



Register/Index/Registro



System description KARL STORZ AIDA® Release 1.4 Software description KARL STORZ AIDA® Release 1.4 Instructrion manual KARL STORZ AIDA® WD300 / WD3504

STORZ—ENDOSKOPE







Welcome

Thank you for your expression of confidence in the KARL STORZ brand name. Like all of our other products, this product is the result of years of experience and great care in manufacture. You and your organization have decided in favor of a modern, high-quality product from KARL STORZ.

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Contents

| 1 | Safety instructions | 1-1 |
|-------|--|------|
| 1.1 | Explanation of Warnings and Cautions | 1-1 |
| 1.2 | General safety instructions | 1-1 |
| 1.3 | Safety precautions at the site of installation | 1-2 |
| 1.4 | Safety precautions during operation | 1-2 |
| 2 | System description | 2-1 |
| 2.1 | System requirements | 2-1 |
| 2.1.1 | System-compatible hardware | 2-1 |
| 2.2 | System versions | 2-2 |
| 2.2.1 | KARL STORZ AIDA WD 300 Full-HD with external Touchscreen | 2-2 |
| 2.2.2 | KARL STORZ AIDA WD350 Full HD with external Smartscreen and Surgical Screen | 2-3 |
| 2.2.3 | KARL STORZ AIDA WD300 Full HD with external Smartscreen and Dual IMAGE1-S with Sugical Screens | 2-4 |
| 2.2.4 | KARL STORZ AIDA WD350 Full-HD with external Smartscreen and Dual IMAGE1-S withSurgical Screens | 2-5 |
| 2.2.5 | KARL STORZ AIDA WD350 Full-HD with external Smartscreen and SCB-Devices | 2-6 |
| 2.2.6 | KARL STORZ AIDA WD350 with external Smartscreen und Dual IMAGE1-S with Multiswitch | 2-7 |
| 2.2.7 | KARL STORZ AIDA WD300 Ultra-HD/4K with external Touchscreen | 2-8 |
| 2.2.8 | KARL STORZ AIDA WD350 Ultra-HD/4K with external Smartscreen and 4K-Screen | 2-9 |
| 2.2.9 | KARL STORZ AIDA WD 350 Full-HD with external Smartscreen and 4K-Screen | 2-10 |
| 2.2.1 | 0KARL STORZ AIDA WD350 Ultra HD/4K with external Smartscreen and SCB-Devices | 2-11 |
| 3 | Installation | 3-1 |
| 3.3 | Installing printer | 3-2 |
| 3.3.1 | Checking the printer installation | 3-11 |
| 4 | Operation | 4-1 |
| 4.1 | General information | 4-1 |
| 4.1.1 | Presets, workflow, and user roles | 4-1 |
| 4.1.2 | Warnings | 4-1 |
| | Switching on and off | |
| | Monitoring memory usage | |
| 4.2 | Start screen and navigation | 4-2 |

Contents



| 4.2.1 | Information bar | .4-2 |
|-------|---|-------|
| 4.2.2 | Main menu | . 4-4 |
| 4.2.3 | Application areas and modules | . 4-4 |
| 4.2.4 | Navigation bar | . 4-5 |
| 4.3 | 'Current procedure' application area | . 4-6 |
| 4.3.1 | Introduction | . 4-6 |
| 4.3.2 | Patient | . 4-6 |
| 4.3.3 | Checklist | 1-15 |
| 4.3.4 | Capture | 1-17 |
| 4.3.5 | Editing | 1-25 |
| 4.3.6 | Finishing | 1-28 |
| 4.3.7 | Forced restart | 1-3C |
| 4.4 | 'Control' application area | 1-31 |
| 4.4.1 | Medical Device Control – SCB | 1-31 |
| 4.5 | 'Previous procedures' application area | 1-32 |
| 4.5.1 | Filing cabinet | 1-32 |
| 4.6 | 'Communication' application area | 1-36 |
| 4.6.1 | StreamConnect | 1-36 |
| 4.7 | Open tasks | 1-37 |
| 5 | Maintenance | . 5-1 |
| 5.1 | Safety instructions | . 5-1 |
| 5.2 | Reprocessing | . 5-1 |
| 5.2.1 | Legal requirements | . 5-1 |
| 5.2.2 | Safety instructions | . 5-1 |
| 5.2.3 | Required reprocessing agents | . 5-1 |
| 5.2.4 | Required reprocessing materials | . 5-1 |
| 5.2.5 | Manual wipe-down disinfection | . 5-2 |
| 5.3 | Maintenance and repair | . 5-2 |
| 5.3.1 | Maintenance plan | . 5-2 |
| 5.3.2 | Replacing the BIOS battery | . 5-2 |
| 5.3.3 | Changing the device fuse | . 5-2 |
| 5.3.4 | Servicing | . 5-2 |
| 5.4 | Repair program | . 5-3 |
| 5.4.1 | Return of defective devices to KARL STORZ | . 5-3 |
| 5.5 | Limitation of liability | . 5-3 |
| 5.6 | Warranty | . 5-3 |
| 6 | Subsidiaries | . 6-1 |



1 Safety instructions

1.1 Explanation of Warnings and Cautions

The words Warning, Caution and Note convey special meanings. Wherever they are used in this manual, they should be carefully reviewed to ensure the safe and effective operation of this system. To make these words stand out more clearly, they are accompanied by a pictogram.



WARNING: A Warning indicates that the personal safety of the patient or user is at risk. Failure to observe a Warning could result in injury to the patient or user.



CAUTION: A Caution indicates that particular service procedures or precautions must be followed to avoid possible damage to the system.



NOTE: A Note indicates special information about operating the system, or clarifies important issues.

1.2 General safety instructions



WARNING: Installation and commissioning of the device must only be performed by authorized qualified technicians from KARL STORZ GmbH & Co. KG who have been trained in electrical or electronic engineering or by an authorized contractual partner.



WARNING: Only use accessories which have been specified for use with the device by KARL STORZ GmbH & Co. KG.



WARNING: Combinations of medical devices are only assured to be safe if they are identified as such in the respective instruction manuals or if the intended use and interface specifications of the products used in combination permit this.



WARNING: The various components of the device are only grounded reliably when the equipment is connected to a 'Hospital Only' or 'Hospital Grade' outlet (i.e., approved for use in an operating room environment). Routinely inspect the electrical plug and cord. Do not use if the inspection reveals damage.



WARNING: Do not open the various components! Danger of electric shock. Any opening of the device by unauthorized persons will void all warranty claims.



WARNING: Only operate the various components of the device with the voltage stated on the rating plate.



WARNING: Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g., IEC 60950 for data processing equipment). Furthermore, all configurations must satisfy the requirements for medical electrical systems (see IEC 60601-1-1 and IEC 60601-1, paragraph 16, 3rd edition). Any person who connects additional devices to electrical medical devices configures a medical system, and is therefore responsible for ensuring that this system complies with the requirements for medical electrical systems. It must be taken into account that local regulations take priority over the aforementioned requirements. If in doubt, consult the technical service department or your local representative.



1.3 Safety precautions at the site of installation

NOTE: Only those parts of the system which are approved as medical devices are suitable for use within the patient environment.



WARNING: To avoid the risk of an electric shock, the device must only be connected to a power supply with a protective conductor.



WARNING: The device must only be operated under the ambient conditions specified.



WARNING: Keep the various device components out of reach of patients.



WARNING: Only insert the power plugs of individual devices into and remove them from electrical outlets located outside areas subject to explosion hazards.



WARNING: Always unplug the device from the power supply before carrying out any maintenance work.



WARNING: The installation should be carried out in such a way that the respective device is able to receive sufficient ventilation.



WARNING: The use of additional multiple socket outlets or extension cables is not permitted.



WARNING: The use of freely accessible multiple socket outlets is not permitted.



WARNING: Multiple socket outlets must not be placed on the floor.

1.4 Safety precautions during operation



WARNING: It is the user's responsibility to make sure all devices connected to the system and the complete system are safe and operate properly before using them. The respective device should not be used if any damage is evident.



WARNING: If the volume of the loudspeaker or headset is too high, an unexpected audio signal could startle the attending physician. Check volume control before each procedure.



WARNING: Connecting non-compatible signal types to the connection panel in the OR can cause picture interference and malfunctioning of the device. Only connect permitted signal types and perform device tests before use.



WARNING: Avoid allowing liquids to enter the device. Do not store any liquids in the vicinity of the device. If liquids penetrate the device despite the precautionary measures, sufficient time should be allowed for evaporation.



WARNING: Do not connect equipment to the system which has not been specified by KARL STORZ GmbH & Co. KG.



WARNING: The display of image signals which do not originate from a KARL STORZ device may only be used for information purposes.



WARNING: Devices from other manufacturers which can display or play back recordings must be set up prior to connection to the device so that recordings are marked as such.

1-2 96296083EN / BA







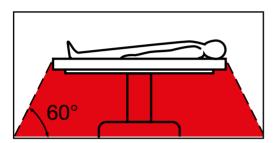
WARNING: If an external signal is routed to the surgical monitor, it must be ensured that the physician is aware that the local live image is being replaced by the external signal.



WARNING: For safety reasons, do not simultaneously touch the device output sockets and the patient.



WARNING: The device is not suitable for operation in potentially explosive atmospheres and oxygenated areas. This means, for example, that when using easily combustible and explosive inhalation anesthetics or mixtures thereof, the device must not be operated inside the demarcated hazard zone shown below. This also applies for easily combustible and explosive chemicals, e.g., skin disinfectants and fast-acting surface disinfectants.



Safety instructions



1-4 96296083EN / BA



2 System description

2.1 System requirements

Only the system components/standards approved by KARL STORZ may be used within the system.

If necessary, you can request detailed information from your responsible KARL STORZ contact partner.

2.1.1 System-compatible hardware

Control units

- KARL STORZ AIDA™ WD 300
- KARL STORZ AIDA™ WD 350 including SmartScreen

Supported light sources

- Power LED 170 (recommended)
- Power LED 300 (recommended)

Supported touchscreen models

- 20 0905 21, 21.5"
- 20 0905 24, 24"

Supported display types

| 2D | | 3D | 4K |
|--------|----------|-----------|--------|
| 9524NB | 9526NBL | 9826NB-3D | TM 341 |
| 9726NB | 9619NB | 9832NB-3D | TM 340 |
| 9626NB | 9626NB-2 | | |
| 9627NB | 9826NB | | |

Supported camera types

| 2D | 3D | 4K |
|-----------|----------|--------------------------|
| IMAGE1 S | IMAGE1 S | Ultra HD/4K Video source |
| IMAGE1 HD | | |

Remote activation

• W23174 12 VDC

Footswitch

• 20014430

NOTE: Other system configuration options are generally possible in principle, but must always be considered and planned individually. Additional costs may be incurred here. Note: KARL STORZ AIDA® is supplied as a unit comprising complementary hardware and software. Any changes to the hardware or software which are not authorized by KARL STORZ void the approval for medical use, the warranty, and the manufacturer's warranty.

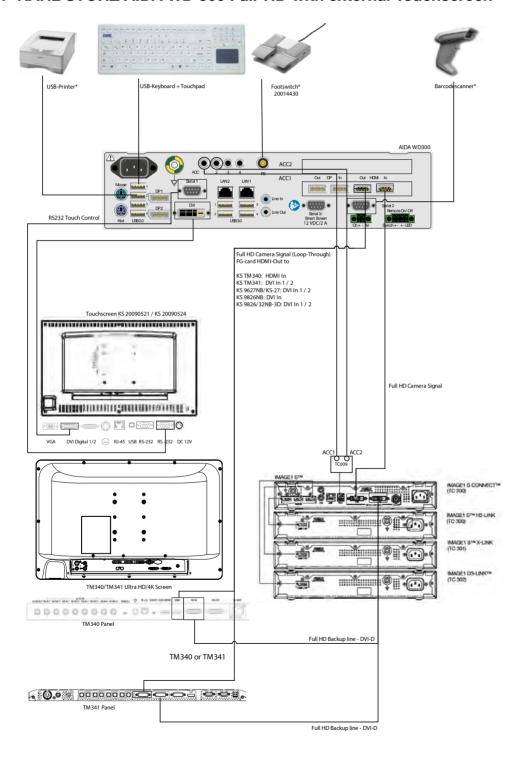


2.2 System versions



WARNING: Connecting non-compatible signal types to the connection panel in the OR can cause image interference and malfunctioning of the KARL STORZ AIDA®. Only connect permitted signal types and perform device tests before use.

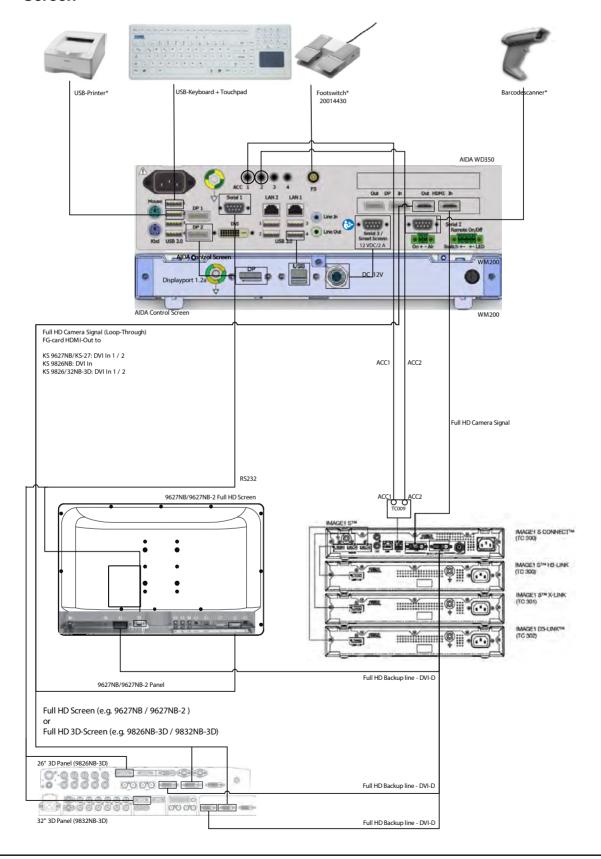
2.2.1 KARL STORZ AIDA WD 300 Full-HD with external Touchscreen



2-2 96296083EN / BB

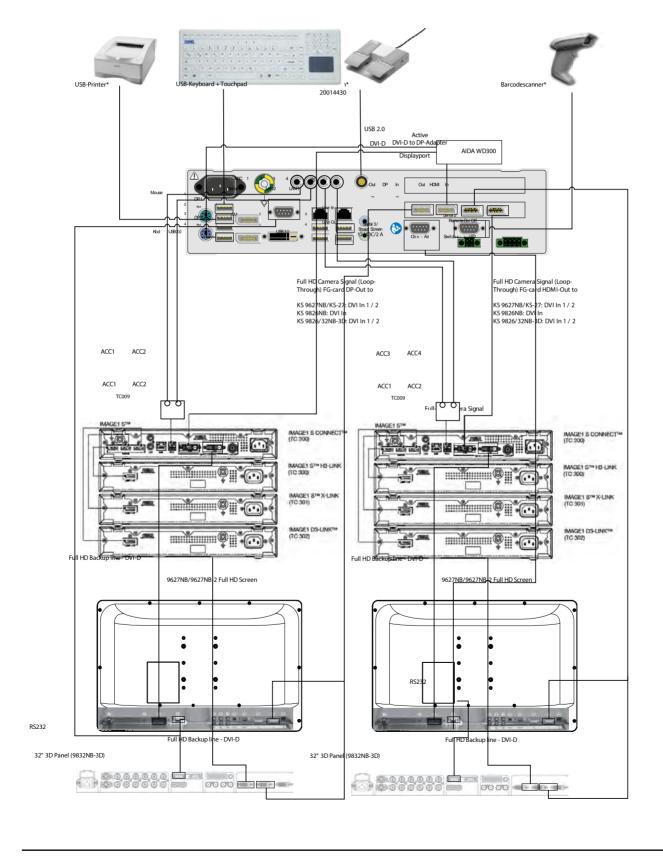


2.2.2 KARL STORZ AIDA WD350 Full HD with external Smartscreen and Surgical Screen





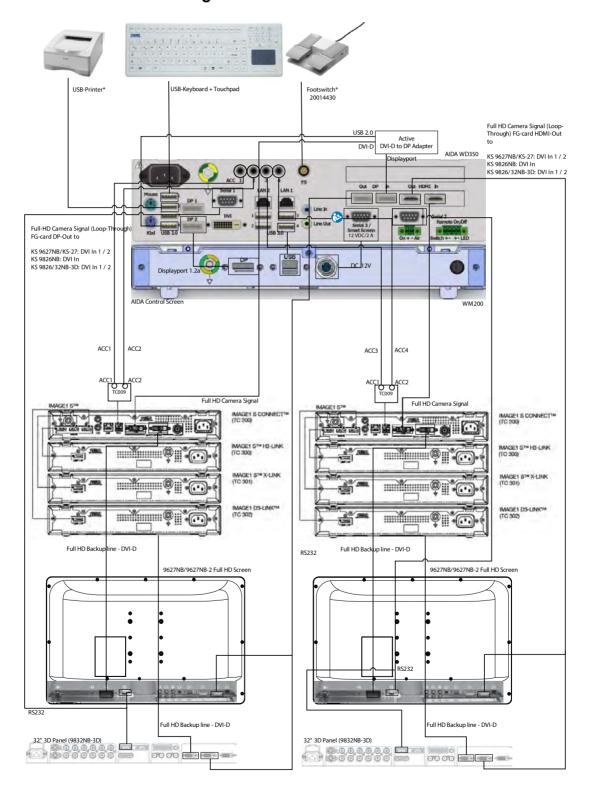
2.2.3 KARL STORZ AIDA WD300 Full HD and Dual IMAGE1-S with Sugical Screens



2-4 96296083EN / BB

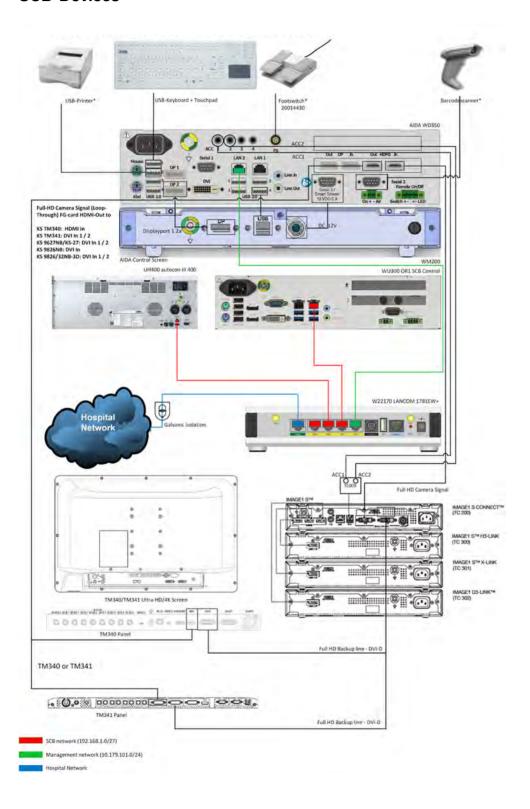


2.2.4 KARL STORZ AIDA WD350 Full-HD with external Smartscreen and Dual IMAGE1-S with Surgical Screens





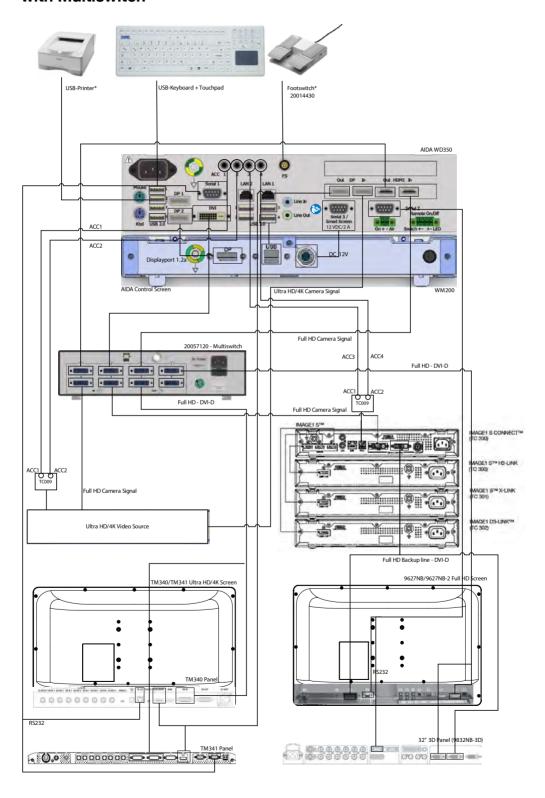
2.2.5 KARL STORZ AIDA WD350 Full-HD with external Smartscreen and SCB-Devices



2-6 96296083EN / BB

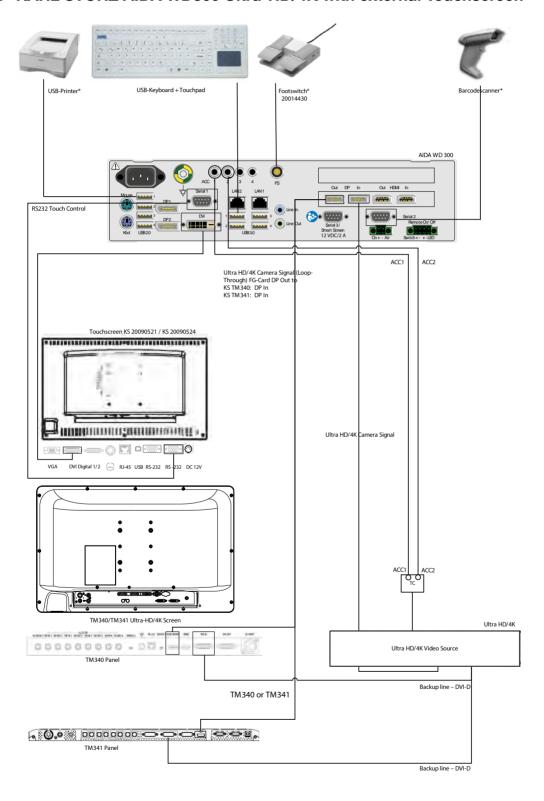


2.2.6 KARL STORZ AIDA WD350 with external Smartscreen und Dual IMAGE1-S with Multiswitch





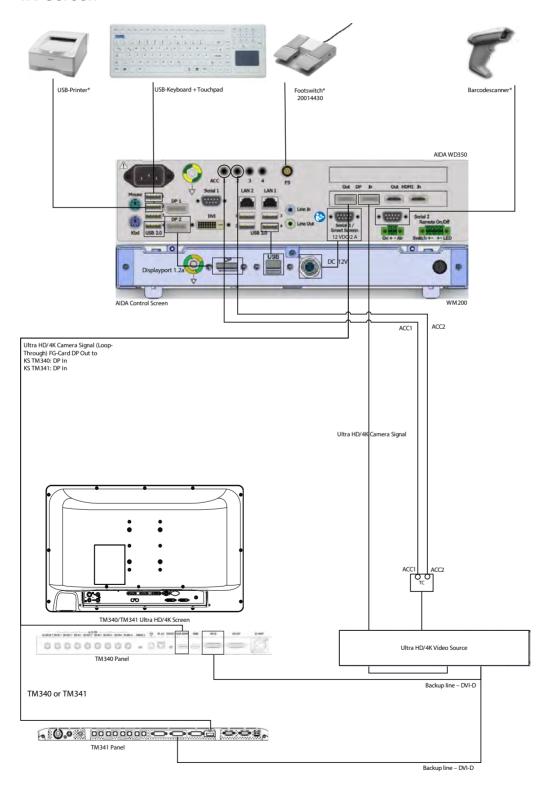
2.2.7 KARL STORZ AIDA WD300 Ultra-HD/4K with external Touchscreen



2-8 96296083EN / BB

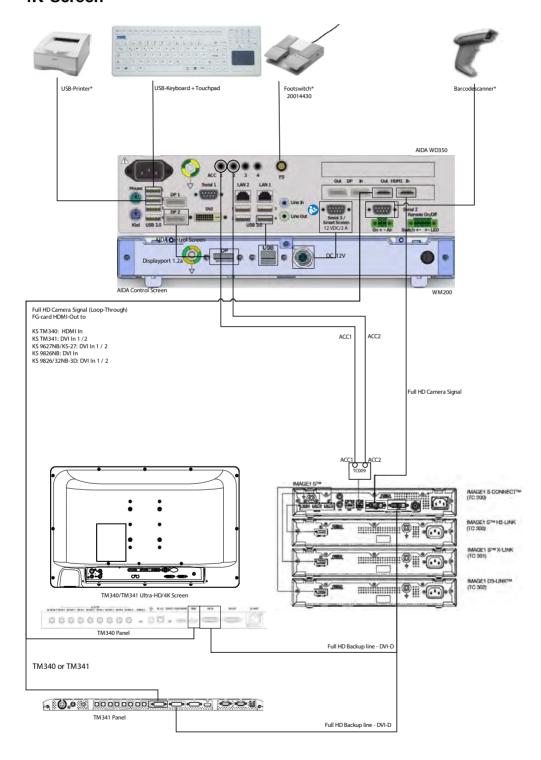


2.2.8 KARL STORZ AIDA WD350 Ultra-HD/4K with external Smartscreen and 4K-Screen





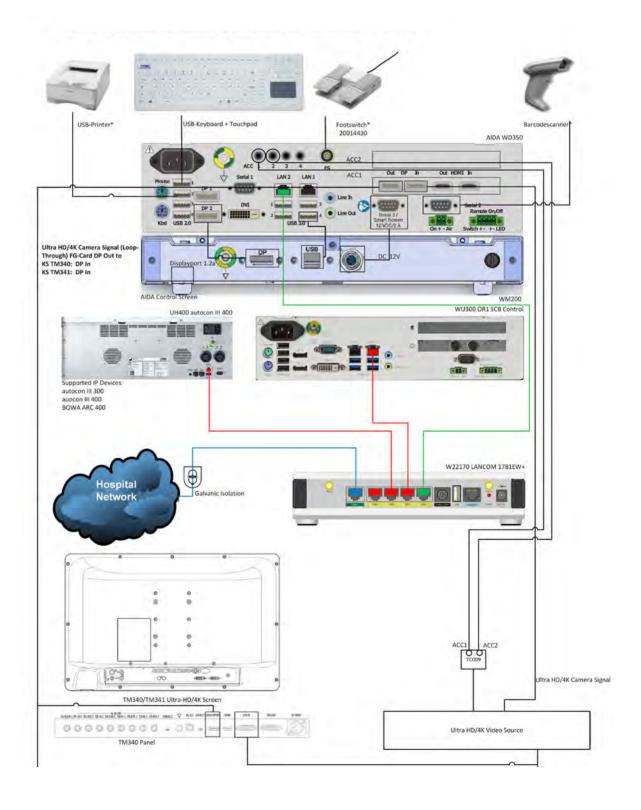
2.2.9 KARL STORZ AIDA WD 350 Full-HD with external Smartscreen and 4K-Screen



2-10 96296083EN / BB



2.2.10KARL STORZ AIDA WD350 Ultra HD/4K with external Smartscreen and SCB-Devices



System description



2-12 96296083EN / BB



3 Installation

3.1 Unpacking

Check the delivery for missing items and evidence of shipping damage. Please file any complaints with the manufacturer or supplier immediately.

