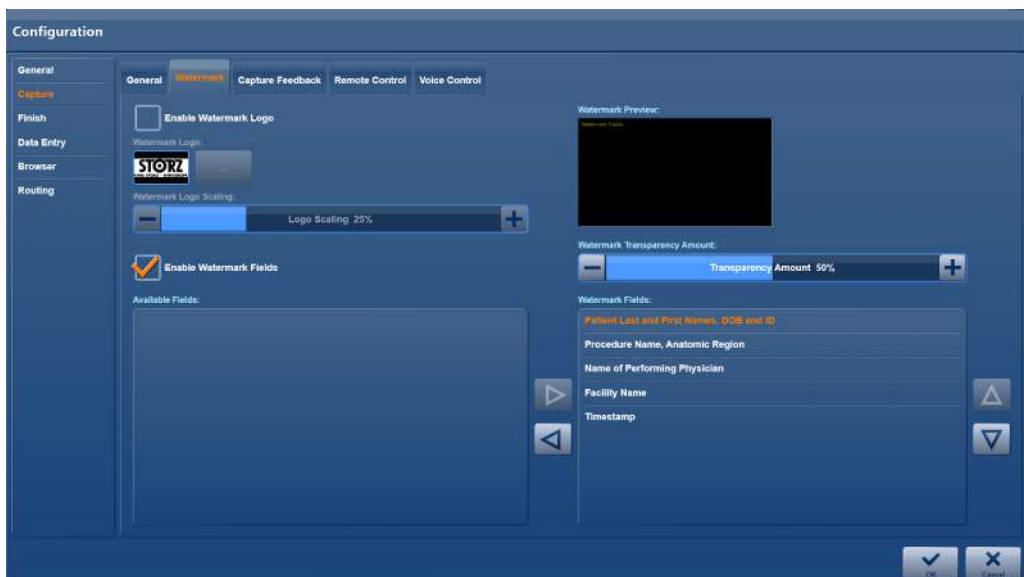
4. Adjust the size of the watermark if necessary under *Watermark Logo Scaling* using the plus/minus buttons.
 5. Set the transparency of the logo under *Watermark Transparency Amount* using the plus/minus buttons.
- ⇒ The watermark created is displayed in the preview window.

Setting up image labeling

1. Place a check mark next to *Enable Watermark Fields*.



2. Select the desired entries in the *Available Fields* list.
3. Tap the arrow to copy the entries to the *Watermark Fields* list.

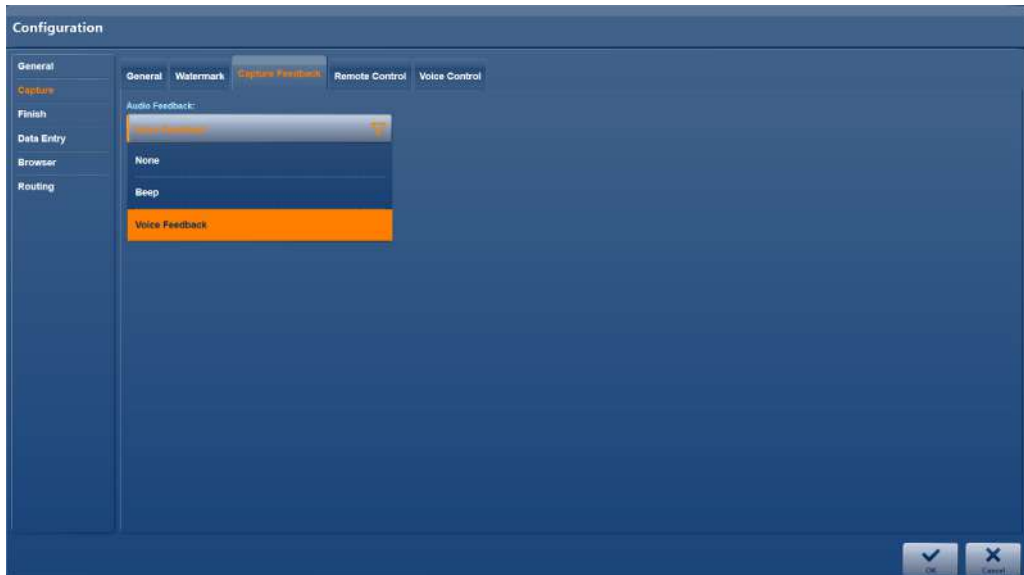


4. Place the entries in the order in which they are to appear on the images.
5. Press **OK** to confirm.

6.1.3.3 Capture feedback

The *Capture Feedback* tab is used to specify whether the user receives visual and/or acoustic feedback about a captured image or recorded video.

1. Tap the *Capture Feedback* tab.

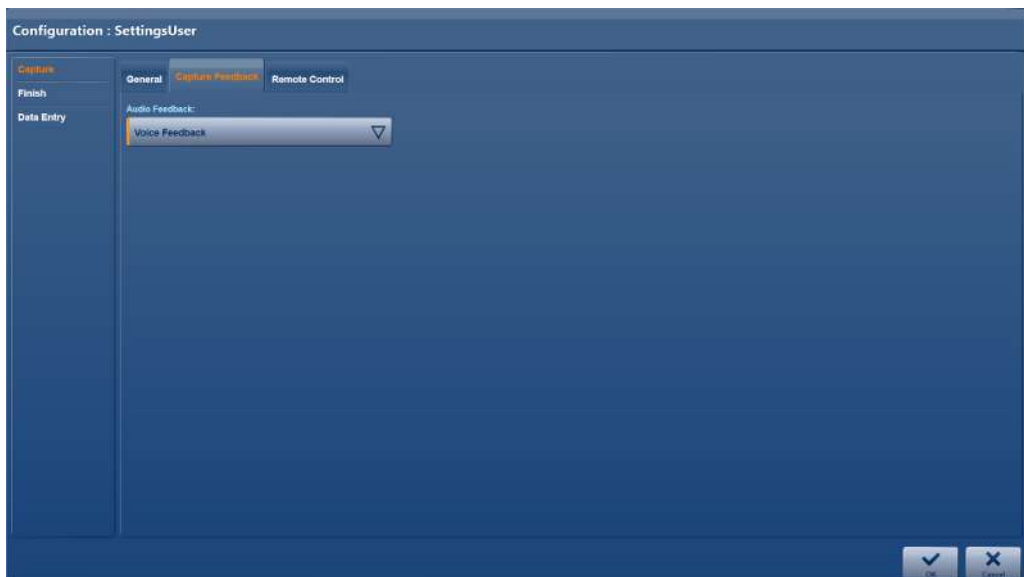


2. Enable the required feedback display.
3. Press **OK** to confirm.

6.1.3.4 Remote control

The *Remote Control* tab is used to specify the assignment and functioning of the remote control. Depending on the installation, the remote control can be set up for the footswitch and, if necessary, also for the camera head.

- ▶ Tap the *Remote Control* tab.



Remote control via the footswitch

1. If a two-pedal footswitch is connected, set up all 4 operating options: *Left full press / Left half press, Right full press / Right half press*.
2. If a one-pedal footswitch is connected, deactivate the *Right full press / Right half press* operating options using the *None* setting.

| Setting | Meaning |
|-----------------------------------|---|
| Still capture Channel 1 | Source 1 still capture |
| Still capture Channel 2 | Source 2 still capture |
| Still capture channels 1 & 2 | One still capture from source 1 and source 2 at the same time |
| Video start / stop Channel 1 | Start or stop the video recording from source 1 |
| Video start / stop Channel 2 | Start or stop the video recording from source 2 |
| Video start / stop Channels 1 & 2 | Start or stop a video recording from source 1 and source 2 at the same time |
| None | No function |

Remote control via camera head buttons

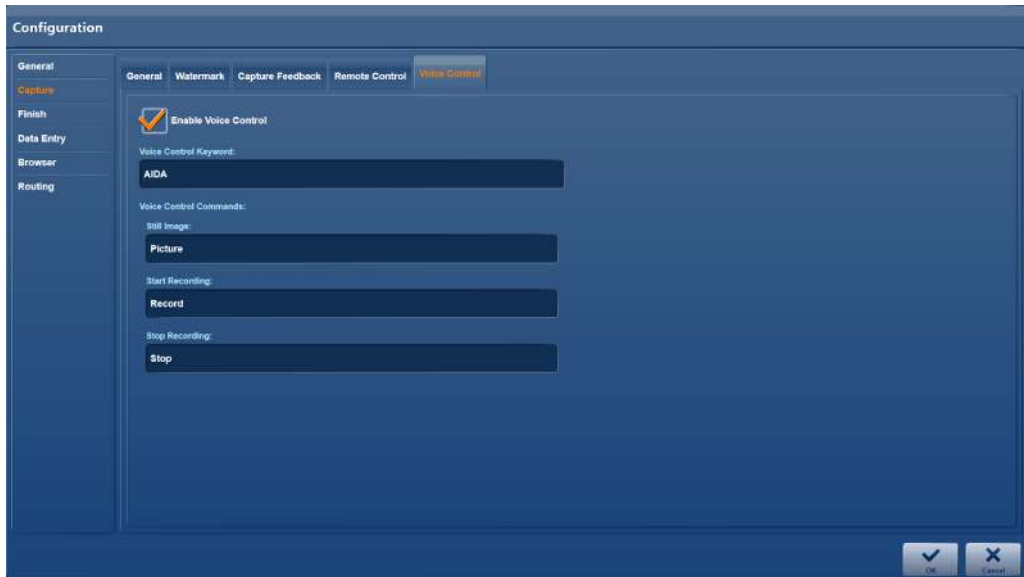
1. If a foot pedal is connected, start by setting up the foot pedal.
⇒ The connections for the two camera head buttons are defined.
2. Connect the camera head buttons to the desired serial ports. Make sure that the camera head buttons and footswitch are operated in the same way.

| Connection | Meaning |
|------------|---|
| ACC1 | Left full press / left pedal full press |
| ACC2 | Left half press / left pedal half press |
| ACC3 | Right half press / right pedal half press |
| ACC4 | Right full press / right pedal full press |

6.1.3.5 Voice control

The *Voice Control* tab is used to trigger image capturing and video recording with predefined commands. An activation word, which is specified on the tab, must be prefixed to the command.

1. Tap the *Voice Control* tab.



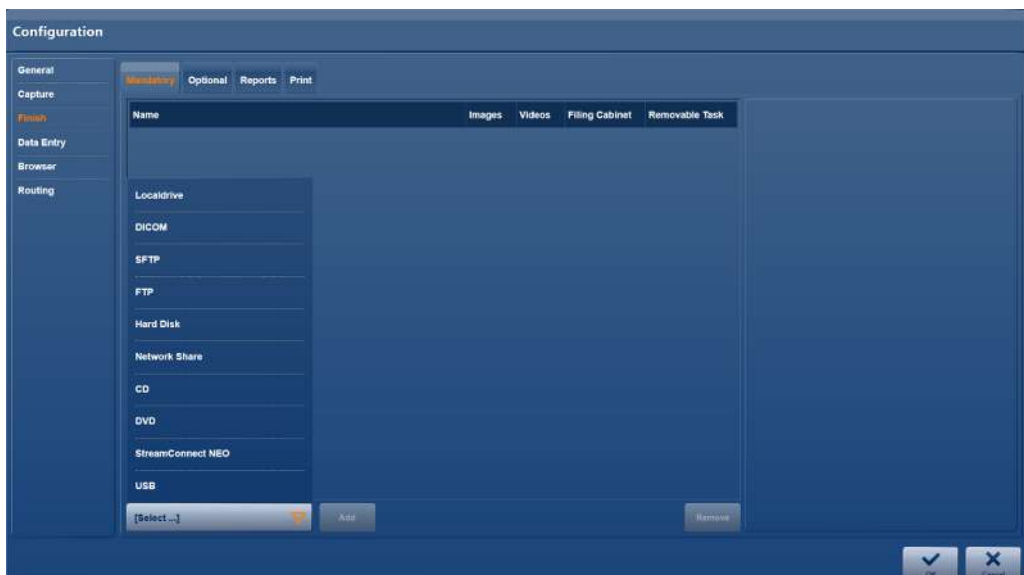
2. Place a check mark next to *Enable Voice Control*.
3. Enter an activation word in the *Voice Control Keyword* field.
4. Adjust the *Voice Control Commands* if necessary.
5. Press **OK** to confirm.

6.1.4 Finish

6.1.4.1 Mandatory and optional

The *Mandatory* and *Optional* tabs are used to specify the destinations for automatic and manual data storage.

1. Tap the *Finish* menu.
 - ⇒ The *Mandatory* tab is displayed.
2. Open the *Select* drop-down menu and select a required destination.



3. Tap the **Add** button to add the selected destination to the list.

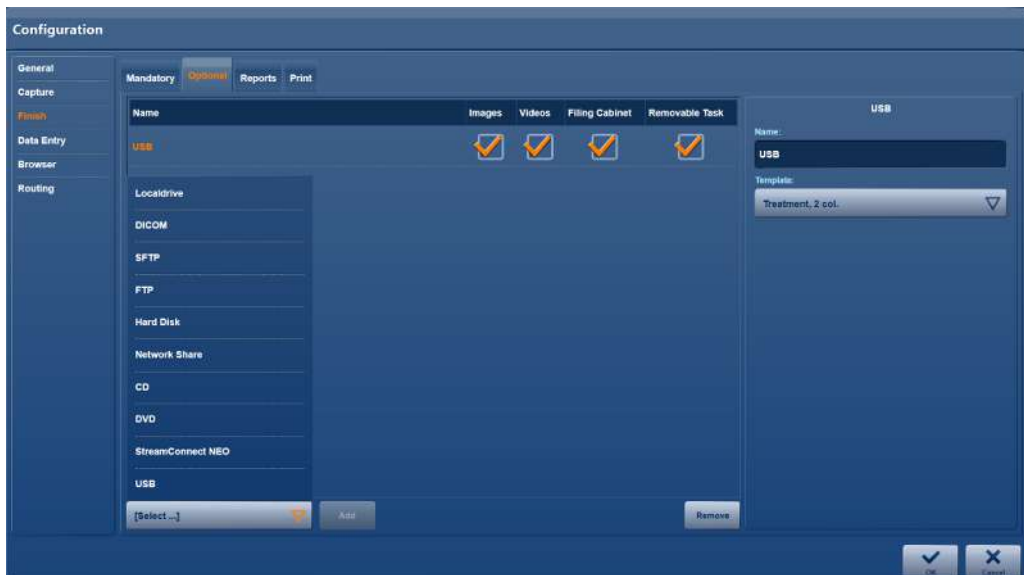
4. To delete a destination from the list, highlight it and tap the **Remove** button.
5. To allow data to be stored automatically, check the relevant checkboxes in the list. When storing manually, all data is stored.



6. To enable data to be retrieved again for display and editing purposes, check the *Reference* checkbox.
7. To specify whether data in the *Open Tasks* module can be deleted, check the *Removable* checkbox.

6.1.4.2 Required field

The *Mandatory* tab is used to specify the destinations for the data backup. When saving data via the network, the accesses for this are also to be stated, e.g., DICOM or SFTP.



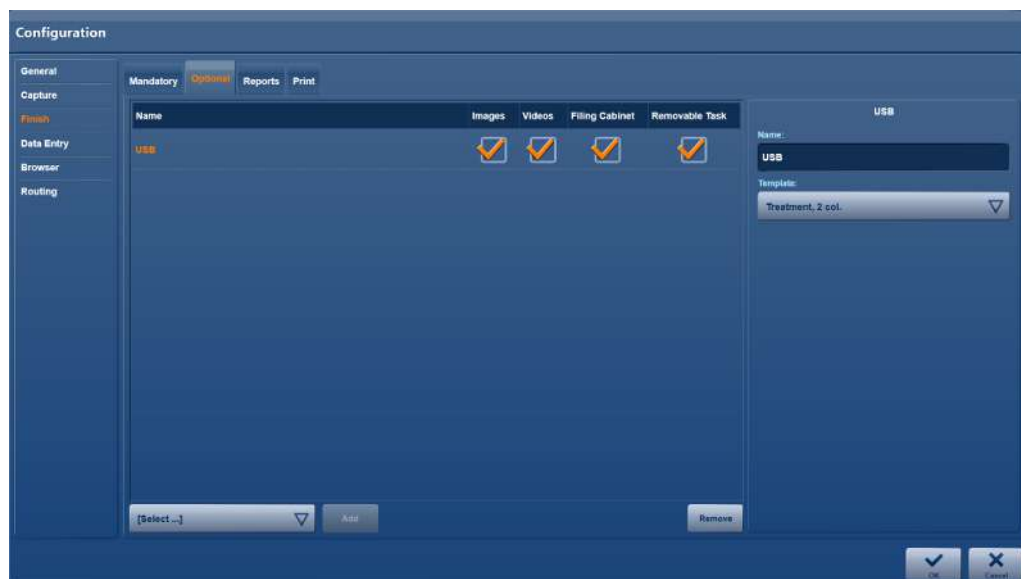
The configured destinations can be manually selected or deselected by the user. Automatic storage of the image and video data cannot be ensured.

Specifying destinations for data storage

1. Open the *Select* drop-down menu and select a destination to be included in data storage.
2. Tap the **Add** button.
 - ⇒ The selection is included in the list of destinations.
 - ⇒ All checkboxes (Stills, Videos, Reference, and Removable) are automatically enabled.
3. To add further destinations for data storage, repeat steps 1 and 2.
4. Check the *Reference* checkbox to allow saved data to be retrievable again for displaying and editing in the Filing Cabinet.
5. Uncheck the checkbox if you do not wish the data to be retrievable.
6. Check the *Removable* checkbox if the data in the *Open Tasks* module should be deleted.
7. Tap the relevant destination for further information and to enter details such as the path or server name for the destination, login name and password, and report form.
8. To delete a destination from the list, highlight it and tap **Remove**.

For the *DICOM* storage destination, also set a timeout period:

- Stills: 30 seconds
- Stills and videos: 120 seconds



Saving data on a hard disk

The export destination *Localdrive* is predefined; the name and the file path **D:\Export** cannot be edited.

1. To create an additional export destination on the hard disk D:\ or an external storage medium, tap the *Hard Disk* or *USB* export destination.
2. Specify the name of the export destination and the file path.

Storing data with minimum memory space

The system continuously checks the memory space on the hard disk to ensure that enough space is available for the recordings.

- ▶ Check the *Remove old exports as required* checkbox.

- ⇒ Old exports are overwritten as of a memory capacity of less than 250 GB.
- ⇒ As of a memory capacity of 100 GB or less, storage on the hard disk is aborted.

Data storage on the DICOM server

1. Enter the destination address and test the connection using the **Echo** button.
2. Set the timeout time.
 - ⇒ If only stills are to be saved, a timeout time of approx. 30 seconds is recommended.
 - ⇒ If stills and video recordings are to be saved, a timeout time of approx. 120 seconds is recommended.
3. Select the video format.
 - ⇒ The video data is exported in the same format as the recording or in SD proxy format.
4. Check the *Storage Commitment* checkbox if you would like to receive confirmation that the data has been securely stored in PACS.

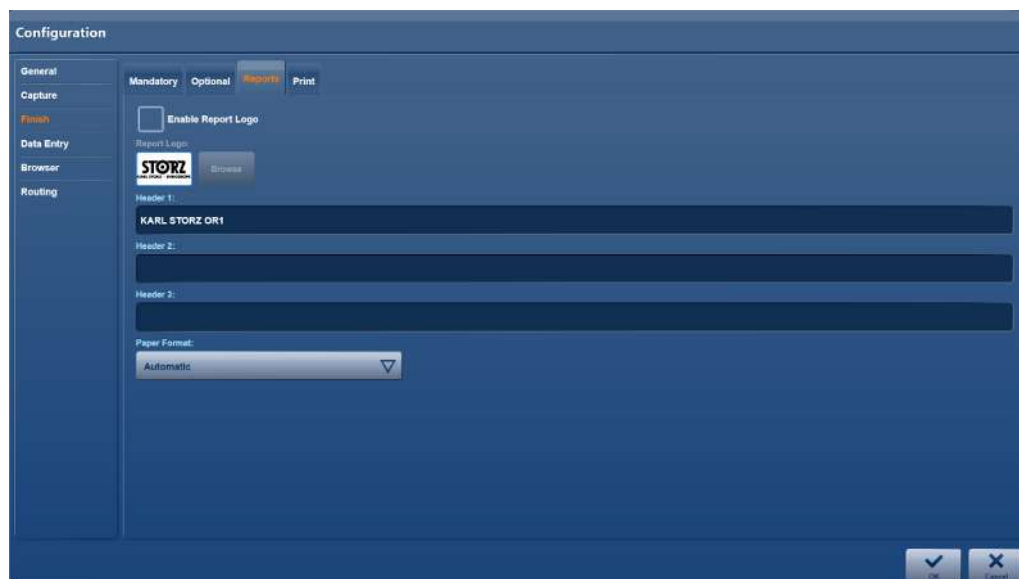
Report at the end of the procedure

1. For each destination (apart from the DICOM server), specify whether a data storage report should be added as a PDF.
 - ⇒ The *Template* field appears.
2. Select a template from the drop-down menu.
3. If the report is to be printed, select an additional layout from the templates.
4. Tap the *Print* tab to specify an alternative layout.
5. Check the *Use print layout* checkbox to use the alternative layout.
- ① When printing an anonymous report, patient data may be mixed up.

6.1.4.3 Reports

The *Reports* tab is used to set up the surgical report.

1. Tap the *Reports* tab.



2. Place a check mark next to *Enable Report Logo* to enable the watermark for the report.

3. Tap the button below *Report logo* to select a logo.
4. In the *Header 1* field, enter a standard title for the report.
5. If necessary, add further headings in fields *Header 2* and *Header 3*.

6.1.4.4 Print

The *Print* tab is used to set up the settings for automatic printing.

1. Tap the *Print* tab.



2. Adjust the following settings:
 - Selection and preview of template
 - Enable for print
 - Print mode
 - Number of copies
 - Layout (only available for standard template)
 - Number of images (only available for standard template)
 - Time stamp

Press **OK** to confirm.

Only the standard template can be altered and printed automatically during surgery. All other templates can be printed following surgery.

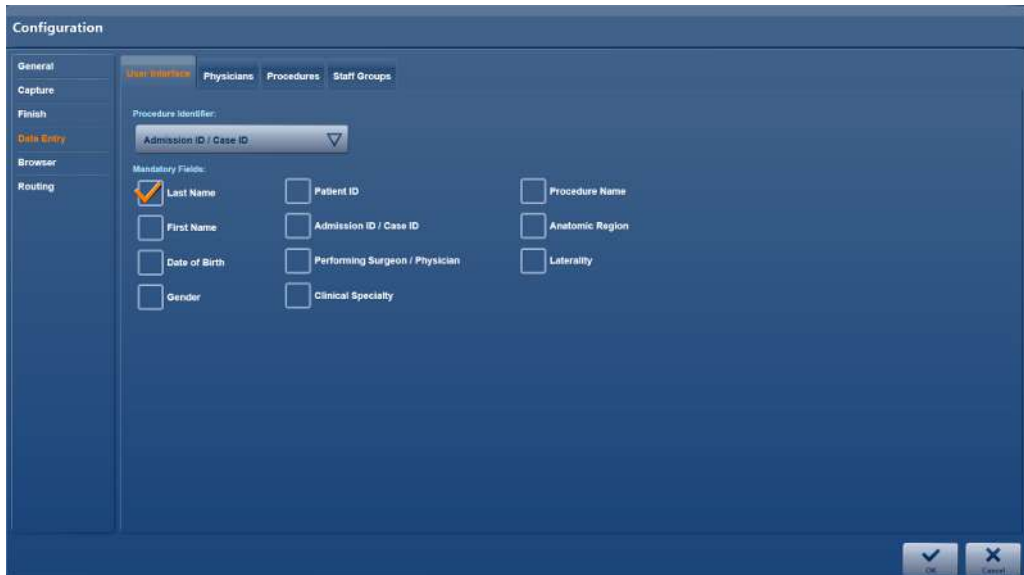
Printing is available in the *Filing Cabinet* and *Edit* modules.

6.1.5 Data entry

6.1.5.1 User interface

The *User Interface* tab is used to specify the scope and options for patient documentation.

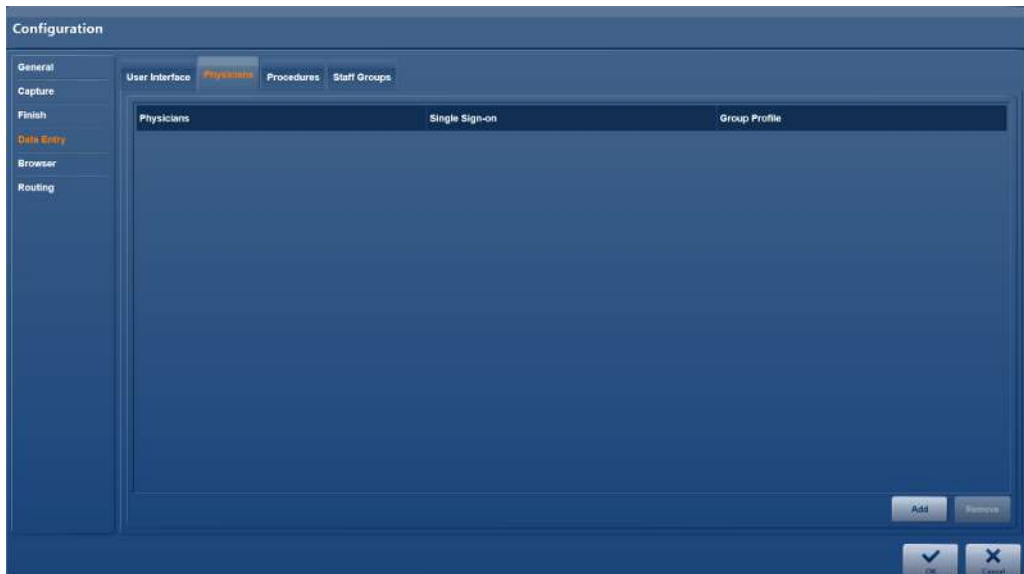
1. Tap the *Data Entry* menu.
 - ⇒ The *User Interface* tab is displayed:



2. Open the *Procedure Identifier* drop-down menu and specify the date for primary identification of the patient.
3. Specify the *Mandatory* fields for documentation.

6.1.5.2 Physicians

The *Physicians* tab is used to enter available personnel resources (users). The group profile of the attending physician can be managed.



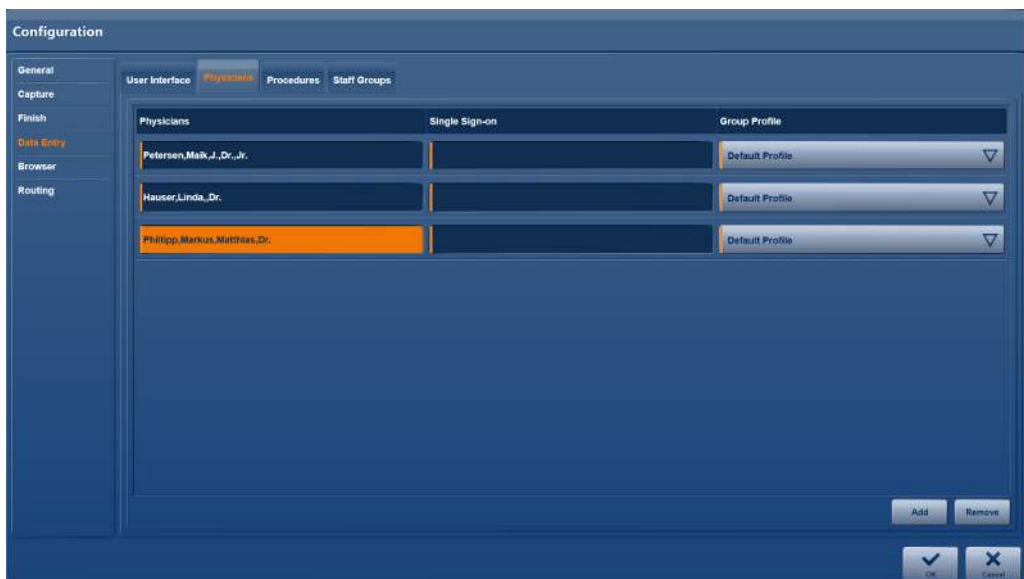
Performing physician

1. Activate access control to the Filing Cabinet so that the performing physician can view the documentation in the Filing Cabinet.
 - ⇒ Once the performing physician has been selected for the current procedure, all profile settings are loaded.
2. Specify the physician for the procedure when entering the outline data.

- ⇒ The default or group profile is linked to the performing physician.
 - ⇒ The default profile is active if no performing physician is specified.
3. Switch to the *SuperUser* user role to view the procedures. Access control must be activated.

Adding a physician and assigning a group profile

1. Tap the **Add** button.
 - ⇒ A new row for entering the data is inserted.
2. In the *Physicians* field, enter the physician data in a DICOM-compliant manner in the specified order and separated by commas: last name, first name, middle name, title, suffix.



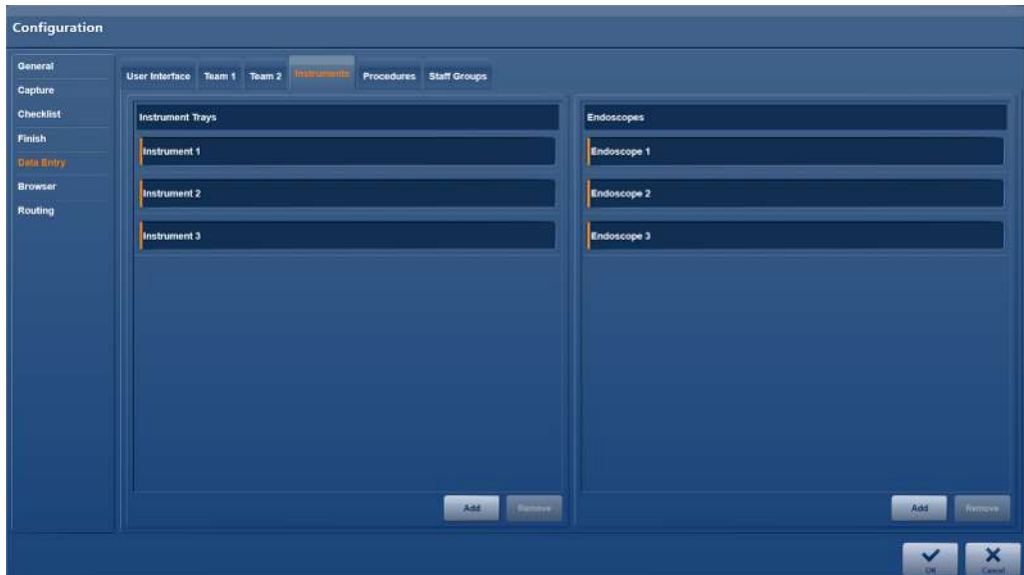
3. If *StreamConnect* is used: enter the username in the *Single Sign-On* field to create a *StreamConnect* export directory.
4. Select the desired profile in the *Group Profile* list.



6.1.5.3 Instruments

The *Instruments* tab is used to enter the identification numbers of instruments or instrument trays as well as the serial numbers of endoscopes.

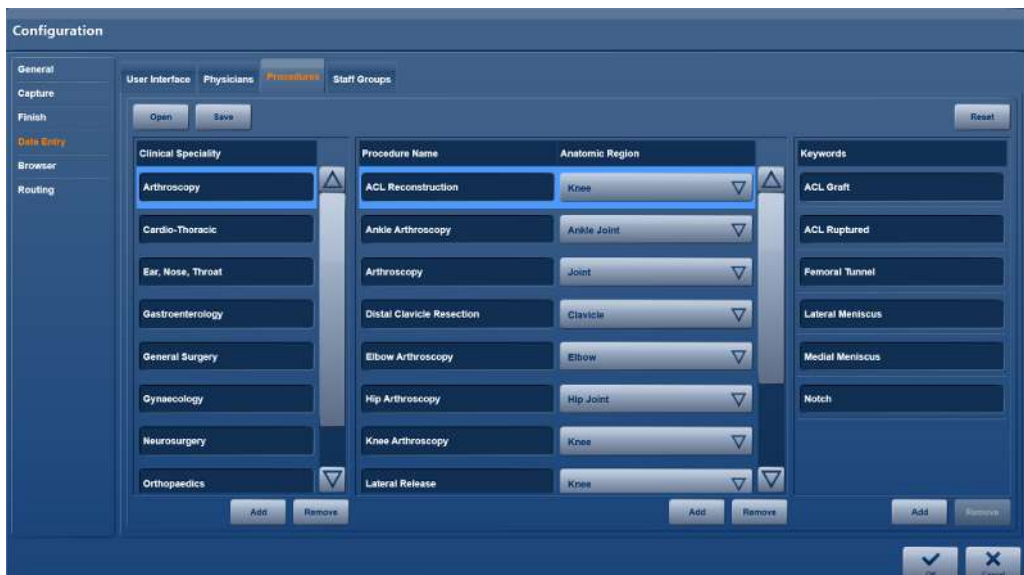
1. Tap the *Instruments* tab.



2. Enter the data.
3. Tap the **Add** button.
 - ⇒ The data is available on the user interface.
4. To delete an entry, tap the **Remove** button.
5. Press **OK** to confirm the entries.

6.1.5.4 Procedures

1. Tap the *Procedures* tab.



2. Select the medical specialization, e.g., urology, under *Clinical Speciality*.

3. Select the nature of the surgical procedure, e.g., cystoscopy, under *Procedure Name*.
4. Select the anatomical region of the procedure, e.g., bladder, under *Anatomic Region*.



5. Tap the **Add** button in each case.
⇒ The data is available on the user interface if the fields are enabled.
6. To edit an entry, highlight the field and make the change.
7. To delete an entry, tap the **Remove** button.
8. Press **OK** to confirm the entries.

6.1.5.5 Staff groups

The *Staff Groups* tab is used to set the automatic import of the staff groups from the Active Directory. The imported users are entered on the *Team 1* tab. The group content is updated once a day when there is a connection to the Active Directory server.

Users which have been entered manually are overwritten.

In order to be able to use this setting, there must be a connection to a Microsoft Active Directory server. If this connection has not been set up, the settings will be deactivated or not designated for the facility. Should you have further questions, contact the system administrator or the IT department.



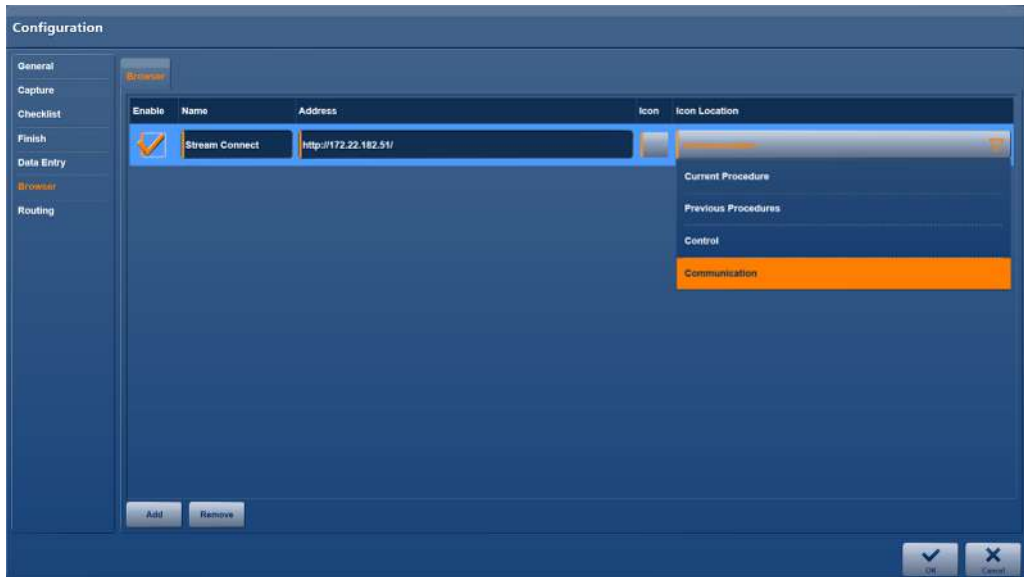
Importing a staff group from the Active Directory

1. Activate the *Active Directory Import* checkbox.
2. In the *Physician* text field, enter the group name that was assigned for the required group of physicians by the IT department in the Active Directory.
3. Confirm the configuration with **OK**.
 - ⇒ The settings are saved.
 - ⇒ If the configuration area is opened again, the imported entries are shown on the *Team 1* tab under *Physicians*.

6.1.6 Browser

The *Browser* module is used to create connections to streaming servers, cloud services, Internet services, etc. A maximum of 5 web-based third-party products can be integrated into the AIDA® system. Only products verified and approved by KARL STORZ may be used.

1. Tap the *Browser* menu.



2. Tap the **Add** button to create a connection.
3. Enter the name and *Address* of the server or service.
4. Select a suitable *Symbol*.
5. Open the drop-down menu under *Icon Location* and select the application area in which the connection appears in the main menu.
6. Activate the connection.
7. Restart the system.

6.1.7 User management

The *User Management* module is used to assign certain access rights to individual groups of people. KARL STORZ recommends making settings here to optimize your IT security.

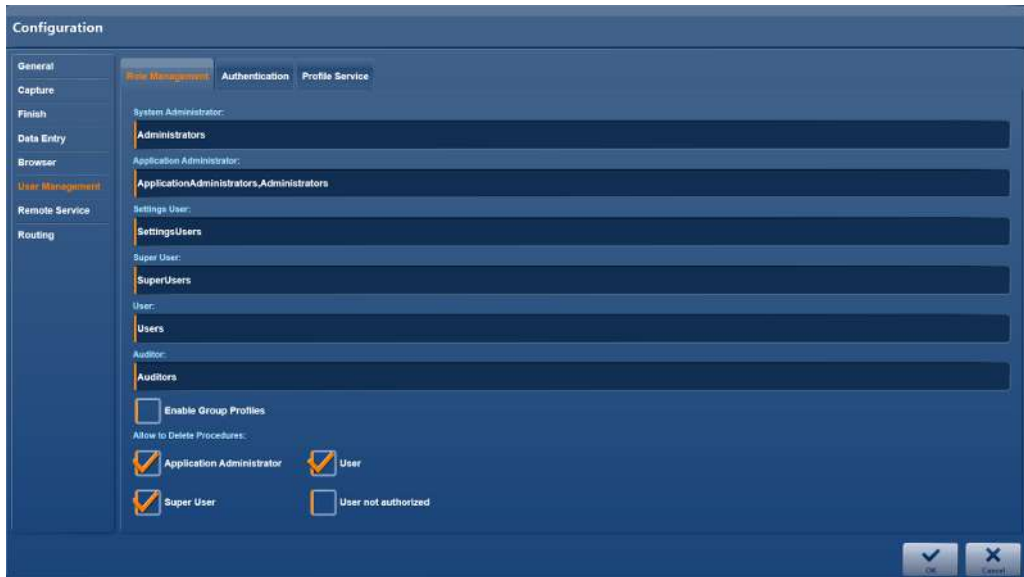
- ▶ Open Windows Computer Management to create new users.

6.1.7.1 Role management

The *Role Management* tab is used to manage the individual groups. The predefined user roles with assigned groups can be used without further configuration.

To use your own groups, the predefined values can be replaced in the respective text fields with your own group names, e.g., when using Microsoft Active Directory. The access rights for the application can be combined. Multiple entries from the Active Directory can be entered in the text fields, separated by commas.

1. Tap the *Role Management* tab.

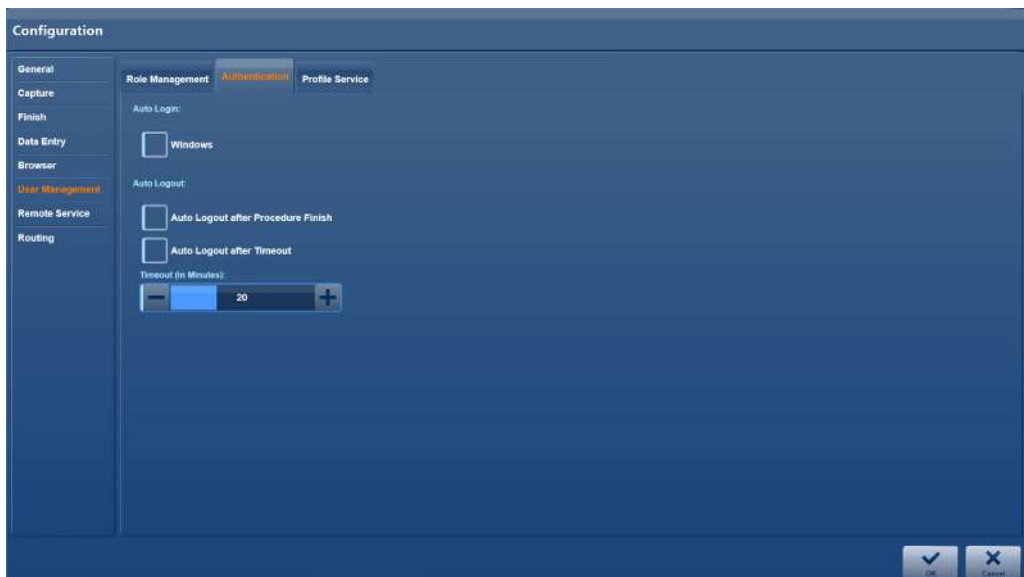


2. Enter the desired names in the fields.
3. Place a check mark next to *Activate Group Profile* to create group profiles.
4. Assign the group profile to the users.
5. Press **OK** to confirm.

6.1.7.2 Authentication

The *Authentication* tab is used to configure automatic Windows login and automatic login to the application for *or1user*.

1. Tap the *Authentication* tab.



2. Check the required checkboxes.
3. Use the plus or minus buttons to set the time.
4. Press **OK** to confirm.

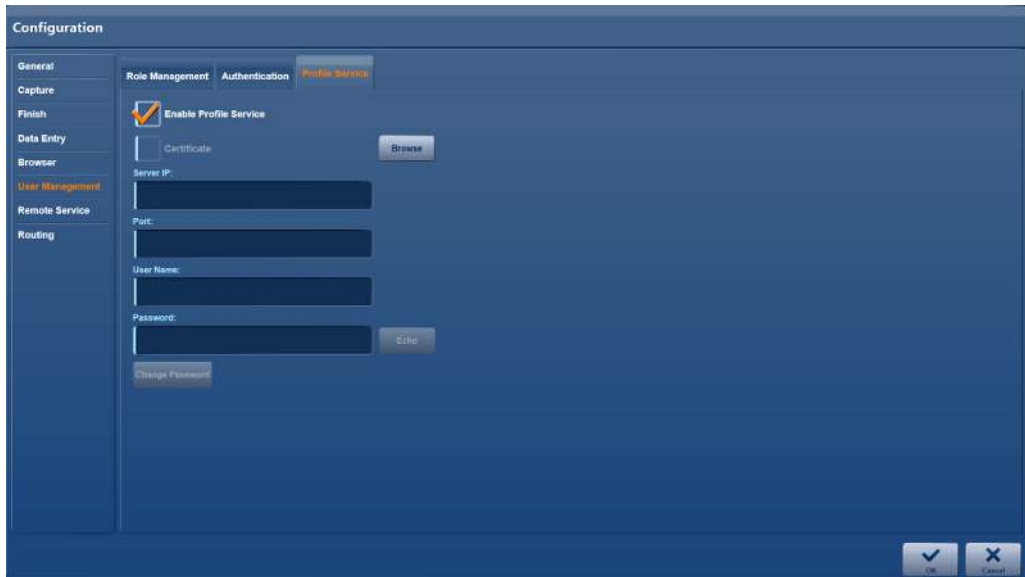
6.1.7.3 Profile service (only with network integration)

To enable the setting on the *Profile Service* tab for the first time, you must authenticate yourself with the following standard user account:

- Username: Admin
- Password: 12345

It is then mandatory to change the password in order to enable the service. The service is disabled for security reasons when the standard password is used.