Retain the original packaging for later use. This may be useful if the device has to be transported.

3.2 Installation and commissioning



WARNING: Installation and commissioning of the KARL STORZ AIDA® must only be performed by authorized, electrotechnically qualified specialists from KARL STORZ GmbH & Co. KG or by an authorized contractual partner.



WARNING: Combinations of medical devices are only assured to be safe if they are identified as such in the respective instruction manuals or if the intended use and interface specifications of the products used in combination permit this.



WARNING: The KARL STORZ AIDA® devices must be installed free-standing so as to ensure sufficient ventilation.



WARNING: Connect the potential equalization cable to the potential equalization connector. The device's ground line should be installed by a qualified electrician.



WARNING: The electrical installations in the operating room in which the device is installed and operated must comply with the applicable IEC standards.



3.3 Installing printer

1. Log on to the PC as an administrator.



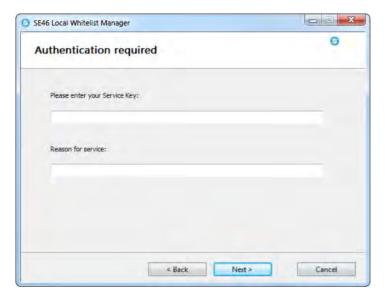
- 2. Click on Start\Nexus\SE46\Agent **Local Whitelist Manager**.
- The following window opens:



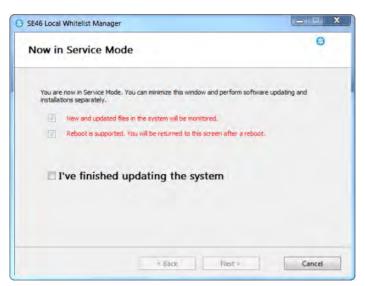
- 3. Click on Next.
- The following input window opens:

3-2 96296083EN/BA





- 4. Enter the following service key in the top line:
 - Service-MLAACDET-ACAA-HHTPZATZ
- 5. Enter the reason for modification in the bottom line and then click on Next.
- The following window opens:



◆ The system is now in Service Mode and the printer driver can be installed.



NOTE: Please do not close the window above as additional input is required at a later point. **NOTE:** You can now install a printer driver.

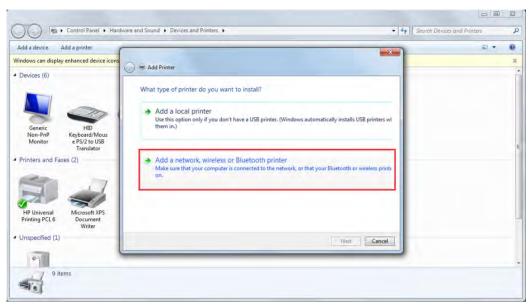
It is important to specify the following under IPv4 for setting up a printer in the network:

- IP address
- Network mask
- Gateway address

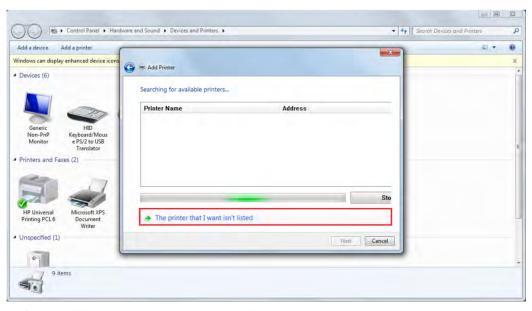


Example installation of a printer driver for a Xerox printer

- NOTE: The steps are not explained here as they depend on the driver and printer. Once the printer driver has been successfully installed, either the system switches to the following screen automatically or it can be reached under Start\Device and Printers.
 - 1. Click on Add a Printer.
 - The following window opens:



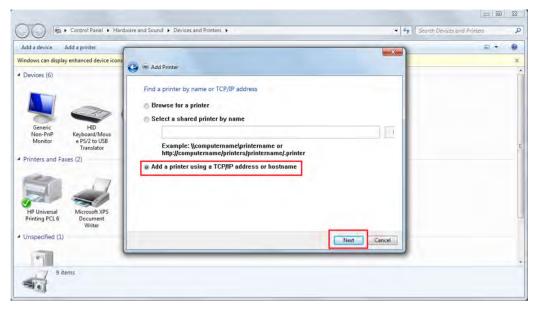
- 2. Click on Add a network, wireless or Bluetooth printer.
- The following window opens:



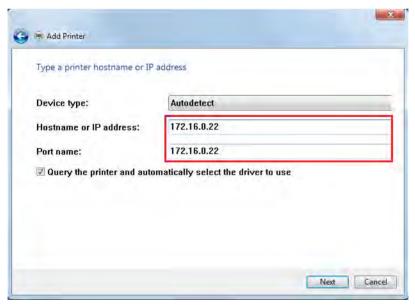
- 3. Click on The printer that I want isn't listed.
- → The following window opens:

3-4 96296083EN / BA





- 4. Select Add a printer using a TCP/IP address or hostname and click on Next.
- The following input window opens:



5. Enter the IP address of the printer in the **Hostname or IP address** field (see note on page 3-3) and click on **Next**.

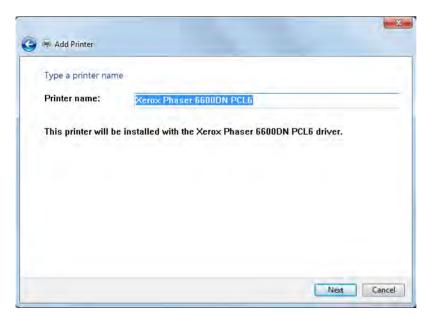
NOTE: The address in the Port name field is automatically copied from the Hostname or IP address field. If necessary, you can also enter another address manually simply by overwriting the address.



- 6. Please wait until the printer is found.
- The following window opens:



- 7. Select the printer driver and click on Next.
- The following window opens:

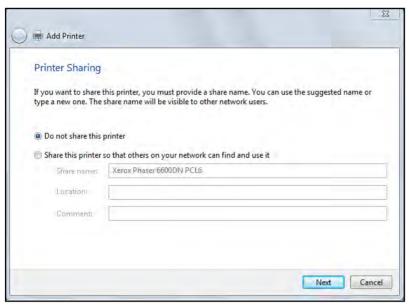


■ The Printer name field shows the printer driver with which the selected printer should be installed. The printer is automatically named after the printer driver selected in window 12. You can overwrite this name at any time with any other name.

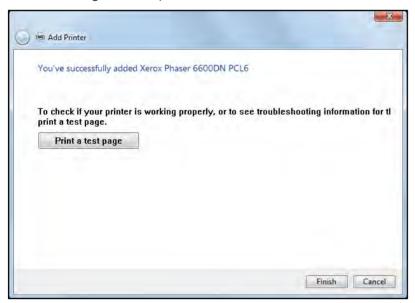
3-6 96296083EN / BA



- 8. Click on Next.
- The following window opens:

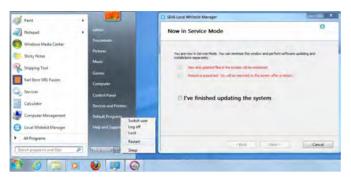


- 9. Select Do not share this printer.
- 10. Click on Next.
- The following window opens:

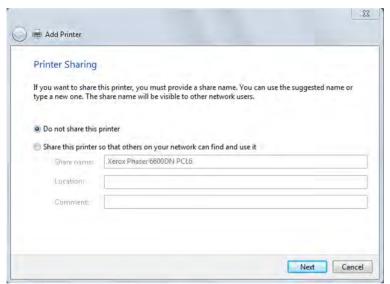


- This window shows that the printer has been successfully installed.
- 11. Click on Finish.

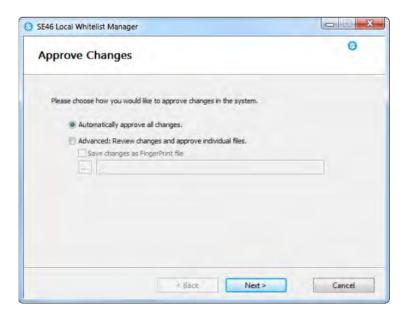




- 12. Now restart the system by clicking **Restart**.
- 13. Following the restart, log on as an administrator.



- 14. Select **I've finished updating the system** and click on Next.
- The following window opens:



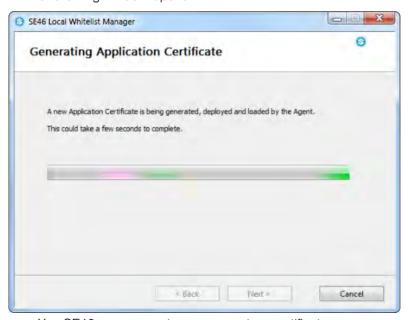
3-8 96296083EN / BA



- 15. Click on Next.
- The following window opens:

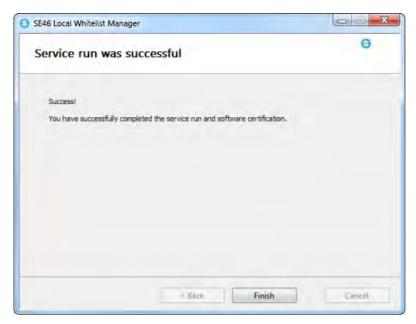


- 16. Enter additional information on the modifications and then click on **Next**.
- The following window opens:

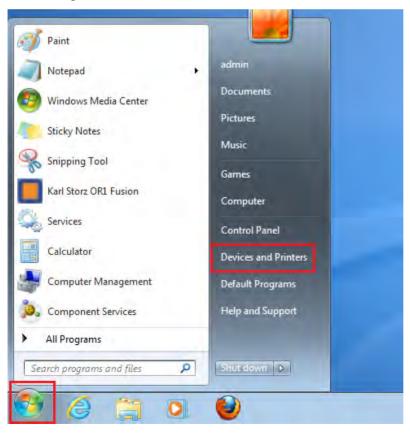


- The following window opens:





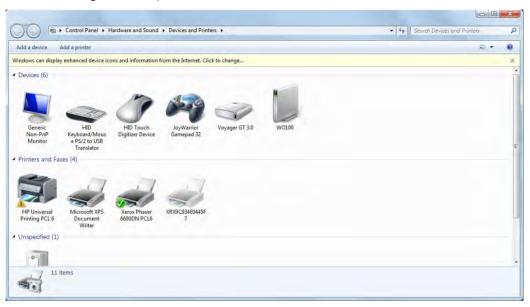
- 17. Click on **Finish** and restart the system.
- 18. Log on as an administrator.



3-10 96296083EN / BA



- 19. Click on Start\Devices and Printers.
- The following window opens:



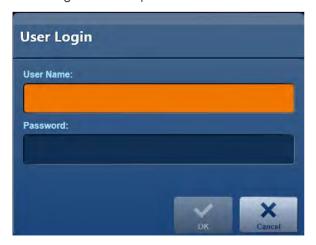
- The selected printer has now been installed successfully.
- 20. Select this printer as the default printer.

3.3.1 Checking the printer installation

- 1. Start the KARL STORZ AIDA®, assuming this has not already been done.
- 2. Open the configuration area. You can access it at any time by clicking on the tool symbol in the header.



- 1. Tap on the tool symbol.
- The login window opens.



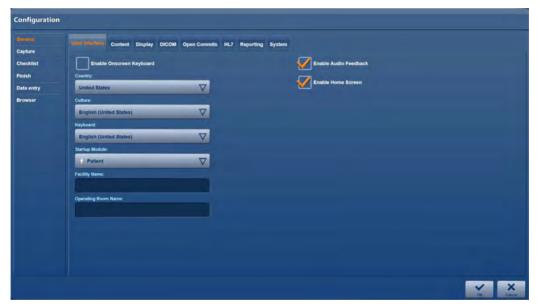
2. Enter the user details and password and tap **OK** or **Enter** on your keyboard to confirm.

(i)





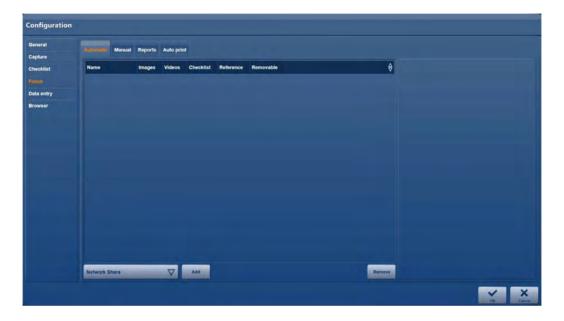
- NOTE: If you have entered the password via the on-screen keyboard, confirm this entry by pressing the **Enter** button.
 - The configuration area opens.



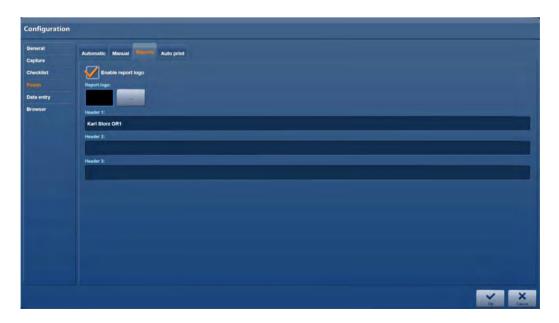
- 3. In the configuration window, click in the left-hand column on **Finish**.
- The Finish selection menu opens.

3-12 96296083EN / BA





- 4. Click on the **Reporting** tab.



- 5. Click in the bar next to **Printer**.



3.4 Configuration

Complete configuration of KARL STORZ AIDA® is described in the separate software description for the device (96296082EN).

3-14 96296083EN / BA



4 Operation

4.1 General information

4.1.1 Presets, workflow, and user roles

The system is designed for operation in sterile areas or at the nurse's working station. The operation can be performed identically at both locations.

In order to operate the program in the sterile area, a KARL STORZ touchscreen with a sterile disposable cover is required.

Adapt the system to suit your daily requirements before using it. To do so, please read the **Configuration** section in the **software description** 96296082.

It is recommended that the distribution of the roles in the team for the operation of the system be defined. For example, you should define who is responsible for the entry of the patient data and for the subsequent data storage.

Whenever possible, compile the patient data prior to the procedure and specify whether you wish to work with one or two sources.

4.1.2 Warnings

The SCB module is equipped with a system of warning messages. Read the 96296080 'KARL STORZ SCB® Software' software description for more information about the meanings of these warning messages.

4.1.3 Switching on and off

Switching the system on

- 1. Switch the connected peripheral devices on (cameras, monitors, Multiswitch).
- 2. Switch the system on using the AIDA main switch.

Switching the system off



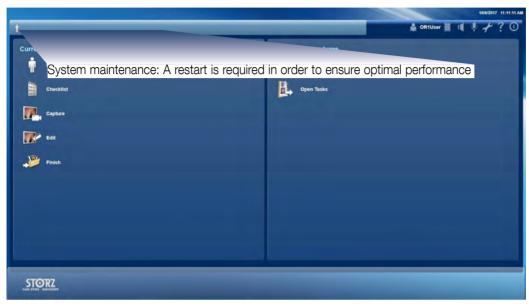
WARNING: Shutting down the system whilst processing patient data results in the loss of image data. Only switch off the device using the ON/OFF switch.

- 1. Tap on the switch off symbol in the top right corner.
- The system is shut down and switched off.
- 2. Switch the connected peripheral devices off.



4.1.4 Monitoring memory usage

The memory usage on the hard disk is continuously monitored. As soon as a certain limit is reached, the user is notified via the information bar that a restart should be performed when possible.



The message persists until a restart is performed. If the limit is exceeded considerably, a restart is forced once the operation is complete (see chapter 4.3.7).

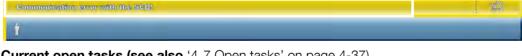
Start screen and navigation 4.2

4.2.1 Information bar

The information bar is functionally divided into a left and right area.

System information and current open tasks, patient data (left area)

System information



Current open tasks (see also '4.7 Open tasks' on page 4-37)



NOTE: If there are system messages and current open tasks, these will be displayed alternately. **(i)**

4-2 96296083EN / BA



Patient data



In this area, the information of the current patient is entered.

- Gender
- Last Name
- First Name
- · Date of birth
- · Age (in brackets)
- Patient ID

The patient data appears in all modules except for the Filing Cabinet and web-based KARL STORZ/third-party products.

System information, date and time (right area)

The right area offers you direct access to access status selection, general audio settings, the configuration menu, the product information, and the option to exit the system.



User currently logged in

The user currently logged in is shown at the right-hand side next to the user icon. Clicking on this icon takes the user to the login screen.

Microphone and volume of the audio outputs

The volume of the optional microphone can be set and, if necessary, switched to mute using the microphone symbol.

'Mute' is set as standard and must be activated manually.

Volume settings

The output volume of the optional loudspeaker (or headphones) can be set and, if necessary, switched to mute using the loudspeaker symbol.

Configuration

The tool symbol takes you to the password-protected area for configuration of the system (see software description).



Product information

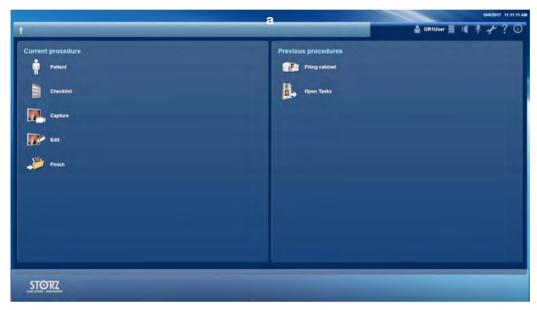
Tapping the question mark takes you to the product information and licenses window, where you can save this information to a USB stick.

System shutdown

NOTE: Depending on the setting, tapping on this pictogram either shuts KARL STORZ AIDA® down or logs the user out.

4.2.2 Main menu

In the main menu, you have access to all the modules that belong to the functional scope of your system.



a. Main menu

4.2.3 Application areas and modules

The application areas contain the modules that belong to the functional scope of your system.



b. Applications c. Modules

4-4 96296083EN / BA



'Current procedure' application area

In the 'Current procedure' application area, you will find all the modules for administrating and processing current patient data and for documentation of a procedure.

'Control' application area

In the 'Control' application area, you will find additional modules for the monitoring and control of other KARL STORZ control units. These devices do not have any influence on previous or ongoing procedures.

'Previous procedure' application area

The 'Previous procedure' application area offers you the possibility of displaying previously created patient documentation and completing the documentation of previous procedures.

'Communication' application area

The 'Communication' application area offers you access to the optional communication modules.

4.2.4 Navigation bar

The navigation bar is functionally divided into a left and right area.



a. Rapid access to following modules

The right area of the navigation bar shows the respective active module with an enlarged pictogram and offers you access to the main menu at any time.



4.3 'Current procedure' application area

NOTE: Depending on the upgrade and configuration of your system, some of the individual modules described below may not be available.

4.3.1 Introduction

The documentation of operative procedures is indispensable for patient safety and quality assurance. KARL STORZ AIDA® offers an optimized and ergonomic workflow for the documentation of surgical procedures.

The application area is divided into modules throughout the workflow:



Patient: Input of outline data for procedure.

Capture: Capturing of still images and video sequences as well as flagging of images.

Checklist: Safety checklist for procedure preparation.

Edit: Checking, selecting, and editing images and videos.

Finish: Data storage, and additional export of video and image data to a selection of data carriers.

4.3.2 Patient

In the **Patient** module, you compile the outline data concerning a surgical procedure. The documentation covers the patient data, the composition of the surgical team, the type of procedure, and the instruments used.

NOTE: The scope of documentation can be restricted of extended by admin and must be configured in collaboration with the KARL STORZ technicians during the installation and commissioning.

4-6 96296083EN / BA



- NOTE: The system requires that you enter all details in the mandatory fields at the latest when saving data. The system does not allow you to save incomplete data. For this reason, you should compile the outline data prior to the surgical procedure whenever possible.
- NOTE: You can enter data using either the on-screen keyboard or an external connected keyboard. In some cases, you can select predefined entries using a selection field.

On-screen keyboard



The on-screen keyboard is set up like a standard PC keyboard and is used in the same way.

- **NOTE:** The keys on the on-screen keyboard are arranged similarly to normal keyboards, with the arrangement varying for different countries. If the language is changed, the keyboard layout will change accordingly.
- **NOTE:** The connected keyboard and selected language settings must be compatible. Please set the languages accordingly (see software description, chapter 5.3, 'General' module).

Compiling the outline data for the surgical procedure manually

Compile the data for the procedure manually or load a data set from the DICOM worklist.

- NOTE: You can find out how to load a data set from the DICOM worklist in the following section.
- **NOTE:** Your entries are saved automatically.

Data entry

Depending on the scope of documentation, the following input masks are available:

- **Simple entry** if the team-, procedure- and instrument-related data have not been enabled in configuration mode for the scope of documentation.
- **Expanded entry** when at least one of the three data areas (team-, procedure- or instrument-related data) has been enabled.



NOTE: By double-clicking in the header **a**, the menu with the patient data for the current patient will open.



Reduced entry

- 1. Tap on **Patient** in the main menu.
- The **Patient** module is displayed.



- 2. Enter the requested data completely or check and complete the data.
- NOTE: If necessary, also add the preceding zeros when entering the date so that the entry always comprises 8 digits (e.g., 05.05.2012).

Simple entry

- 1. Tap on **Patient** in the main menu.
- The **Patient** module is displayed.



- 2. Enter the requested data completely or check and complete the data.
- NOTE: If necessary, also add the preceding zeros when entering the date so that the entry always comprises 8 digits (e.g., 05.05.2012).

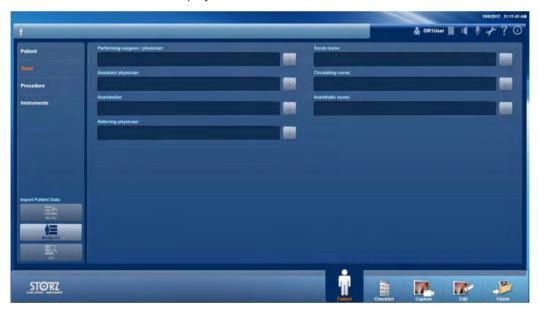
4-8 96296083EN / BA



Expanded entry



- 1. Enter the requested data completely or check and complete the data. Tap on **Team**.
- ▼ The **Team** submenu is displayed.

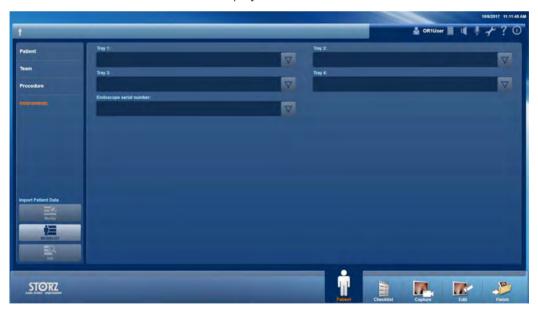


- 2. Enter all the members of the surgical team completely.
- 3. To enter a team member from a list, tap on the symbol to the right of the input field.
- 4. Tap on **Procedure**.
- ▼ The Procedure submenu is displayed.





- 5. Enter all the procedure data completely.
- 6. Tap on the arrow on the right edge of the input field to select data from a list.
- 7. Tap on **Instruments**.
- The Instruments submenu is displayed.



- 8. Enter the identification number of the instrument tray and the serial number of the endoscope used.
- NOTE: After capturing the audio and/or video recordings, the mandatory fields are blocked. Tap on the Modify button to subsequently change the content of mandatory fields.
 - 9. Tap on the **Modify** button.
 - The mandatory fields are unblocked.

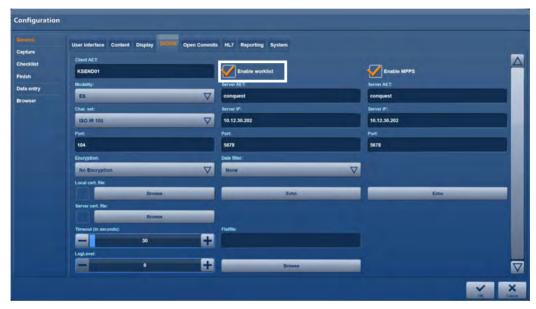
4-10 96296083EN / BA



Loading outline data from the DICOM worklist

If the patient is already in the DICOM worklist, you can load the data without having to enter them again.

NOTE: For this function, the DICOM Worklist must be enabled in the menu General/DICOM in the configuration mode.



- NOTE: The loaded data set is write-protected as standard and cannot be changed. If you want to clear the loaded data set from the system because of an emergency, please read the following section.
 - 1. Tap on **Patient** in the main menu.
 - The Patient module is displayed.





- 2. Tap on the **Import DICOM Worklist** button at the bottom left.
- The submenu opens for searching in the DICOM worklist.

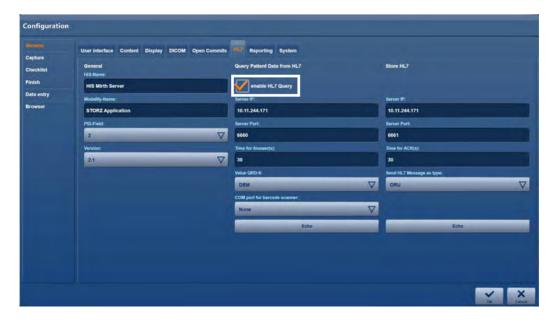


- 3. Select a parameter for searching and enter your search term.
- 4. Tap on the magnifying glass symbol.
- The list of results is displayed.
- 5. Select the data set you require and tap on **Select patient**.
- The selected data set is loaded and displayed in the **Patient** module.

Loading outline data from the HIS (hospital information system)

If the patient is already stored in the HIS, you can load the data without having to enter it again.

• **NOTE:** For this function, the HL7 query must be enabled in the General/HL7 menu in configuration mode.