1. Place a check mark next to *Enable Profile Service*.



2. Enter all necessary data in the fields.
3. Tap the **Echo** button.
 - ⇒ The connection parameters are checked.



4. Enter the new password and confirm it with **OK**.

5. If necessary, assign the password again using the **Change Password** button.
⇒ The profile service is enabled.

Selecting a certificate

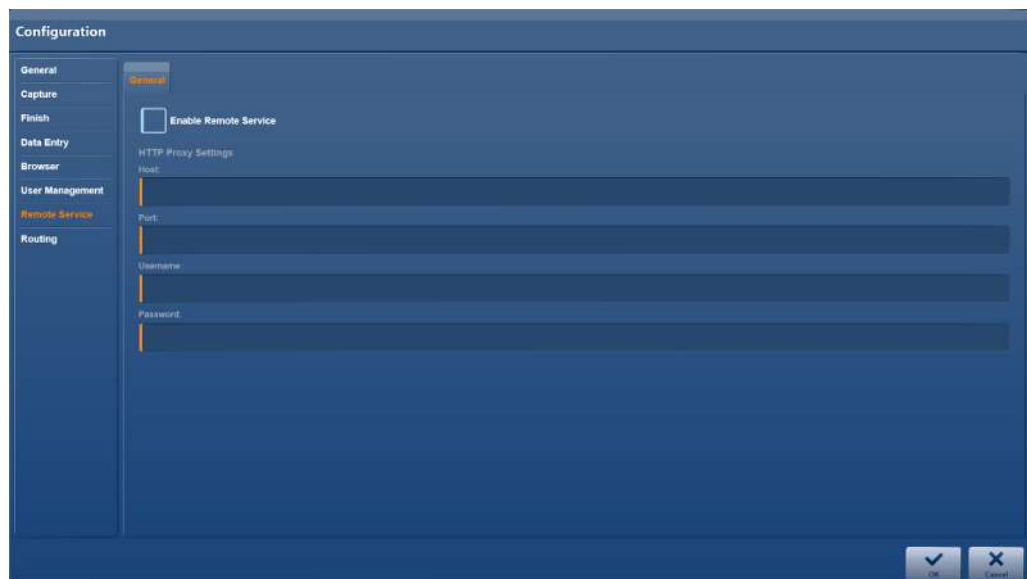
Communication between the product and the profile service is encrypted. It is possible to use a certificate to protect against "man-in-the-middle" attacks. This certificate is generated in the profile service program directory when the profile service is installed. The certificate file is not automatically distributed for security reasons.

1. Tap the **Browse** button to read in the certificate file.
2. Select the file with the "*.cer" format.
⇒ If the certificate is valid, the following text appears: *Certificate validation successful.*
⇒ The *Certificate* checkbox is activated.
3. Tap the **Echo** button to check the validity of the certificate.

6.1.8 Remote service

The *Remote Service* module offers a KARL STORZ service technician direct access via a secure VNC connection. The product does not need to be removed from the operation room.

1. Tap the *Remote Service* module.



2. Place a check mark next to *Enable Remote Service*.
3. Complete the fields.
4. Press **OK** to confirm.

6.1.9 Routing

1. Tap the *Routing* module.



2. Enter the password.
3. Tap the **Connect** button.
4. Press **OK** to confirm.

6.2 Start configuration

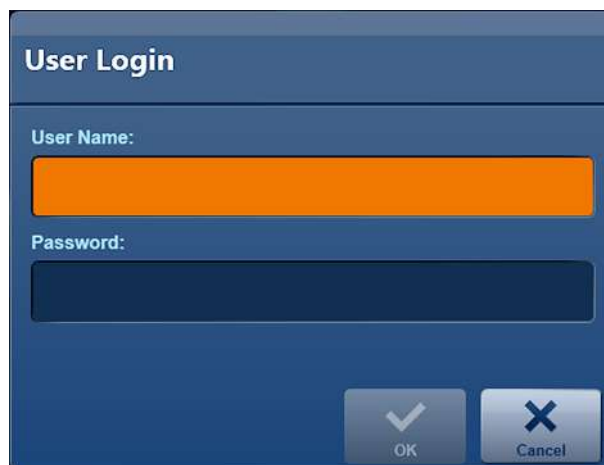
⚠ CAUTION

Damage due to unauthorized access!

Damage to the software or network due to unauthorized access or malware.

- ▶ Start the device without a network connection and external hard disk.

1. Start the product via the rocker switch.
 - ⇒ The start screen appears.
2. Tap the **Settings** button.
 - ⇒ The login window appears.



3. Enter the username and password for the desired access.
4. Press **OK** to confirm.

6.3 User roles and access rights

The following user roles with various authorizations are predefined for configuration:

| User role | Group | Field of activity | Authorization |
|---------------------------|---------------------------|--|--|
| System administrator | Administrators | IT department | Making settings at operating system level and Windows level in the configuration area. |
| Application administrator | ApplicationAdministrators | Responsible for the configuration of the application | Making settings at application level in the configuration area. |
| Configuration user | SettingsUsers | Performing physician | Creating a personal user profile in the configuration area. |
| Super user | SuperUsers | Chief physician | Access to all the entries in "Open Tasks" and to the "Filing Cabinet", "Patients", "Edit", and "Finish" modules. |
| User | Users | Performing physician | Access to their own entries in "Open Tasks" and to the "Filing Cabinet", "Patients", "Edit", and "Finish" modules. |
| Auditor | Auditors | Auditor | Access to the application's system and security protocols |

6.3.1 Default profile

The default profile is available after installation and contains basic configuration settings, which can be adapted to your specific requirements.

Settings are made globally or locally depending on the user role.

Further profiles can be created and edited. A group profile can thus be created for different user groups for which field-specific settings are required, for example. Profiles that you create yourself are referred to as group profiles.

6.3.2 Profile management

Profile management is possible when the system administrator has enabled the function *Activate Group Profile*.

The application administrator can assign area-related settings to individual user groups and assign these settings as a group profile.

Group profiles can be created, edited, and deleted for different user groups.

A group profile can be assigned in the *Data Entry* menu on the *Team 1* tab.

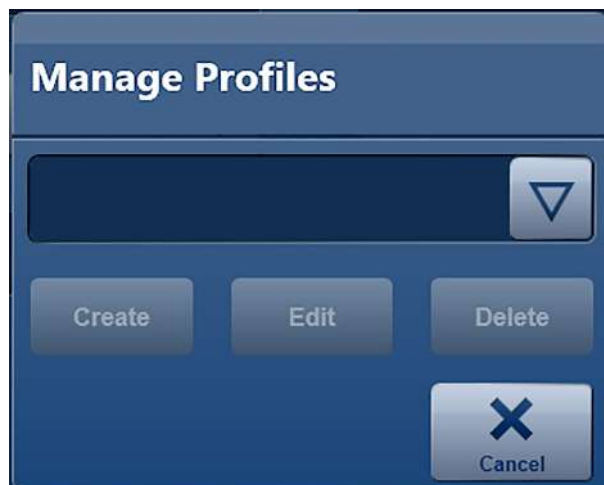
6.3.3 User accounts

The following roles have been created with the corresponding authorizations for the following user accounts:

| Username | Password | Role |
|----------------------|----------|---|
| or1admin | or1admin | <ul style="list-style-type: none"> - System administrator - Application administrator - User |
| or1user | or1user | <ul style="list-style-type: none"> - Application administrator - SuperUser - Auditor - User |
| Windows user account | | - Configuration user |

KARL STORZ recommends creating a new user account with administrator rights and deactivating the standard administrator accounts. You must not forget your password. More detailed information on creating new user accounts can be found on the *User Management* tab.

- ▶ Confirm with **OK** or by pressing **Enter**.
 - ⇒ The configuration area appears.
 - ⇒ If the system administrator has activated group profiles, the window *Manage Profiles* appears.

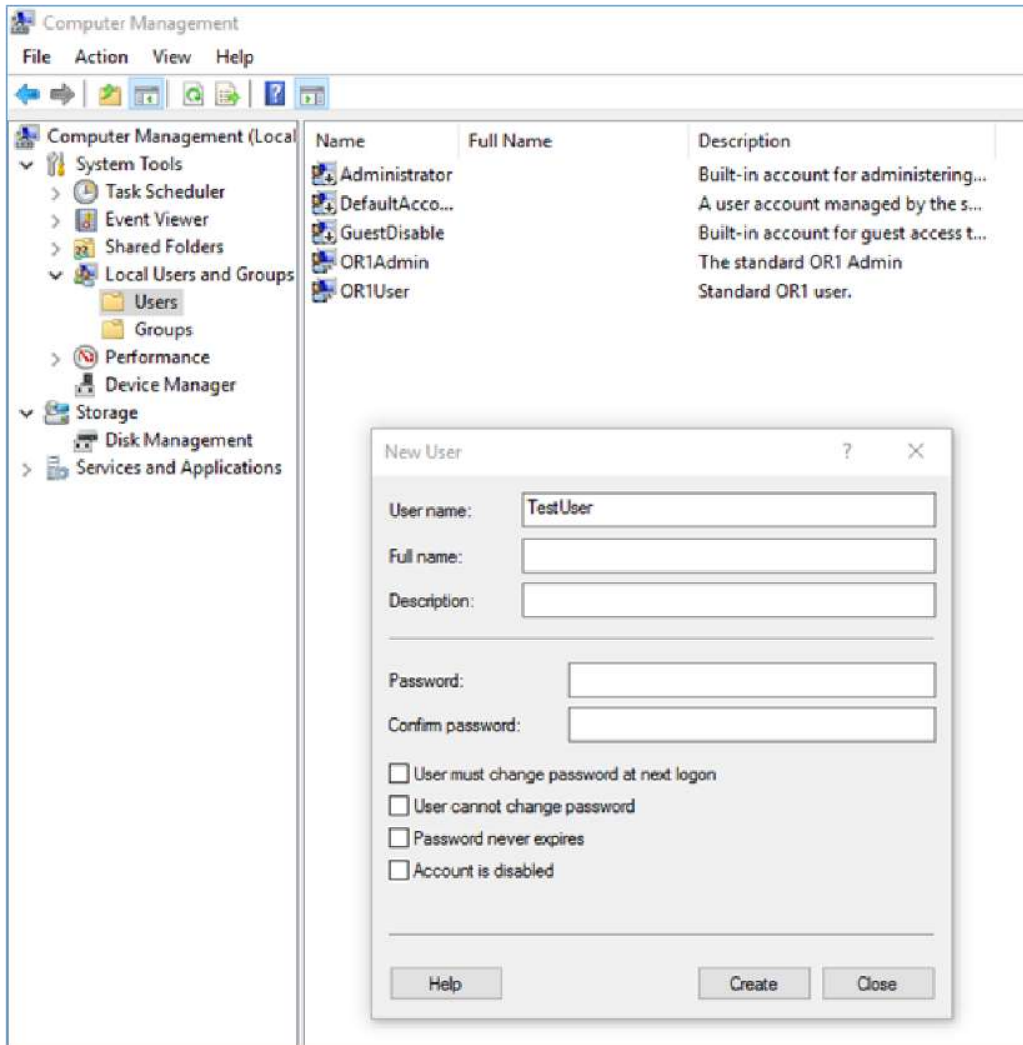


6.3.4 Creating user accounts

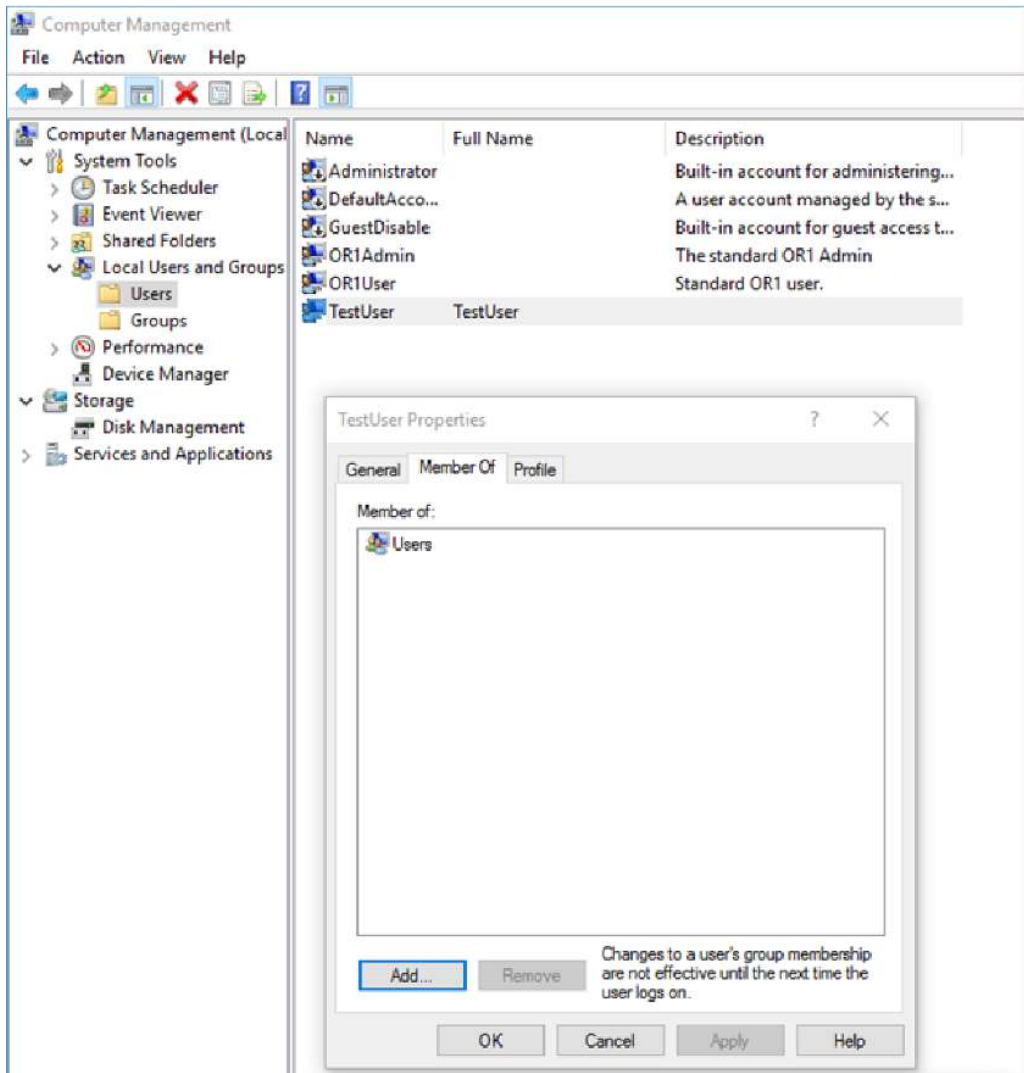
User accounts are created and managed via the Windows operating system. The individual accounts can be assigned to predefined user groups.

1. Tap the **Windows Desktop** button on the *System* tab.
 - ⇒ The prompt to exit AIDA® appears.
2. Tap the **Shutdown** button.
 - ⇒ The application is closed.
 - ⇒ The Windows login window appears.
3. Log on as the system administrator.

4. Call up Computer Management. Computer Management can be searched for and started via the Windows search field.
5. In the console tree, select **System Tools > Local Users and Groups > Users**.
6. Right-click on the *Users* folder and select *New User* in the context menu.
 - ⇒ The following window appears.

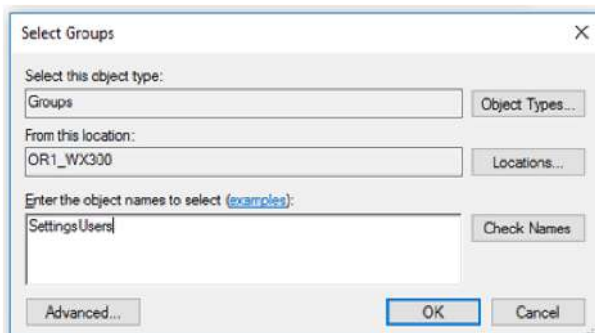


7. Enter the user data and click on **Create**.
8. Right-click on the new user and select *Properties* in the context menu.



9. Select the *Member of* tab.

10. Click the **Add** button.



11. In the text field enter one of the predefined groups, e.g., "SettingsUsers", and confirm with **OK**.

⇒ The created user has all the authorizations of the assigned group.

6.3.5 Settings as system administrator

The system administrator can make settings at operating system level. These include the following areas, to name but some examples:

- System-related settings, such as domain and network settings
- Security-related settings, such as activation of access control
- Settings for user management, such as activation of group profiles. The group profiles must be activated to allow the application administrator to create and edit additional group profiles as well as the predefined default profile
- Configuration of the profile service, which distributes the default and group profiles to all AIDA applications
- Configuration of the remote service

The table below provides an overview of the settings which the system administrator may make:

| Menu | Tab | Setting |
|------------|----------|--|
| General | System | Make domain settings |
| | | Make network settings |
| | | Make Windows desktop settings |
| | | Make NTP settings |
| | | Make WLAN settings |
| | Security | Specify access control for different modules |
| | | Enable login banner |
| | | Format hard disk (D:) |
| Capture | | |
| Finish | | |
| Data Entry | | |
| Browser | | |

| Menu | Tab | Setting |
|-----------------|-----------------|---|
| User Management | Role Management | Assign user roles to definable groups of people |
| | | Allow the creation of group profiles |
| | Authentication | Enable automatic login for local login |
| | | Enable automatic Windows login |
| | | Enable automatic logout after procedure finish |
| | | Enable automatic logout after timeout |
| | Profile Service | Enable profile service for automatic profile distribution |
| | | Set up profile service |
| Remote Service | General | Enable remote service |
| | | Set up remote service |

6.3.6 Settings as application administrator

The application administrator can make application settings, such as the configuration of the user interface. The application administrator can create and edit group profiles, provided that the function was enabled by the system administrator.

The table below provides an overview of the settings which the application administrator may make:

| Menu | Tab | Settings |
|---------|----------------|---|
| General | User Interface | Enable Onscreen Keyboard |
| | | Select country and language variant |
| | | Select keyboard |
| | | Select startup module |
| | | Enter facility name |
| | | Enable home screen |
| | | Enable turnover measurement timer |
| | Content | Specify available modules |
| | Display | Select screen type |
| | | Enable feedback for image capture and video recording |
| | | Enable display input switching if there are two video sources |
| | DICOM | Set up DICOM parameters |

| Menu | Tab | Settings |
|---------|------------------|---|
| | | Enable and set the interface to the DICOM Worklist Provider |
| | | Enable and set the interface to the MPPS Provider |
| | Open Commits | Display the active, ongoing, open commits and their status |
| | Reports | Select standard printer and paper format for automatic printing |
| | System | Display system information |
| Capture | General | Enter DisplayPort source |
| | | Enter HDMI source |
| | | Select camera system |
| | | Select image format |
| | | Select video format |
| | | Select video quality |
| | | Select video resolution |
| | | Specify how the complete video should be divided into sorted sub-sections |
| | Watermark | Enable watermark logo for captured stills and video recordings |
| | | Select watermark logo |
| | | Watermark logo scaling |
| | | Specify watermark transparency amount |
| | | Enable watermark fields |
| | | Select watermark fields |
| | Capture Feedback | Enable feedback for a captured image |
| | | Enable feedback for a recorded video |
| | | Select acoustic feedback for a captured image |
| | Remote Control | Specify the assignment and functioning of the remote control |
| | Voice Control | Enable voice control for image capture and video recording |

| Menu | Tab | Settings |
|--|------------|--|
| | | Enter activation words |
| Finish | Prechecked | Specify storage media for automatic data backup |
| | | Select templates for the report type |
| | Manual | Specify storage media for manual data backup |
| | | Select templates for the report type |
| | Reports | Enable logo for the report |
| | | Select logo |
| | | Enter standard headings for the header |
| | Print | Enable auto print |
| | | Select layout |
| | | Specify the number of copies |
| | | Specify the number of images per page |
| | Data Entry | User Interface |
| Specify areas for extended patient entry | | |
| Select procedure identifier | | |
| Specify mandatory fields | | |
| Team 1 | | Put together a clinical team |
| | | Enter referring physicians |
| Team 2 | | Enter anesthetists |
| | | Enter nurses |
| Instruments | | Enter instrument trays |
| | | Enter endoscopes |
| Procedures | | Enter clinical speciality |
| | | Enter procedure name |
| | | Select anatomic region |
| | | Assign keywords |
| Staff groups | | Import staff groups from the Active Directory |
| Browser | Browser | Add connections to, for example, streaming servers, cloud services, or Internet services |

6.3.7 Settings as configuration users

The configuration user can make additional settings, e.g., their own settings for video resolution and video format.

A user has the rights of the configuration user if they have been assigned the role of SettingsUser in the system or at operating system level. Configuration users are created by the administrator.

The table below provides an overview of the settings which the configuration user may make:

| Menu | Tab | Settings |
|------------|---------------------------------------|---|
| General | | |
| Capture | General | Select image format |
| | | Select video format |
| | | Select video quality |
| | | Select video resolution |
| | | Specify how the complete video should be divided into sorted sub-sections |
| | Remote Control | Specify the assignment and functioning of the remote control |
| | Watermark | |
| | Voice Control | |
| Finish | Prechecked | |
| | Manual | |
| | Reports | |
| | Print | Enable auto print |
| | | Select layout |
| | Specify the number of images per page | |
| Data Entry | User Interface | |
| | Team 1 | |
| | Team 2 | |
| | Instruments | |
| | Procedures | Assign keywords |
| | Staff groups | |
| Browser | Browser | |

6.3.8 Group profile and default profile

The system administrator can decide that only the supplied default profile should be used. The default profile is automatically loaded following login and the configuration area appears.

A copy of the default profile is created as a basis for a group profile. Group profiles contain fewer setting options than the default profile. Settings which affect the default profile are marked by the colors orange or light blue on the input field.

Only settings without an orange or light blue marking can be assigned to a group profile.

The profile service is updated every 5 minutes. KARL STORZ recommends configuring settings on one device at a time to avoid overwriting the settings.

6.4 Additional installations

Additional installations can be implemented on the system.

6.4.1 KARL STORZ AIDA® Secure

The system is delivered with KARL STORZ AIDA® Secure (SE46 Local Whitelist Manager) as standard. This security software can be used to install software and hardware in Service Mode. The software uses the whitelist approach. Only approved, certified software can be run on the system.

KARL STORZ also recommends combination with an intrusion prevention system (IPS) in order to guarantee maximum protection of the network.

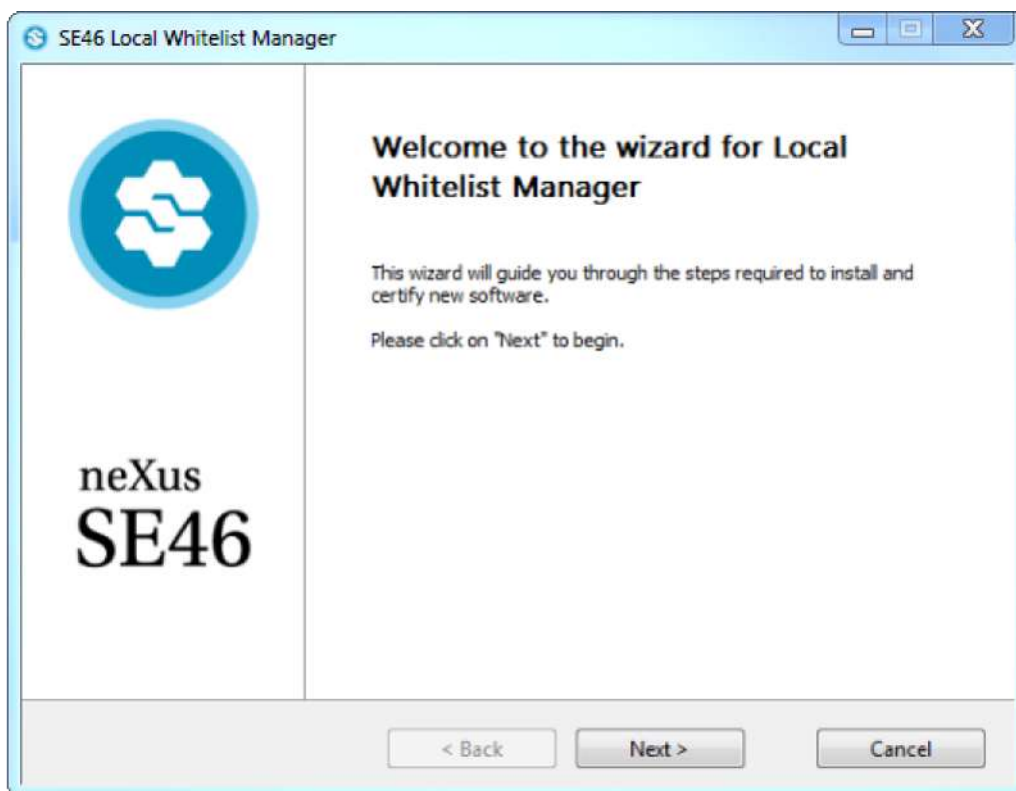
KARL STORZ cannot accept any liability for malfunctions or loss of data on modified systems.

6.4.2 Installing and approving hardware and software components

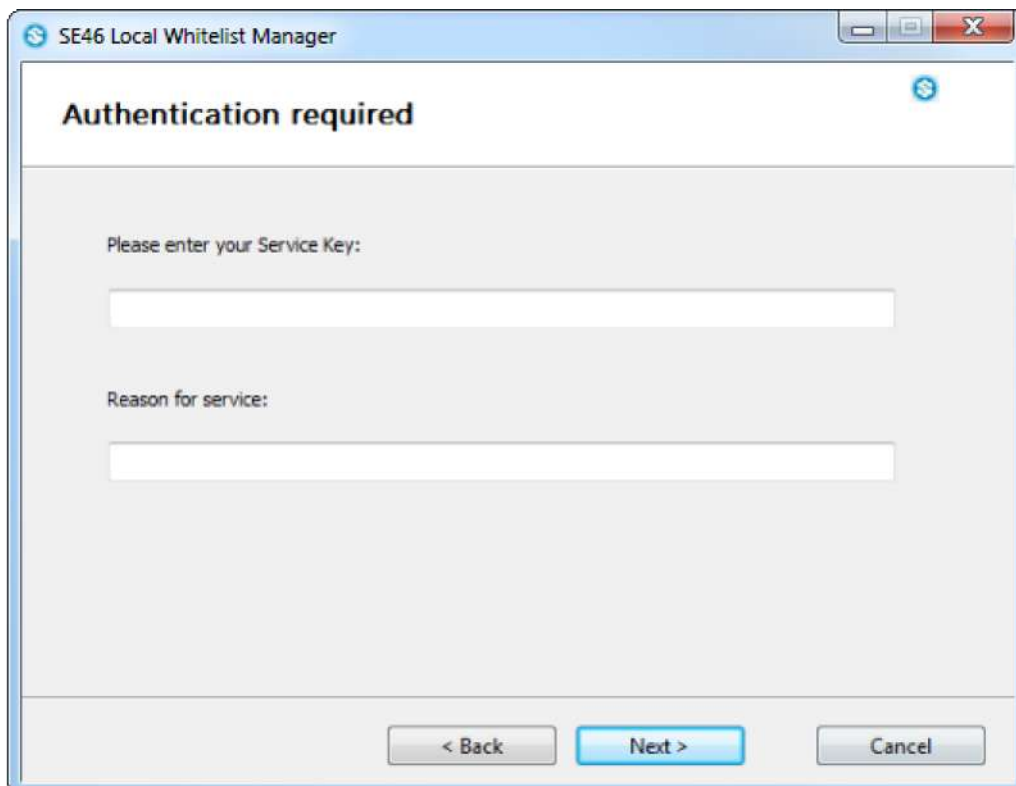
Damage to the operating system!

Viruses and other malware can damage the operating system during installation processes.

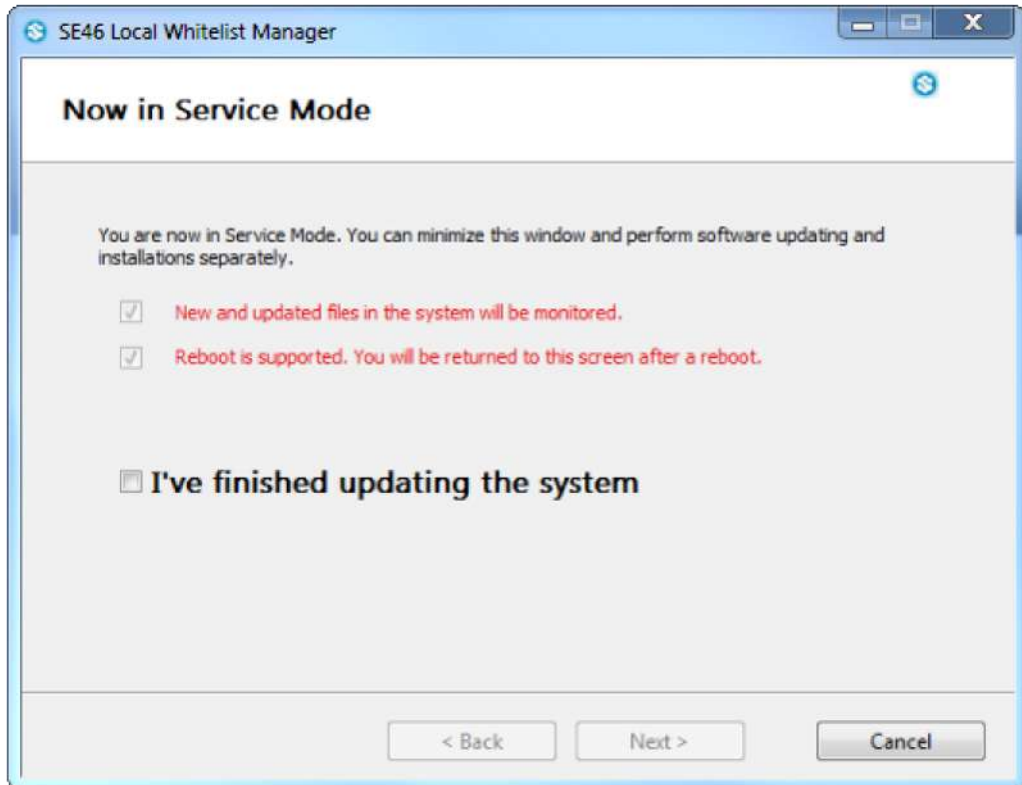
- ▶ Check the data carrier and the software to be installed with an up-to-date anti-virus program.
 - ▶ Only use the data carrier you have checked throughout the entire process.
 - ▶ Ensure that the network is free from viruses and other malware.
1. Ensure that the software to be installed comes from a safe and trustworthy source and can be installed on the system without any risks.
 2. Disconnect unnecessary data carriers from the system, e.g., USB hard disks.
 3. Disconnect the system from the network if necessary.
 4. Switch to Windows and log in with administrator rights. Call up the Windows desktop in the Configuration menu under General > System.
 5. Click on **Start\Programs\neXus\SE46\Local Whitelist Manager**.
 - ⇒ The following window appears:



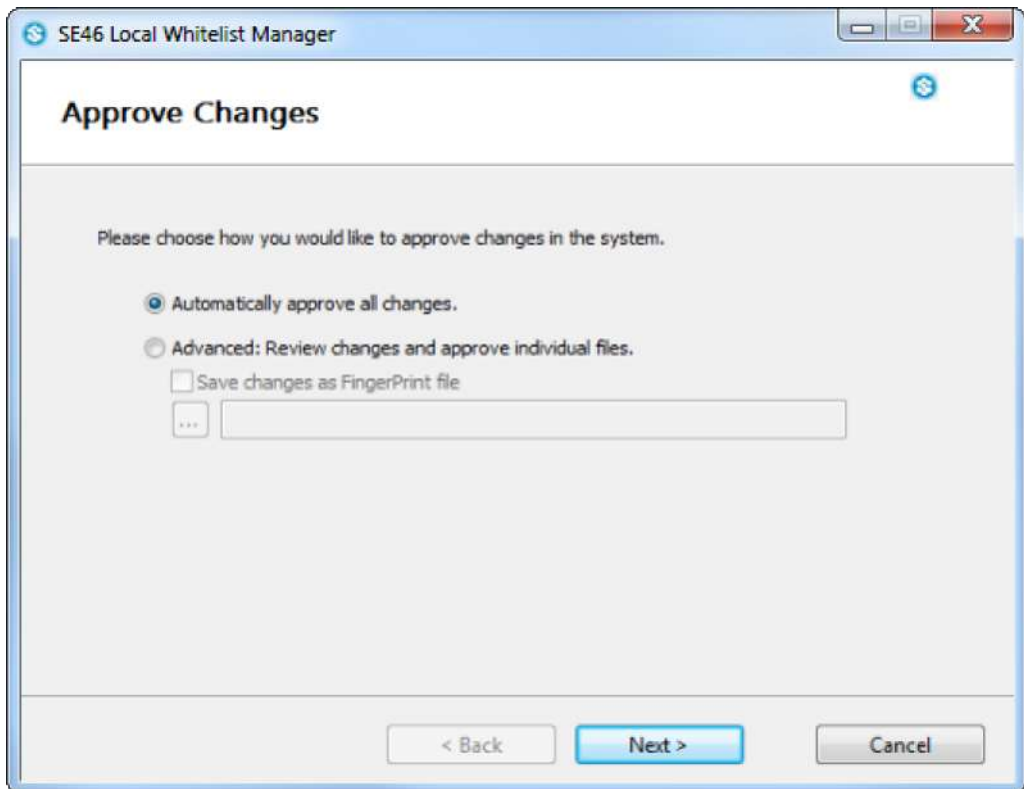
6. Click the **Next** button.
7. Enter the following service key: **Service-MLAACDET-ACAA-HHTPZATZ**. The entry is case sensitive.



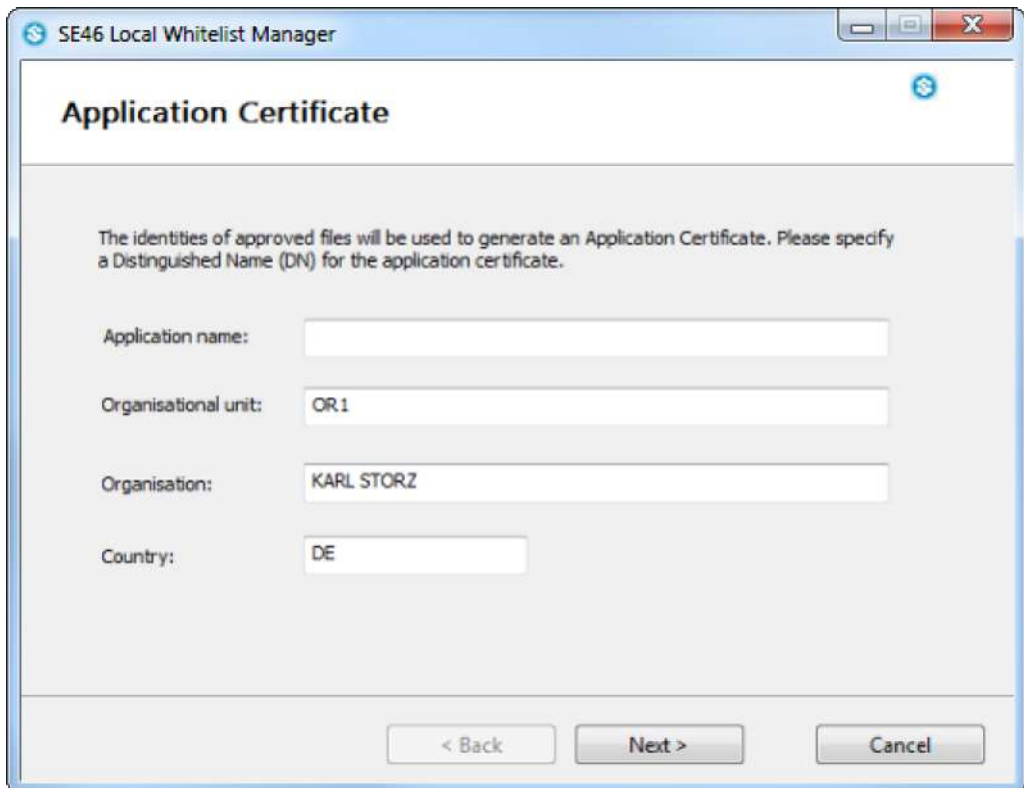
8. Enter the reason for service and click **Next**.
 - ⇒ The system is now in Service Mode.
 - ⇒ New system components can be installed.



9. Run the installation program.
10. Restart the system if necessary.
 - ⇒ The system is still in Service Mode and installation can be continued.
11. Once installation is complete, activate *I've finished updating the system* and click on **Next**.
 - ⇒ The Whitelist Manager checks the changes.

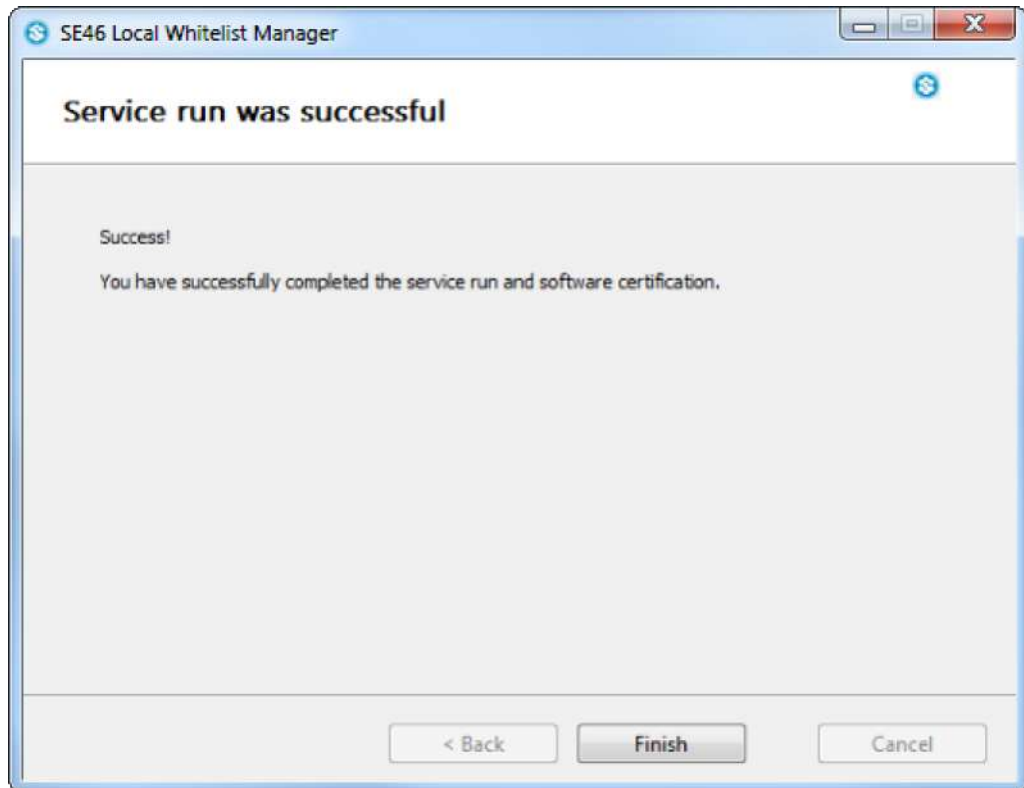


12. Select *Automatically approve all changes* and click on **Next**.



13. Complete the fields and click on **Next**.

⇒ The Whitelist Manager creates a new system certificate.



14. Click the **Finish** button.
 - ⇒ The software is now installed and has been checked by the Whitelist Manager.
 - ⇒ Service Mode is ended.
15. Reconnect the product to the network or connect a data carrier.
16. Carry out a system test.
 - ⇒ Installation is complete.

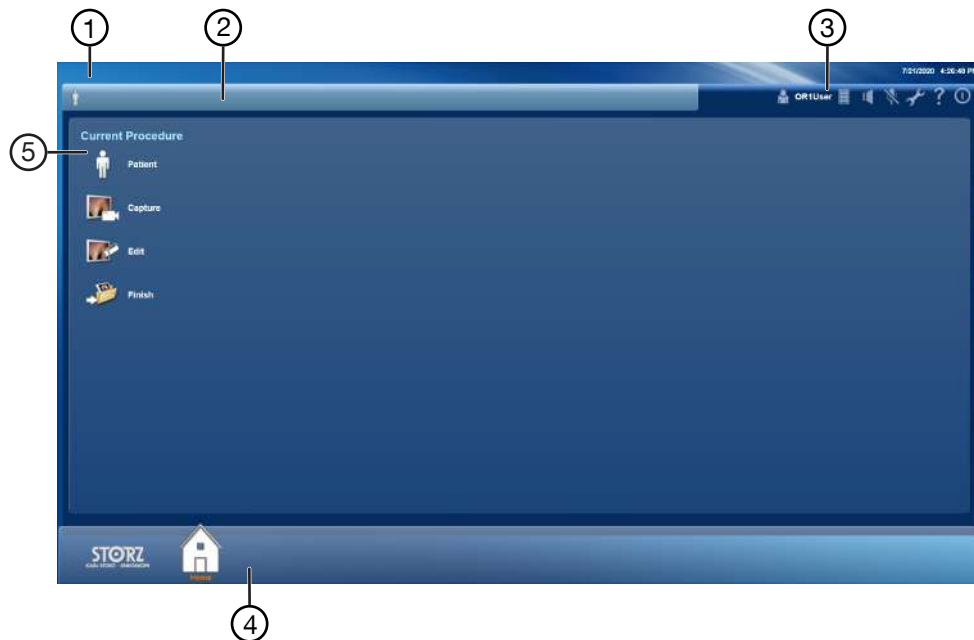
7 Operation

7.1 Switching on the product

1. Check the audio system.
2. Switch on the connected peripheral devices (camera, monitor, etc.).
3. Switch on the product via the rocker switch.
 - ⇒ The software will start up.
4. Have the user rights set up by the administrator.

7.2 User interface

The user interface has the following structure:



- | | | | |
|---|------------------|---|-------------------|
| 1 | Information bar | 4 | Navigation bar |
| 2 | Title bar | 5 | Application areas |
| 3 | Function buttons | | |

Information bar

The information bar displays system messages and information such as the number of open tasks.

Title bar

The title bar displays the data for the selected patient:

- Gender
- Last name
- First name
- Date of birth
- Age (in brackets)

- Patient ID

Function buttons

The icons are used to call up system functions, see section Symbols on the user interface [p. 18].