4-12 96296083EN / BA



- NOTE: The loaded data set is write-protected as standard and cannot be changed. If you want to clear the loaded data set from the system because of an emergency, please read the following section.
 - 1. Tap on **Patient** in the main menu.
 - The Patient module is displayed.



- 2. Enter the patient ID and click the HIS button.
- ▼ The selected data set is loaded and displayed in the Patient module.



Enter patient data manually



WARNING: If you have already created recordings before switching back to manual data compilation, they will be assigned to the new patient.

- 1. Tap on **Patient** in the main menu.
- The Patient module is displayed.



- 2. Tap on the **Modify** button at the bottom left.
- The input fields are cleared.
- The system is ready for the manual compilation of a new procedure.

4-14 96296083EN / BA



4.3.3 Checklist

In this module, you edit a safety checklist for surgical procedures.

Use of the checklist can be divided into the following phases:

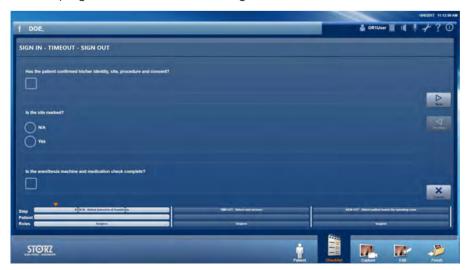
- · Selecting and starting a checklist
- Editing the points in the checklist
- Finishing the checklist

Selecting and starting a checklist

- 1. Tap on Checklist in the main menu.
- ▼ The Select Checklist start screen opens.



- NOTE: The selection of a checklist cannot be canceled.
 - 2. Select the checklist you require and press **OK** to confirm.
 - The selected checklist starts.
 - Any patient and procedure information which has already been entered is displayed.
 - The progress indicator for the editing of the checklist is shown.





Editing and finishing the checklist

The orange triangle above the progress bar indicates the editing status of the checklist.

The progress bar indicates a subdivision of the checklist into editing phases: the **steps**. You can browse backward and forward within a step using the arrow keys.

The transitions between the steps are signaled with **gates**. A gate is used to monitor the documentation of a step: if a step is not documented as required, a dialog box opens with a report on the missing documentation.

- 1. Start with the patient data and place a **checkmark** to confirm the entries.
- NOTE: Without entering the patient's last name, the checklist cannot be finished after editing.
 - 2. Tap on **Next** on the right edge.
 - 3. Edit the checkpoints of the step.
 - a. Confirm that the tasks have been completed and all open questions have been answered by placing the required **checkmark**.
 - b. Answer closed questions by selecting one of the **Selection buttons**.

If you have skipped the documentation of individual checkpoints and the dialog window **Missing checkmarks in a step** appears as a result, select one of the following actions:



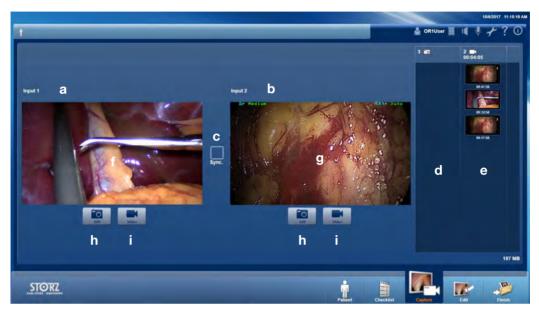
- Select **Complete** if you want to jump directly back to the location of the missing documentation to fill them out.
- Select **Cancel** to close the dialog window and navigate to the location of the missing documentation manually using the arrow keys.
- Select **Skip** if you want to skip over the documentation and finish it at a later point in time.
- **NOTE:** Checkpoints that have not been documented are indicated in the progress indicator with a warning symbol.
 - 4. Edit all the steps of the checklist as described above.
 - 5. To finish the checklist, tap on **Finish**.

4-16 96296083EN / BA



4.3.4 Capture

In this module, you can capture videos and still images during a procedure. You have the possibility of checking, labeling, forwarding directly, or deleting your images.



- a. Camera 1 (2D)
- b. Camera 2 (3D)
- c. Button for synchronous recording via both cameras
- d. Area for captured images
- e. Area for captured videos

- f. Preview for capture with camera 1
- g. Preview for capture with camera 2
- h. Button for image capture
- i. Button for video capture



NOTE: Remote capturing with the foot pedal or the camera head is possible at all times, even if the module is not displayed on the screen in that moment.

Remote capturing does not work when the **SAVE button** has just been pressed.



WARNING: Compressed image and video files can contain artifacts and should therefore not be used for diagnostics and treatment purposes.

Documenting the recordings



- a. Number
- b. Duration
- c. Start time



Assigning Comments

For documentation purposes, the start time can be overwritten with your own term.

1. Open the patient screen.



- 2. In the list of **Procedure names**, select the entry for which you have created the keyword.
- 3. Then go to the Capture module.



- 4. Click on the photo icon **a** to capture an image.
- 5. Right-click on the captured image.
- A dialog field opens.
- 6. Select the **Comments** field.
- The Comments field opens.

4-18 96296083EN / BA





- 7. Select your entry from the list.
- The keyword is then assigned to the desired image.



Capturing a still image



WARNING: If a watermark was set up during configuration of the system, the current patient data are inserted in the still image and cannot be changed. Therefore, in this case, before capturing the first still image, it must be ensured that all relevant patient data (ID, surname, first name, date of birth) is entered correctly.

NOTE: The last recording is shown at the top of the list alongside the preview window.

- 1. Tap on the Still image button **h** for Input 1 **a** or Input 2 **b**.
- The recording is confirmed to the right of the preview window in area d.



Recording a video sequence

- NOTE: Video sequences can only be recorded and saved if this function was set up accordingly during the configuration.
- NOTE: Audio sequences can only be recorded from one source. The simultaneous capture of two sources is not possible.
- NOTE: With video recordings, the audio is also recorded as standard. It is, however, possible to suppress the audio recording; see next chapter.
- **NOTE:** The last recording is shown at the top of the list alongside the preview window. Pay attention to the time specified for the recording.



- 1. Start a video by clicking button **a** or **b**.
- The start of the recording is confirmed to the right of the preview window in area c.
- 2. To start another recording with another camera when video recording is in progress, tap on button **a** or **b**.
- 3. To stop a video recording, tap on button **a** or **b**.
- **NOTE:** When an external loudspeaker is connected, an acoustic signal will sound to indicate when a recording is started and stopped, and when images are captured.

4-20 96296083EN / BA



Suppressing audio recording

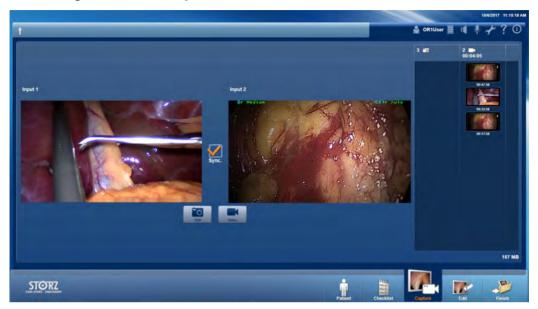


- 1. Tap on the microphone icon **a**.
- **▼** The **Microphone** operation field opens.
- 2. Place a check mark next to Mute.
- The microphone icon turns orange.
- 3. Tap on the operation field again to close it.
- ▼ The microphone icon will appear with a strike-through line across it.





Recording two sources synchronized



- 1. Place a checkmark next to Sync..
- 2. Capture synchronous images.
 - a. To capture synchronous still images from both sources, tap on Still image.
 - b. To start recording synchronous videos from both sources, tap on **Video**. To end the synchronous capturing, tap on **Video again**.
- 3. To disable the preset for synchronous capturing, remove the checkmark next to Sync..

Displaying, labeling or deleting a recording

If you want to display, label, forward or delete a recording directly during the procedure, you can use the functions in the **Capture** module.



WARNING: To avoid confusions between the live image from the endoscopic camera and a video recording, videos are labeled 'VIDEO REVIEW' when in full screen mode. Failure to note the labeling can result in treatment errors.

- Tap on the recording to the right of the preview window.
 If necessary, use the scroll bar on the right to find the correct recording.
- A context menu opens.
- 2. Tap on one of the options in the context menu.

You can use **View** to open the recording in the preview window.

- If you want to flag the recording, tap on Flag.
- Start, browse, or pause a video sequence and regulate the volume.
- Switch between full-screen mode and the preview window by clicking on the screen symbol in the top right corner.
- You can use the arrow keys on the sides to view several recordings directly one after another.
- To exit the preview window, tap **OK**.

4-22 96296083EN / BA



You can flag the recording with Flag.

You can select the recording for deletion with **Delete**.

During the procedure, you can restore the recording at any time by tapping on the marked image/ **Undo delete**.

NOTE: A recording which is marked for deletion is not saved together with the other data and, instead, is deleted permanently.

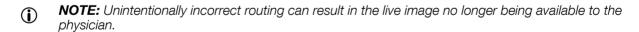
Forwarding a recording

- 1. Click on an image or video.
- 2. Select **View** from the window that appears.





WARNING: By routing to the screen showing the live image from the endoscopic camera, you can replace the live image with a capture image.



The image ID is displayed on the target screen.





Use the arrow keys ${\bf a}$ and ${\bf b}$ to scroll through the captured image and video recordings.

NOTE: The recordings appear in chronological order.

4-24 96296083EN / BA

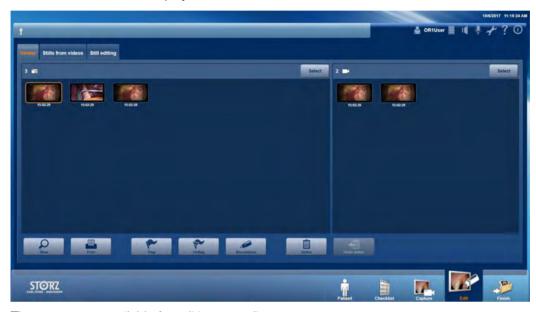


4.3.5 Editing

In this module, you can edit still images and video sequences that you have captured during a procedure.

Editing captures

- 1. Tap on Edit.
- The **Edit** module is displayed.



Three areas are available for editing recordings:

- Viewer
- Stills from videos
- · Still editing

Viewer

This tab offers you the following options:

Setting flags

Select all recordings which you wish to label with flags and then tap on Flag.

Together with **Select**, flags help you to select recordings which you wish to display, print, or delete quickly and easily.

Removing flags

Select the recordings which you wish to unflag and then tap on **Unflag**.

If you select recordings with and without flags and then tap on **Flag**, all the selected recordings will be flagged.

Comments

Select the recordings you wish to annotate, and then tap on **Comments**.

You can enter a name in the input mask.



Select

Use **Select** together with flags to quickly and simply select recordings which you wish to display, print or delete.

Example of how to proceed:

- Flag all recordings which you wish to continue using.
- Then tap on **Select** and select **Select all unflagged** in the context menu.
- To delete all recordings which you no longer require, tap on **Delete**.

Stills from videos

This tab offers you the following options:

Viewing recordings

If you wish to view recordings, select one or more recordings and then tap on **View**. Use the arrow buttons on the side to view the selected recordings one directly after the other.

Printing recordings



WARNING: Print-outs may contain errors and must therefore not be used for diagnostics and therapy purposes.



WARNING: If an anonymous report is printed out, there is a possibility of it being mixed up or assigned to the wrong patient.

If you wish to print recordings, select one or more recordings and then tap on **Print**. A window with a print preview opens and you can then either print or cancel printing.

Deleting recordings

If you wish to delete recordings, select one or more recordings and then tap on **Delete**.

The recordings are then highlighted for deletion.

You can restore recordings at any time during the procedure by tapping on **Undo delete**.

NOTE: A recording which is marked for deletion is not saved together with the other data and, instead, is deleted permanently.



4-26 96296083EN / BA



Playing back a video and creating a still image

Select and start a video recording. Tap on **Still** to create a still image of the current view. Your recording is confirmed on the right next to the preview window.

Still editing



This tab offers you the following options:

Editing a still image

Select a still image and change the brightness and contrast.



(i)

NOTE: Changes which you make in the Still editing tab are saved as additional images; the original recordings remain unchanged.

Deinterlace

Enable **Deinterlace** if you see artifacts from interlacing in the still image (analog sources). Your changes are displayed in the preview window.

Saving or rejecting

Save your changes with **Save** or reject them with **Reset.**



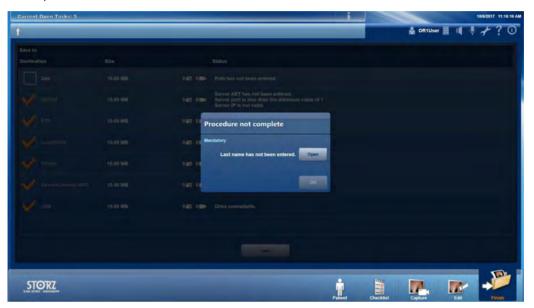
4.3.6 Finishing

In the **Finish** module, you can initiate data storage for the created documentation.

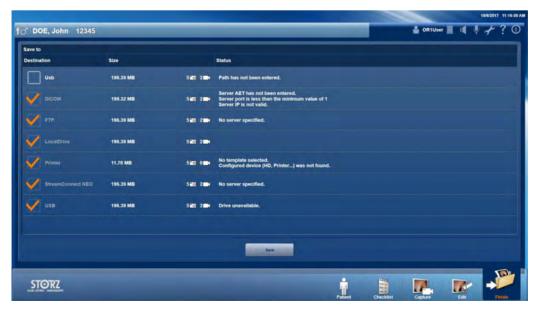
Depending on the configuration, the data is saved either automatically or, if necessary, must also be saved manually.

Initiating data storage

1. Tap on Finish.



- NOTE: If necessary, you are requested to complete all data entries. The module does not open until all the mandatory fields have been completed. Editing of the safety checklist, on the other hand, is optional.
 - If automatic data storage has been configured, you will see a list of the documentation to be saved.
 - If destination folders have been configured for manual saving, you will be given a selection of destination directories.



4-28 96296083EN / BA



- If relevant, select under Save to the destination directories for manual saving by setting a checkmark.
- 3. If required, connect a USB stick or insert a CD or DVD.
- **NOTE:** It is possible to save the data for one patient to a CD/DVD. The data from several patients cannot be saved on a single optical data carrier.



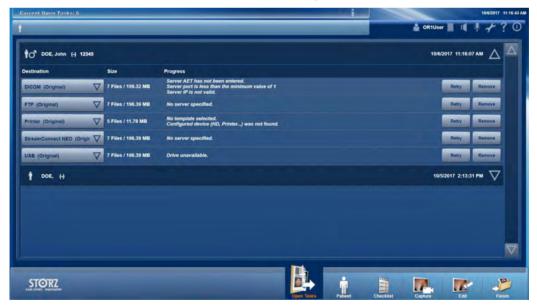
WARNING: The user is responsible for the management of removable data carriers.

- 4. Tap on Save.
- Data storage starts.
- The dialog window Export running opens.



If you tap on **Work list** in this dialog window, you will be taken directly to the sub-menu for searching in the DICOM Worklist in order to select the next patient.

If you tap on **Open tasks** in this dialog window, you will be taken to the list of tasks which have not yet been exported. If the list is empty, the data storage has been successfully concluded.

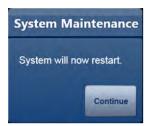




4.3.7 Forced restart

NOTE: A notification will appear before you reach the maximum storage space usage. If you do not respond to these notifications, the system will carry out a forced restart. Please regularly make sure that there are no old images or videos still in the system that are impacting upon the system.

If the limit for memory usage is considerably exceeded, the following window appears upon pressing the Save button.



A restart is enforced upon pressing the Continue button.



CAUTION: A restart may take a few minutes.

4-30 96296083EN / BA



4.4 'Control' application area

- NOTE: Depending on the upgrade and configuration of your system, some of the individual modules described below may not be available.
- NOTE: You only have access to this module via the home screen.

4.4.1 Medical Device Control - SCB



In the **Medical Device Control** module, you can operate the integrated medical devices directly via the touchscreen.

NOTE: More detailed information on the use of the Medical Device Control can be found in the separate instruction manual for the KARL STORZ SCB control NEO system.

Operating medical devices

- 1. Tap on **Home** in the navigation bar.
- 2. Tap on Medical Device Control.
- The SCB screen opens.



- 3. In the list of medical devices, tap on the device which you wish to operate.
- An image of the medical device is shown on the touchscreen.
- 4. Operate the medical device on the touchscreen.
- The medical device is synchronized simultaneously.
- **NOTE:** Operation directly on the medical device is also possible at any time. When operating the device directly, the display on the touchscreen is synchronized simultaneously.
- NOTE: Tapping on the Home button returns you to the AIDA screen.



4.5 'Previous procedures' application area



4.5.1 Filing cabinet

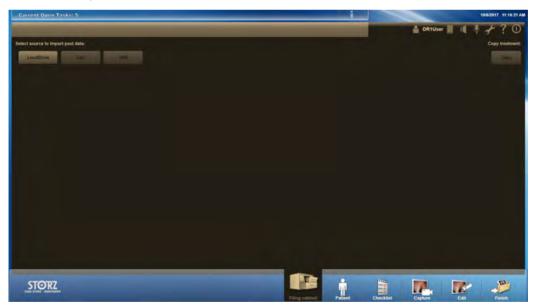
NOTE: Depending on the configuration of your system, this module may not be available.

In the **Filing cabinet** module, you can display documentation which has already been created. This documentation can be saved on a local drive, a network drive, a self-made optical data carrier or a USB stick.

Data, such as images and videos, can also be copied from the system to other destinations (USB, CD, DVD and networks such as PACS, HIS and AAR).

Displaying a data set

- 1. Tap on Filing cabinet.
- The Filing cabinet module is displayed.



- NOTE: The coloring of the module is different to prevent any confusion between the content thereof and the current treatment.
 - 2. Select the data source from which you wish to take the data from the top part of the screen.
 - The available data is shown as a table.

4-32 96296083EN / BA





- NOTE: You can limit the number of data sets in the list via entries in the search field or via preselection by pressing the button
 - 3. Select the treatment you wish to copy.
 - A window with the still images and videos created in this treatment opens.



NOTE: You can view the data again before copying to a target medium. To do so, select the corresponding still image or video and click on **View**.

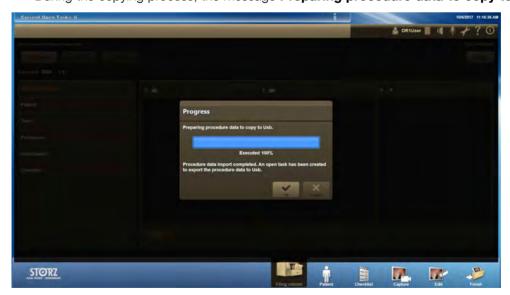


Copying data sets

- NOTE: The Copy function is available for completed procedures.
 - 1. Tap on Copy.
 - A window opens in which you can select the target medium.



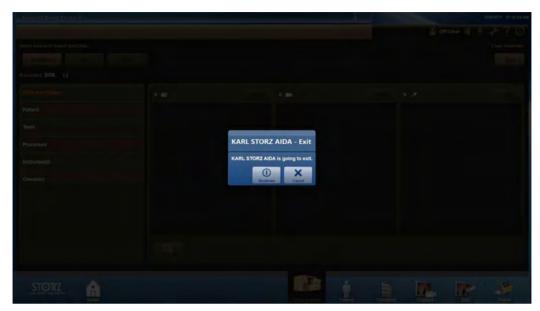
- 2. Select the target medium and tap **OK**.
- Data transfer begins.
- During the copying process, the message Preparing procedure data to copy to USB appears.



- The copying process is carried out. If the process is not carried out, it will be temporarily stored in Open tasks.
- 3. Open tasks can be redirected, deleted or re-activated as required. See also '4.3.6 Finishing' on page 4-28.
- When shutting down, a window indicating that copying is not completed opens.

4-34 96296083EN / BA





NOTE: A progress bar shows that copying is still running and how much time is remaining.

The user can choose between **Shutdown** and **Cancel**.

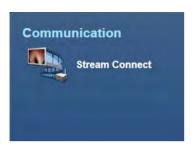
By tapping on **Shutdown**, copying is stopped and the system is shut down.

By tapping on **Cancel**, copying is resumed.



4.6 'Communication' application area

NOTE: Depending on the configuration of your system, some of the modules described below may not be available.



4.6.1 StreamConnect

In the **StreamConnect**® module, you operate the StreamConnect® server in the client's role. StreamConnect® enables you to transmit and receive surgical procedures via live stream.

NOTE: Further information on the use of the StreamConnect® server can be found in the separate instruction manual 'KARL STORZ OR1® StreamConnect® II'.

4-36 96296083EN / BA



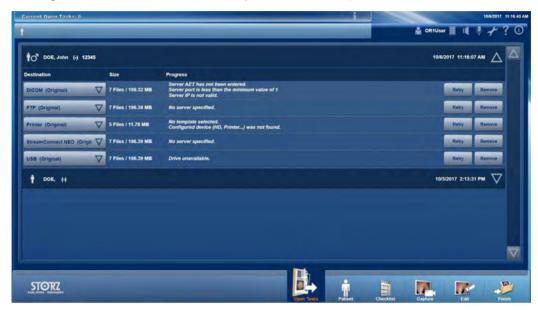
4.7 Open tasks

If open tasks are generated, enter these in the list of open tasks.

They will also appear in Current open tasks, followed by the number of tasks.



Clicking on the information icon a takes you to the list of open tasks.



In the list of **Open tasks**, you can save all patient data that has not yet been saved.

NOTE: It is possible to save the data for one patient to a CD/DVD. The data from several patients cannot be saved on a single optical data carrier.

Saving data

- 1. Tap on Open tasks.
- The patient data which still needs to be saved is displayed.
- 2. Check the data set.
 - a. If necessary, change the destination directory.
 - b. If saving data to a CD, DVD or USB drive, have writeable data carriers at the ready.
- 3. Work through the data sets one after the other by tapping on **Retry** or **Burn CD** for CDs and DVDs.
- Each time data has been burnt, the dialog window Label CD/DVD opens.
- ▼ The CD/DVD can be ejected.

If you have burnt a CD or DVD, label the data carrier immediately afterwards as per the label suggestion. This prevents mix-ups when assigning labels to data carriers.

NOTE: Destinations which cannot be accessed can be reassigned.



If you do not wish to save the data set, tap on **Remove**.

- The data set is permanently deleted.
- NOTE: If a task is completed, the number of unfinished open tasks in the information bar will decrease, or the message will disappear altogether.

4-38 96296083EN / BA



5 Maintenance

5.1 Safety instructions



WARNING: Before performing any cleaning or maintenance work on the central device and the connected devices, disconnect these from the power supply line!



WARNING: All work may only be performed by qualified technicians trained in electrical or electronic engineering, in compliance with the relevant occupational, safety and accident prevention regulations! Prior to carrying out any work on the device, disconnect the device from the mains! A safety test according to VDE 0751 and IEC 62353 must be carried out following service work.



WARNING: By making the enclosed technical information available, KARL STORZ does not authorize any service or repair work by unauthorized service personnel. Any tampering with instruments or devices or unauthorized servicing or repair work to the device will render the warranty void.

5.2 Reprocessing

5.2.1 Legal requirements



WARNING: When carrying out any work on contaminated medical devices, the guidelines of the Employers' Liability Insurance Association and equivalent organizations striving to ensure personal safety must be observed.

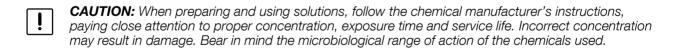


CAUTION: National laws and regulations must be observed.

5.2.2 Safety instructions



WARNING: Risk of infection: Incorrectly reprocessed medical devices expose patients, users and third parties to a risk of infection as well as the risk that the medical device may malfunction. Observe the manual 'Cleaning, Disinfection, Care, and Sterilization of KARL STORZ Instruments' and the accompanying documentation.



NOTE: The manual 'Cleaning, Disinfection, Care and Sterilization of KARL STORZ Instruments' can be downloaded or requested by visiting www.karlstorz.com.

5.2.3 Required reprocessing agents

- Disinfectants
- **NOTE:** Due to their protein-fixating effect and possible material incompatibility, alcohol-based agents must not be used.

The chemical manufacturer's specifications concerning material compatibility must be observed.

5.2.4 Required reprocessing materials

- Disposable cloth or ready-to-use disinfectant cloth
- Dry, low lint cloth



5.2.5 Manual wipe-down disinfection

- **NOTE:** To prevent liquid entering the device, it should not be sprayed with the reprocessing agent.
- **NOTE:** In order to preserve the conductivity of the contacts, you should never allow reprocessing agents to come into contact with the connections on the front and back of the device. When the cleaning agent dries, residues can form which impair conductivity.
 - 1. Use a disposable cloth moistened with disinfectant or a soaked ready-to-use disinfectant cloth.
 - 2. Wipe-clean the exterior surfaces of the medical device.
 - 3. Allow the disinfectant to take effect, observing the instructions of the disinfectant manufacturer.
 - 4. At the end of the necessary exposure time, wipe the surfaces with a dry low lint cloth.
 - 5. After using the cloth, dispose of this in accordance with the disposal regulations.

5.3 Maintenance and repair

5.3.1 Maintenance plan

| Interval | Action | Responsibility |
|---------------|--------------------------|-------------------------------|
| As required | Change fuses | KARL STORZ service technician |
| Annually | Check and inspect device | KARL STORZ service technician |
| Every 4 years | Replace BIOS battery | KARL STORZ service technician |

5.3.2 Replacing the BIOS battery

The BIOS battery must be replaced by KARL STORZ service technicians or appropriately trained specialist personnel.

5.3.3 Changing the device fuse

The device fuse must be changed by KARL STORZ service technicians or appropriately trained specialist personnel.

5.3.4 Servicing

Defective device components must be serviced and repaired exclusively by persons authorized by KARL STORZ; all repair work must employ original KARL STORZ parts only.

All service work may only be performed by KARL STORZ or by an authorized agent.

5-2 96296083EN / BA



5.4 Repair program

5.4.1 Return of defective devices to KARL STORZ

In case you need to return a device to KARL STORZ for repair, we request that you make a backup copy of all the patient and personal data stored on the hard disk and then delete the data from the hard disk prior to returning the device (see software description 96296016, chap. 3.3 and 3.4).

In Germany, you can refer repairs direct to:

KARL STORZ SE & Co.KG Abt. Reparaturservice

Take-off Gewerbepark 83

78579 NEUHAUSEN, Germany

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

In other countries please contact your local KARL STORZ branch or authorized dealer.