Navigation bar

Depending on the configuration, the following buttons are found here:



- | | | | |
|---|---------|---|--------|
| 1 | Home | 4 | Edit |
| 2 | Patient | 5 | Finish |
| 3 | Capture | | |

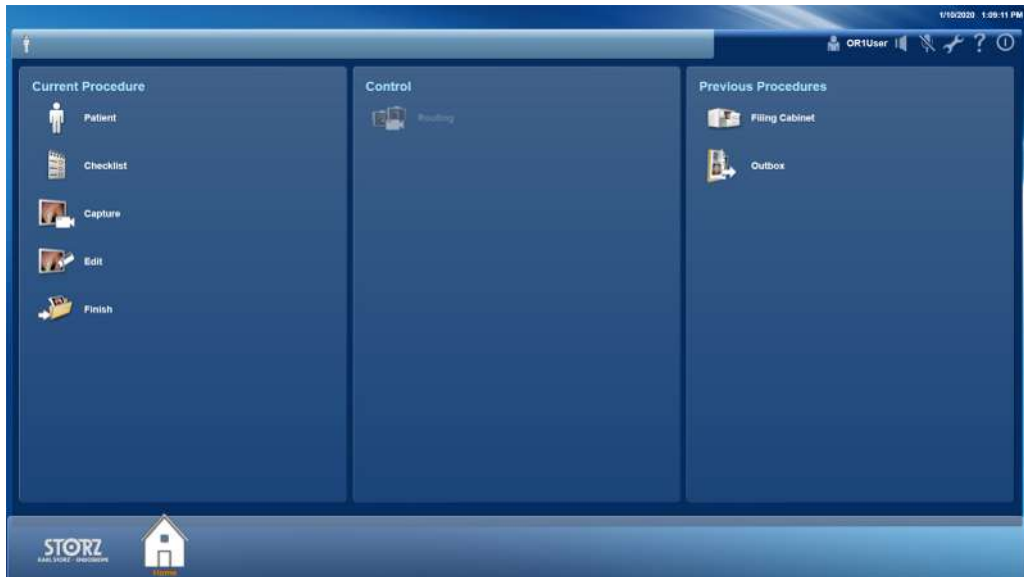
Application areas

The application areas contain modules which can vary depending on the configuration:

| Application area | Description |
|--------------------|--|
| Current procedure | Managing and processing current patient data and documenting the current procedure. |
| Previous procedure | Displaying previously created patient documentation and completing the documentation of previous procedures. |
| Control | Optional module for the monitoring and control of other KARL STORZ control equipment. The <i>Control</i> module can only be opened via the home screen. |
| Communication | Optional module. The <i>Communication</i> module can only be opened via the home screen. |

7.2.1 Home screen

The home screen is the start module which is set as standard and is opened automatically upon switching on the equipment. If the home screen is deactivated, the *Patient* module is automatically used as the new start module. The start module can be specified individually from the application area modules.



7.3 Current procedures

7.3.1 Patient

The *Patient* module is used to compile the outline data for the surgical procedure. This includes the patient data, the performing physician, and the nature of the procedure.

1. Tap the *Patient* module.
2. Select the performing physician.
 - ⇒ The settings for the current procedure are loaded.
3. Record the patient data manually or load it from the hospital information system or from a worklist saved in the system.
4. Complete the mandatory fields in full. Incomplete data cannot be stored.

The scope of the fields depends on what scope of documentation was configured. Three different input screens are available:

Simple entry

Standard entry

Extended entry

If extended patient entry is configured, a navigation bar is available for the outline data.

7.3.1.1 Entering patient data

1. Tap the *Patient* module.
 - ⇒ The relevant patient entry appears.
2. Select the *Performing Physician*.
 - ⇒ The profile with all the settings for the selected physician is loaded.
3. Complete and check the requested data.
 - ⇒ The entries are saved automatically.
4. Tap the **Change** button to make changes.
 - ⇒ The fields are unblocked.

The table below provides an overview of what settings are available to the user in the three variants.

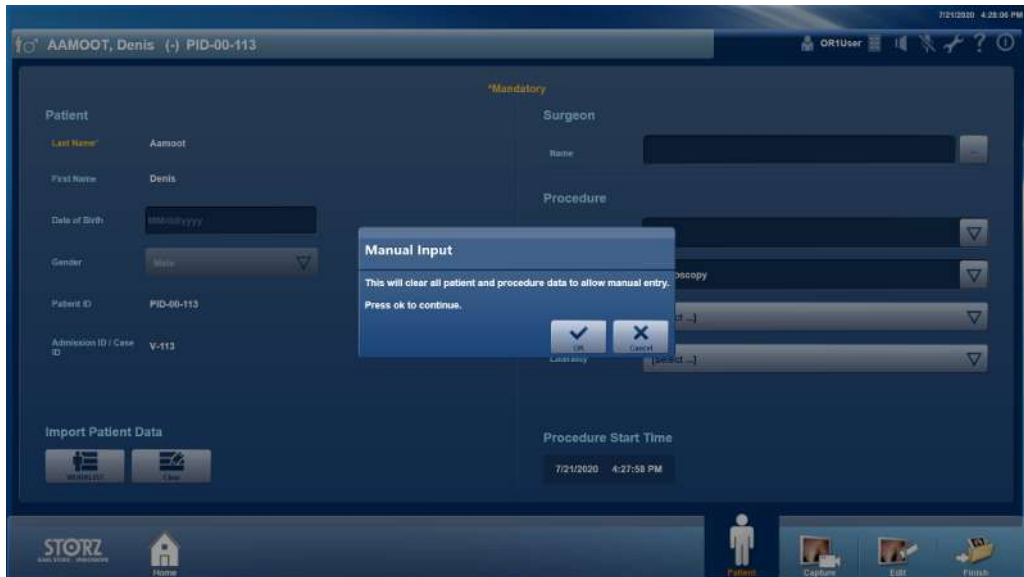
| Input data | Standard | Simple | Extended | Type of data |
|----------------------------------|----------|--------|----------|--------------|
| Last Name | X | X | X | |
| First Name | X | X | X | |
| Middle Name | X | | X | |
| Title | X | | X | |
| Suffix | X | | X | |
| Date of Birth | X | X | X | |
| Gender | X | X | X | |
| Patient ID | X | X | X | |
| Admission ID or Accession Number | X | X | | |

| Input data | Standard | Simple | Extended | Type of data |
|-----------------------------------|----------|--------|----------|-------------------------|
| Admission ID and Accession Number | | | X | |
| Performing Physician | X | X | X | Team-related Data |
| Assistant Physician | | | X | |
| Anesthetist | | | X | |
| Referring Physician | | | X | |
| Scrub Nurse | | | X | |
| Circulating Nurse | | | X | |
| Anesthetic Nurse | | | X | |
| Clinical Speciality | X | X | X | |
| Procedure Name | X | X | X | |
| Anatomic Region | X | X | X | |
| Laterality | X | X | X | |
| Procedure Comment | X | | X | |
| Tray 1 | | | X | Instrument-related Data |
| Tray 2 | | | X | |
| Tray 3 | | | X | |
| Tray 4 | | | X | |
| Endoscope Serial No. | | | X | |

7.3.1.2 Changing patient data

The mandatory fields are blocked after recording image data and/or video data. If you then make changes to the patient data, the footage already recorded will be assigned to the new data.

1. Tap the **Change** button to edit the recorded data.
 - ⇒ The mandatory fields are unblocked.
2. Make the changes.

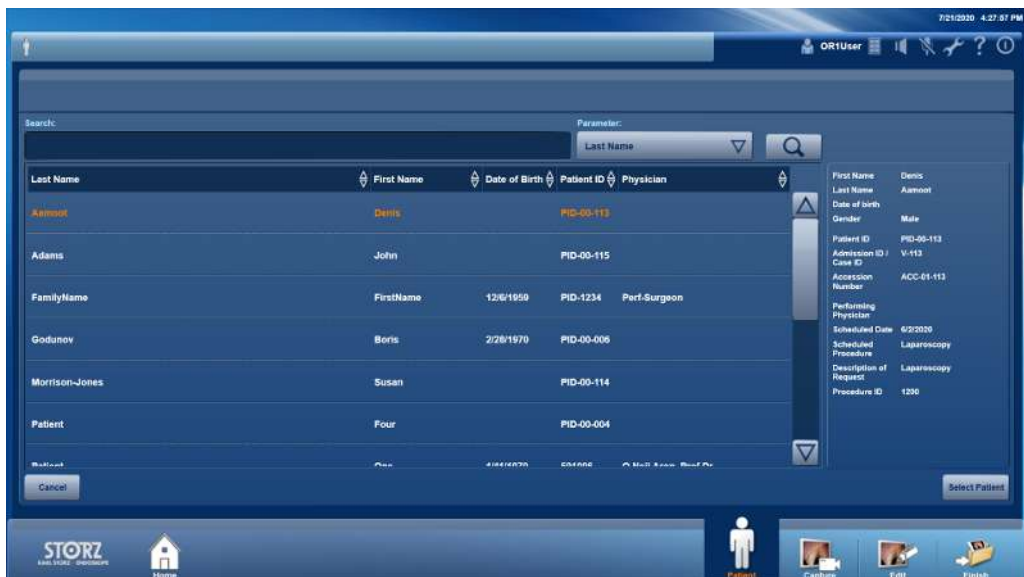


7.3.1.3 Loading patient data from the worklist

If the system is connected to a DICOM server, patient data can be selected and loaded from the DICOM worklist.

The data set is write-protected and cannot be edited.

1. Tap the **WORKLIST** button.
 - ⇒ The DICOM worklist is displayed.



2. Select a search criterion from the *Parameters* drop-down menu.
3. Enter a word to be searched for.
4. Tap the **Search** button.
 - ⇒ The list of results is displayed.
5. Select the desired data set.
6. Tap the **Select patient** button.

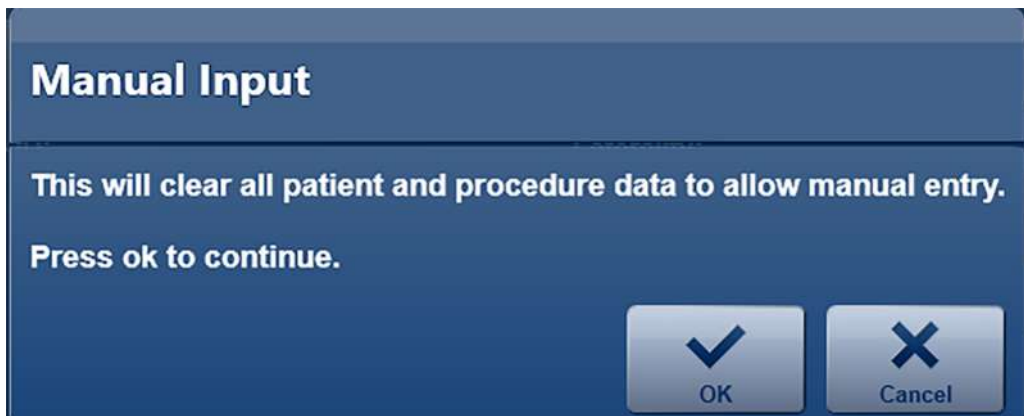
⇒ The selected data set is loaded and displayed.

7.3.1.4 Loading patient data from the HIS (hospital information system)

The patient data can be loaded by entering the patient ID or the accession number or admission ID. The patient must have been created in the hospital information system (HIS) and the system must be connected.

The loaded data set is write-protected and cannot be edited.

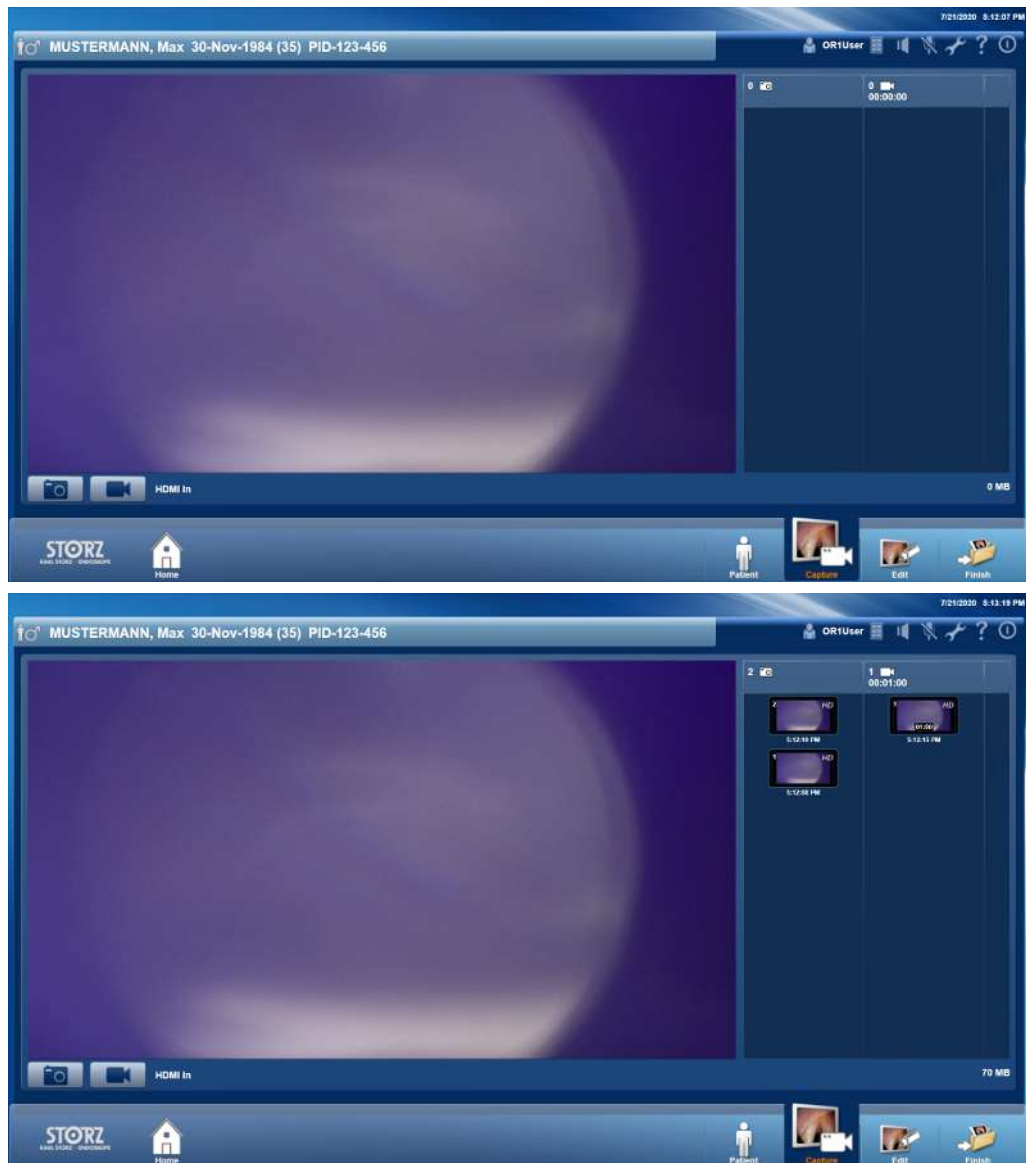
- ✓ The patient has been created in the HIS.
- ✓ The system is connected.
- 1. Enter the patient ID or admission ID.
- 2. Tap the **HIS** button.
 - ⇒ The patient data is loaded.
- 3. To discard the data, tap the **Change** button.
 - ⇒ The following message appears:





- 4. Press **OK** to confirm.
 - ⇒ The data set is discarded. A new data set can be loaded or entered manually.
- ⓘ Images or video footage that have already been recorded will be assigned to the new patient.

7.3.2 Capture

The *Capture* module is used to record and display stills and video sequences.



| Display/Operating element | Description |
|---|----------------|
|  | Capture still. |
|  | Record video. |

The preview area for created stills and videos displays the following information:

- The number of stills or video sequences created.
- The total length of all the video sequences.
- The still capture time or the length of the video.



7.3.2.1 Capturing stills and recording videos

Stills can be captured and videos can be recorded using the buttons on the user interface or via a voice command. They can also be captured or recorded using a foot pedal or the camera head buttons.

1. Tap **Capture still** or **Record video** in the *Input 1* or *Input 2* section.
 - ⇒ The image or recording is created.
2. To stop the video recording, tap the **Record video** button again.
 - ⇒ The most recently created image/video is displayed first in the preview area.

Video sequences recorded using the foot pedal or the camera head buttons are created in the same way as stills are captured.

If the storage space on the hard disk is less than 250 GB, a warning to this effect with the remaining recording time is displayed in the information bar. Video recording is canceled when there is just 100 GB remaining. Stills can still be captured. The administrator is responsible for managing the storage space.

The following table shows the expected file size per minute of capturing depending on the format, resolution, and capture quality:

| Format | Quality | Resolution | Transmission rate | File size per minute of capturing |
|-----------|---------|------------|-------------------|-----------------------------------|
| MPEG4/MOV | High | 1080p | 16 Mbit/sec | 120 MB/min |
| | | 720p | 8 Mbit/sec | 60 MB/min |
| | | SD | 3 Mbit/sec | 23 MB/min |
| | Normal | 1080p | 4 Mbit/sec | 30 MB/min |
| | | 720p | 2 Mbit/sec | 15 MB/min |
| | | SD | 1 Mbit/sec | 8 MB/min |

Voice commands

 Compatible microphone systems must be used for image capture and video recording.

Captures or recordings are always created synchronously from both sources. If one source is not active, a black image is recorded.

The following voice commands are preset:

- Activation word: **AIDA**
- Capture a still image: **Picture**
- Start video recording: **Record**
- End video recording: **Stop**

The response to the voice command may be delayed.

- ✓ Voice control is activated.
 - ✓ The activation word and the voice commands have been specified.
1. Switch on the microphone.
 2. Say the activation word.
 - ⇒ The **Microphone** symbol turns orange.
 3. Say "Picture" or "Record".
 - ⇒ A still image is captured.
 - ⇒ A video recording is started.
 4. Say "Stop" to end the video recording.
 - ⇒ The captures from both sources are displayed in the preview area.

7.3.2.2 Viewing captures

ATTENTION

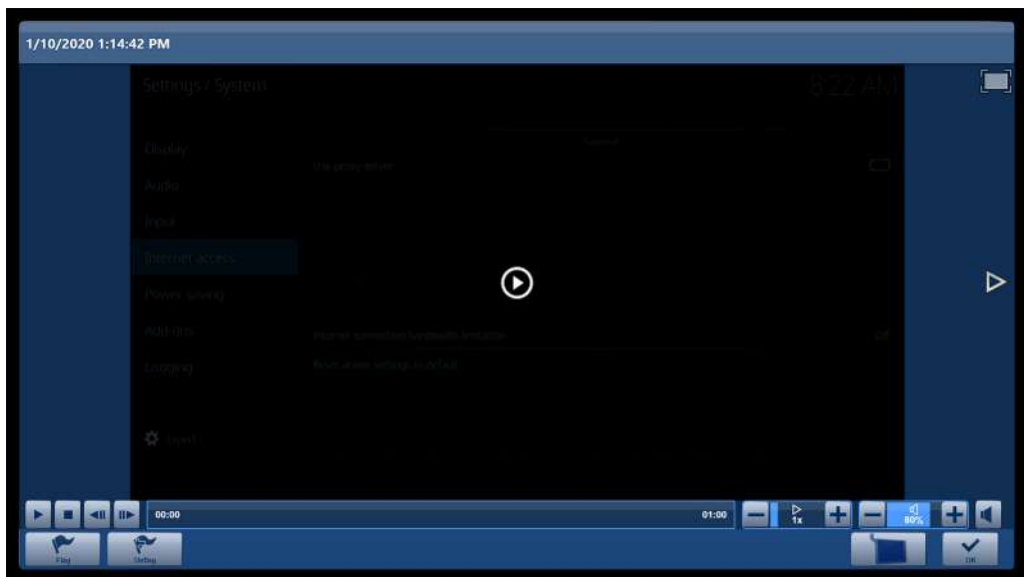
Not live images! Risk of confusion!

The captures shown are not images of live surgery. Captures can be mixed up and this can cause treatment errors.






- ▶ Note the label in the image or video.

To avoid confusion between the live image from the endoscopic camera and a video recording or a still, video recordings are labeled with "Recorded Video Replay" and images are labeled with "Recorded Image Replay".

1. Tap the desired capture.
 - ⇒ A drop-down menu appears.
2. Tap the **View** button.
3. Tap the side arrows to view the captures one after the other.
 - ⇒ The marked capture is displayed in the preview area. Videos can be played back.
4. To play back videos, tap the **Start** button or **Pause** button in the playback bar.



5. Adjust the playback speed and the volume using the plus/minus buttons.
 - ⓘ If the volume is too high, it could startle the attending physician.

| Button | Description |
|---|---|
|  | Mark the capture with a flag. All of the marked captures can be displayed, printed out, or deleted in the <i>Edit</i> module. |
|  | The flag that has been set is deleted. |
|  | Shows the capture in full-screen mode. |
|  | Shows the still or video on an external monitor. |
|  | Display mode is ended. |

7.3.2.3 Deleting a capture

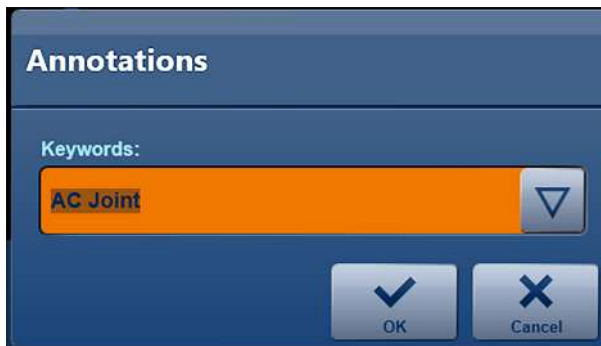
1. Tap the capture you want to delete.
 - ⇒ A menu appears.
2. Tap the **Delete** button.
 - ⇒ The capture is marked as deleted.
3. Tap *Restore* to restore the capture during the ongoing procedure.
 - ⇒ The capture is not saved and is deleted permanently during data storage.

7.3.2.4 Adding annotations

Annotations can be added to video sequences and stills. The annotation is then shown instead of the recording time on the recordings.