5.5 Limitation of liability

KARL STORZ shall be liable for the safe operation, operational reliability, and performance of this system only subject to the following conditions:

- all assembly operations, system expansions, readjustments, modifications or repairs have been performed by a person or persons duly authorized by KARL STORZ;
- all electrical installations in the room in which the system is installed and operated meet the applicable laws and standards, and
- the devices have been used in accordance with their instruction manuals at all times.

5.6 Warranty

For a period of two years after delivery to the end user, we shall replace free of charge equipment that can be proven to have defects in material or workmanship. In so doing we cannot bear the cost of transportation or the risk associated with shipment. The warranty referred to in our Standard Conditions of Business shall additionally apply.

Opening the equipment or performance of any repairs or modifications to the components of the device by unauthorized persons shall relieve us of any liability for its performance. Any such opening, repair, or modification performed during the warranty period shall void all warranty.

Maintenance



5-4 96296083EN / BA

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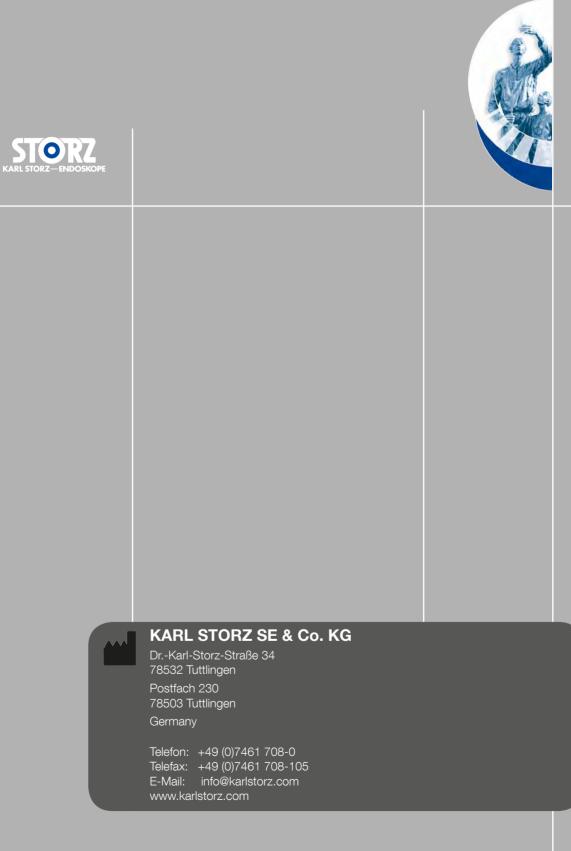
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6-2 96296083EN / BA



SICORZ KARL STORZ—ENDOSKOPE







Welcome

Thank you for your expression of confidence in the KARL STORZ brand name. Like all of our other products, this product is the result of years of experience and great care in manufacture. You and your organization have decided in favor of a modern, high-quality product from KARL STORZ.

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Contents



Contents

| 1 | Installation | . 1-1 |
|-------|--|-------|
| 1.1 | List of supplied documentation | . 1-1 |
| 1.2 | Technical description characteristics of the program | . 1-1 |
| 1.3 | Installation procedure | . 1-1 |
| 1.3.1 | KARL STORZ AIDA® Secure | . 1-1 |
| 1.4 | User-specific modifications | . 1-6 |
| 2 | Description of the program functions | . 2-1 |
| 2.1 | Intended use of the program | . 2-1 |
| 2.2 | Program structure | .2-1 |
| 2.3 | Roles and access rights in configuration mode | . 2-2 |
| 2.4 | Overview of functions with access rights) | . 2-3 |
| 2.5 | Opening the configuration area | . 2-8 |
| 2.6 | Configuration for Configuration-User | .2-9 |
| 2.7 | Configuration for Application Administrator | .2-9 |
| 2.7.1 | 'General' module | .2-9 |
| 2.7.2 | 'Capture' module | 2-18 |
| 2.7.3 | 'Checklist' module | 2-26 |
| 2.7.4 | 'Finish' module | 2-28 |
| 2.7.5 | 'Data entry' module | 2-37 |
| 2.7.6 | 'Browser' module | 2-47 |
| 2.8 | Configuration for System-Administrator | 2-48 |
| 2.8.1 | 'General' module' | 2-48 |
| 2.8.2 | 'User administration' module | 2-5C |
| 2.8.3 | 'Remote Service' module | 2-55 |
| 3 | Data backup and reorganization | . 3-1 |
| 3.1 | Requirements | .3-1 |
| 3.2 | KARL STORZ AIDA® recovery | .3-1 |
| 3.3 | Backing up data from the (D:) hard disk drive | .3-9 |
| 3.4 | Deleting data on the (D:) hard disk drive | 3-11 |
| 4 | Behavior in exceptional situations | . 4-1 |
| 4.1 | Hard shutdown | . 4-1 |
| 4.2 | Reboot (cold. warm start) | . 4-1 |

Contents



| 5 | Support from the program supplier/manufacturer | . 5-1 |
|-----|--|-------|
| 5.1 | Contact address for the user | . 5-1 |
| 5.2 | Service hotline | . 5-1 |
| 5.3 | Education, training, internet etc. | .5-1 |

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1 Installation

The device is supplied with installed software.

NOTE: If the device is on an instrument cart, this should only ever be switched on/off via the AIDA ON/ OFF switch. The central switch on the instrument cart is only suitable for the remaining components such as printers, screens etc.

1.1 List of supplied documentation

• Software description

1.2 Technical description characteristics of the program

- Completed system
- All functions for day-to-day work can be accessed via the touchscreen.

1.3 Installation procedure

1.3.1 KARL STORZ AIDA® Secure

As standard, the system is delivered ex works with KARL STORZ AIDA® Secure (neXus SE46). This security software prevents dangerous or undesirable software from running on your system. It functions based on the white list principle. This means that only approved (certified) software can be run on the system.

- NOTE: KARL STORZ recommends combination with an Intrusion Prevention System (IPS) in order to guarantee maximum protection of your network.
- **NOTE:** We recommend that either you or your IT department create a new user account with administrator rights and deactivate the standard administrator account. If you do so, you must not forget the password.

Installing and approving new software and hardware components

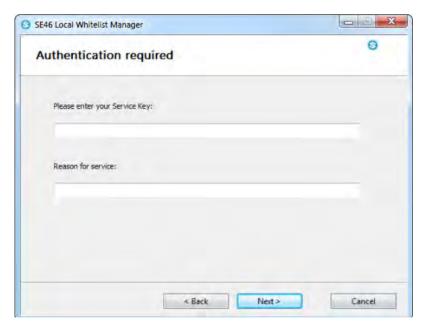
New software and hardware components can be installed and approved as follows:

- 1. Ensure that the new system components come from a reliable and trustworthy source, are free from malware, and can be installed on KARL STORZ AIDA® WD300 or WD350 without any problems.
 - Scan the new software and the data carrier (USB stick) with an up-to-date anti-virus program.
- **NOTE:** Only use data carriers you have checked in advance throughout the entire process.
 - 2. Disconnect all unnecessary data carriers from the system (e.g., USB hard drives).
 - 3. Disconnect the system from the network.
- **NOTE:** If it is not possible to disconnect the system from the network or you do not wish to do so, you must ensure that your network is free from viruses and other malware.
 - 4. Log on using an account with administrator rights.
 - 5. Click on Start\Programs\neXus\SE46\Local Whitelist Manager and start the Local Certification of Software. The following window appears:





6. Click on **Next**; the following window then appears:

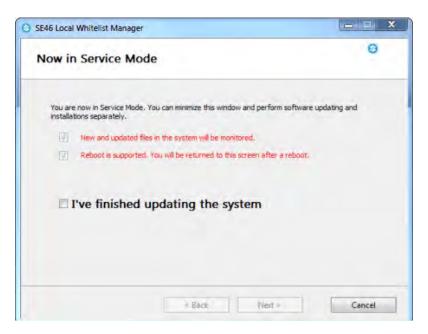


7. Enter the following service key: **Service-MLAACDET-ACAA-HHTPZATZ**Please pay attention to the use of uppercase and lowercase.

Now enter the reason for your changes and click on **Next**; the following window then appears:

1-2 96296082EN / BA



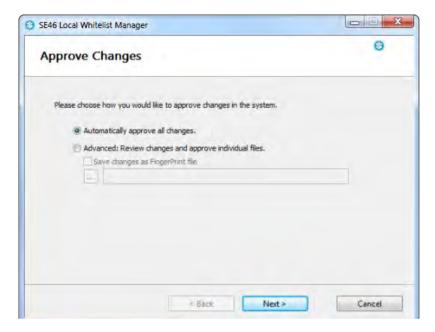


- 8. The system is now in Service Mode and the new system components can be installed.
- NOTE: You can perform a restart in Service Mode if necessary. The system is then restarted in Service Mode and you can continue with the installation.
 - 9. Once the installation is completed, mark **I've finished updating the system** and then click on **Next**; the following window then appears:

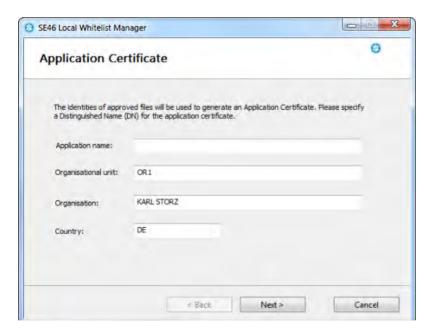


10. KARL STORZ AIDA® Secure now checks the changes; the following window then appears:





11. Select **Automatically approve all changes** and then click on **Next**; the following window then appears:



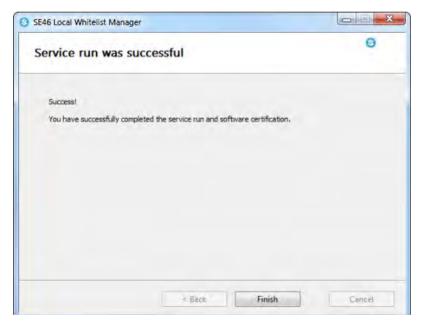
12. Now enter additional information on your changes and click on **Next**; the following window then appears:

1-4 96296082EN / BA





13. KARL STORZ AIDA® Secure now creates a new system certificate; the following window then appears:



14. Click on Finish.

The new system components are now permanently available and the system is once again protected from undesirable software. You can reconnect the system to the network or reconnect any data carriers.

Now perform a system test to verify that the system is working perfectly.

NOTE: The addition of new software or hardware can, under certain circumstances, cause the KARL STORZ AIDA® system to malfunction (including loss of data). Consequently, it is essential that a system test after adding new software or hardware be performed, which verifies the perfect functioning. KARL STORZ cannot accept any liability for malfunctions or loss of data on modified systems.



1.4 User-specific modifications

Within the scope of available configuration options ("2.7 Configuration for Application Administrator" on page 2-9 and "2.8 Configuration for System-Administrator" on page 2-48), a wide range of application-oriented system modifications can be performed.

1-6 96296082EN / BA



2 Description of the program functions

2.1 Intended use of the program

The program is used for the documentation of audiovisual data and patient data during diagnostic and therapeutic interventions. It allows the operation to be recorded and described for documentation purposes. The audiovisual data which is recorded and forwarded using the KARL STORZ AIDA® is for examination and information purposes, and not primarily for making diagnoses.

2.2 Program structure

The program principally offers two different modes.

- Operation mode: See systemdescription
- Configuration mode: In this mode, you can select the functional scope and application-specific settings. The configuration mode is described below.



2.3 Roles and access rights in configuration mode

The following user roles with various rights are predefined for configuration mode.

| Role | Group | Field of activitiy | Authorization |
|------------------------------|----------------------------|---|--|
| Confuguration User | Settings Users | Attending Physician | Creating personal user profile |
| Application Administrator | Application Administrators | Responsible for the configuration of an application | Adjusting settings at application level |
| System Administrator | Administrators | IT department | Adjusting settings at operating system level |

The following two user accounts have already been created with the corresponding rights for the roles of system administrators and application administrators.

| | System Administrator | Applikations Administrator |
|----------|-------------------------|-------------------------------|
| OR1User | | X |
| OR1Admin | X | |

2-2 96296082EN / BA



2.4 Overview of functions with access rights)

The following abbreviations are used in the table:

- Role 1: Configuation User
- Role 2: Application Administrator
- Role 3: System Administrator

| Settings | Settings | | | Access | rights |
|----------|-------------------|---|--------|--------|--------|
| Level 1 | Level 2 | Level 3 | Role 1 | Role 2 | Role 3 |
| General | User interface | Country | | Х | |
| | | Culture | | Х | |
| | | Keyboard | | Х | |
| | | Startup module | | Х | |
| | | Enable onscreen keyboard | | Х | |
| | | Enter facility name | | Х | |
| | | Operating room name | | Х | |
| | | Activate audio feedback | | Х | |
| | | Activate start screen | | Х | |
| | Content | Enable modules | | Х | |
| | Display | Touchscreen | | Х | |
| | | Calibration | | Х | |
| | | Scaling factor | | Х | |
| | | Select screen type | | X | |
| | | Select COM connection | | Х | |
| | | Set playback options on the operation monitor | | Х | |
| | | Activate display switchover | | Х | |
| | | Test settings | | Х | |



| Settings | | | | Access | rights |
|----------|---------|---------------------------------------|--------|--------|--------|
| Level 1 | Level 2 | Level 3 | Role 1 | Role 2 | Role 3 |
| General | DICOM | Client AET | | Х | |
| | | Modality | | Х | |
| | | Character set | | Х | |
| | | Port | | Х | |
| | | Encryption | | Х | |
| | | Local cert. file | | Х | |
| | | Server cert. file | | Х | |
| | | Timeout | | Х | |
| | | Log level | | Х | |
| | | Enable Worklist | | Х | |
| | | Server AET | | Х | |
| | | Server IP | | Х | |
| | | Port | | Х | |
| | | Date filter | | Х | |
| | | Flat file | | Х | |
| | | Enable MPPS | | Х | |
| | | Server AET | | Х | |
| | | Server IP | | Х | |
| | | Port | | Х | |
| | Open | ID | | Х | |
| | Commits | Time | | Х | |
| | | Status | | Х | |
| | HL7 | General | | Х | |
| | | Query patient data from HL7 | | Х | |
| | | HL7 export settings | | Х | |
| | Reports | Standard printer | | Х | |
| | | Paper format | | Х | |
| | System | System information | | Х | |
| | | Domain settings | | | X |
| | | Network settings | | | Х |
| | | Windows desktop | | | Х |
| | | NTP settings | | | Х |
| | | WLAN settings | | | |
| | Safety | Activate access control | | | Х |
| | | Activate information window for login | | | Х |

2-4 96296082EN / BA



| Settings | | | | Access | rights |
|-----------|---------------------------------|---|--------|--------|--------|
| Level 1 | Level 2 | Level 3 | Role 1 | Role 2 | Role 3 |
| Capture | General | Enable dual capture | Х | Х | |
| | | High (2D) video profile | • | • | • |
| | | Image format | Х | Х | |
| | | Video format | Х | Х | |
| | | Video quality | Х | Х | |
| | | Video resolution | Х | Х | |
| | | Video chaptering | Х | Х | |
| | | Maximum size for each video | Х | Х | |
| | | Normal (2D) video profile | • | | • |
| | | Image format | Х | Х | |
| | | Video format | Х | Х | |
| | | Video quality | Х | Х | |
| | | Video resolution | Х | Х | |
| | | Video chaptering | Х | Х | |
| | | Maximum size for each video | Х | Х | |
| | Watermark | Enable watermark logo | | Х | |
| | | Select watermark logo | 1 | Х | |
| | | Watermark logo scaling | | Х | |
| | | Watermark transparency amount | | Х | |
| | | Enable watermark fields | | Х | |
| | | Select watermark fields | | Х | |
| | Capture | Still image | | Х | |
| | feedback | Capture feedback position | | Х | |
| | | Video | | Х | |
| | Remote control | Assign functions to camera head buttons | Х | Х | |
| Checklist | Checklist sto- rage path | | | Х | |
| | Checklist re- port logo path | | | Х | |
| | Horizontal alignment of logo | | | Х | |
| | Vertical align- ment of logo | | | Х | |



| Settings | | | | Access | rights |
|------------|-------------------------------|---|--------|--------|--------|
| Level 1 | Level 2 | Level 3 | Role 1 | Role 2 | Role 3 |
| Finishing | Automatic | Adding and removing storage media | | Х | |
| | Manual | Adding and removing storage media | | Х | |
| | Reports | Specify headers | | Х | |
| | | Select logo | | Х | |
| | Auto print | Enable auto print | Х | Х | |
| | | Name | | Х | |
| | | Number of copies | Х | Х | |
| | | Number of images per page | Х | Х | |
| Data entry | User interface | Visible sections | | Х | |
| · | | Procedure identifier shown in simple treatment screen | | Х | |
| | | Specify mandatory fields | | Х | |
| | Team 1 | Put together a clinical team | | Х | |
| | | Enter referring physicians | | Х | |
| | Specify indivi- dual login | | | Х | |
| | Team 2 | Enter anesthesiologists | | Х | |
| | | Nurses | | Х | |
| | Instruments | Enter instrument trays | | Х | |
| | | Enter endoscopes | | Х | |
| | Procedures | Enter discipline | | Х | |
| | | Enter procedure designation | | Х | |
| | | Select anatomical rules | | Х | |
| | | Assign keywords | Х | Х | |
| | Personnel | Activate employee directory | | Х | |
| | groups | Physicians | | Х | |
| Browser | | Name | | Х | |
| | | Address | | Х | |
| | | Symbol | | Х | |
| | | Icon display location | | Х | |

2-6 96296082EN / BA



| Settings | Settings | | | Access | rights |
|----------------|---------------------|---------------------------|--------|--------|--------|
| Level 1 | Level 2 | Level 3 | Role 1 | Role 2 | Role 3 |
| User | Role | System Administrator | | | Х |
| administration | administration | Application Administrator | | | Х |
| | | Settings User | | | Х |
| | | Super User | | | Х |
| | | User | | | Х |
| | | Auditor | | | X |
| | | Activate group profiles | | | Х |
| | Authentication | Auto login | | | Х |
| | | Application | | | Х |
| | | Windows | | | Х |
| | | Auto logout | | | Х |
| | | Timeout | | | Х |
| | HTTP proxy settings | Host | | | X |
| | | Port | | | Х |
| | | User name | | | Х |
| | | Password | | | Х |

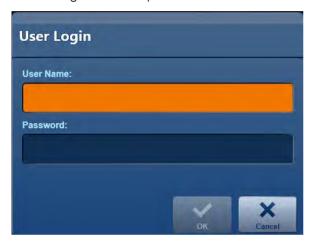


2.5 Opening the configuration area

The configuration area can be accessed at any time by tapping on the tool symbol in the header.



- 1. Tap on the tool symbol.
- The login window opens.



2. Enter the user details and password and press **OK** or **Enter** on your keyboard to confirm.

| User | Password |
|----------|----------|
| OR1User | XXXXX |
| OR1Admin | XXXXX |

NOTE: The password can be changed in the Windows user accounts.



- **NOTE:** If you have entered the password via the on-screen keyboard, confirm this entry by pressing the **Enter** key.
 - The configuration area opens.

2-8 96296082EN / BA



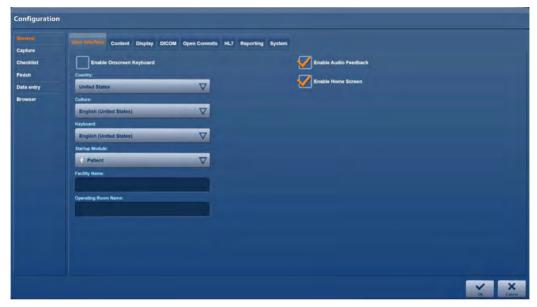
2.6 Configuration for Configuration-User

All setting options for the configuration user can be seen in table in the chapter 'Menu structure (functional overview with access rights)' and are also available to the application administrator. The description can be found in the following chapter.

2.7 Configuration for Application Administrator

2.7.1 'General' module

'User interface' menu

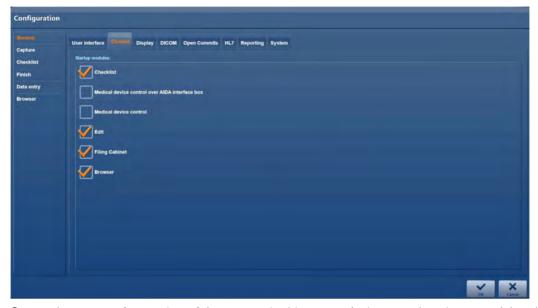


Specify the system language, key assignment and start screen in this menu. You can also activate the virtual keyboard for entries via the touchscreen here.

- 1. Under **Country**, specify the location.
- 2. Under Culture, specify the language variety.
- 3. Under **Keyboard**, specify the keyboard assignment on your keyboard.
- 4. Under **Startup module**, specify which module is to be displayed on starting the system.
- 5. If a virtual keyboard screen is to be available for entering text on the touchscreen, place a check mark next to **Enable onscreen keyboard**.
- 6. Place a check mark next to **Activate acoustic feedback** if you would like an acoustic signal to sound whenever an image or video is captured.
- 7. If you would like the start screen to be available after the program has started up, then place a check mark next to **Enable Home Screen.**
- 8. Enter the name of the facility in the field **Facility name** field, e.g., ... hospital.
- 9. Enter the operation room in the **Operation room name** field.

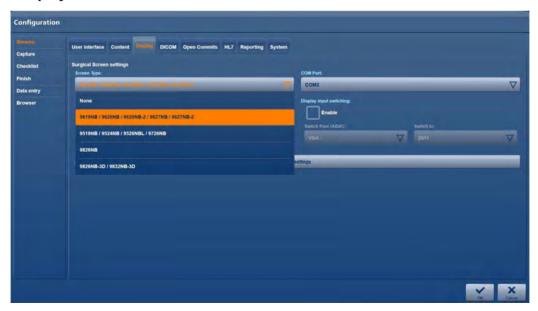


'Content' menu



Set up the scope of operation of the system in this menu. Activate or deactivate modules depending on whether they should be available to the user or not.

'Display' menu



In this menu, select the screen type.

- 1. Tap the screen type button and choose a model.
- **NOTE:** The COM connection is based on the connected medical screen. Please observe the wiring diagrams.
 - 2. Restart the computer.

2-10 96296082EN / BA



'DICOM' menu



Set up the DICOM interface in this menu.

NOTE: Consult with your facility's IT department as regards setting up the DICOM interface.

Setting up DICOM parameters

- 1. Under **Client AET**, enter the AE title which was assigned to the KARL STORZ AIDA® system by your IT department.
- 2. Under **Modality**, select a Modality Type.

ES: Endoscopy **US**: Ultrasound **OT**: Other

- 3. Under Char. set, select the character set in collaboration with your IT department.
- 4. The port describes the channel on which the DICOM service of the AIDA application is running. This is required for the Storage Commitment and in order to check the connection between the DICOM server and the AIDA application.
- 5. Pressing the **Encryption** button will take you to a selection screen where you can choose between two encryption protocols for data transfer; ISCL (Internet Security Consulting Language) or TLS (Transport Layer Security)

 If no encryption protocol is selected, data will be transferred without any encryption.
- 6. If a check mark is placed next to 'Local Cert. file', the local computer's certificates for TLS have been imported on this computer. These are imported by pressing the **Browser** button, and are usually imported from a USB stick. The certificates are managed by the hospital's IT department.
- 7. If a check mark is placed next to 'Server Cert. file', certificates have been loaded for the DICOM server used by the application, also via the **Browser** function. These server certificates are managed by the hospital's IT department.
- 8. Leave the **LogLevel** as the factory setting.
- NOTE: The LogLevel can be adjusted for service purposes, but should normally remain in factory settings.

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Description of the program functions

Setting up the interface to the DICOM Worklist provider or MPPS

- If you want to allow access to a DICOM Worklist or MPPS, place a check mark next to Enable Worklist or Enable MPPS.
- NOTE: If you remove the check mark, the **Import DICOM Worklist** or **MPPS** button will no longer be displayed on the user interface.
- NOTE: Do not make the settings described below when you have removed the check mark.
- NOTE: The fields Server AET, Server IP and Port are outlined in yellow until an entry has been made.
 - 2. Under Server AET, enter the AE title of the DICOM Worklist server.
 - 3. Under Server IP, enter the IP address of the DICOM Worklist server.
 - 4. Under Port, enter the port for the DICOM Worklist server.
- NOTE: With MPPS, the option to select different date display options is not available.
 - 5. Under **Date filter**, limit the date range which is to be displayed when searching for patient data in the DICOM Worklist.

Today: Only display the patients on the Worklist for the current day.

One Day: plus/minus 1 day Two Days: plus/minus 2 days Three Days: plus/minus 3 days

Select **None** if you do not wish to limit the date range.

6. Set the **Timeout**.

Timeout: 30 seconds

- **NOTE:** The Timeout can be changed if necessary, but should otherwise remain in factory settings.
 - 7. Tap on **Echo** to test the connection to the DICOM server or MPPS.
- (i) **NOTE:** If the connection test fails, there is probably an error in the network connection or in the entered server access data.
- NOTE: Consult with your facility's IT department as regards connection problems.

2-12 96296082EN / BA



'Open Commits' menu

The 'Storage Commitment' DICOM function confirms that an image has been securely stored in PACS. The Storage Commitment message is only generated by PACS once the data has not only been completely received but also securely stored in non-volatile memory. If DICOM has been selected as a medium and Storage Commitment is activated, the following list will show all active ongoing Commits, together with their status.



ID: Unique media data ID

Time: Time of the requested Storage Commitment

Status: Current status of the request

List of expected messages

| Status | Description | Actions |
|---------------|---|--|
| Unknown | Unknown error/error in retrieving the methods, no return value for the status. | Please re-send the Commit request. |
| | | Error: There is a DICOM error. Please contact the DICOM administrator. |
| Failed | The Commitment server has sent the response 'Failed' for (at least) one object. | Please re-send the Commit request. |
| | | Error: There is a DICOM error. Please contact the DICOM administrator. |
| CommitTimeout | 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. | Warning: Please re-send the Commit request. |
| | If there are both failed and timed out objects, 'Timeout' will be displayed. | |



| Status | Description | Actions |
|----------------------|---|---|
| CommitPending | 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. | Normal status. Request being processed. |
| CommitIncomplete | No Commit request was sent for (at least) one object. | Normal status. Please observe the timeout period and then re-send the Commit request. |
| StorageIncomplete | At least one object was not stored. | Normal status. Please observe the timeout period and then re-send the Commit request. |
| StorageNotDone | Error when storing the objects on the store server (no Commit request was sent). | Please re-send the Commit request. Error: Please contact the DICOM administrator. |
| StorageNotConfigured | No store server configured (also no Commit request). | Error: Please check the DICOM server settings. |

A Storage Commitment can be requested again by tapping **Send**.

An ongoing 'Open Commit' can be deleted from the list by tapping **Delete**.

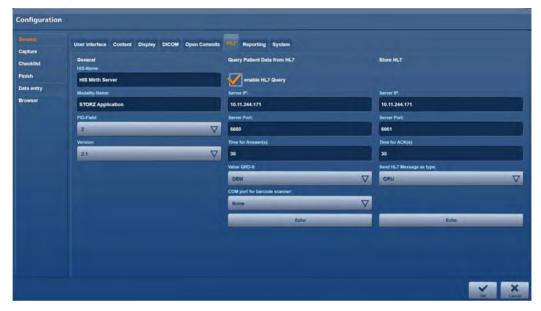
The list can be updated by tapping **Refresh**.

NOTE: The list is updated automatically every 30 seconds.

2-14 96296082EN / BA



'HL7' menu



Set up the HL7 interface in this menu.

Two separate HL7 server settings can be configured.

- Query patient data from HL7 configuration, with a choice between DEM and APA
- **HL7 export settings** configuration for the storage of ORU and MDM messages.

Both server settings have an echo function, meaning that the server availability can be checked immediately after configuration has been carried out.

Setting up HL7 parameters

- 1. Under **HIS name**, enter the name of the hospital information system.
- 2. Under **Modality name**, select the name for the AIDA system allocated to you by the IT department.
- 3. Under **PID field**, select the position you would like the patient ID to appear within the HL7 messages.
- 4. Under **Version**, select the version of the HL7 standard currently in use.

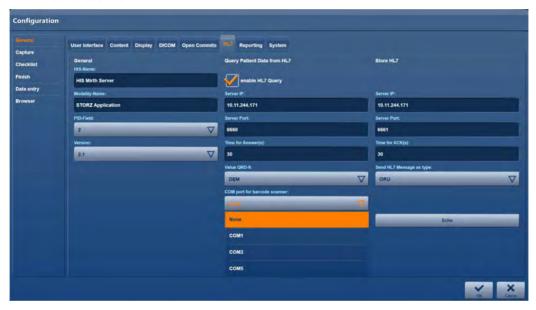
Setting up an interface to the HL7 server

- 1. If you wish to allow a request for patient data, place a check mark next to Allow HL7 request.
- 2. Under Server IP, enter the IP address of the HL7 server.
- 3. Under **Port**, enter the port for the HL7 server.
- 4. Set the **Max. time for answer**. Time for Answer: **60** seconds
- 5. Under Value QRD-9, select the patient search type.

DEM: Search according to patient ID APN: Search according to case number



6. Under **COM port for barcode scanner**, select the channel to which you want to connect a barcode scanner.



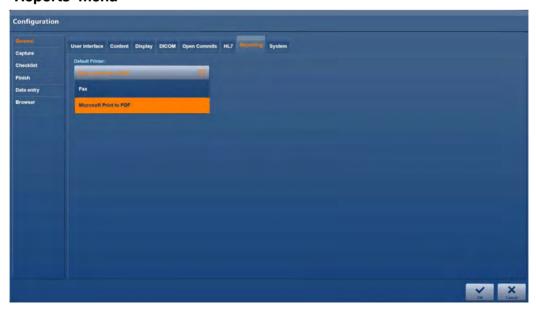
Setting up an interface for storing data on the HL7 server

- 1. Under **Server IP**, enter the IP address of the HL7 server.
- 2. Under **Port**, enter the port for the HL7 server.
- 3. Set the **Max. send time**. Send time: **60** seconds
- 4. Under **Send HL7 message in type**, select the message type you are using to send the data.

ORU: All information in an HL7 message

MDM: Per fragment (image, video) of an HL7 message

'Reports' menu



In the **Reports** menu, you can select on which default printer and in which paper format the reports are to be printed.

2-16 96296082EN / BA



'System' menu



The system information can be found in the **System** menu.

Description Description

Description of the program functions

2.7.2 'Capture' module

'General' menu

In the **General** tab, you can receive signals from different types of source via 2 channels:

- Display Port sources at Input 1
- HDMI sources at input 2

Each signal from these sources can be assigned a profile, which is generated from the following settings:

- Image format
- Video format
- Video quality
- Video resolution
- Video chapter
- Maximum size for each video



Place a check mark next to the relevant check box to activate the appropriate source.

If the source supports 3D format, place a check mark next to '3D'.

NOTE: Because the 3D format has a defined quality profile, the current profile settings are deactivated (apart from the video section).

Placing a check mark next to 'sRGB' will enable you to use this color space.

NOTE: To minimize the transmission rates and storage requirements, it is recommended that different capture qualities be set for the channels.

This does not apply to 3D sources!

2-18 96296082EN / BA

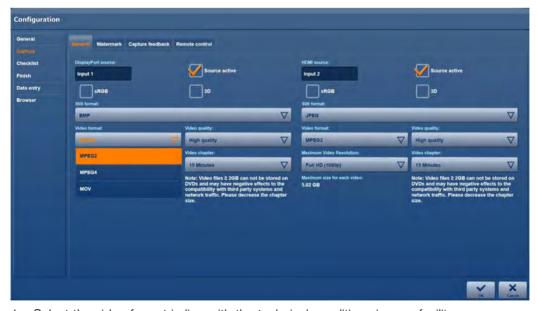


Image format



- 1. Select the image format for still images in line with the technical conditions in your facility.
- **NOTE:** JPEG files are compressed whilst BMP files are not.
- NOTE: Compressed files can contain artifacts and thus must not be used for diagnosis and therapy purposes.

Video format



- 1. Select the video format in line with the technical conditions in your facility.
- NOTE: All the available video formats produce compressed files which may contain artifacts.
- NOTE: The settings MPEG4, normal quality and a resolution in HD (720p) quality offer the best combination in terms of storage space and quality.



Video quality



1. Select the capture quality.

Take note of the expected file size per minute of capturing depending on the format, resolution and capture quality as per the table below.

| Format | Quality | Resolution | Transfer rate Storage space | | |
|--------|---------|-------------|-----------------------------|--------------|--|
| WMV | high | SD | 6 Mbit/sec | 45 MB/min | |
| | normal | SD | 3 Mbit/sec | 23 MB/min | |
| MPEG2 | high | 1080p | 35 Mbit/sec | 263 MB/min | |
| | | 720p | 18 Mbit/sec | 135 MB/min | |
| | | SD | 6 Mbit/sec | 45 MB/min | |
| | normal | 1080p | 8.75 Mbit/sec | 65.63 MB/min | |
| | | 720p | 6 Mbit/sec | 45 MB/min | |
| | | SD | 3 Mbit/sec | 23 MB/min | |
| MPEG4/ | high | 1080p | 16 Mbit/sec | 120 MB/min | |
| MOV | | 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 | |
| 4K | high | 4 x Full HD | 80 Mbit/sec 600 MB/min | | |

2-20 96296082EN / BA



Video resolution



1. Select the screen resolution for the recording.

Video chaptering



1. Divide the video recordings into sections.

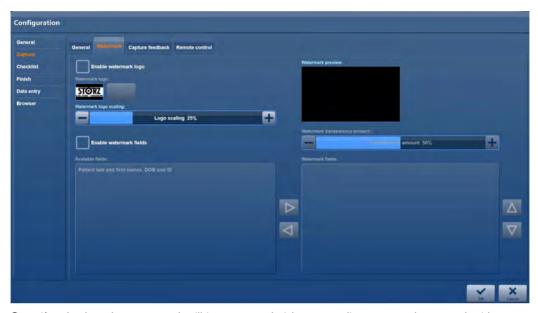
Select the length of the sections depending on the storage capacity of the intended storage medium.

NOTE: When selecting the section length, ensure that the file size shown is not greater than the storage space available on the intended storage medium.

NOTE: When saving via the network, a section size of 950 MB should not be exceeded. Select **OFF** if you do not wish the recording to be divided into sections.

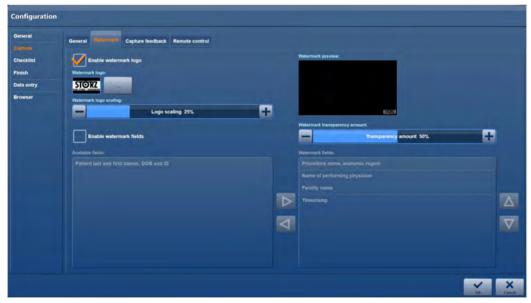


'Watermarks' menu



Specify whether the captured still images and video recordings are to be saved with a watermark in the **Watermark** menu. You can also specify the data for labeling the recordings.

Setting up the watermark



- 1. Place a check mark next to **Enable watermark logo**.
- 2. Tap the button next to **Watermark logo** and navigate to where the image file which you wish to use is stored.
- **NOTE:** The place where you have stored the watermark logo must be on the local hard drive! If necessary, a relevant archive must be created by a service technician.

2-22 96296082EN / BA



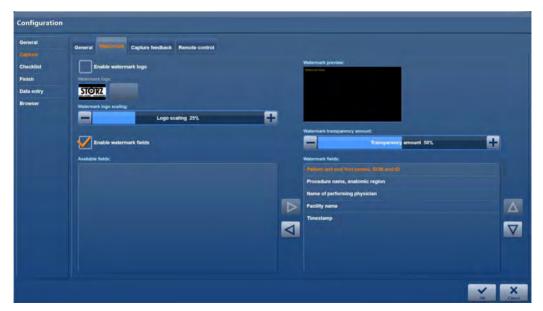
- 3. Highlight the file and tap on **Open**.
- 4. Set the transparency of the logo under **Watermark transparency**. Check the result in the preview on the right-hand side.
- 5. Set the size of the logo under **Watermark logo scaling**. Check the result in the preview on the right-hand side.

Setting up image labeling

1. Place a check mark next to Enable watermark fields.



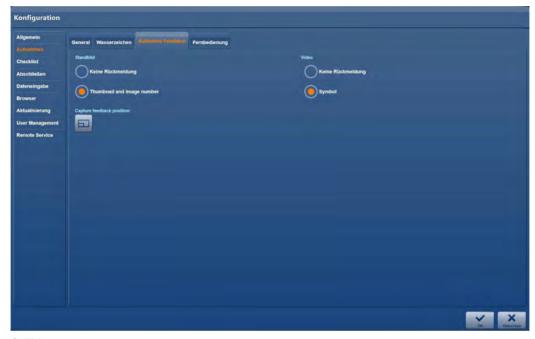
2. Select the desired metadata in Available fields.



- 3. Using the arrow buttons on the right-hand side, place the entries in the order in which they are to appear on the images.
- 4. Tap Close.



'Capture feedback' menu



Still image

In this section, you can configure whether there should be any feedback about a captured image, or whether to activate the surgical overlay on the surgical screen where the still images are shown.

Capture feedback position

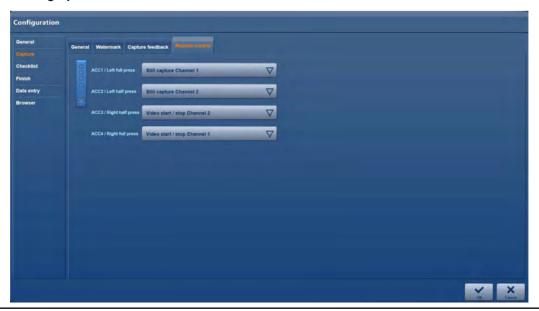
In this section, you can set the corner of the screen where the still image is to be displayed.

Video

In this section, you can set whether a symbol is to be shown on the surgical screen during video recording.

'Remote Control' menu

Setting up the remote control



2-24 96296082EN / BA



In this menu, you can specify the assignment and functioning of the remote control. Depending on the installation, the remote control can be set up for the footswitch or, if necessary, also for the camera head. If a footswitch is connected, set this up first of all.

- 1. Set up the assignment of the footswitches for all operating options.
 - a. If a dual footswitch is connected, set up all four operating options (left/right pressed all the way down/pressed half way down) as described below.
 - b. If a single footswitch is connected, deactivate the operating options right pressed all the way down/pressed half way down by setting **None**. Set up the operating options left pressed all the way down/pressed half way down as described below.

Select **Still capture Channel 1** if an image is to be captured from source 1 when the footswitch is operated accordingly.

Select **Still capture Channel 2** if corresponding operation of the pedal should result in image capture from source 2.

Select **Still capture Channels 1 & 2** if an image is to be captured from source 1 and source 2 at the same time when the footswitch is operated accordingly.

Select **Video start/stop Channel 1** if video recording from source 1 is to be started/stopped when the footswitch is operated accordingly.

Select **Video start/stop Channel 2** if video recording from source 2 is to be started/stopped when the footswitch is operated accordingly.

Select **Video start/stop Channels 1 & 2** if video recording from sources 1 and 2 is to be started/ stopped at the same time when the footswitch is operated accordingly.

Select **None** if no action is to be taken when the footswitch is operated accordingly.

Setting up remote control for the camera head buttons

If a footswitch is connected, set this up first of all.

The connections for the two camera head buttons are defined on setting up the footswitch.

1. Connect the camera head buttons to the connection sockets which meet your requirements in terms of footswitch assignment.

Ensure that the operating options of the footswitch and connection sockets for the camera head buttons correspond:



ACC1: Left pressed all the way down/image capture channel 1

ACC2: Left pressed half the way down/image capture channel 2

ACC3: Right pressed half the way down/start/stop video channel 2

ACC4: Right pressed all the way down/start/stop video channel 1



2.7.3 'Checklist' module

'General' menu



Storage locations of the checklist templates

Entering the path

The checklist templates can be located locally on the hard disk or on the facility server. The paths are preset to match the storage location on the computer's hard disk.

- 1. If necessary, specify the storage location for the checklist templates and enter the path under **Checklist storage path**.
- 2. If necessary, specify the storage location for the company logo in the report. To do this, tap on Browse and set up the link to the logo storage location.

Positioning the logo in the report



1. Under Horizontal alignment of logo, specify the horizontal alignment of the logo.

2-26 96296082EN / BA





2. Under **Vertical alignment of logo**, specify the vertical alignment of the logo.



2.7.4 'Finish' module

'Automatic' and 'Manual' menu



Specify the targets for automatic data saving in the Automatic menu. In the **Manual** menu, specify the targets for manual, optionally selectable data saving.

- 1. Under [Select ...], select a target which you wish to include in data saving.
- 2. Tap on Add.
- Your selection is included in the list of targets.
- **NOTE:** If you wish to delete a target from the list, highlight it and tap on **Remove**.
 - 3. Repeat the first two steps for all targets which are to be included in data saving.
 - 4. For each target, specify which data you wish to have saved. For this, if necessary, place or remove the checkmarks next to **Stills, Videos** and **Checklist**.
- NOTE: In principle all data is saved when saving manually.
 - 5. Specify for each target whether the saved data is to be called up again for display and processing.
 - For this, if necessary, place or remove the check mark next to **Reference**.
 - 6. Specify whether the data in the module **Open tasks** is to be protected before deletion. For this, if necessary, place or remove the check mark next to **Removable**.
 - 7. Configure the target.

2-28 96296082EN / BA



Data saving on the facility's DICOM server

NOTE: You can configure several DICOM servers.



Under **Name**, enter a designation for the DICOM server. Select an **individual designation** for each server as these are required by the system for identification.

Under Server AET, enter the AE title of the DICOM server.

Under Server IP, enter the IP address of the DICOM server.

Under **Server Port**, enter the port of the DICOM server.

Tap on **Echo** to test the connection.

If the connection test fails, there is probably an error in the network connection or in the entered server access data.

NOTE: Consult with your facility's IT department as regards connection problems.

Set the **Timeout** time.

• If only still images are to be saved:

Timeout: **30** seconds

• If still images and video recordings are to be saved:

Timeout: 120 seconds

Video format for DICOM exports

If a 3D camera is connected and a 3D video is being recorded, a 2D video will be created as well as the 3D video during the creation of the MPEG2 MP@ML. Only the 2D video will be transmitted when transferring in MPEG2 MP@ML format.

The following video formats are available for video data export.

Same as the record settings

Exports the video data in the same format as the recording.

NOTE: If the DICOM server does not accept this video format, then AIDA will automatically send the video in MPEG2 MP@ML format.

MPEG2 MP@ML

MPEG2 MP@ML is a video-streaming format with the profile MP and the level ML.



Saving data on a USB stick



Under Name, enter a designation for the target.

Under **Template**, select the nature of the report which is to be added to data saving.

- For each template type, select how many columns the report is to be divided into.
- Select **Procedure** if in the configuration for the user interface several input masks are set up for the procedure data.
- Select **Simple** if in the configuration for the user interface a single input mask is set up for input of the procedure data.
- Select Image if you want an anonymous report only with the images created and the header.
- Select Image, ..., No header if you want an anonymous report only with the images created.



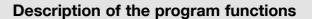
WARNING: When an anonymous report is printed, there is a risk of mix ups and of the report being assigned to the wrong patient.

- Select No PDF if you do not want an additional report.
- Select **No logo** if you want a report with 4 images per page.



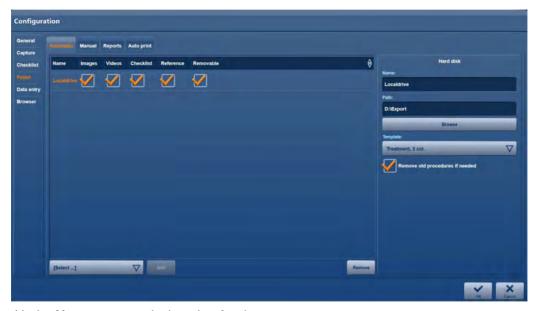
WARNING: Please note that when transferring data to a USB stick, the transfer process will need to be complete before the system is switched off. Otherwise, data may be lost.

2-30 96296082EN / BA





Saving data on a hard disk



Under Name, enter a designation for the target.

Under Path, enter the path or tap on Browse in order to select the target directory for saving data.

Place or remove the check mark next to **Remove old exports as necessary** if you wish to allow new storage space to be created as necessary by deleting older files.





Data saving on an FTP, StreamConnect® server or network share



NOTE: There is no option for using FTP, DICOM or StreamConnect® as references. If Reference is activated, then it will still be possible to view data on the medium (e.g., USB, hard disk) after the export.

Under **Name**, enter a designation for the target.

Under Server or Path, enter the target directory for saving data.

Under Login/(Network Share) Username, enter the login name for the server.

Under **Password**, enter the password for accessing the server.

Under **Template**, select the nature of the report which is to be added to data saving.

- For each template type, select how many columns the report is to be divided into.
- Select **Procedure** if in the configuration for the user interface several input masks are set up for the procedure data.
- Select **Simple** if in the configuration for the user interface a single input mask is set up for input of the procedure data.
- Select Image if you want an anonymous report only with the images created and the header.
- Select Image, ..., No header if you want an anonymous report only with the images created.



WARNING: When an anonymous report is printed, there is a risk of mix ups and of the report being assigned to the wrong patient.

- Select **No PDF** if you do not want an additional report.
- Select **No logo** if you want a report with 4 images per page.

2-32 96296082EN / BA



Printing automatically at the end of the procedure



Set up automatic printing on conclusion of the procedure in the **Automatic** menu.

- 1. Under [Select...], select 'Printer' and tap on Add.
- Your selection is included in the list of targets.



- **NOTE**: If you wish to delete a target from the list, highlight it and tap on **Remove**.
 - Specify which data you wish to print automatically.
 For this, if necessary, place or remove the checkmarks next to Stills, Checklist and Removable
 - 3. Configure the printer.
 - 4. Under **Name**, enter a designation for this printing procedure.





Under **Template**, select the type of report which you wish to use for automatic printing.

For each template type, select how many columns the report is to be divided into.

Select **Procedure** if in the configuration for the user interface several input masks are set up for the procedure data.

Select **Simple** if in the configuration for the user interface a single input mask is set up for input of the procedure data.

Select Image if you want an anonymous report only with the images created and the header.

Select Image, ..., No header if you want an anonymous report only with the images created.



WARNING: When an anonymous report is printed, there is a risk of mix ups and of the report being assigned to the wrong patient.

Select No PDF if you do not want an additional report.

Select **No logo** if you want a report with 4 images per page.

2-34 96296082EN / BA





Under **Printer**, select the printer which you wish to use for automatic printing.

'Reports' menu

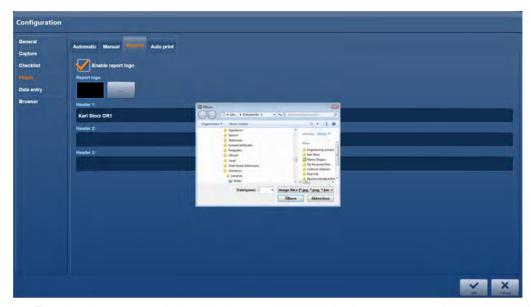
Setting up the surgical report



Set up the surgical report in the Reports menu.

- 1. Under **Header 1**, select a standard title for the surgical report.
- 2. If desired, specify further standard titles for the surgical report under **Header 2** and **Header 3**.



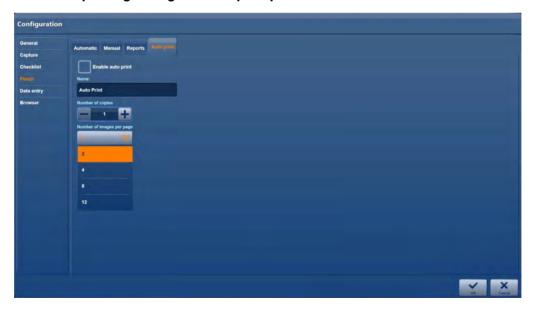


3. To select the watermark logo for the report, tap on the button next to the Logo input field. Navigate to the storage location of the logo, highlight the file and tap on **Open**.

'Autoprint' menu

(i)

Automatic printing during the Auto print procedure



Set up automatic printing for regular printing during the ongoing procedure once the specified number of images for printing has been reached in the **Auto print** menu.

- 1. Place or remove the check mark next to **Enable auto print** in order to activate or deactivate automatic printing.
- 2. Under **Name**, enter a designation for this printing procedure.
- 3. Under **Number of copies**, set the number of copies which are to be printed automatically.
- 4. Under **Number of images per page**, specify the number of images which are to be placed on each page. Printing starts automatically once this number has been reached.

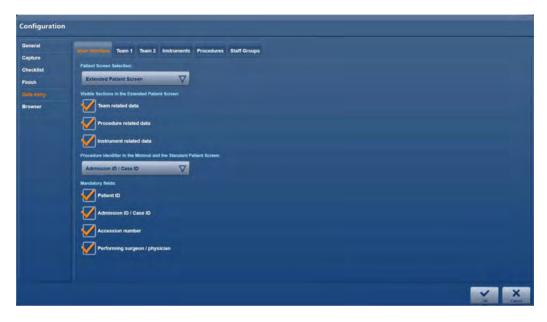
NOTE: The remaining images are automatically printed at the end of the procedure.

2-36 96296082EN / BA



2.7.5 'Data entry' module

'User interface' menu



In the **General** menu, specify the possible documentation scope and options under the User interface tab.

Selecting the patient input mask

You can choose from three different entry screens depending on the specific requirements.

- Minimal patient entry
- Standard patient entry
- Extended patient entry

Visible sections for extended patient entry

Define the scope of documentation which is to be available for each procedure.

- Place a check mark next to **Team related data** if the surgical team is to be documented in full.
- Place a check mark next to **Procedure related data** if the nature of the procedure is to be documented in full.
- Place a check mark next to Instrument related data if the instruments used are to be documented in full.
- Remove the check marks if you wish to restrict the documentation to
 - patient data, including the anatomical region and body side
 - medical specialization
 - nature of the surgical procedure
 - responsible surgeon



Intervention identifier shown in the minimal and standard patient input mask

Specify which of the following numbers are to be used for primary identification of the patient here.

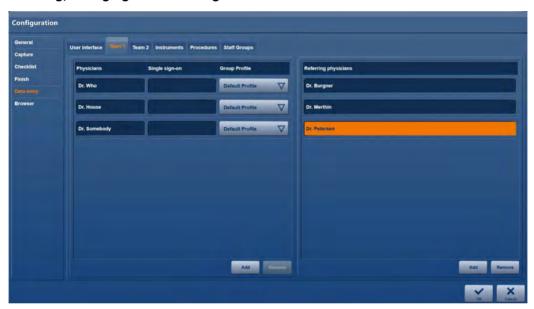
- Case number
- Order number

Mandatory fields

Specify which mandatory fields are to be included for data entry here.

'Team 1' and 'Team 2' menu

Creating, changing and removing resources



In the input masks **Team 1** and **Team 2**, enter the existing personnel resources so as to make these available to the user in the selection lists on the user interface.

Enter the data in a DICOM-compliant manner in the order stated and separated by commas.

[Last name, first name, middle name, title, prefix/suffix]

Example: Team 1



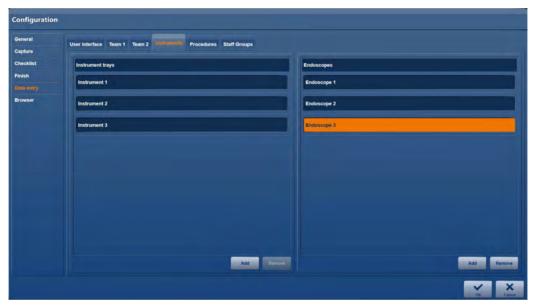
NOTE: If you wish to delete an entry from the list, highlight it and tap on Remove.

2-38 96296082EN / BA



'Instruments' menu

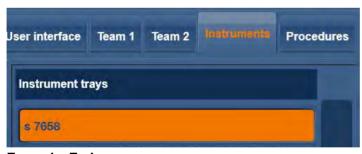
Creating, changing and removing IDs and serial numbers of medical equipment



In this input mask, enter the available IDs of trays (instrument trays) and the serial numbers of endoscopes so as to make these available to the user in the selection lists on the user interface.

1. Enter the data.

Example: Instrument trays



Example: Endoscopes



NOTE: If you wish to delete an entry from the list, highlight it and tap on Remove.



'Procedures' menu

Creating, changing and removing procedures in the procedure list



In this input mask, you can add new procedures or change and remove existing ones.