Annotations are linked to a procedure designation. A procedure designation can be selected before adding annotations to restrict the annotations list and make selection easier.

1. Tap the image.
2. Select *Annotations* from the drop-down menu.
 - ⇒ The *Annotations* window appears.



3. Tap the drop-down menu and select the desired entry.
 4. Enter the desired term in the text field.
 5. Press **OK** to confirm.
- ⇒ The annotation appears under the image.

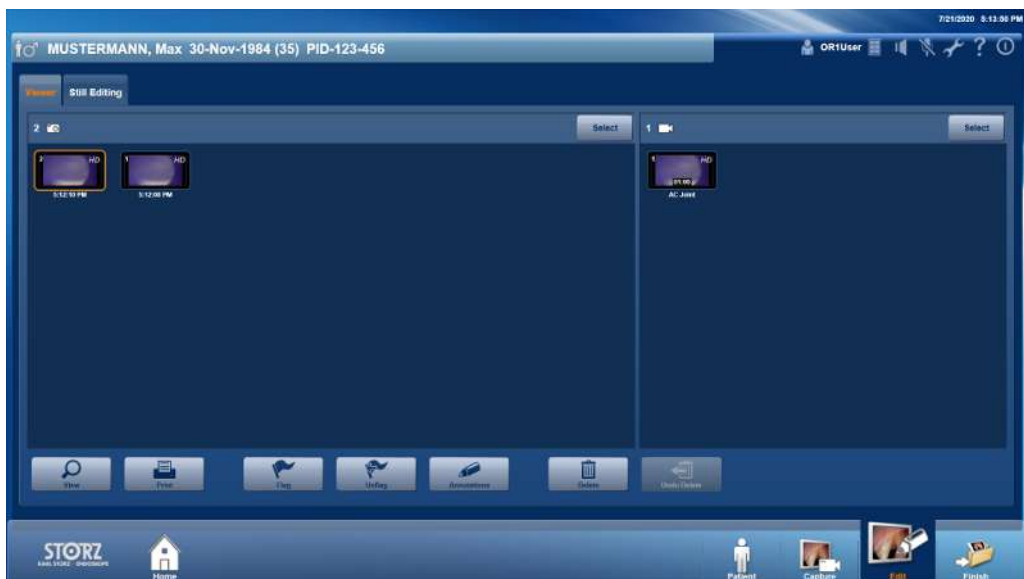
7.3.3 Edit






Stills and video sequences can be post-edited in the *Edit* module.


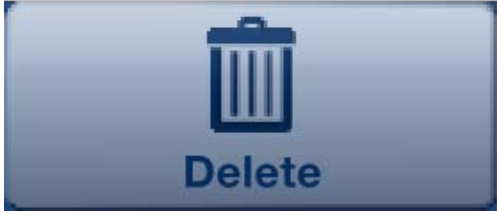

- ▶ Tap the **Edit** button.
- ⇒ The *Edit* module appears.

7.3.3.1 Viewer

The *Viewer* tab is used to view, print, delete, or annotate captures. All of the created stills and videos are displayed in a preview.



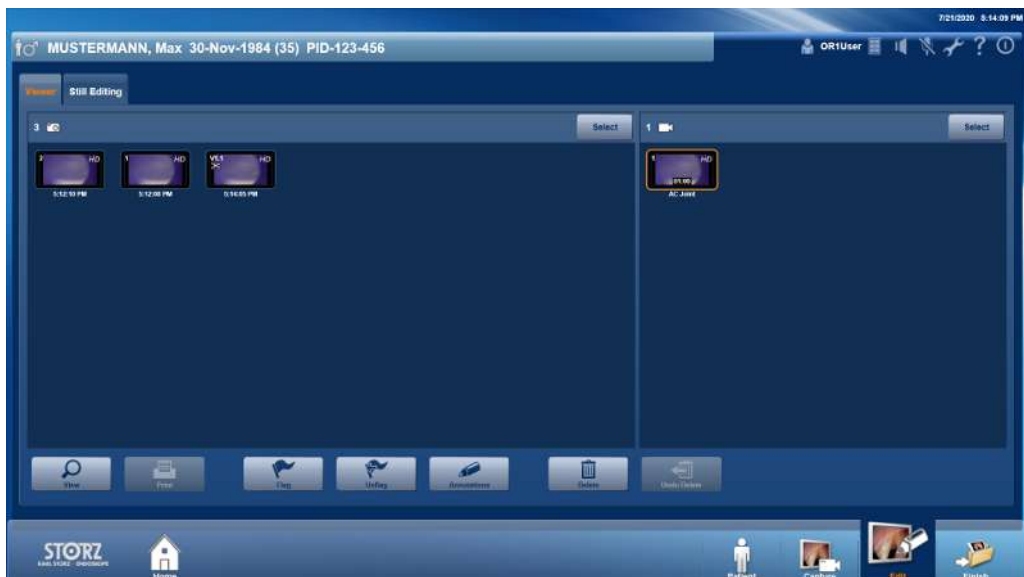
| Button | Description |
|--|---|
|  <p>The button features a blue gradient background with the word "Select" in a bold, dark blue sans-serif font centered on the screen.</p> | <p>The following functions appear:</p> <ul style="list-style-type: none"> - Select all - Deselect all - Select all flagged - Select all unflagged |
|  <p>The button features a blue gradient background with a magnifying glass icon above the word "View" in a bold, dark blue sans-serif font.</p> | <p>Captures are shown/played back in a separate viewer.</p> <p>The captures can be viewed one after the other using the arrows at the side.</p> |
|  <p>The button features a blue gradient background with a printer icon above the word "Print" in a bold, dark blue sans-serif font.</p> | <p>The selected captures are printed.</p> |
|  <p>The button features a blue gradient background with a flag icon above the word "Flag" in a bold, dark blue sans-serif font.</p> | <p>Selected captures are marked with a flag. The captures can be shown, printed out, or deleted.</p> |
|  <p>The button features a blue gradient background with an icon of a flag and a left-pointing arrow above the word "Unflag" in a bold, dark blue sans-serif font.</p> | <p>The flag is removed for selected captures.</p> |

| Button | Description |
|--|--|
|  | Annotations can be added to selected captures. |
|  | Selected captures are marked for deletion, are not saved upon finishing, and are permanently deleted. |
|  | Captures can be restored. The button is only enabled if data that has been marked for deletion is available. |

Printouts may contain display errors and must not be used for diagnostics and therapy purposes. When printing out an anonymous report, make sure that the report is assigned to the correct patient.

7.3.3.2 Creating stills from videos

1. Tap the **View** button.
⇒ The following window appears:



2. Tap the side arrows to view the selected captures one after the other.
3. Tap the **Play back** button to create a still from a video.

4. Tap the **Capture still** button at the desired position.
⇒ The still created appears.

7.3.3.3 Still editing

The *Still Editing* tab is used to adjust the brightness and contrast of the captured images. Changes to stills are saved as additional images. The original captures remain unchanged.



1. Tap the desired still.
2. Tap the plus/minus buttons to adjust the contrast and/or brightness.
3. Tap the **Reset** button to discard all changes.
4. Tap the **Save** button to save the changes as an additional image.

7.3.4 Finish

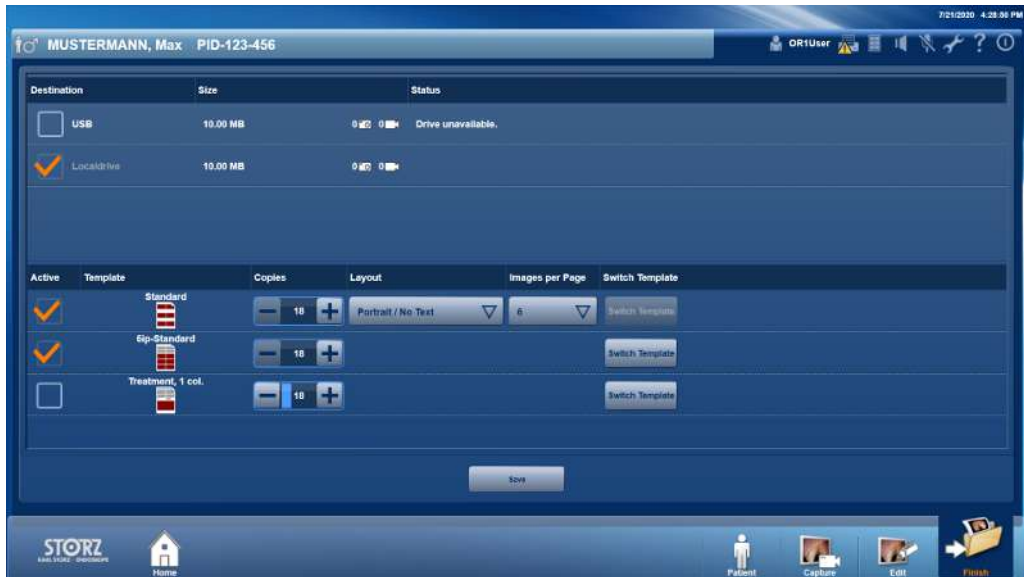
The *Finish* module is used to initiate data storage. All videos and stills which are not designated for deletion are saved. Any data that has been marked for deletion will be permanently deleted.

The data can be stored on various media (USB hard disk, CD/DVD, DICOM server), other network servers (FTP, SFTP, etc.), or locally on the system (local drive). The storage destinations are preset by the administrator.

Data is stored either automatically or manually:

- The destinations for automatic data storage are grayed out and the checkboxes are checked. They cannot be excluded from data storage.
- The destinations for manual data storage are deactivated but not grayed out.

1. Tap the **Finish** button.
 - ⇒ If necessary, you will be prompted to complete all data entries. The module does not appear until all the mandatory fields for patient data have been completed.
 - ⇒ A list containing all of the configured destination directories on which data can or must be stored appears.



2. Check whether the data storage locations have been configured.
 3. To store data, check the checkboxes for the destinations.
 4. Connect a USB stick or insert a CD or DVD.
 5. Tap the **Save** button.
- ⇒ Data export starts.
- ⇒ The *Export running* window appears.



⇒ Other functions are possible:

| Function | Description |
|------------|--|
| Worklist | If DICOM has been configured, the next patient can be selected via the DICOM worklist. |
| Open Tasks | List of incomplete exports. If the list is empty, data storage has been finished successfully. |

7.3.4.1 Data storage on CD/DVD

The system saves all the patient data on CD/DVD. Several data carriers may be required. Once a data carrier has reached full capacity, it is ejected. A message appears stating that a new carrier must be inserted.

Once the data has been saved on CD/DVD, the window *Label CD/DVD* appears. This provides a suggestion for labeling the data carrier. KARL STORZ recommends using this suggestion as this prevents mix-ups or assignment problems between the data carrier and patient file.

Data from several patients/procedures cannot be saved on one CD/DVD.

7.3.4.2 Storing data with minimum memory space

-  The user is responsible for using and managing removable storage devices.

The system continuously checks the memory space on the hard disks. This ensures that enough space is available for the images and video recordings.

Old exports are overwritten automatically as soon as the memory capacity gets too low. A warning with the remaining recording time is displayed in the information bar.

- ▶ Ensure that there is enough storage space available on the hard disk.

7.3.4.3 Forced restart during data backup

The RAM on the hard disk is continuously monitored. Once a particular limit has been reached, a restart is required. A message to this effect appears in the information bar and remains there until the restart is performed.

Once the limit has been exceeded, a restart will be forced. Old images and video recordings can impair the system and should be removed.

7.4 Previous procedures

The *Previous procedures* tab contains all the data of previous procedures.

1. Tap the **Filing Cabinet** button to display patient documentation that has already been created.
2. Tap the **Open Tasks** button to edit and finish the documentation from previous procedures.

7.4.1 Filing Cabinet

The *Filing Cabinet* module is used to display documentation which has already been created and which can be stored in the following destinations:

- Local data carrier
- Network drive
- Self-made optical data carrier
- USB stick

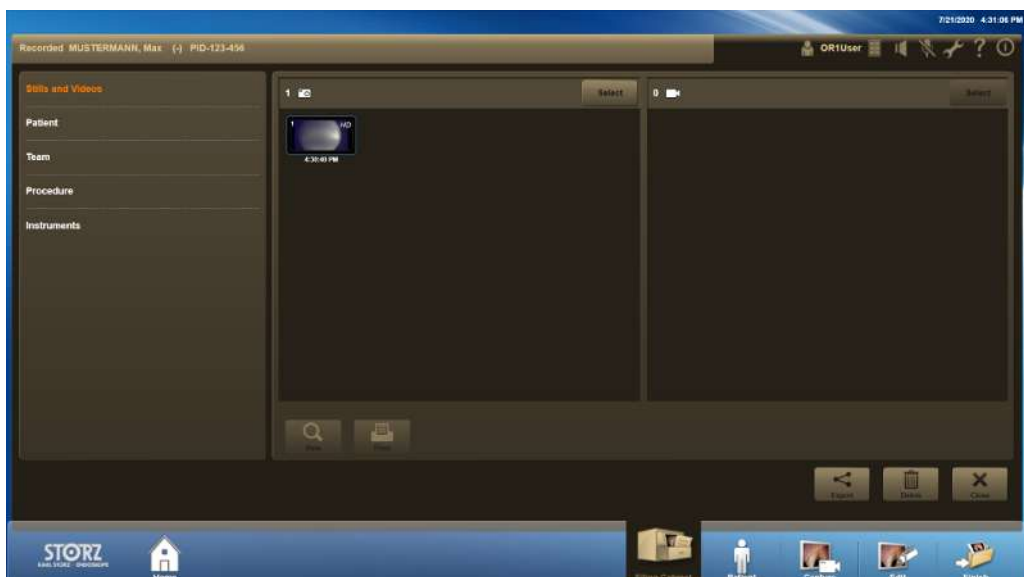
The data can be viewed, played back, or copied to other destinations, e.g., USB, CD, DVD, and networks such as PACS, HIS, and AAR. The data cannot be deleted.

To avoid mix-ups with data from ongoing treatments, the module is a different color from the rest of the user interface.



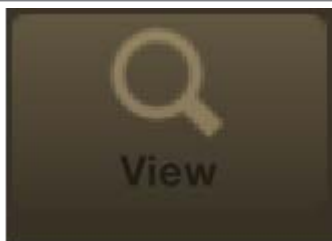
1. Tap the **Filing Cabinet** button.
 - ⇒ The *Filing Cabinet* module is displayed.



2. Open the *Select Source* drop-down menu and select the required data source.
⇒ The available data is shown as a table.
3. Open the *Parameters* drop-down menu and select a search criterion.
4. Enter the search term.
5. Tap the **Search** button.
6. Select the desired data set.
⇒ The following window appears:



The following further functions are possible:

| Function | Description |
|---|--|
|  | <p>The following functions appear:</p> <ul style="list-style-type: none"> - Select all - Deselect all - Select all flagged - Select all unflagged |
|  | <p>Copy selected data to another destination. If the process cannot be carried out, it is temporarily stored in the <i>Open Tasks</i> module. When shutting down, a window indicating that copying is not completed appears.</p> |
|  | <p>View selected stills or videos.</p> |

7.4.2 Open tasks

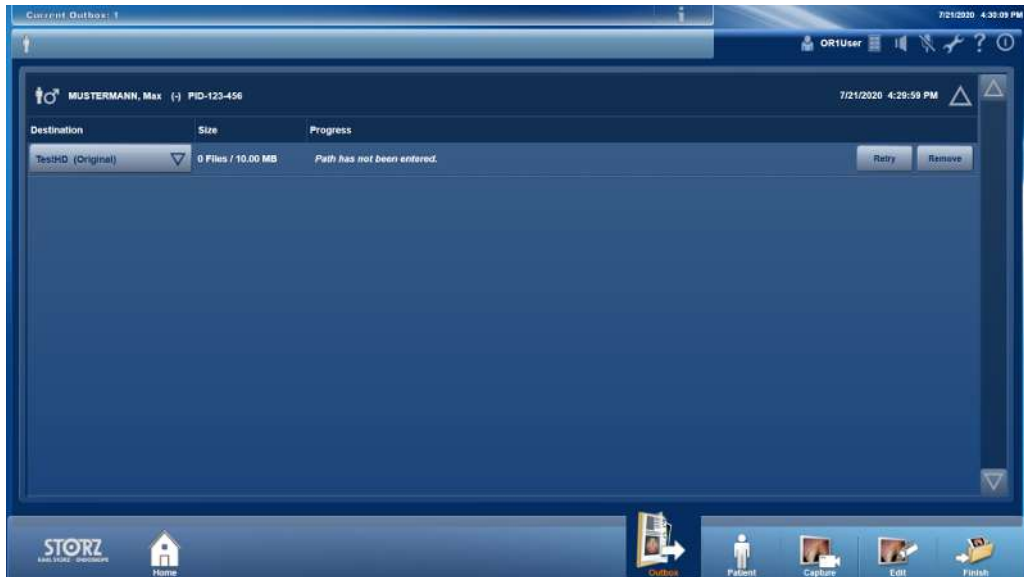
The following actions/issues can result in open tasks:

- There is not enough storage space
- Network disruptions occur during data transmission
- The memory is overloaded

Data transmission is interrupted. To ensure complete data archiving, the interrupted storage processes are recorded and listed under *Open Tasks*.

After the system has shut down, a message is displayed indicating that there are open tasks. When the system is running, the *Current Open Tasks* display appears in the information bar. This is followed by the number of open tasks.

Incomplete patient data can be stored at any time.



1. Tap the **Info** button.
 - ⇒ The list shows the patient/procedure data which has not yet been transmitted.
2. Check the data set in the list of *Open Tasks* for size and status.
3. Select another destination directory from the drop-down menu and tap the **Try again** button.
4. Alternatively: Place a data carrier in the drive and tap the **Burn** button.

7.5 Control and communication

The *Control* and *Communication* tabs are used to display and call up the user interfaces of other systems. Additional equipment can be operated via a screen and communication modules can obtain access.

The tabs can be opened via the home screen. If the **Home** button is not displayed, this function is not available.

The following equipment and systems can be connected:

- OR1™ .avm

More information on the use of the connected systems can be found in the separate instructions for use of the respective equipment.

7.6 Switching off the product

Data loss!

Shutting down the system while processing patient data results in the loss of image data.

- ▶ Only switch the product off using the switch-off button on the user interface.

1. Tap the **Shutdown** button.
2. Confirm the dialog with *Shut down*.
 - ⇒ The software is shut down and the product switches to standby mode.
3. Alternatively: Briefly press the rocker switch.
 - ⇒ The software is shut down and the product switches to standby mode.

8 Maintenance, repair, and disposal

8.1 Maintenance

⚠ 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.

Maintenance work may only be performed by KARL STORZ or by a company authorized by KARL STORZ.

The following maintenance work must be performed at regular intervals throughout the life cycle of the product:

| Interval | Action | Responsibility |
|-------------|--------------------------|--------------------------------|
| As required | Change fuses | KARL STORZ service technicians |
| Annually | Inspect the product * | KARL STORZ service technicians |
| 4 years | Replace the BIOS battery | KARL STORZ service technicians |

Table 1: Maintenance plan

* The annual inspection of the product must cover the following EMC-related points:

- Check the housing for damage
- Check that the ferrite cores are undamaged and secure
- Measure the leakage currents
- ▶ After completing maintenance work, arrange for a safety test in accordance with the valid standard to be performed by a qualified electrician and have it recorded.

8.2 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 on the scope and performance of the safety check can be found in the service manual.

8.2.1 Visual inspection

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

8.2.2 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.

8.2.3 Functional test

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

8.3 Repairing devices

Before returning a faulty device, all the data on the hard disk must be backed up and then deleted.

In Germany, you can contact the following address for repairs:

KARL STORZ SE & Co. KG

Abt. Reparaturservice
Take-off Gewerbepark 83
78579 Neuhausen

Service hotline: +49 7461 708-980
E-mail: technicalsupport@karlstorz.com

In other countries, the respective KARL STORZ branches or specialist dealers are responsible.

8.4 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 regulations and laws at a suitable collection point for the reprocessing of electrical and electronic equipment.
2. Dispose of accessories in compliance with country-specific laws and regulations.
3. To prevent damage to the environment and personal injury, contact KARL STORZ SE & Co. KG, a KARL STORZ branch, or an authorized dealer and find out the address of the collection point in your area.

9 Accessories and spare parts

9.1 Recommended accessories

| Item | Order no. |
|---|------------|
| Power cord, length 300 cm, not suitable for the wall-mounted solution | 400A |
| “Hospital grade” power cord (USA), length 200 cm | 400B |
| OR1 Update/Install.Stick AIDA WD300 V1.5 | WD10004 |
| OR1 adaptor cable, DP 1.2, 4K, 60 Hz, length 180 cm | WA1000C |
| DVI connecting cable, length 200 cm | 20040086 |
| HDMI TO DVI CABLE 2M / KAB24, length 200 cm | 4800288 |
| OR1 cable HDMI to DVI, length 300 cm | WD10002 |
| ACC connecting cable, to control peripheral devices, length 180 cm | 20221070 |
| USB silicone keyboard with touchpad | 20040240XX |
| RJ-45 network cable, length 500 cm | 20040076 |

10 Electromagnetic compatibility

10.1 General information 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 product may be used in the vicinity of high frequency surgical units. If the product is used at the same time as high frequency surgical units, it may experience temporary image interference.

- ❗ 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

Electromagnetic interference! Malfunction!

Electromagnetic interference may cause the product to malfunction. As a result of this malfunction, it may be necessary to replace the defective product or to continue the surgery as an open procedure.

- ▶ Do not use the product next to or together with other devices. If such use is required, monitor the product and the other devices, and follow the relevant instructions in the event of malfunctions.
- ▶ Portable HF communications equipment including peripheral devices (e.g., antenna cables and external antennas) should be used no closer than 30 cm from the product, including cables specified by the manufacturer.