Creating a new entry

- NOTE: The procedure list is pre-set as per the DICOM standard. Consult with the PACS archive management before making any changes.
 - 1. Tap on Add.
 - 2. Enter the medical specialization under **Clinical speciality**, e.g., urology.
 - 3. Enter the nature of the surgical procedure, e.g., cystoscopy, under **Procedure name**.
 - 4. Enter the anatomical region of the procedure, e.g., bladder, under **Anatomic region**.

2-40 96296082EN / BA



Creating keywords



- 1. Mark an entry in the **Procedure name** column
- 2. Then click on **Add a** in the **Keywords** column.
- 3. Enter a keyword in the orange field.
- 4. Press **OK** to confirm the entry.

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Description of the program functions

Profile management

The application allows you to save different configuration screen settings in relation to personnel and personnel groups, and to use these in the form of **profiles**. Profile management is split into 3 categories.

Default profile (preset)

This profile is pre-defined and contains all settings for administering the application.

Editing the default profile:

- (i) NOTE: The user account OR1User is set as the default:
 - 1. Click on the configuration button and log in with the role of Application Administrator.
 - Once logged in, the Manage profile dialog window will appear.



- 2. Click on the selection list and select the entry **Default Profile**.
- 3. Then click on Edit.
- Once the configuration screen has opened, you will be able to edit the standard profile.

Group profile (optional)

This profile allows you to allocate different settings to personnel groups in addition to the default profile, such as the creation of field-related export destinations. Group profiles contain fewer setting options than the default profile.

Activating a group profile

- 1. To create group profiles, open the configuration as an Application Administrator and then go to 'User administration'.
- 2. Place a check mark next to ,Activate group profile'.

2-42 96296082EN / BA



Creating a group profile

- **NOTE:** The user account **OR1User** is set as the default:
 - 1. Click on the configuration button and log in with the role of Application Administrator.
 - Once logged in, the Manage profile dialog window will appear.



- 2. Enter the desired group name in the text field, e.g., 'Gynecology'.
- 3. Then click on Create.
- NOTE: Once the configuration screen has opened, you will be able to edit the **Gynecology** group profile.

Editing a group profile



1. In the Manage profile dialog window, select the group name and click on Edit.

Deleting a group profile



1. In the **Manage profile** dialog window, select the group name and click on **Delete**.

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Description of the program functions

Assigning a group profile

- 1. Log in as an Application Administrator and open the default profile.
- 2. Go to the **Team 1** screen in the **Data entry** section.
- NOTE: The default profile will be assigned to a newly created or imported physician as standard.



3. You can now assign a new profile in the 'Group profile' column.

User profile (optional)

This profile should only be created if an **Attending Physician** wishes to make settings that deviate from his or her assigned standard or group profile. In order to set up a user profile, the user account will need to be available with the authorizations granted to the Configuration User role. (see Role administration)

Creating a user profile

- 1. Log in to the application with your user name.
- Once logged in, the Manage profile dialog window will appear, showing the currently assigned standard or group profile.



- 2. Select Edit.
- The configuration screen then opens, with a reduced selection of settings that can be personalized.

2-44 96296082EN / BA





3. To delete the user profile, click on **Reset** in the **Manage profile** dialog window.

The special significance of the Attending Physician

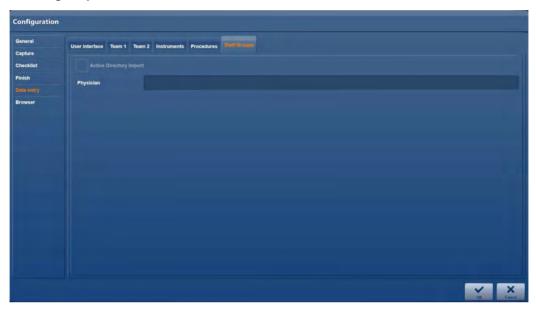


At the start of a new procedure, the **Attending Physician** will firstly need to be selected on the patient screen. He or she will be assigned to the default or group profile loaded for the procedure, including the import and export destinations for example, and the configuration of the **Capture** module. If the procedure is concluded via the **Exit** module, the procedure will be assigned to the Attending Physician. They will then be able to import the procedure in the **Filing Cabinet** module of his or her user account.

NOTE: If no Attending Physician is selected, the default profile will be active. Procedures that have not been assigned to a physician can only be imported by a **Super User**.



"Stuff groups' menu



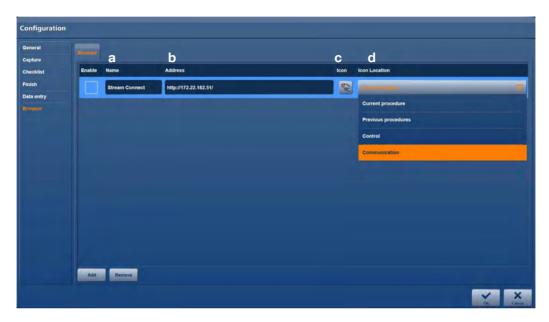
- 1. Place a check mark next to **Active Directory Import**.
- 2. In the **Physician** text field, enter the group name that was assigned for the required group in the Active Directory by the IT Department.
- 3. Please exit the configuration in order to save it.
- 4. Please open the configuration again and go to the Data entry > Team 1 screen.
- The imported entries are displayed under **Physicians**.
- NOTE: 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. The group content is updated in the background once a day when there is a connection to the Active Directory server.

2-46 96296082EN / BA



2.7.6 'Browser' module

'Browser' menu



One or more connections to, for example, streaming servers, cloud services or Internet services can be established in the **Browser** menu.

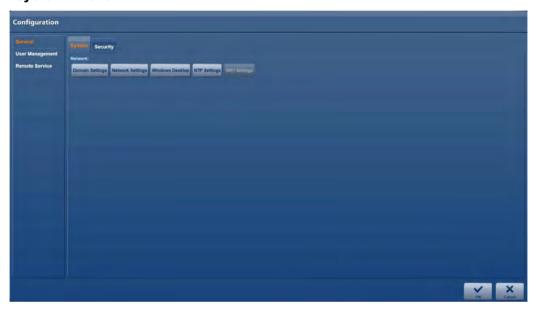
- **NOTE:** Up to 5 web-based third-party products can be integrated into the KARL STORZ AIDA®.
- **NOTE:** Web-based KARL STORZ/third-party products may only be used if they have been verified and approved by KARL STORZ. Additional system information can be found in the KARL STORZ AIDA® white paper. For further information, please contact your responsible KARL STORZ OR1® contact partner.
 - 1. Enter the name **a** of the server or service.
 - 2. Enter the corresponding address **b**.
 - 3. Choose a matching icon c.
 - 4. Select an appearance location **d** on the start screen.
- **NOTE:** We recommend restarting the system once configuration is complete.



2.8 Configuration for System-Administrator

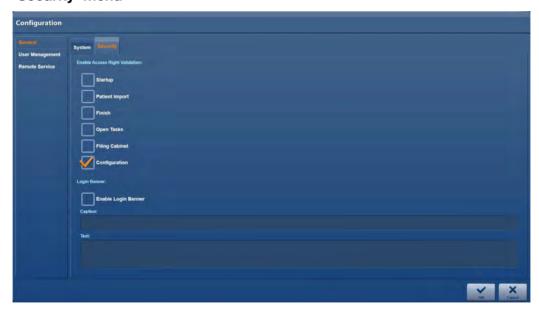
2.8.1 'General' module'

'System' menu



In the System menu, you can manage various system settings such as network or WLAN settings.

'Security' menu



In the **Security** menu, you can increase the system security:

Activate access control

You can make access to the listed modules subject to an access control by placing a check mark next to the corresponding module.

2-48 96296082EN / BA



Activate information window after successful login

You can activate an information message that will be displayed to all users once they have logged in. This message is stored in the Microsoft Active Directory as standard. If this message is not pre-stored, you can create the title and message text yourself.

In the **Title** field, enter the title of the information window.

In the **Text** field, enter the information text.



2.8.2 'User administration' module

'Role administration' menu



As part of IT security, the application allows users to assign access rights to definable groups of people. The following roles with the assigned groups are preset, and can be used for independent operation without the need for any further configuration.

| Role | Group | Field of activitiy | Authorization | |
|------------------------------|----------------------------|---|--|--|
| System Administrator | Administrators | IT department | Adjusting settings at operating system level | |
| Application Administrator | Application Administrators | Responsible for the configuration of an application | Adjusting settings at application level | |
| Confuguration User | Settings Users | Attending Physician | Creating personal user profile | |
| Super User | Super Users | Chief Physician | Access to all entries in 'Open Tasks' and all data in 'Filing Cabinet' | |
| Users | Users | Attending Physician | Access to own entries in 'Open Tasks' and own data in 'Filing Cabinet' | |
| Auditor | Auditors | Auditor | Access to the application's system and security protocols | |

2-50 96296082EN / BA



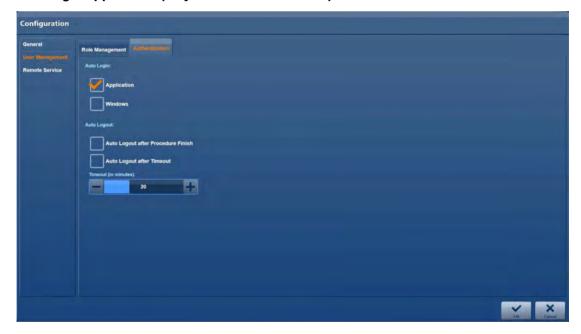
The installed users and user groups are assigned as follows:

| | System Administrator | Application Administrator | Configuration User | Super User | Users | Auditor |
|----------|-------------------------|------------------------------|-----------------------|---------------|-------|---------|
| OR1User | | X | | Х | Х | Χ |
| OR1Admin | X | | | | | |

To use your own groups, e.g. when using the Microsoft Active Directory, you can replace the pre-defined data with your own group names in the relevant text fields. As access rights for the application can be combined, you can enter multiple entries in one text field, separated by commas.

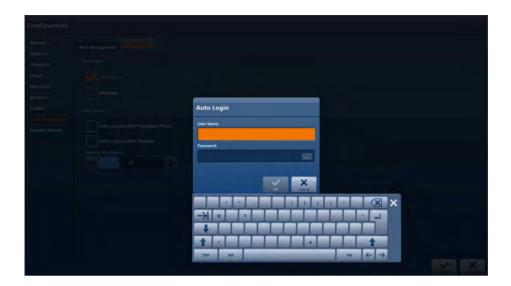
Authentication

Auto login/application (only accessible for Admin)



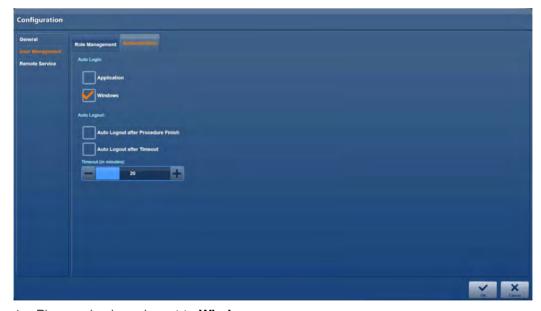
- 1. Place a check mark next to **Application**.
- The Auto login screen opens.





- 2. Enter the user to be notified automatically after start-up.
- NOTE: If Application is not activated, no user will be notified after start-up.

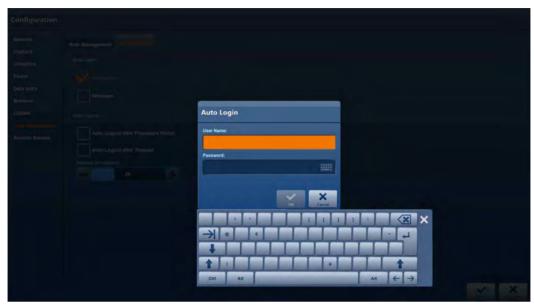
Auto login/Windows (only accessible for System Admin)



- 1. Place a check mark next to **Windows**.
- ▼ The Auto login screen opens.

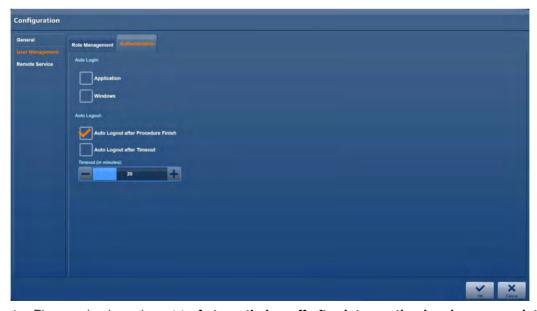
2-52 96296082EN / BA





- 2. Enter a user for whom the system is to start.
- NOTE: If Windows Auto Login is not activated, a user will need to log in to Windows manually in the Microsoft Windows Active Directory each time the system is started up!

Auto logout after completion of the procedure

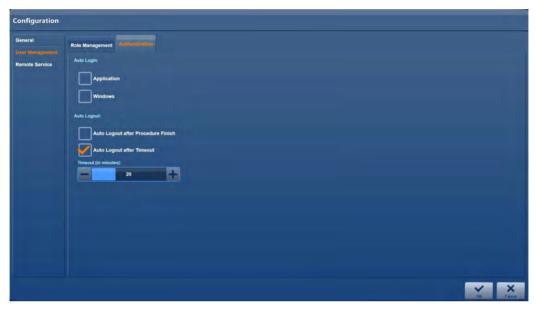


- 1. Place a check mark next to **Automatic log off after intervention has been completed**.
- 2. At the end of the procedure, click on Finish.
- The current user will be logged out.

KARL STORZ AIDA® 2-53



Auto logout after timeout



- 1. Place a check mark next to Automatic switch off after timeout.
- If no action is performed within the specified time, the current user will be logged out.

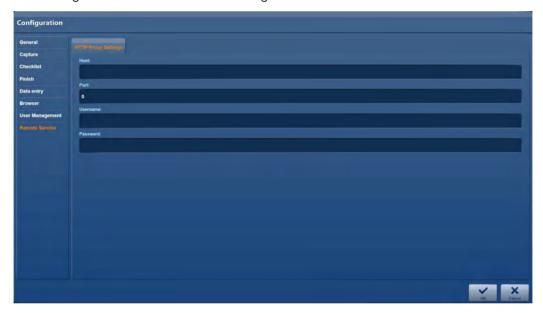
2-54 96296082EN / BA



2.8.3 'Remote Service' module

KARL STORZ AIDA® Remote Service is a device interface to KARL STORZ via which we aim to guarantee our customers an efficient and comprehensive service. This allows for largely smooth and failure-free surgical operations for users. Relevant device parameters can be made available to KARL STORZ automatically via Remote Service. Depending on the situation, the customer can provide the KARL STORZ service technician with direct VNC access to the KARL STORZ AIDA® via a secure connection.

Depending on the hospital network configuration, it may be necessary to enter details of an HTTP proxy host in order to establish the KARL STORZ AIDA® Remote Service connection to KARL STORZ. This setting can be made in the AIDA configuration menu.



NOTE: Details of the host and port must be provided as a minimum in order for access to be granted via the proxy server. Depending on the configuration, it may also be necessary to enter the user and password.

Deactivating Remote Service

You must log on as the Administrator to deactivate the Remote Service.

1. Start AIDA.



- 2. Click on Windows Desktop.
- 3. Log in again.

KARL STORZ AIDA® 2-55



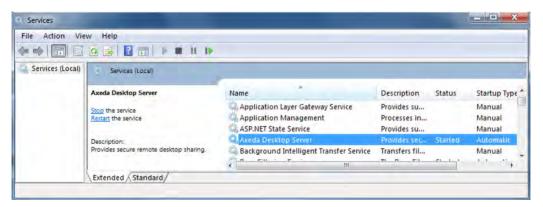
Deactivating Remote Service Windows services

1. If possible, start the services by tapping on **Service** or entering **Service** in the search field.





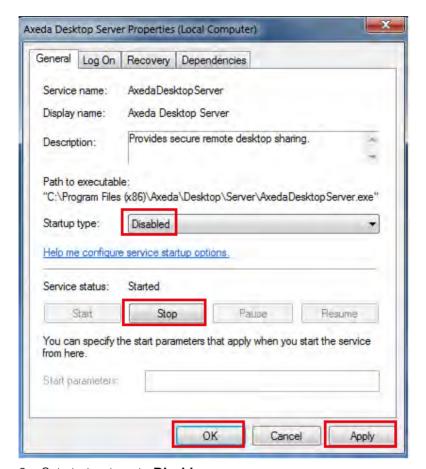
Deactivating Axeda Desktop Server service



- 1. Right-click on Axeda Desktop Server and select Properties.
- The Server Properties window opens.

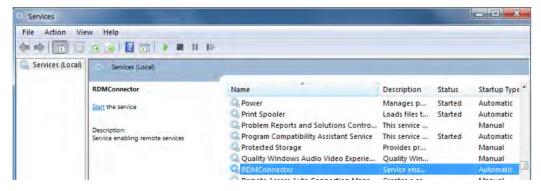
2-56 96296082EN / BA





- 2. Set startup type to **Disable**.
- 3. Stop the service by clicking on **Stop**.
- 4. Click on Apply.
- 5. Close the window by clicking on **OK**.

Deactivating the RDM Connector

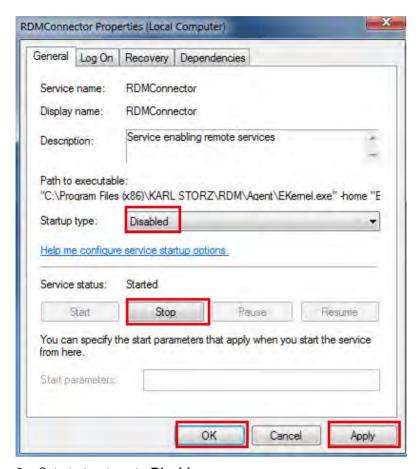


1. Right-click on **RDMConnector** and select **Properties**.

The RDMConnector Properties window opens.

KARL STORZ AIDA® 2-57





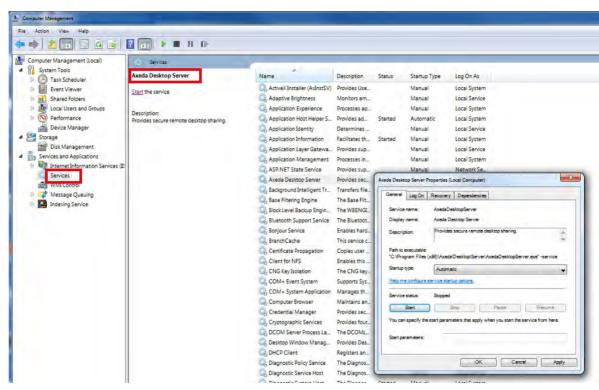
- 2. Set startup type to **Disable**.
- 3. Stop the service by clicking on **Stop**.
- 4. Click on **Apply**.
- 5. Close the window by clicking on **OK**.

2-58 96296082EN / BA

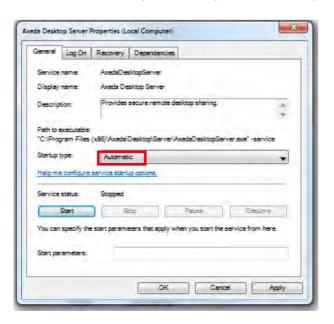


Activating Remote Service

- 1. Log on to the system as the Administrator.
- 2. Restart the Computer Management console.



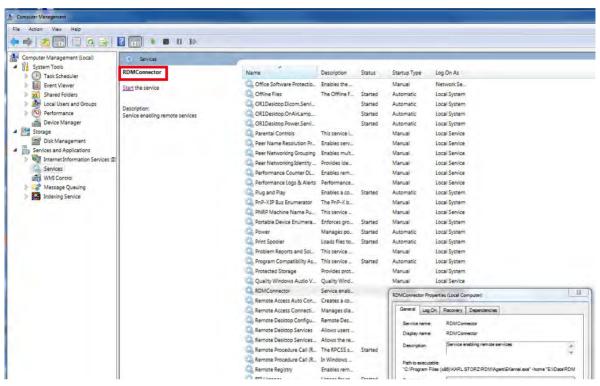
- 3. Open Computer Management (local)/Service and Applications/Services.
- 4. Select the Axeda Desktop Server.
- 5. Open Properties.
- The Axeda Desktop Server Properties window opens.



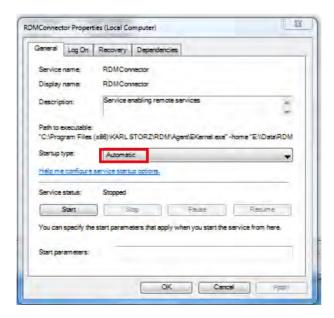
KARL STORZ AIDA® 2-59



6. Set start type to Automatic.



- 7. Activate the RDM Connector service.
- 8. Open Properties.
- ▼ The RDM Connector Properties window opens.



- 9. Set start type to **Automatic**.
- 10. Restart the system.

2-60 96296082EN / BA



3.1 Requirements

The AIDA recovery USB stick is inserted.

3.2 KARL STORZ AIDA® recovery

- 1. Start the WD300.
- 2. To access the drive selection window, press the **F12** key as soon as the KARL STORZ window opens.



- The password input window opens.
- 3. Enter the password. The standard password is 123456.



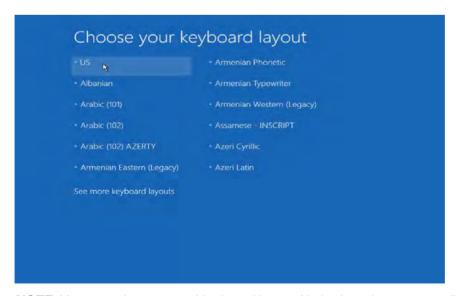
KARL STORZ AIDA® 3-1



The following window opens.



- 4. Select the USB drive as the boot device.
- NOTE: The name is that of the physical USB drive. In the above window, this is SanDisk. This is normally the third entry in the list.
 - 5. Select the USB drive as the boot device and confirm the selection by pressing the **Enter** button.
 - The following screen appears after a brief period.

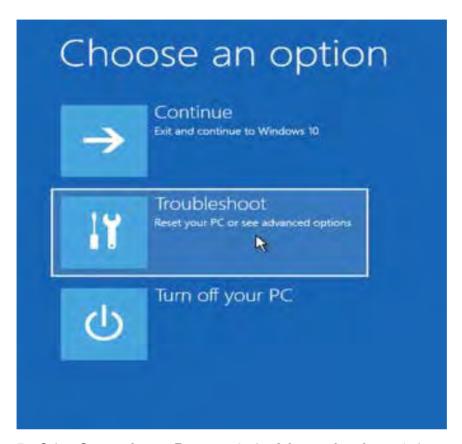


NOTE: You can select a special keyboard layout. No keyboard entry is usually required for the following procedure. For this reason, you can press **US**.

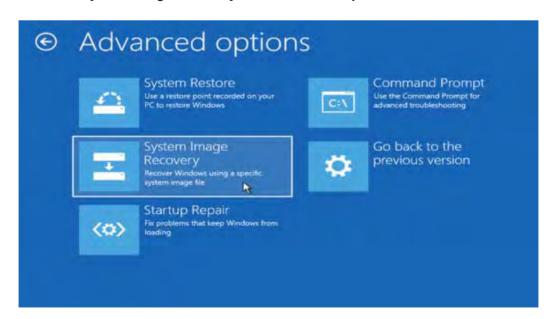
3-2 96296082EN / BA



6. Click on **Troubleshoot** in the next window.



7. Select **System Image Recovery** in the **Advanced options** window.



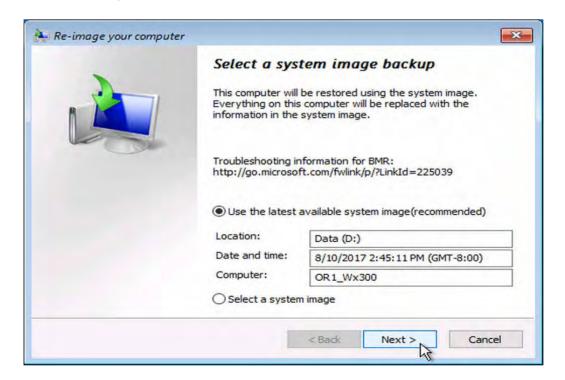
KARL STORZ AIDA® 3-3



8. The following window appears when the C drive is open.



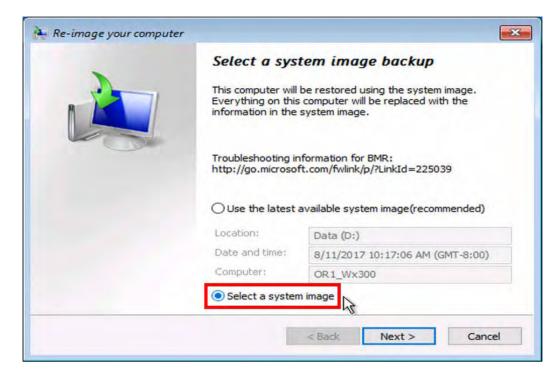
- 9. Click on Windows 10.
- NOTE: If you have installed a new SSD drive, this window may not appear.
 - The following window opens.



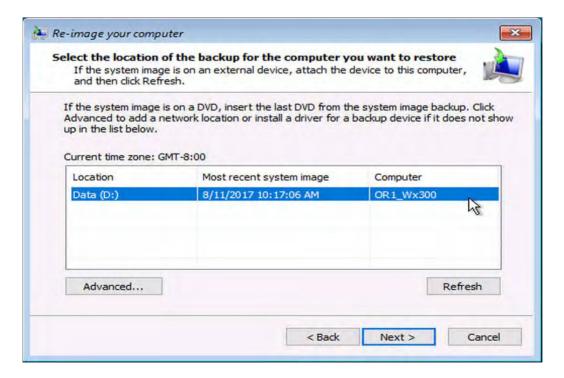
- 10. Select the operating system.
 - a. If the latest backup, which is normally on drive $\bf D$, is found, click on $\bf Next$ and proceed with step 12.

3-4 96296082EN / BA





- b. If no backup is found or if you wish to select a particular backup, click on **Select a system image** followed by **Next**.
- The following window opens.