10.2 Cables

⚠ WARNING

Reduced immunity! Risk of injury!

The use of accessories or cables other than those specified in the KARL STORZ instructions for use may result in increased emissions or decreased immunity of the product. The cables listed have been shown to comply with the requirements of IEC 60601-1-2.

- ▶ When using other cables, the operator is responsible for checking that they comply with IEC 60601-1-2:2014.

Cables which have been shown to comply with EN/IEC 60601-1-2:

| Order no. | Interface | Max. length [m] | Type | | | Use |
|-----------------------|---------------------|-----------------|-----------------|----------|------------|-------------------------------|
| | | | Number of wires | Shielded | Unshielded | |
| 400A | AC power cord | 3.0 | 3 | | x | Power connection |
| - | PE | 1.0 | 1 | | x | POAG grounding connection |
| 20221070 | ACC1-4 | 2.0 | 3 | x | | Camera head buttons |
| 20221070 | Line In/Out | 1.8 | 3 | x | | Audio In/Out |
| 20014430 | Lemo 5-pin | 3.0 | 5 | x | | Footswitch |
| - | RS232 (1) | 3.0 | 9 | x | | Control cable |
| - | RS232 (2) | 3.0 | 9 | x | | Barcode reader |
| WM200 scope of supply | RS232 (3) 12 VDC | 0.3 | 9 | x | | Smart Screen power connection |
| - | DVI * | 3.0 | 29 | x | | Touch-screen |
| PS3000-020 (PureLink) | HDMI 4K | 2.0 | 19 | x | | In/Out |
| WA1000C | DP 4K | 1.8 | 20 | x | | In/Out |
| WA1000C | DP PC | 1.8 | 20 | x | | DP 1/2 |
| 20040076 23057380 | LAN1 | 5.0 | 8 | x | | Ethernet |
| 20040076 23057380 | LAN2 | 5.0 | 8 | x | | Ethernet |
| - | USB 2.0 (back) | 1.8 | 4 | x | | |
| - | USB 3.0 (back) | 3.0 | 4 | x | | |
| - | USB 3.0 (front) | 3.0 | 4 | x | | |
| W22146 | Phoenix plug | 5.0 | 2 | | x | On Air light |
| W23174 | Phoenix plug, 4-pin | 30.0 | 4 | | x | Remote switch |

* The DVI connecting cables used have the following properties:

- DVI-D Single Link
- Full HD 1920*1200 pixels
- 60 Hz
- Molded connectors
- Double shielding
- Integrated ferrite core, 2x

10.3 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> 100% for 250/300 cycles | <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> 100% for 250/300 cycles | 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 operated with an uninterruptible power supply or a battery. |

| Interference immunity tests | EN/IEC 60601 test level | Compliance level | Electromagnetic environment – guidelines |
|---|--|--|--|
| 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 | |

10.4 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 & 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 | | | | | |
| 1,720 | 1,700 – 1,990 | GSM 1800, CDMA 1900, GSM 1900, DECT, | Pulse modulation 217 Hz | 28 | 28 |
| 1,845 | | | | | |


| Test frequency MHz | Frequency band MHz | Radio service | Modulation | Immunity test level V/m | Compliance level V/m |
|--------------------|--------------------|---|----------------------------|-------------------------|----------------------|
| 1,970 | | LTE band 1, 3, 4, 25, UMTS | | | |
| 2,450 | 2,400 – 2,570 | Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE band 7 | Pulse modulation 217 Hz | 28 | 28 |
| 5,240 | 5,100 – 5,800 | WLAN 802.11 a/n | Pulse modulation 217 Hz | 9 | 9 |
| 5,500 | | | | | |
| 5,785 | | | | | |

10.5 Table 3 – Test levels for radiated and conducted 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 |
|---|---|--------------------|---|
| Conducted HF disturbances acc. to IEC 61000-4-6 | 3 V _{rms} 150 kHz to 80 MHz | 3 V _{rms} | Portable and mobile HF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation 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 separation distance in meters [m]. Field strengths from fixed HF transmitters as determined by an electromagnetic site survey ^a should |
| Radiated HF disturbances acc. to IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | |

| Interference immunity tests | EN/IEC 60601 test level | Compliance level | Electromagnetic environment – guidelines |
|---|-------------------------|------------------|---|
| | | | <p>be less than the compliance level in each frequency range ^b.</p> <p>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>Interferences may occur in the vicinity of equipment marked with the following symbol:</p>  |
| <p>Note: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>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.</p> <p>^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 due to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location where the device is used exceeds the above compliance levels, the device should be monitored to ensure proper function. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the product.</p> <p>^b Over the frequency range from 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> | | | |

10.6 Table 4 – Emission class and group

Guidelines and manufacturer's declaration – electromagnetic emissions

The device is intended for use in such an environment as specified below. The customer or user of the device 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 | |

10.7 Table 5 – 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 power of the transmitter [W] | Separation distance d [m] according to the transmitter frequency | | |
|------------------------------------|--|---|--|
| | 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ | 80 MHz to 800 MHz $d = 1.2 \sqrt{P}$ | 800 MHz to 2.5 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 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.

10.8 Regulatory information on telecommunications

10.8.1 USA

The device corresponds to Section 15 of the FCC Regulations. The application is subject to the following two conditions:

- The device must not cause harmful interference.
- The device must be able to withstand harmful interference, including interference which may lead to undesirable functions.

Includes FCC ID: PD98265NG

10.8.2 Canada

The device corresponds to Industry Canada's license-free RSS standards. The application is subject to the following two conditions:

- The device must not cause harmful interference.
- The device must be able to withstand harmful interference, including interference which may lead to undesirable functions.

Includes IC: 1000M-8265NG

10.8.3 European Union

The device may only be used indoors.

Radio Equipment Directive (RED) 2014/53/EU

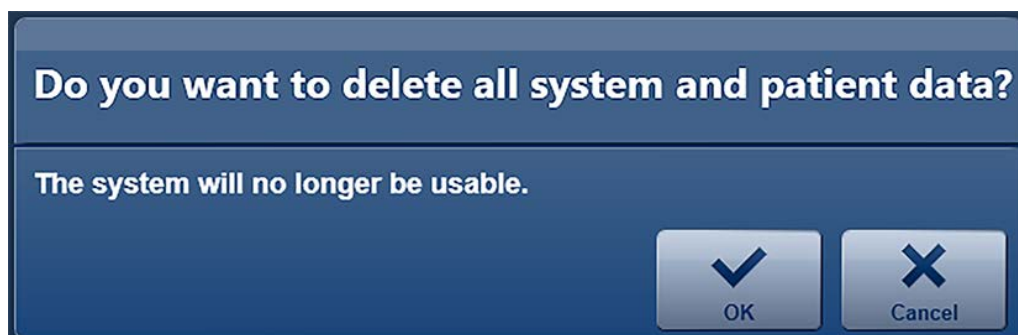
11 Fault correction

11.1 Formatting the hard disk

The patient, image, and video data is saved on the hard disk (D:). The data carrier D: can be formatted with the **Delete All Data from the System** button to remove all data (e.g., should the device be returned to KARL STORZ for repair, etc.).

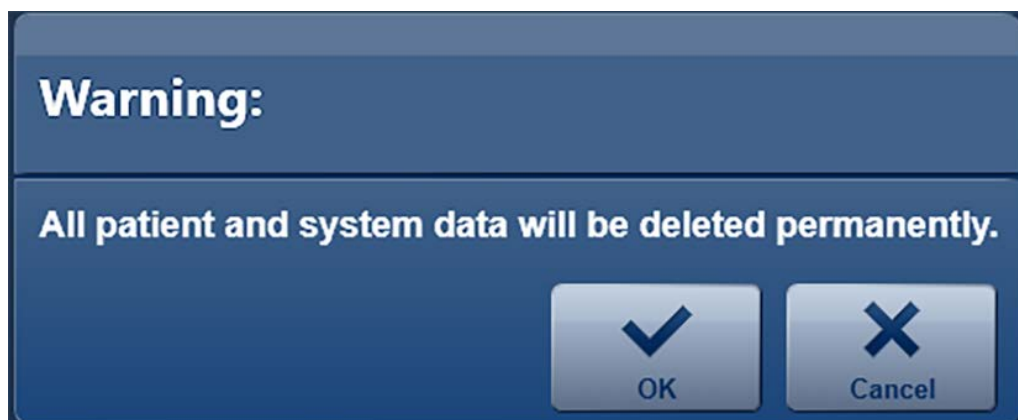
1. Tap **Delete All Data from the System**.

⇒ A prompt appears.



2. Press **OK** to confirm.

⇒ A warning appears.



3. Press **OK** to confirm.

⇒ The window for the Windows authentication appears.

4. Enter the username and password and confirm by pressing **Yes**.

⇒ The hard disk (D:) is formatted and all the data is deleted. An information window visualizes this process.

⇒ Once formatting is complete, a window opens to confirm that formatting has taken place.

⇒ The system is automatically shut down after a few seconds.

11.2 System recovery

ATTENTION

System recovery! Data loss!

If a full system recovery is carried out, all procedure data from the hard disk will be deleted.

- ▶ Back up data from the DATA (D:) drive prior to system recovery.

System recovery can be carried out in two ways:

- Complete system recovery: Both hard disk drives are reset via the recovery files on the USB stick.
- Operating system recovery: The system drive (C:) is reset.

11.2.1 Backing up data from the (D:) drive

Data should be backed up in advance as all data on the hard disks is deleted during system recovery.

The data can be saved via Windows and Windows Explorer to a backup data carrier by means of drag-and-drop.

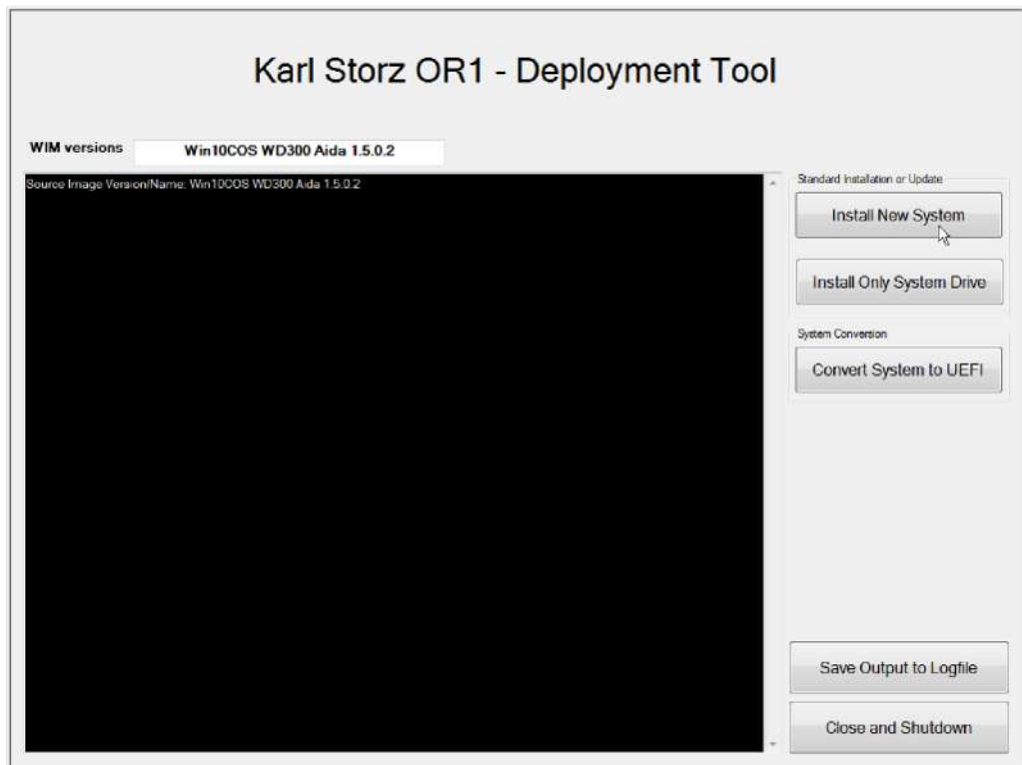
To access the operating system, you must log in as the system administrator. Log into the Configuration menu and call up the Windows desktop under General > System.

11.2.2 Complete system recovery

1. Plug the recovery USB stick into the USB port on the front of the equipment before it is switched on.
2. Switch on the product.
3. Wait until the KARL STORZ logo appears.
4. Press the **F12 key**.
 - ⇒ The password entry window for accessing BIOS appears.
5. Enter the password (standard password: 123456).
 - ⇒ The following window opens in BIOS.



6. Select the USB drive of the recovery stick as the boot drive. The name of the USB drive is the name of the physical USB stick. In the above window, this is *SanDisk*.
 - ⇒ The KARL STORZ OR1 deployment tool launches.



7. Click on the **Install New System** button.
 - ⇒ A window opens.
8. Press **OK** to confirm.
 - ⇒ The system data is deleted.
9. If the message *Restoring image finished, please reboot* appears in the Logfile window on the left, press the **Close and Shutdown** button.
10. The system shuts down.
11. For recovery a BitLocker encryption was saved on the connected USB stick. Do not remove the AIDA recovery USB stick.
12. When restarting, ensure that the equipment is connected to the Internet in order to guarantee the necessary registration with Microsoft.
13. Start the equipment.
 - ⇒ The system automatically logs in as OR1 Admin and starts the BitLocker hard disk encryption. This will take about 1 minute.

```

Administrator: C:\Windows\system32\cmd.exe
C:\Windows\system32>REM Copyright (c) 2018 KARL STORZ SE & Co. KG, Tuttlingen (D). All rights reserved.
C:\Windows\system32>REM This batchfile must be run as Admin
C:\Windows\system32>REM This batchfile calls the corresponding powershell script with appropriate execution policy.
C:\Windows\system32>cd C:\Program Files (x86)\KARL STORZ AIDA\Deployment\
C:\Program Files (x86)\KARL STORZ AIDA\Deployment>
C:\Program Files (x86)\KARL STORZ AIDA\Deployment>Run script: Adjusts BitLocker encryption state
C:\Program Files (x86)\KARL STORZ AIDA\Deployment>
Handles  NPM(K)  Mem(K)  Pri
-----  -
52       8
16       2

Encryption state of partition C: 76.3%
Encryption state of partition D: 99.9%
BitLocker is still encrypting partitions...

Waiting for 0 seconds, press a key to continue ...
Encryption state of partition C: 76.6%
Encryption state of partition D: 99.9%
BitLocker is still encrypting partitions...

Waiting for 0 seconds, press a key to continue ...
Encryption state of partition C: 76.9%
Encryption state of partition D: 99.9%
BitLocker is still encrypting partitions...

Waiting for 0 seconds, press a key to continue ...
Encryption state of partition C: 77.2%
Encryption state of partition D: 100.0%
BitLocker is still encrypting partitions...

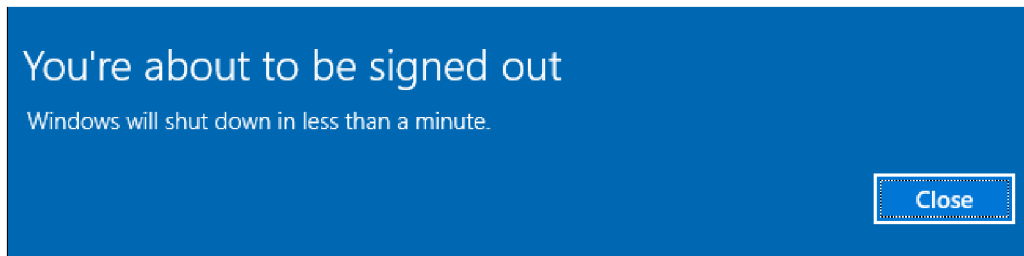
Waiting for 0 seconds, press a key to continue ...
Encryption state of partition C: 77.5%
Encryption state of partition D: 100.0%
BitLocker is still encrypting partitions...

Waiting for 0 seconds, press a key to continue ...
Encryption state of partition C: 77.8%
Encryption state of partition D: 100.0%
BitLocker is still encrypting partitions...

Waiting for 2 seconds, press a key to continue ...

```

14. Complete the steps for system recovery.



⇒ The system shuts itself down.

The next time AIDA is started, the system logs in as OR1 User again.

► Remove the recovery USB stick.

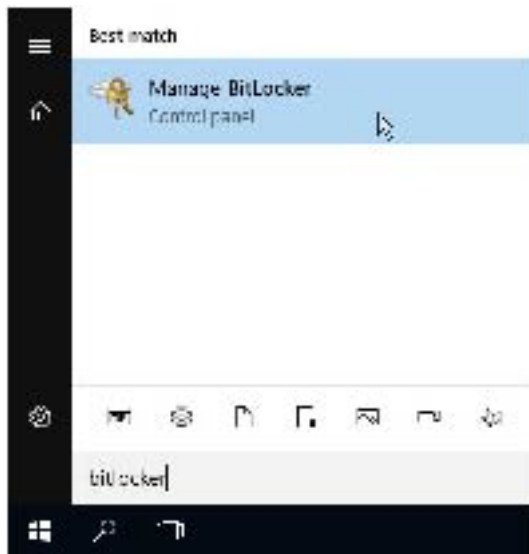
⇒ Full recovery is complete.

11.2.3 Operating system recovery

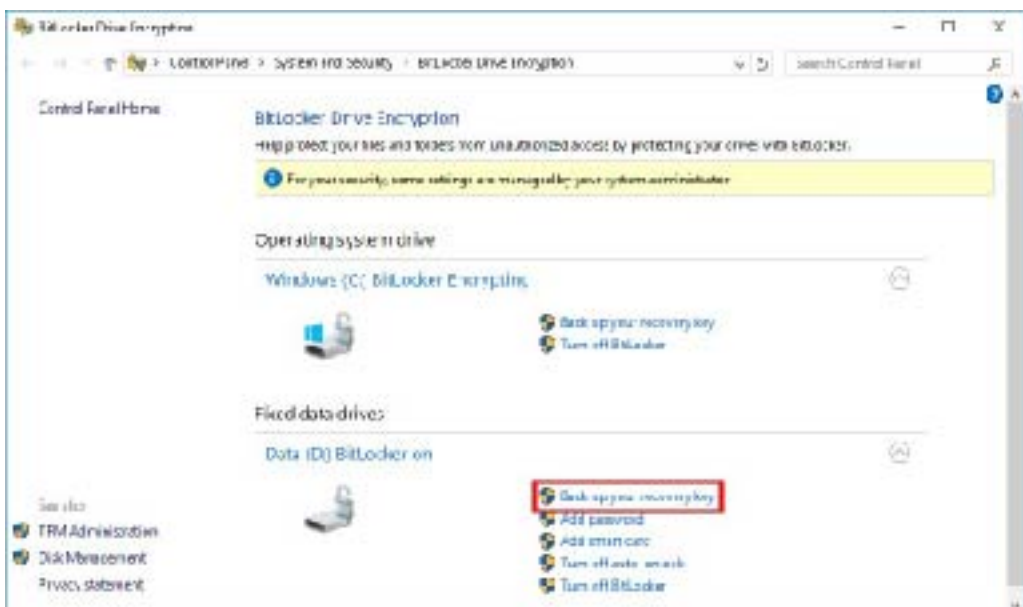
With operating system recovery only drive C: is recovered. Drive D: is untouched.

To allow the operating system to subsequently access drive D, the BitLocker drive key must be saved prior to system recovery.

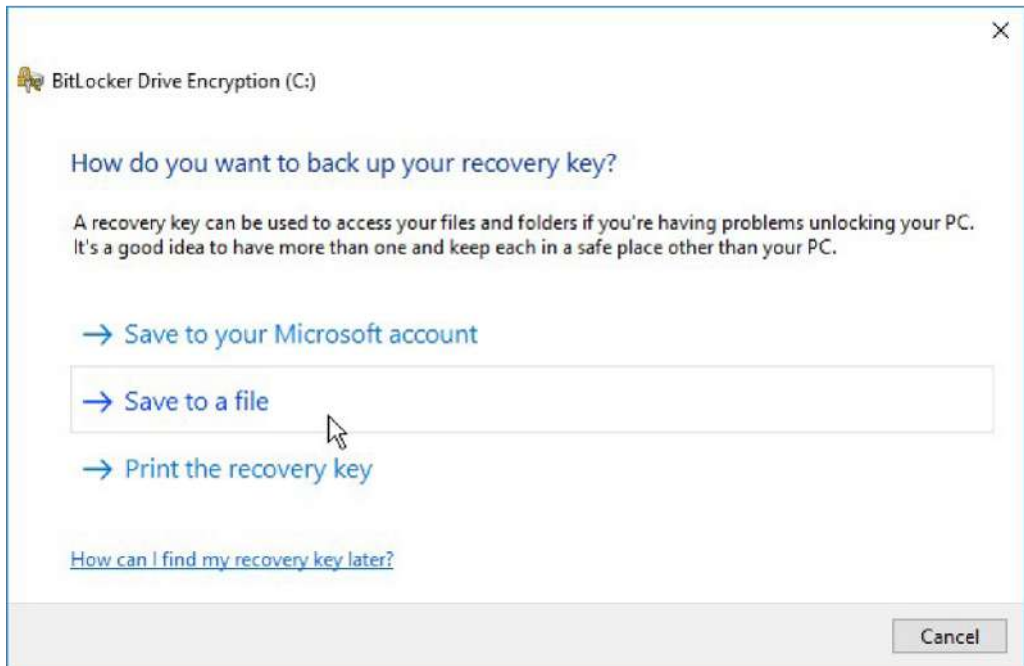
1. Log on to the system as the administrator to access the Windows operating system.
2. Call up the Windows desktop in the Configuration menu under *General > System*.
3. Log in as OR1 Admin.
4. Open the start menu and enter "Bitlocker" into the search field.
5. Select the entry *Manage BitLocker*.