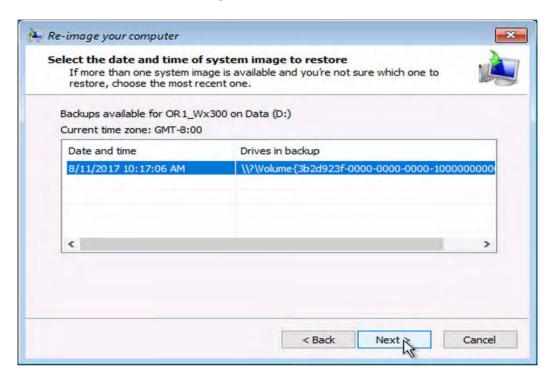


11. Select a backup and click on Next

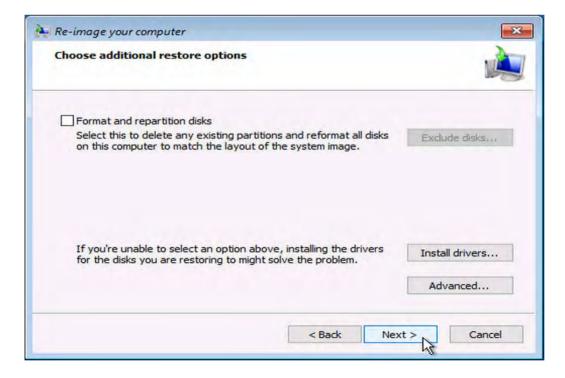
KARL STORZ AIDA® 3-5



12. Select a backup in the following window and click on **Next**.



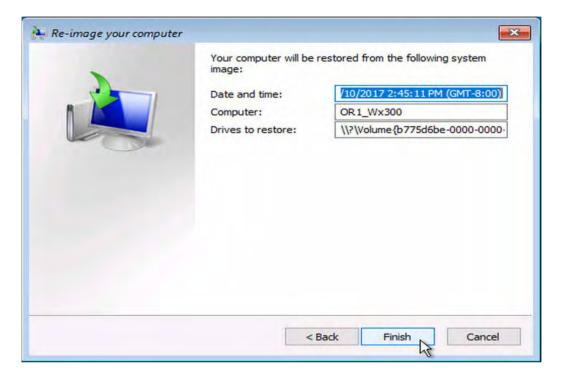
The following window opens in both cases.



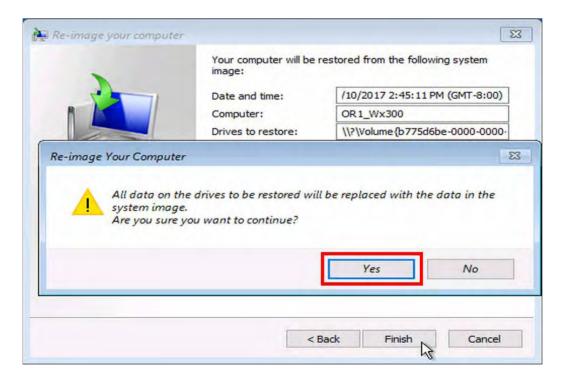
13. Click on Next.

3-6 96296082EN / BA





14. Confirm the settings for the backup by clicking on Finish.

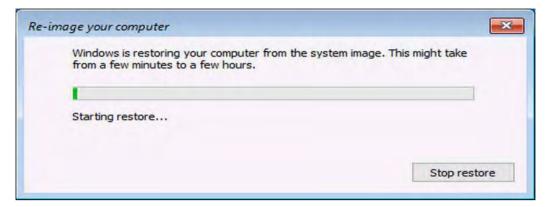


15. Confirm the warning by clicking on **Yes**.

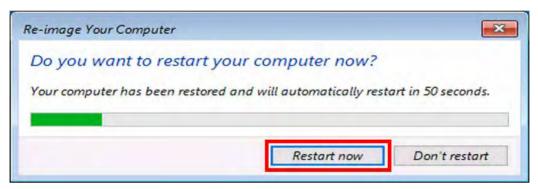
16. Wait until **re-imaging** is complete.

KARL STORZ AIDA® 3-7





- Once re-imaging is complete, the WD300 starts automatically after 60 seconds.
- 17. You can skip the waiting time by clicking on Restart now.



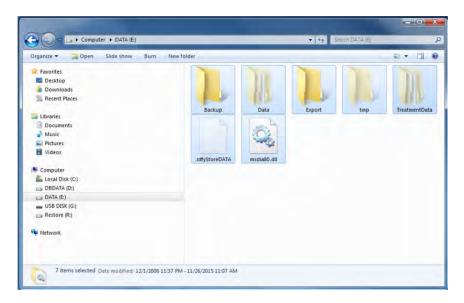
- The WD300 normally starts up in Windows 10.
- Drive C now has the same status as it had prior to the system image backup

3-8 96296082EN / BA

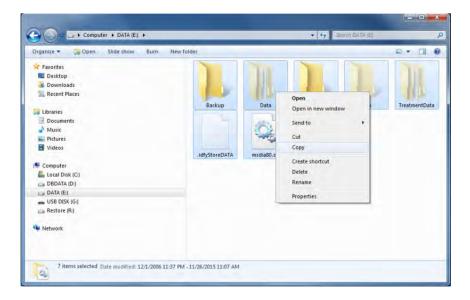


3.3 Backing up data from the (D:) hard disk drive

- 1. Click on **Windows Explorer** in the task bar.
- The Windows Explorer window opens.



- 2. Select the DATA (D:) drive.
- 3. Select all the folders and data in this drive.
- 4. Click on the right mouse button.
- The selection menu opens.



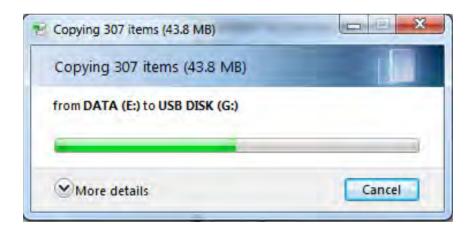
- 5. Click on Copy.
- 6. Select the removable media, e.g., USB DISK.
- 7. Click on the right mouse button.
- The selection menu opens.

KARL STORZ AIDA® 3-9





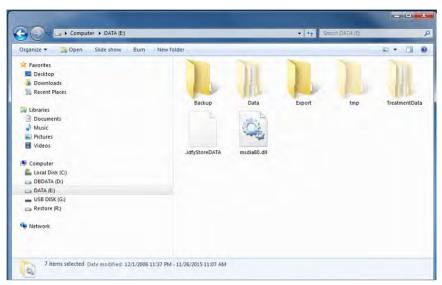
- 8. Click on Paste.
- ▼ The data are saved on the removable media, e.g., USB DISK.
- Copying progress is displayed.



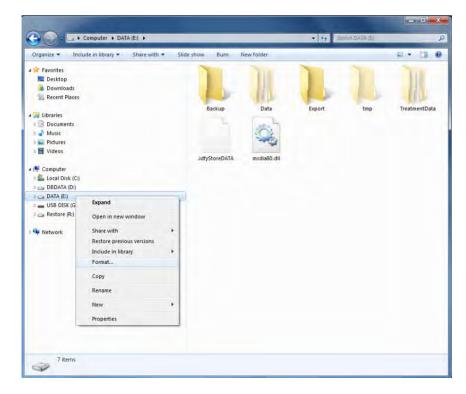
3-10 96296082EN / BA



3.4 Deleting data on the (D:) hard disk drive



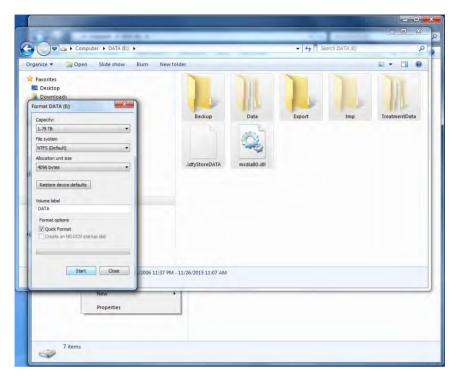
- 1. Select the **DATA (D:)** drive.
- 2. Click on the right mouse button.
- The selection menu opens.



- 3. Click on Format...
- 4. The Format DATA (D:) window opens.

KARL STORZ AIDA® 3-11





- 5. Click on Start.
- The data are deleted from the drive.

3-12 96296082EN / BA



4 Behavior in exceptional situations

4.1 Hard shutdown

If you want to perform a hard shutdown, proceed as follows:

- 1. Press the power button for 5 seconds.
- The system is switched off.

4.2 Reboot (cold, warm start)

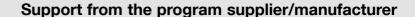
NOTE: When the Windows start menu appears, always start in Normal mode.

KARL STORZ AIDA® 4-1





4-2 96296082EN /BA





5 Support from the program supplier/manufacturer

5.1 Contact address for the user

KARL STORZ SE & Co.KG Abt. Reparaturservice Take-off Gewerbepark 83 78579 NEUHAUSEN, Germany

5.2 Service hotline

Tel.: +49 (0)7461/708 980

E-mail: technicalsupport@karlstorz.com

5.3 Education, training, internet etc.

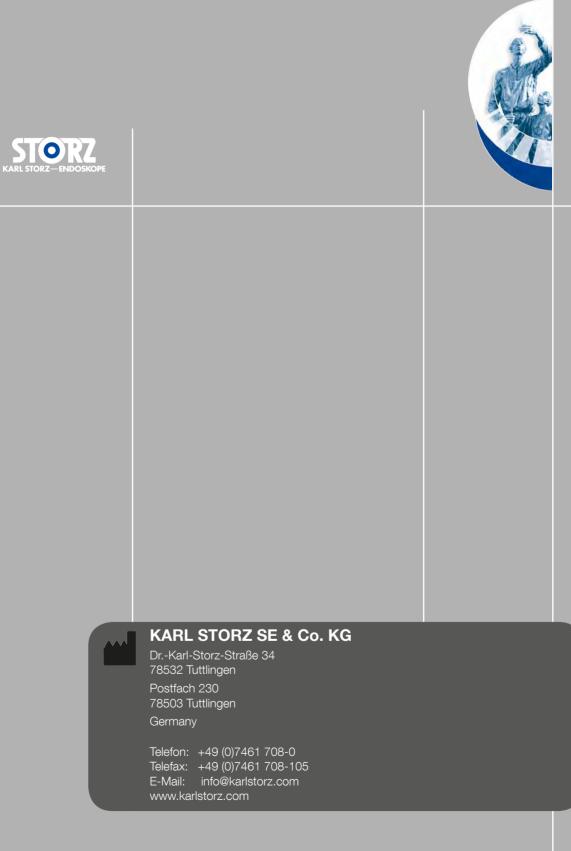
If you need training, contact KARL STORZ SE & Co. KG directly. KARL STORZ offers training seminars for different target groups at various levels.

KARL STORZ AIDA® 5-1



Support from the program supplier/manufacturer

5-2 96296082EN / BA



SICORZ KARL STORZ—ENDOSKOPE







Welcome

Thank you for your expression of confidence in the KARL STORZ brand name. Like all of our other products, this product is the result of years of experience and great care in manufacture. You and your organization have decided in favor of a modern, high-quality product from KARL STORZ.

Copyright

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Contents



Contents

| 1 | Important information for safe use | 1-1 |
|-------|--|-----|
| 1.1 | Details for the identification of the device | 1-1 |
| 1.2 | Details for the identification of the instruction manual | 1-1 |
| 1.3 | Designation of groups of people | 1-1 |
| 1.3.1 | Operators | 1-1 |
| 1.3.2 | Users | 1-1 |
| 1.3.3 | Specialists | 1-1 |
| 1.4 | Notes for operators | 1-2 |
| 1.4.1 | Initial commissioning | 1-2 |
| 1.4.2 | Availability of the instruction manual | 1-2 |
| 1.4.3 | Warranty | 1-2 |
| 1.5 | Information for users | 1-3 |
| 1.5.1 | Training in the operation of the device | 1-3 |
| 1.5.2 | Obligation of the user to check and inform | 1-3 |
| 1.6 | Intended use of the device | 1-3 |
| 1.6.1 | Labeling | 1-3 |
| 1.6.2 | Standards and dirctives | 1-3 |
| 1.6.3 | Intended use | 1-4 |
| 1.6.4 | Contraindication | 1-4 |
| 1.6.5 | Warnings and cautions: | 1-4 |
| 1.7 | Ambient conditions for operation and storage | 1-4 |
| 1.7.1 | Ambient conditions for storage and transport | 1-4 |
| 1.7.2 | Ambient conditions for operation | 1-4 |
| 1.8 | Disposal | 1-5 |
| 1.8.1 | Conventions in this instruction manual | 1-5 |
| 2 | Safety instructions | 2-1 |
| 2.1 | Explanation of warnings and cautions | 2-1 |
| 2.2 | General safety instructions | 2-1 |
| 2.3 | Safety precautions at the installation site | 2-2 |
| 2.4 | Safety measures during operation | 2-2 |
| 3 | Product description | 3-1 |
| 3.1 | Technical description | 3-1 |
| 3.2 | Symbols and labels | 3-1 |
| 3.2.1 | Packaging | 3-1 |
| 3.2.2 | Front of device | 3-2 |

Contents



| 3.2.3 | Back of device | 3-3 |
|-------|--|-----|
| 3.2.4 | Manufacturer's identification plate | 3-3 |
| 3.3 | Technical data | 3-5 |
| 3.4 | Connections | 3-6 |
| 3.4.1 | Front | 3-6 |
| 3.4.2 | Rear | 3-6 |
| 4 | Installation | 4-1 |
| 4.1 | Safety instructions | 4-1 |
| 4.2 | Unpacking | 4-1 |
| 4.3 | Installation and Comissioning | 4-2 |
| 4.3.1 | Minimum requirements | 4-2 |
| 5 | Maintenance | 5-1 |
| 5.1 | Safety instructions | 5-1 |
| 5.2 | Reprocessing | 5-1 |
| 5.2.1 | Legal requirements | 5-1 |
| 5.2.2 | Safety instructions | 5-1 |
| 5.2.3 | Required reprocessing agents | 5-1 |
| 5.2.4 | Required reprocessing materials | 5-2 |
| 5.2.5 | Wipe-down disinfection | 5-2 |
| 5.3 | Maintenance and repair | 5-2 |
| 5.3.1 | Maintenance plan | 5-2 |
| 5.3.2 | Changing the BIOS battery | 5-2 |
| 5.3.3 | Servicing | 5-2 |
| 5.4 | Repair program | 5-3 |
| 5.5 | Responsibility | 5-3 |
| 5.6 | Warranty | 5-3 |
| 6 | Accessories | 6-1 |
| 7 | Appendix | 7-1 |
| 7.1 | Information on electromagnetic compatibility (EMC) | 7-1 |
| 7.2 | Regulatory Statements Radio Equipment | 7-8 |
| 7.2.1 | USA | 7-8 |
| 7.2.2 | Canada | 7-8 |
| 7.2.3 | European Union | 7-8 |



1.1 Details for the identification of the device

This instruction manual is exclusively intended for the device which is available in two versions. The information on the manufacturer's identification plate clearly identifies the relevant version.

• Device designation: KARL STORZ AIDA®

• Type designation: **WD** 300

1.2 Details for the identification of the instruction manual

The material number and version number of this instruction manual are specified on all pages.

1.3 Designation of groups of people

The following three groups of people are named in this instruction manual.

1.3.1 Operators

The term operator applies to all individuals or legal entities:

- Who use the device themselves or allow a third party to use it in a doctor's practice, hospital, etc. and exercise actual physical authority over the device during operation.
- It is incumbent upon the operator to provide a safe device and properly instruct the user in the operation and intended use of the device.

1.3.2 Users

The term user applies to persons:

- Who, due to their education and the appropriate training provided by the persons delegated by the operator, are qualified to operate the device and work with it.
- Users are fully responsible for using the device safely and in accordance with its intended use.

1.3.3 Specialists

The term specialist applies to persons:

- Who have obtained their know-how via technical training in a medical or medical-technical field.
- Who are able to assess their work on the basis of professional experience and instruction in the safety-related regulations and recognize potential dangers whilst carrying out their work.
- In countries in which the performance of an activity in the medical or medical-technical fields is certified, the classification of individuals as specialist personnel assumes a corresponding accreditation.

KARL STORZ AIDA® **WD** 300



1.4 Notes for operators

- This device is produced in accordance with state-of-the-art technology and is safe to
 operate. Nonetheless, the device may still be a source of risk, especially if it is operated by
 personnel who are not adequately trained or if it is used incorrectly and for a purpose other
 than its intended use.
- The device must be operated, cleaned, and disinfected by specialist personnel only.



WARNING: All of the assembly work, disassembly work and setting adjustments described in this instruction manual must only be carried out by trained specialist personnel who have been delegated to do so by the operator.

For safety reasons, actions or interventions which extend beyond those described in
this manual must only be carried out by KARL STORZ or a company authorized by
KARL STORZ. Before a company can receive this authorization, the service personnel of the
company in question must successfully participate in a technical training course conducted
by KARL STORZ. Authorization is then granted for a fixed period of time.

1.4.1 Initial commissioning

- This instruction manual is valid following an initial commissioning procedure which has been properly carried out.
- The device must be thoroughly cleaned and disinfected before initial use.

1.4.2 Availability of the instruction manual

- The instruction manual is a component of the device and must therefore be kept at a location in the immediate vicinity of the device to enable reference to safety instructions and important information regarding its use at any time.
- Do not pass the device on to a third party without a valid instruction manual. With the aid of the identity number and version number, ensure that an up-to-date, valid instruction manual is passed on with the device.

1.4.3 Warranty

KARL STORZ guarantees the safe and proper functioning of the device only subject to the following conditions:

- The device is used only as designated and operated in accordance with the information provided in this manual.
- Only original replacement parts or accessories which are defined and approved by KARL STORZ SE & Co. KG are used. The use of other parts poses unknown risks and must be avoided at all times.
- No structural modifications are made to the device. Unauthorized modifications or alterations to the device or the software are not permitted for safety reasons and void the guarantee.
- Inspection and maintenance work is carried out in accordance with the prescribed time intervals.
- Initial commissioning has been performed.

1-2 96296081EN / BA



1.5 Information for users

• All of the actions described in this instruction manual must only be carried out by trained specialist personnel who have been delegated to do so by the operator.

1.5.1 Training in the operation of the device

- Training must be conducted by KARL STORZ, a company authorized by KARL STORZ, or a person delegated by the operator, and must provide direct, practical experience of operating the device.
- When the training has been completed, the user's understanding of the special actions required to operate the device in accordance with its intended use must be documented.

1.5.2 Obligation of the user to check and inform

- Read this instruction manual carefully before using the device for the first time. This is
 the best way to get the most out of the device and avoid potential injuries and material
 damage.
- The user must inspect the device to ensure that it is in proper condition and functioning correctly before every use or before handing it over for use by a third party.
- If particular problems arise which are not addressed in sufficient detail for you in this instruction manual, please consult your supplier for your own safety.

1.6 Intended use of the device

1.6.1 Labeling



CE-conformity marking: With this marking, the manufacturer declares the compliance of the product with the applicable regulations and directives.



CSA certification mark for the USA and Canada: With this marking, the manufacturer declares compliance with the certification requirements.

The manufacturer declares the conformity of this device with the essential requirements outlined in Annex I of the MDD and documents this by means of the CE mark.

Directive conformity

The **WD** 300 is a medical device in accordance to the Medical Device Directive 93/42/EWG (MDD). Risk class: I

1.6.2 Standards and dirctives

The device complies with the safety requirements of the following standards an directives:

- Electrical safety according to IEC 60601-1
 - Protection against electric shock: Class I ME Equipment
 - IP Classification: IPX0
- Electromagnetic Compatibility according to IEC 60601-1-2
- **NOTE:** Observe the information on electromagnetic compatibility in chapter 7.
 - 2014/53/EU Radio equipment Dirctive (RED)
 - Frequency band: 5 GHz
 - Maximum radio-frequency power transmitted in the frequency band: 250 mW
 - 2012/19/EU Waste electrical and electronic equipment directive (WEEE)
 - 2011/65/EU –Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS2)

KARL STORZ AIDA® **WD** 300 1-3



1.6.3 Intended use

The KARL STORZ AIDA® **WD** 300 is intended for use by qualified personnel in the Doctor's Office or Operating Room. The KARL STORZ AIDA® **WD** 300 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 the capture and the annotation of the surgical procedure for documentation purposes. Audio-visual data recorded and distributed by KARL STORZ AIDA® **WD** 300 are not intended for diagnostic or therapeutic purposes. Recorded audio-visual data is not intended for intraoperative display on the surgical monitor.

1.6.4 Contraindication

No contraindications were known at the time of printing. The use of this device is generally contraindicated if, in the opinion of an experienced physician, such an application presents an unjustifiable risk to the patient's health, e.g., due to the general condition of the patient.

1.6.5 Warnings and cautions:

The video signals and recordings shown may display artifacts as a result of compression and/or scaling.

The image preview on the touchscreen is not intended to be used for diagnostic and therapeutic purposes.

Signals in 3D and 4K are only correctly displayed on suitable display devices.

The display of image signals which do not originate from a KARL STORZ device may only be used for information purposes.

The data recorded with the system may only be used for documentation purposes, in particular

- Image information in printed form
- Image information which was compressed or recorded in non-native resolution
- Image information which originates from or was recorded by a device which was not manufactured by KARL STORZ



WARNING: Avoid allowing liquids to enter the device. Do not store liquids in the vicinity of the device. If liquids penetrate the device despite the precautionary measures, sufficient time should be allowed for evaporation.



WARNING: If any defects or shortcomings which could endanger patients, personnel or others are ascertained during these safety checks/repeat inspections, the device must not be operated until such time as these defects or shortcomings have been eliminated by qualified technical servicing.



WARNING: The device is not suitable for operation in potentially explosive atmospheres and oxygenated areas.



WARNING: Only insert the power plugs of individual devices into and remove them from electrical outlets located outside areas subject to explosion hazards.



WARNING: Shutting down the system whilst processing patient data results in the loss of image data. Only switch off the device using the ON/OFF switch.



WARNING: Damaged equipment components must only be maintained and repaired by KARL STORZ.

1-4 96296081EN / BA





WARNING: Connecting non-compatible signal types to the connection panel in the OR can cause picture interference and malfunctioning of the device. Only connect permitted signal types and perform device tests before use.

1.7 Ambient conditions for operation and storage

Different ambient conditions apply for the operation and intermediate storage of the device.

1.7.1 Ambient conditions for storage and transport

• Ambient temperature: -10 °C to 60 °C

• Relative humidity: 5 % to 95 %

• Atmospheric pressure: 500 hPa - 1080 hPa

1.7.2 Ambient conditions for operation

Ambient temperature: 5 °C to 35 °C
Relative humidity: 10 % to 90 %

• Atmospheric pressure: 700 hPa - 1080 hPa

• Max. hight above sea level: 3000 m

KARL STORZ AIDA® **WD** 300



1.8 Disposal

- The device meets the requirements of Directive 2011/65/EU RoHS (on the restriction of the use of certain hazardous substances in electrical and electronic equipment) and old electronic devices (waste electrical and electronic equipment WEEE).
- In order to avoid causing harm to the environment and to persons, we ask that you contact KARL STORZ SE & Co. KG, a KARL STORZ subsidiary or your specialist dealer for information on your local collection point if you permanently decommission the device with the aim of disposal.



WARNING: The device must be disposed of in accordance with the applicable national regulations at a suitable collection point for the recycling of electrical and electronic equipment.

• Within the scope of application of this Directive, KARL STORZ SE & Co. KG is responsible for the proper disposal of this device.

1.8.1 Conventions in this instruction manual

In this instruction manual the KARL STORZ AIDA® WD 300 is referred to as the device.

1-6 96296081EN / BA



2 Safety instructions

2.1 Explanation of warnings and cautions

The words Warning, Caution, and Note convey special meanings. Wherever they are used in this manual, they should be carefully reviewed to ensure the safe and effective operation of this system. To make these words stand out more clearly, they are accompanied by a pictogram.



WARNING: A Warning indicates that the personal safety of the patient or user may be endangered. Failure to observe a Warning could result in injury to the patient or user.



CAUTION: A Caution indicates that particular service procedures or precautions must be followed to avoid possible damage to the system.



NOTE: A Note indicates special information about operating the system, or clarifies important issues.

2.2 General safety instructions



WARNING: Make sure that those persons working with the device have sufficient qualifications and training.



WARNING: Read this instruction manual thoroughly before operating the system. Read the section on safety instructions carefully to avoid putting your patients, personnel or yourself at risk.



WARNING: Installation and commissioning of the device must only be performed by authorized qualified technicians from KARL STORZ SE & Co. KG who have been trained in electrical or electronic engineering or by an authorized contractual partner.



WARNING: Combinations of medical devices are only assured to be safe if they are identified as such in the respective instruction manuals or the intended use and interface specifications of the products used in combination permit this.



WARNING: Grounding reliability can only be achieved when the device is connected to a 'Hospital Only' or 'Hospital Grade' outlet (i.e. approved for use in an operating room environment). Routinely inspect the electrical plug and cord. Do not use if the inspection reveals damage.



WARNING: Do not open the device! Danger of electric shock. Refer servicing to the manufacturer or the manufacturer's authorized service personnel. Any opening of the device by non-authorized personnel will void the warranty.



WARNING: The instruction manuals and interface specifications for medical devices and/or system components used in combination must be observed precisely.



WARNING: The device may only be operated at the voltage stated on the rating plate.





CAUTION: Only the software and hardware components which have been tested and approved by KARL STORZ and listed in chapter 2.1.1 of the system description 96296083 may be used. The maximum permitted values at the inputs and outputs of the device must be observed. If components are connected which exceed these values, this will void the warranty.

2.3 Safety precautions at the installation site

NOTE: Only those parts of the system which are approved as medical devices are suitable for use within the patient environment.



WARNING: The electrical installation of the operating room in which the device is installed and operated must comply with the applicable IEC standards.



WARNING: To avoid the risk of an electric shock, the device must only be connected to a power supply with a protective conductor.



WARNING: The device must only be operated under the ambient conditions specified (see chapter 1.7).



WARNING: Keep the device out of reach of patients.



WARNING: The device is only voltage-free when the power plug has been disconnected.



WARNING: The device must be positioned so as to ensure that the power connection can simply be disconnected at any time.



WARNING: The device must be installed so as to ensure sufficient ventilation.

2.4 Safety measures during operation



WARNING: It is the user's responsibility to make sure all devices connected to the system and the complete system are safe and operate properly before using them. The device should not be used if any damage is evident.



WARNING: Avoid allowing liquids to enter the device. Do not store liquids in the vicinity of the device. If liquids penetrate the device despite the precautionary measures, sufficient time should be allowed for evaporation.



WARNING: The display of image signals which do not originate from a KARL STORZ device may only be used for information purposes.



WARNING: For safety reasons, do not simultaneously touch the device output sockets and the patient.



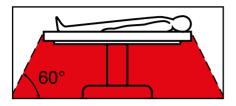
WARNING: If the volume of the loudspeaker or headset is too high, an unexpected audio signal could startle the attending physician. Check volume setting before each procedure.