6. In the window that follows, click on *Back up your recovery key* in the *Data (D:)* area.



7. Select *Save to a file*.
⇒ The saving dialogue opens.



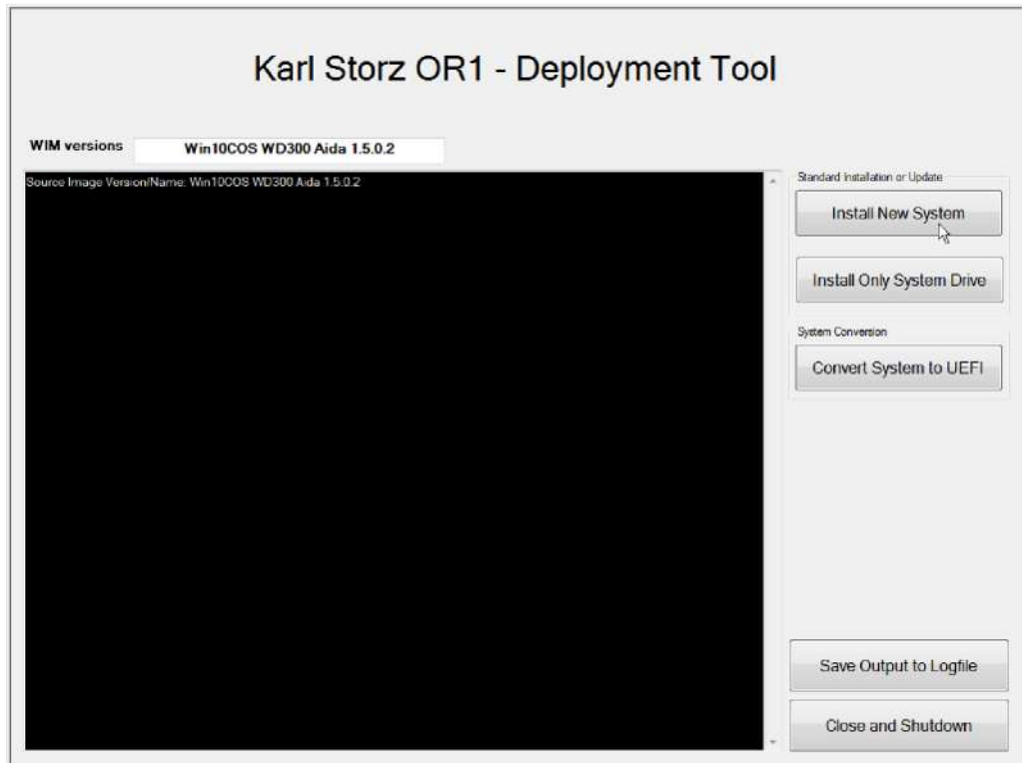
8. Save the BitLocker key as a .txt file on the AIDA® recovery USB stick. An NTFS-formatted USB stick can be used for saving. The same USB stick must be used when restarting for the first time after recovery.
9. Confirm the saving dialogue and close the window with **Finish**.

11.2.4 Performing system recovery

1. Switch the system off.
2. Plug the AIDA® recovery USB stick into the USB port on the front of the equipment.
3. Start the product.
4. Wait until the KARL STORZ logo appears.
5. Select the **F12 key**.
 - ⇒ The password entry window for accessing BIOS appears.
6. Enter the password (standard password: 123456).
 - ⇒ The following window opens in BIOS.



7. Select the USB drive of the recovery stick as the boot drive. The name of the USB drive is the name of the physical USB stick. In the above window, this is SanDisk.
⇒ The KARL STORZ OR1 deployment tool launches.



8. Click on the **Install Only System Drive** button.
 - ⇒ A window appears.
9. Press **OK** to confirm.
10. If the message *Restoring image finished, please reboot* appears in the Logfile window, click on the **Close and Shutdown** button.
 - ⇒ The system shuts down.
11. When restarting for the first time, ensure that the equipment is connected to the Internet in order to guarantee the necessary registration with Microsoft.
12. Ensure that the USB stick is connected to the system.
13. Start the product.
 - ⇒ The system automatically logs in as OR1 Admin and starts the BitLocker hard disk encryption.
14. If you have not changed the key, no further action is necessary.
15. If the following error message appears, the key has changed:
 - ⇒ *ERROR: The password failed to unlock volume D:. "The D: partition could not be unlocked" Please enter the recovery password to unlock the D: partition:*
16. Copy the 48-character password from the text file to the prompt.
17. Press the **Enter key**. The following windows appear:

```

Administrator: C:\Windows\system32\cmd.exe
C:\Windows\system32>REM Copyright (c) 2018 KARL STORZ SE & Co. KG, Tuttlingen (D). All rights reserved.
C:\Windows\system32>REM This batchfile must be run as Admin
C:\Windows\system32>REM This batchfile calls the corresponding powershell script with appropriate execution policy.
C:\Windows\system32>cd C:\Program Files (x86)\KARL STORZ\KARL STORZ AIDA\Deployment\
C:\Program Files (x86)\KARL STORZ\KARL STORZ AIDA\Deployment>Run-script.ps1
Run script: Adjusts Bitlocker encryption state of partitions...
C:\Program Files (x86)\KARL STORZ\KARL STORZ AIDA\Deployment>
Handles  NPM(K)  Mem(K)  Pri
-----  -
52       8
16       2

Waiting for 0 seconds, press a key to continue ...
Encryption state of partition C: 76.3%
Encryption state of partition D: 99.9%
Bitlocker is still encrypting partitions...

Waiting for 0 seconds, press a key to continue ...
Encryption state of partition C: 76.6%
Encryption state of partition D: 99.9%
Bitlocker is still encrypting partitions...

Waiting for 0 seconds, press a key to continue ...
Encryption state of partition C: 76.9%
Encryption state of partition D: 99.9%
Bitlocker is still encrypting partitions...

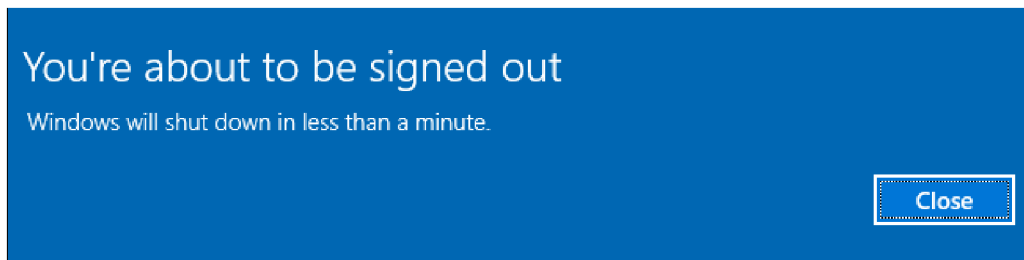
Waiting for 0 seconds, press a key to continue ...
Encryption state of partition C: 77.2%
Encryption state of partition D: 100.0%
Bitlocker is still encrypting partitions...

Waiting for 0 seconds, press a key to continue ...
Encryption state of partition C: 77.5%
Encryption state of partition D: 100.0%
Bitlocker is still encrypting partitions...

Waiting for 0 seconds, press a key to continue ...
Encryption state of partition C: 77.8%
Encryption state of partition D: 100.0%
Bitlocker is still encrypting partitions...

Waiting for 2 seconds, press a key to continue ...

```



18. Complete the steps for system recovery.
19. The system shuts itself down.

ATTENTION

Restart

The next time AIDA is started, the system logs in as OR1 User again. With every start, decryption takes place in the background.

20. Remove the USB stick.
 - ⇒ Full recovery is complete.
 - ⇒ The next time AIDA is started, the system logs in as OR1 User again. With every start, decryption takes place in the background.

12 Subsidiaries

KARL STORZ SE & Co. KG

Dr.-Karl-Storz-Straße 34, 78532 Tuttlingen/Germany
Postfach 230, 78503 Tuttlingen/Germany
Phone: +49 7461 708-0, Fax: +49 7461 708-105
Email: info@karlstorz.com

KARL STORZ Endoskope Berlin GmbH

Scharnhorststr. 3, 10115 Berlin/Germany
Phone: +49 30 3069090, Fax: +49 30 30 19452

KARL STORZ Endoscopy Canada Ltd.

7171 Millcreek Drive, Mississauga, Ontario L5N 3R3 Canada
Phone: +1 905 816-4500, Fax: +1 905 816-4599
Toll free (Canada only) Phone: 1-800-268-4880, Fax: 1-800-482-4198
(Canada only)
Email: info-canada@karlstorz.com

KARL STORZ Endoscopy-America, Inc.

2151 East Grand Avenue, El Segundo, CA 90245-5017, USA
Phone: +1 424 218-8100, Fax: +1 424 218-8525
Toll free (USA only) Phone: 800 421-0837, Fax: 800 321-1304 (USA only)
Email: communications@ksea.com

KARL STORZ Veterinary Endoscopy-America, Inc.

1 South Los Carneros Road, Goleta, CA 93117, USA
Phone: +1 805 968-7776, Fax: +1 805 685-2588
Email: info@karlstorzvet.com

KARL STORZ Endoscopia Latino-America, Inc.

815 N. W. 57th Avenue, Suite 480, Miami, FL 33126-2042, USA
Phone: +1 305 262-8980, Fax: +1 305 262-8986
Email: info@ksela.com

KARL STORZ Endoscopia México S.A. de C.V.

Edificio Atlantic, Oficina 3G, Calle D e/ 1ra y 3ra, 10400 Vedado, Havana, Cuba
Phone: +537 836 95 06, Fax: +537 836 97 76
Email: kstorzcuba@gmail.com

KARL STORZ Endoscopia México S.A. de C.V.

Av. Ejercito Nacional No. 453 Piso 2, Colonia Granada, Alcaldia Miguel Hidalgo, C.P. 11520 Ciudad de México
Phone: +52 (55) 1101 1520
Email: mx-info@karlstorz.com

KARL STORZ Marketing América Do Sul Ltda.

Rua Joaquim Floriano, nº. 413, 20º andar – Itaim Bibi, CEP-04534-011 São Paulo, Brasil
Phone: +55 11 3526-4600, Fax: +55 11 3526-4680
Email: br-info@karlstorz.com

KARL STORZ Endoscopia Argentina S.A.

Zufriategui 627 6º Piso, B1638 CAA - Vicente Lopez, Provincia de Buenos Aires, Argentina
Phone: +54 11 4718 0919, Fax: +54 11 4718 2773
Email: info@karlstorz.com.ar

KARL STORZ Endoskopi Norge AS

Stamveien1, 1483 Hagan, Norway
Phone: +47 6380 5600, Fax: +47 6380 5601
Email: post@karlstorz.no

KARL STORZ Endoskop Sverige AB

Sörsåtragränd 14, 127 39 Skårholmen, Sweden
Phone: +46 8 505 648 00
Email: kundservice@karlstorz.se

KARL STORZ Endoscopy Suomi OY

Taivaltie 5, 01610 Vantaa, Finland
Phone: +358 (0)96824774, Fax: +358 (0)96824775
Email: asiakaspalvelu@karlstorz.fi

KARL STORZ SE & Co. KG

Representation Office
Kęstučio st. 59 / Lenktoji st. 27, 08124 Vilnius, Lithuania
Phone: +370 5 272 0448, Mobile: +370 685 67 000
Email: info-lt-lv@karlstorz.com

KARL STORZ Endoskopi Danmark A/S

Skovlytoften 33, 2840 Holte, Denmark
Phone: +45 45162600, Fax: +45 45162609
Email: marketing@karlstorz.dk

KARL STORZ Endoscopy (UK) Ltd.

415 Perth Avenue, Slough, Berkshire, SL1 4TQ, United Kingdom
Phone: +44 1753 503500, Fax: +44 1753 578124
Email: info-uk@karlstorz.com

KARL STORZ Endoscopie Nederland B. V.

Displayweg 2, 3821 BT Amersfoort, Netherlands
Phone: +31 (0)33 4545890
Email: info-nl@karlstorz.com

KARL STORZ Endoscopy Belgium N. V.

Phone: +31 (0)33 4545890
Email: info-be@karlstorz.com

KARL STORZ Endoscopie France S. A. S.

12, rue Georges Guynemer, Quartier de l'Europe, 78280 Guyancourt, France
Phone: +33 1 30484200, Fax: +33 1 30484201
Email: marketing-fr@karlstorz.com

KARL STORZ Endoskop Austria GmbH

Landstraßer Hauptstr. 148/1/G1, 1030 Wien, Austria
Phone: +43 1 71 56 0470, Fax: +43 1 71 56 0479
Email: storz-austria@karlstorz.com

KARL STORZ Endoscopia Ibérica S. A.

Parque Empresarial San Fernando, Edificio Munich – Planta Baja, 28830 Madrid, Spain
Phone: +34 91 6771051, Fax: +34 91 6772981
Email: info-es@karlstorz.com

KARL STORZ Endoscopia Italia S. r. l.

Via dell'Artigianato, 3, 37135 Verona, Italy
Phone: +39 045 8222000, Fax: +39 045 8222001
Email: info-ita@karlstorz.com

KARL STORZ Croatia d.o.o.

Capraška 6, 10000 Zagreb, Croatia
Phone: +385 1 6406 070, Fax: +385 1 6406 077
Email: info@karlstorz.hr

KARL STORZ Endoskopija d.o.o.

Cesta v Gorice 34b, 1000 Ljubljana, Slovenia
Phone: +386 1 620 5880, Fax: +386 1 620 5882
Email: pisarna@karlstorz.si

KARL STORZ Polska Sp. z o.o.

ul. Bojkowska 47, 44-100 Gliwice, Poland
Phone: +48 32 706 13 00, Fax: +48 32 706 13 07
Email: info-pl@karlstorz.com

KARL STORZ Endoszkóp Magyarország Kft.

Toberek utca 2. fsz. 17/b, HU-1112 Budapest, Hungary
Phone: +36 195 096 31, Fax: +36 195 096 31
Email: info-hu@karlstorz.com

KARL STORZ Endoscopia Romania srl

Str. Prof. Dr. Anton Colorian, nr. 74, Sector 4, 041393 Bukarest, Romania
Phone: +40 (0)31 4250800, Fax: +40 (0)31 4250801
Email: info-ro@karlstorz.com

KARL STORZ Endoskope Greece M.E.P.E.*

Patriarhou Grigoriou E' 34, 54248 Thessaloniki, Greece
Phone: +30 2310 304868, Fax: +30 2310 304862
Email: info-gr@karlstorz.com
*Repair & Service Subsidiary

KARL STORZ Industrial**

Gedik Is Merkezi B Blok, Kat 5, D 38-39, Bagdat Cad. No: 162, Maltepe
Istanbul, Turkey

Phone: +90 216 442 9500, Fax: +90 216 442 9030

**Sales for Industrial Endoscopy

000 KARL STORZ Endoscopy – WOSTOK

Derbenyevskaya nab. 7, building 4, 115114 Moscow, Russia

Phone: +7 495 983 02 40, Fax: +7 495 983 02 41

Email: info-ru@karlstorz.com

TOV LLC KARL STORZ Ukraine

Avenue Geroyiv Stalingrada Str. 2D, office 717 Kyiv, 04210/Ukraine

Phone: +38 095 000-895-0, +38-097-000-895-0, +38 073 000-895-0

Email: marketing@karlstorz.com.ua

KARL STORZ SE & Co. KG Representation Office

Sabit Orudschow 1184, apt. 23, 1025 Baku, Azerbaijan

Phone: +99 450 613 30 60

Email: info-az@karlstorz.com

KARL STORZ ENDOSKOPE – East Mediterranean and Gulf (Offshore) S.A.L.

Spark Tower 1st floor Charles Helou St., Horch Tabet – Sin El Fil, Beirut,
Lebanon

Phone: +961 1 501105, Fax: +961 1 501950

Email: info@karlstorz-emg.com

KARL STORZ Endoscopy (South Africa) (Pty) Ltd.

P.O. 6061, Roggebaai, 8012 Cape Town, South Africa

Phone: +27 21 417 2600, Fax: +27 21 421 5103

Email: info@karlstorz.co.za

T00 KARL STORZ Endoscopy Kasachstan

Saryarka, 6, BC "Arman", off. 910, 010000 Astana, Republic of Kazakhstan

Phone: +7 7172 552-549, 552-788, Fax: -444

Email: info@karlstorz.kz

KARL STORZ ENDOSKOPE East Mediterranean & Gulf (branch)

Building West Side 7A – Unit 7WA – 3008, Dubai Airport Free Zone, P.O. Box
54983, Dubai - United Arab Emirates

Phone: +971 (0)4 2958887, Fax: +971 (0)4 3205282

Service Hotline: +971 (0)4 3415882

Email: info-gne@karlstorz-emg.com

KARL STORZ Endoscopy India Private Limited

11th Floor, Dr. Gopal Das Bhawan, 28, Barakhamba Road, New Delhi
110001, India

Phone: +91 11 4374 3000, Fax: +91 11 4374 3010

Email: corporate@karlstorz.in

KARL STORZ SE & CO. KG

Interchange 21 Tower, Level 33, 399 Sukhumvit Road, North Klongtoey,
Wattana, 10110 Bangkok, Thailand

Phone: +84 28 3823 8000, Fax: +84 28 3823 8039

Email: infovietnam@karlstorz.com

KARL STORZ SE & Co. KG

Resident Representative Office

14th Floor, MPlaza Saigon, 39 Le Duan, District 1, Ho Chi Minh City, Vietnam

Phone: +84 28 3823 8000, Fax: +84 28 3823 8039

Email: infovietnam@karlstorz.com

KARL STORZ Endoscopy China Ltd.

Room 2503-05, 25F AXA Tower, Landmark East, No. 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong, People's Republic of China

Phone: +852 28 65 2411, Fax: +852 28 65 4114

Email: inquiry@karlstorz.com.hk

KARL STORZ Endoscopy (Shanghai) Ltd., Beijing Branch

Room 1805-1807, Building B, 18F Beijing IFC, No. 8, Jianguomenwai Street,
Chaoyang District, 100022, Beijing, People's Republic of China

Phone: +86 10 5638188, Fax: +86 10 5638199

Email: info@karlstorz.com.cn

KARL STORZ Endoscopy (Shanghai) Ltd., Shanghai Branch

Room 701A Building 5 & Room 501 Building 7, No. 3000 Longdong Avenue,
Pilot Free Trade Zone, 201203, Shanghai, People's Republic of China

Phone: +86 21 60339888, Fax: +86 21 60339808

Email: info@karlstorz.com.cn

KARL STORZ Endoscopy (Shanghai) Ltd., Chengdu Branch

Room 803-805, 8F Jin Jiang International Building, No. 1 West Linjiang
Road, Wuhou District, 6100414, Chengdu, People's Republic of China

Phone: +86 28 86587977, Fax: +86 28 86587975

Email: info@karlstorz.com.cn

KARL STORZ Endoscopy (Shanghai) Ltd., Shenyang Branch

Room 2001-2005, 20F N-MEDIA International Center, No. 167 Youth Avenue,
Shenhe District, 110014, Shenyang, People's Republic of China

Phone: +86 24 23181118, Fax: +86 24 23181119

Email: info@karlstorz.com.cn

KARL STORZ Endoscopy (Shanghai) Ltd., Guangzhou Branch

Room 02B & 03 & 04A, 35F Teem Tower, No. 208 Tianhe Road, Tianhe
District, 510620, Guangzhou, People's Republic of China

Phone: +86 20 87321281, Fax: +86 20 87321286

Email: info@karlstorz.com.cn

KARL STORZ Endoscopy Asia Marketing Pte Ltd.

No. 8 Commonwealth Lane #03-02, Singapore 149555, Singapore

Phone: +65 69229150, Fax: +65 69229155

Email: infoasia@karlstorz.com

KARL STORZ Endoscopy Singapore Sales Pte Ltd

No. 8 Commonwealth Lane #03-02, Singapore 149555, Singapore

Phone: +65 69229150, Fax: +65 69229155

Email: infoasia@karlstorz.com

KARL STORZ SE & Co. KG Representative Office Indonesia

Sinarmas MSIG Tower Level 37, Jl. Jend. Sudirman No. Kav. 21, Jakarta
Selatan

DKI Jakarta 12920

Email: infoindonesia@karlstorz.com

KARL STORZ Endoscopy Korea Co. Ltd.

9F Hyowon-Building, 97, Jungdae-ro, Songpa-gu, 05719 Seoul, Korea

Phone: +82-70-4350-7474, Fax: +82-70-8277-3299

Email: infokorea@karlstorz.com

KARL STORZ Endoscopy Taiwan Ltd.

12F, No. 192, Sec. 2, Chung Hsin Rd., Sindian District, New Taipei City,
Taiwan

Phone: +886 933 014 160, Fax: +886 2 8672 6399

Email: info-tw@karlstorz.com

KARL STORZ SE & Co. KG Representative Office Philippines

1901 Picadilly Star Bldg., 4th Avenue, BGC, Taguig City 1636, Philippines

Phone: +63 2 317 45 00, Fax: +63 2 317 45 11

Email: philippines@karlstorz.com

KARL STORZ Endoscopy Japan K. K.

Stage Bldg. 8F, 2-7-2 Fujimi, Chiyoda-ku, Tokyo 102-0071, Japan

Phone: +81 3 6380-8622, Fax: +81 3 6380-8633

Email: info@karlstorz.co.jp

KARL STORZ Endoscopy Australia Pty. Ltd .

68 Waterloo Road, Macquarie Park NSW 2113, P O Box 50 Lane Cove NSW
1595, Australia

Phone: +61 (0)2 9490 6700, Fax: +61 (0)2 9420 0695

Toll free: 1800 996 562 (Australia only)

Email: info@karlstorz.au

www.karlstorz.com

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KARL STORZ SE & Co. KG

Dr.-Karl-Storz-Straße 34
78532 Tuttlingen

Postfach 230
78503 Tuttlingen
Germany

Phone: +49 7461 708-0
Fax: +49 7461 708-105
E-mail: info@karlstorz.com
www.karlstorz.com