Safety instructions





WARNING: The device is not suitable for operation in potentially explosive atmospheres and oxygenated areas. This means, for example, that when using easily combustible and explosive inhalation anesthetics or mixtures thereof, the device must not be operated in demarcated hazard zone. This also applies for easily combustible and explosive chemicals, e.g., skin disinfectants and fast-acting surface disinfectants.



Safety instructions





3 Product description

3.1 Technical description

KARL STORZ AIDA® WD 300 is designed for use in the Doctor's Office or Operating Rooms.

KARL STORZ AIDA® **WD** 300 serves to aid the implementation and documentation of medical interventions aimed at examining and treating patients.

When performing medical interventions, KARL STORZ AIDA® **WD** 300 can be used to carry out the following from the central touch screen:

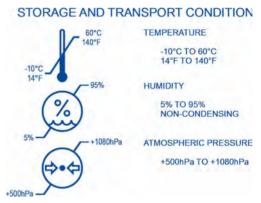
- · Controlling non-medical devices
- Transferring and displaying video and audio signals from the integrated signal sources to the integrated peripheral devices
- Recording, saving, editing, forwarding and printing medical examinations and interventions in the form of still images and video and audio sequences

3.2 Symbols and labels

3.2.1 Packaging

Label





| | Manufacturer |
|--|---|
| REF | Catalogue number |
| SN | Serial number |
| QTY | Number of products in the product packaging |
| 95% | Humidity limitation |
| ************************************** | Temperature limit |

KARL STORZ AIDA® **WD** 300 3-1



| | Protect from moisture |
|------------------------|--|
| Ţ | Fragile, handle with care |
| | Do not use if package is damaged |
| $\bigcap_{\mathbf{i}}$ | Consult instructions for use |
| 500 hPa | Atmospheric pressure limitation |
| 5 | Stack limitation |
| (| CE-Konformitätskennzeichnung |
| | With this marking, the manufacturer declares the compliance of the product with the applicable standards and directives. |

3.2.2 Front of device



| | Follow instructions for use! |
|--------------|--|
| ● → + | USB port |
| (1) | Standby. The device is in power saving mode. Yellow indicator light. |
| | ON. The device is switched on. Green indicator light. |
| | Access to hard disk. Red indicator light. |



3.2.3 Back of device





Dangerous voltage.

Danger of electric shock.

Pull out the plug before opening the housing.



Follow instructions for use!



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.

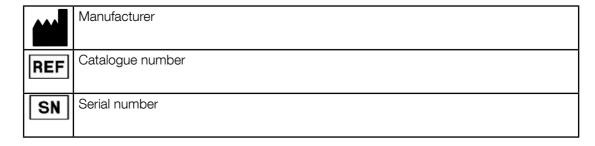




WARNING: A regulated voltage of 12 V is connected to Pin 4 + 7. The corresponding ground is provided via Shield and Pin 5. Danger of electric shock. Do not touch during operation and only connect cable when the device is switched off.

3.2.4 Manufacturer's identification plate





KARL STORZ AIDA® **WD** 300 3-3



| $\left(\left(\left(\bullet\right) \right) \right)$ | Non-ionizing radiation |
|---|---|
| 0 | Electronic information product pollution control (China RoHS) |
| X | Separate collection of electrical and electronic equipment. |
| | Do not dispose of as municipal waste. |
| (1) | CSA certification mark for the USA and Canada |
| 257474 | With this marking, the manufacturer declares compliance with the certification requirements |
| \sim | Alternating voltage |
| | Date of manufacture |
| CE | CE conformity marking |
| 6 | With this marking, the manufacturer declares the compliance of the product with the applicable regulations and directives |
| FCC ID | The FCC Identification number refers to the internal WLAN Adapter. |
| IC | The IC Identification number refers to the internal WLAN Adapter. |





3.3 Technical data

Input voltage: 100 VAC - 240 VAC

Input frequency: 50 Hz - 60 Hz

Power consumption max: 5 - 2 A

Dimensions (mm): 305 x 74,5 x 355 (W x H x D)

Max. weight: 6.0 kg

Degree of protection

against elektric shock:

Degree of protection

against humidity: IPX0
Hard disk capacity: 2 TB
RAM: 16 GB

CPU: Intel® Core™ i7-6700@3.4 GHz

Operating system: Windows 10 IoT Enterprise

Operating mode: Continuous operation



3.4 Connections

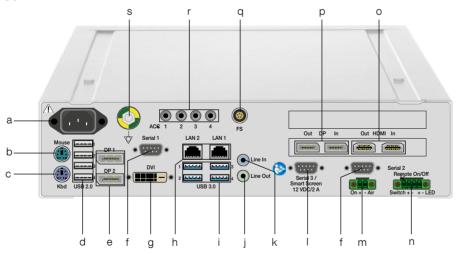
3.4.1 Front



- a. Switch between standby and operating mode
- b. Yellow standby LED
- c. "Green" operating LED

- d. Red LED for hard disk access
- e. USB
- f. WLAN-antenna (at the inner side of the front panel)

3.4.2 Rear



- a. Power supply
- b. PS/2 (mouse)
- c. 8-pole Lemo (keyboard)
- d. 4x USB 2.0
- e. 2x DP (Display Port)
- f. 2x DE 9 (serial interface)
- g. DVI (monitor)
- h. 2x RJ-45 (LAN)

- i. 4x USB 3.0
- j. Mini jack (audio OUT)
- k. Mini jack (audio IN)
- I. DE 9 (serial interface, 12 VDC/2 A, Pin 4 + 7)
- m. Phoenix 2-pole (On Air Lamp for future use)
- n. Phoenix 4-pole (Remote activation of KARL STORZ OR1 FUSION®)

- o. 2x HDMI 2.0 In/Out
- p. 2x DP 1.2a In/Out
- q. Lemo 5-pole (footswitch)
- r. 4x 3.5 mini jack (camera head buttons)
- s. POAG earth connection



4 Installation

4.1 Safety instructions



WARNING: Installation and commissioning of the device must only be performed by authorized qualified technicians from KARL STORZ SE & Co. KG who have been trained in electrical or electronic engineering or by an authorized contractual partner.



WARNING: Combinations of medical devices are only assured to be safe if they are identified as such in the respective instruction manuals or the intended use and interface specifications of the products used in combination permit this.



WARNING: The device must be installed so as to ensure sufficient ventilation. so as to ensure sufficient ventilation.



WARNING: Connect the supplied potential equalization cable to the potential equalization connector. In doing so, observe the applicable national regulations.



WARNING: The electrical installations in the room in which the device is installed and operated must comply with the applicable IEC standards.



WARNING: The device must only be connected using the power cord supplied by KARL STORZ or a comparable power cord with a national test seal.



WARNING: The use of freely accessible multiple socket outlets is not permitted.



WARNING: Multiple socket outlets must not be placed on the floor.



WARNING: Additional devices that are connected to electronic medical devices must conform to the respective IEC or ISO standards (e.g., IEC 60950 for data processing equipment). Furthermore, all configurations shall comply with the standard requirements for medical systems (see IEC 60601-1-1 or Clause 16 of the 3rd Ed. of IEC 60601-1, respectively). Any person who connects additional equipment to medical electrical equipment configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements for medical electrical systems. Please note that local laws take priority over the requirements mentioned above. If in doubt, consult the technical service department or your local representative.

4.2 Unpacking

Check the delivery for missing items and possible damage. File any complaints with the manufacturer or supplier immediately.

Keep the original packaging for later use. This may be useful if the device has to be transported.

KARL STORZ AIDA® WD 300 4-1

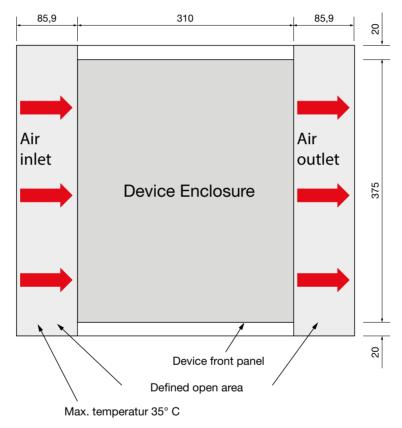


4.3 Installation and Comissioning

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

4.3.1 Minimum requirements

- Ambient conditions for operation as described in section 1.7.
- Consideration of the technical data as described in section 3.3.
- Consideration of the free area dimensions based on the graphic below to guarantee that the device is properly ventilated.



Note: Nothing may be mounted to the left and right of the device in the defined free areas.



5 Maintenance

5.1 Safety instructions



WARNING: Before performing any cleaning or maintenance work on the central device and the connected devices, disconnect these from the power supply line.



WARNING: Repairs may only be performed by qualified technicians trained in electrical or electronic engineering, in compliance with the relevant occupational, safety and accident prevention regulations! Always unplug the device from the power supply before carrying out any work on it! A safety test according to VDE 0751 and IEC 62353 must be carried out following service work.



WARNING: By making the enclosed technical information available, KARL STORZ does not authorize any service or repair work by unauthorized service personnel. Any tampering with instruments or devices or unauthorized servicing or repair work to the device will render the warranty void.



WARNING: Damaged equipment components must only be maintained and repaired by KARL STORZ.

5.2 Reprocessing

5.2.1 Legal requirements



WARNING: When carrying out any work on contaminated medical devices, the guidelines of the Employer's Liability Insurance Association and equivalent organizations striving to ensure personal safety must be observed.

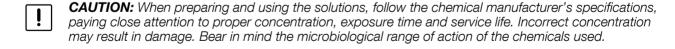


CAUTION: National laws and regulations must be observed.

5.2.2 Safety instructions



WARNING: Risk of infection: Incorrectly reprocessed medical devices expose patients, users and third parties to a risk of infection as well as the risk that the medical device may malfunction. Observe the 'Cleaning, Disinfection, Care and Sterilization of KARL STORZ Instruments' instructions and the accompanying documentation.



NOTE: The manual 'Cleaning, Disinfection, Care and Sterilization of KARL STORZ Instruments' can be downloaded or requested by visiting www.karlstorz.com.

5.2.3 Required reprocessing agents

- Disinfectants
- **NOTE:** Due to their protein-fixating effect and possible material incompatibility, alcohol-based agents must not be used.

The chemical manufacturer's specifications regarding material compatibility must be observed.



5.2.4 Required reprocessing materials

- Disposable cloth or ready-to-use disinfectant cloth
- · Dry, low lint cloth

5.2.5 Wipe-down disinfection

- NOTE: To prevent liquid entering the device, it should not be sprayed with the disinfectant.
- **NOTE:** In order to preserve the conductivity of the contacts, you should never allow disinfectants to come into contact with the connections on the front and back of the device. When the disinfectant dries, residues can form which impair conductivity.
 - 1. Use a disposable cloth moistened with disinfectant or a soaked ready-to-use disinfectant cloth.
 - 2. Wipe-clean the exterior surfaces of the medical device.
 - 3. Allow the disinfectant to take effect, observing the instructions of the disinfectant manufacturer.
 - 4. At the end of the necessary exposure time, wipe the surfaces with a dry low lint cloth.

5.3 Maintenance and repair

5.3.1 Maintenance plan

| Interval | Action | Responsibilities |
|---------------|--------------------------|-------------------------------|
| Annually | Check and inspect device | KARL STORZ service technician |
| Every 4 years | Replace BIOS battery | KARL STORZ service technician |

5.3.2 Changing the BIOS battery

The BIOS battery is changed by KARL STORZ service staff.

5.3.3 Servicing

Defective device components must be serviced and repaired exclusively by persons authorized by KARL STORZ; all repair work must employ original KARL STORZ parts only.

All service work must only be performed by KARL STORZ or by an authorized agent.



WARNING No changes may be made to device without the manufacturer's approval.



5.4 Repair program

In Germany, you can refer repairs directly to:

KARL STORZ SE & Co. KG Abt. Reparaturservice

Take-Off Gewerbepark 83

78579 NEUHAUSEN, Germany

Service hotline: +49 7461/708 980 Email: technicalsupport@karlstorz.com

In other countries please contact your local KARL STORZ branch or authorized dealer.

5.5 Responsibility

KARL STORZ SE & Co. KG shall be liable for failure or deterioration in the safe operation, operational reliability, and performance of this system only subject to the following conditions:

- all assembly operations, system expansions, readjustments, modifications, or repairs have been performed by a person or persons duly authorized by KARL STORZ,
- all electrical installations in the room in which the system is installed and operated meet the applicable laws and standards, and
- the devices have been used in accordance with their instruction manuals at all times.

5.6 Warranty

For a period of two years from delivery to the end user, we shall replace equipment that can be proven to have defects in material or workmanship free of charge. In so doing, we cannot bear the cost of transportation or the risks associated with shipment. The warranty referred to in our Standard Conditions of Business shall apply.

Opening the equipment or performance of any repairs or modifications to the components of the device by unauthorized persons shall relieve us of any liability for its performance. Any such repair or modification performed during the warranty period shall void all warranty.

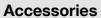
Maintenance





6 Accessories

| Article/Article no. | | Designation | Quantity |
|---|------------|---|----------|
| | 400A | Power cord EU | 1 |
| | | length 3 m | |
| | | 'Not suitable for the wall-mounted solution!' | |
| | 400 B | Power cord US | 1 |
| | | length 2 m | |
| | | | |
| | 1460795 | AIDA Recovery USB Stick | 1 |
| STORZ MAIL STORZ HADDOGODA | | | |
| 4K | WA1000C | DP 1.2 4K 60Hz, DeLock connecting cable | 1 |
| | | length 1.8 m | |
| | | | |
| | 20040086 | DVI connecting cable for WD300 | 2 |
| | | length 2 m | |
| | 4800288 | HDMI to DVI cable | 2 |
| | | length 2 m | |
| | | | |
| | 20221070 | ACC connecting cable | 2 |
| | | length 1.8 m | |
| property of the second | 20040240US | Medical keyboard with touchpad | 1 |
| | | | |
| | | | |
| | 20040076 | CAT5e/6 Network-Patch cable | 1 |
| | _ | Länge 5 m | |
| | | | |
| F11 | W23174 | Remote activation of KARL STORZ OR1 | 0 |
| | 1,720,7,7 | FUSION®, 12 VDC | |
| | | | |
| | | | |
| | | | |





| Article/Article no. | | Designation | Quantity |
|-----------------------|------------|-------------------------------|----------|
| | 96296081EN | User Manual | 1 |
| KARL STOKZ—IN-GOSKOPH | | Contained in Folder 96296084D | |



7 Appendix

7.1 Information on electromagnetic compatibility (EMC)



WARNING: Medical electrical devices are subject to special precautions regarding Electromagnetic Compatibility (EMC). Observe the EMC instructions in this appendix during installation and commissioning.

The KARL STORZ AIDA® **WD** 300complies with IEC 60601-1-2:2007 [CISPR 11 Class A] and therefore meets the EMC requirements of the Medical Device Directive (MDD) 93/42/EEC.

- NOTE: The tables and guidelines that are included in this appendix provide information to the customer or user that is essential in determining the suitability of the device or system for the electromagnetic environment of use, and in managing the electromagnetic environment of use to permit the device or system to perform its intended use without causing interferences in other devices or systems or non-medical electrical devices. If this device does cause electromagnetic interference with other devices, the user is encouraged to try to correct this by one or more of the following measures:
 - · reorient or relocate the receiving device
 - increase the separation between the individual devices
 - connect the devices to different electrical circuits.

If you have any further questions, please contact your local representative or our service department.



WARNING: The use of portable and mobile RF equipment may have an impact on this or other pieces of medical equipment.



WARNING: The use of cables other than those specified in the KARL STORZ instruction manual may result in increased emissions or decreased immunity of the KARL STORZ AIDA® **WD** 300. The cables listed below have been shown to comply with the requirements of IEC 60601-1-2:2007. When using cables other than those specified here, it is the responsibility of the user to ensure that they comply with IEC 60601-1-2:2007.



WARNING: The connection of other devices to the system should be avoided as this could jeopardize smooth running. If it is necessary to link the system with other devices, it must be established that this is possible without any interference.



WARNING: The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device or system should be observed to verify normal operation in the configuration in which it will be used.



WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used not closer than 30 cm (12 inches) to any part of the **WD** 300 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

KARL STORZ AIDA® **WD** 300 7-1



Table 200 Cables by means of which conformity with EN/IEC 60601-1-2 was proven:

| Interface | Length [m] | | Туре | Use | |
|----------------------|---------------|-----------------|----------|------------|--------------------------|
| | | Number of wires | shielded | unshielded | |
| AC power cord | 3.0 | 3 | | х | |
| PE | 1.0 | 1 | | × | grounded |
| ACC1-4 | 2.0 | 3 | Х | | Camera head buttons |
| Line In/Out | 1.8 | 3 | X | | Audio In/Out |
| Lemo 5 pole | 3.0 | 5 | Х | | Footswitch |
| RS232 (1) | 3.0 | 9 | Х | | Control cable |
| RS232 (2) | 3.0 | 9 | Х | | Bar code scanner |
| RS232 (3) 12 VDC | 3.0 | 9 | Х | | SmartScreen Power supply |
| DVI | 3.0 | 9 | Х | | Monitor |
| HDMI 4K | 3.0 | 19 | Х | | In/Out |
| DP 4K | 3.0 | 20 | Х | | In/Out |
| DP PC | 3.0 | 20 | Х | | DP 1/2 |
| LAN1 | 5.0 | 8 | Х | | Ethernet |
| LAN2 | 5.0 | 8 | Х | | Ethernet |
| USB 2.0 (back) | 1.8 | 4 | Х | | |
| USB 3.0 (back) | 3.0 | 4 | Х | | |
| USB 3.0 (front) | 3.0 | 4 | Х | | |
| PS/2 | 1.8 | 9 | Х | | Keyboard/Mouse |
| Phoenix Connector | 5.0 | 2 | | X | On Air Lamp |



Guidelines and manufacturer's declaration - electromagnetic emissions

The KARL STORZ AIDA® WD 300 is intended for use in the electromagnetic environment specified below. The user of the device should make sure that the KARL STORZ AIDA $^{\! @}$ WD 300 is operated in such an environment.

| Interference emission measurements | Conformity level | Electromagnetic environment – guidelines | | | |
|---|--------------------------|---|--|--|--|
| RF emissions acc. to CISPR 11 | Complies with 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 interference in nearby electronic equipment. | | | |
| RF emissions acc. to CISPR 11 | Complies with Class A | The device is suitable for use in all establishment other than domestic and those directly connected | | | |
| Emission of harmonic oscillations acc. to IEC 61000-3-2 | Complies with Class A | to the public low voltage power supply network that supplies buildings used for domestic purposes. | | | |
| Voltage fluctuations/ flicker emissions acc. to IEC 61000-3-3 | Complies | | | | |



Guidelines and manufacturer's declaration - electromagnetic immunity

The KARL STORZ AIDA® \mathbf{WD} 300 is intended for use in the electromagnetic environment specified below. The user of the KARL STORZ AIDA® \mathbf{WD} 300 should make sure that they are used in such an environment.

| Interference immunity tests | IEC 60601-1-2:2007 test level | Conformity level | Electromagnetic environment – guidelines |
|---|--|---|--|
| Electrostatic discharge (ESD) acc. to IEC 61000-4-2 | ± 6 kV contact discharge ± 8 kV air discharge | Complies ± 8 kV contact discharge ± 2kV, ± 4kV, ± 8 kV, ± 15kV air discharge | Floors should be made of wood or concrete or covered with ceramic tiles. If floors are covered with synthetic material, the relative humidity must be at least 30%. |
| Rapid transient electric interferences/ bursts acc. to IEC 61000-4-4 | \pm 1 kV for input and output lines \pm 2 kV for mains lines \pm 1 kV for input and | | The quality of the supply voltage should correspond to that of a typical business or hospital environment. |
| Surges acc. to IEC 61000-4-5 | ± 1 kV push-pull voltage ± 2 kV common-mode voltage | Complies ± 1 kV push-pull voltage ± 2 kV common- mode voltage | The quality of the supply voltage should correspond to that of a typical business or hospital environment. |
| Voltage dips, short interruptions and fluctuations of the supply voltage | <5% U _T * (>95% dip in U _T) for 1/2 cycle | Conforms $<5\%$ U _T * $(>95\%$ dip in U _T) for 1/2 cycle | The quality of the supply voltage should correspond to that of a typical business or hospital environment. |
| acc. to IÉC 61000- 4-11 | $40\% \ U_T$ $(60\% \ dip \ in \ U_T)$ for 5 cycles $70\% \ U_T$ $(30\& \ dip \ in \ U_T)$ for 25 cycles | Conforms $40\% \ U_T$ $(60\% \ dip \ in \ U_T)$ for 5 cycles Conforms $70\% \ U_T$ $(30\% \ dip \ in \ U_T)$ for 25 cycles Conforms | If the user of the device requests continued functioning even when interruptions of the power supply occur, it is recommended that the device be supplied from a power supply that is free of interruptions. |
| | <5% U _T (>95% dip in U _T) for 5 seconds | <5% U _T (>95% dip in U _T) for 5 seconds | |
| Magnetic field at the supply frequency (50/60 Hz) acc. to IEC 61000-4-8 | 3 A/m | Complies 30 A/m | The magnetic fields at the mains frequency should be at the values typical of business or hospital environments. |

 $^{^{\}ast}$ Note: U_{T} is the mains alternating voltage before applying the test levels.



Test specification for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment (according to IEC 60601-1-2)

The KARL STORZ AIDA® **WD** 300 is intended for use in the electromagnetic environment specified below. The user of the KARL STORZ AIDA® **WD** 300 should make sure that they are used in such an environment.

| Test frequency MHz | Band MHz | Service | Modulation | Maximum Power W | Distance m | IMMUNITY TEST LEVEL V/m |
|--------------------------|--------------------|---|---------------------------------|-----------------------|---------------|-------------------------------|
| 385 | 380 bis 390 | TETRA 400 | Puls modulation 18 Hz | 1,8 | 0,3 | 27 |
| 450 | 430 bis 470 | GMRS 460, FRS 460 | FM ± 5kHz Hub 1 kHz Sinus | 2 | 0,3 | 28 |
| 710 | | | | | | |
| 745 | 704 bis 787 LTE | Band 13, 17 | Puls modulatio 217 Hz | 0,2 | 0,3 | 9 |
| 780 | | | 217 112 | | | |
| 810 | | GSM 800/900 | | | | |
| 870 | | TETRA 800, | Puls modulatio 18 Hz | 2 | 0,3 | 28 |
| 930 | 800 bis 960 | iDEN 820, CDMA 850, LTE Band 5 | | | | |
| 1720 | | GSM 1800, | | | | |
| 1845 | | CDMA 1900, | | | | |
| 1970 | 1700 bis 1990 | GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS | Puls modulatio 217 Hz | 2 | 0,3 | 28 |
| 2450 | 2400 bis 2570 | Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7 | Puls modulatio 217 Hz | 2 | 0,3 | 28 |
| 5240 | | | | | | |
| 5500 | 5100 bis | WLAN 802.11 | Puls modulatio | 0,2 | 0,3 | 9 |
| 5785 | - 5800 a/n | | <u> </u> | 217 Hz | | |

^{*} NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the KARL STORZ AIDA® WD 300 may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.



Guidance and manufacturer's declaration – electromagnetic immunity – for equipment and systems that are not life-supporting

The KARL STORZ AIDA® **WD** 300 are intended for use in the electromagnetic environment specified below.

The user of the KARL STORZ AIDA® **WD** 300 should make sure that they are used in such an environment.

| Interference immunity tests | IEC 60601- 1-2:2007 test level | Conformity level | Electromagnetic environment – guidelines |
|-----------------------------------|--------------------------------------|--------------------|--|
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the KARL STORZ AIDA® WD300, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |
| | | | Recommended separation distance: |
| Conducted RF disturbances acc. to | 3 V _{ms} 150 kHz to | 3 V _{eff} | $d = [3,5/3]\sqrt{P}$ |
| IEC 61000-4-6 | < 80 MHz | eff | 150 kHz to < 80 MHz |
| Radiated RF | | | $d = [3,5/3]\sqrt{P}$ |
| disturbances | 3 V/m 80 MHz to | 3 V/m | 80 MHz to < 800 MHz |
| according to IEC 61000-4-3 | 2.5 GHz | 3 V /111 | $d = [7/3]\sqrt{P}$ |
| | | | Where P is the nominal power of the transmitter in watts [W] according to the information provided by the manufacturer of the transmitter and d is the recommended separation distance in meters [m]. The field strength of stationary transmitters at all frequencies on site a should be, according to a study, less than the conformity level b . Interference may occur in the vicinity of equipment marked with the following symbol: |
| | | | |

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

a Field strengths from fixed transmitters, such as 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 of the stationary transmitters, a site survey should be considered. If the measured field strength in the location at which the device is used exceeds the above conformity levels, the device should be observed to verify normal operation. If unusual performance characteristics are observed, additional measures may be necessary, such as a modified orientation or a different location for the device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than **3** V/m.



Recommended separation distances between portable and mobile RF communications equipment and the KARL STORZ AIDA® WD 300

The KARL STORZ AIDA® **WD** 300 are intended for use in an electromagnetic environment in which the RF disturbances are controlled. The user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device – as a function of the output power of the communication device, as shown below.

| | Separation distance d [m] according to frequency of transmitter | | | | |
|----------------------------------|---|---|---|--|--|
| Nominal power of transmitter [W] | 150 kHz to < 80 MHz | 80 MHz to < 800 MHz | 800 MHz to 2.5 GHz | | |
| | $d = \left[\frac{3.5}{3}\right] \sqrt{P}$ | $d = \left[\frac{3.5}{3}\right] \sqrt{P}$ | $d = \left[\frac{7}{3}\right] \sqrt{P}$ | | |
| 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 rated at a maximum output power not listed above, the recommended separation distance \mathbf{d} in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where \mathbf{P} is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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



7.2 Regulatory Statements Radio Equipment

7.2.1 USA

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- a. This device may not cause harmful interference, and
- b. This device must accept any interference received, including interference that may cause undesired operation.

Contains FCC ID: PD98265NG

7.2.2 Canada

This device complies with Industry Canada's licence-exempt RSSs. Operation is subject to the following two conditions:

- a. This device may not cause interference; and
- b. This device must accept any interference, including interference that may cause undesired operation of the device.

Contains IC: 1000M-8265NG

7.2.3 European Union

For indoor use only

Radio Equipment Directive (RED) 2014/53/EU

Subsidiaries



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E-Mail: info@karlstorz.com

KARL STORZ Endoskope Berlin GmbH

Scharnhorststr. 3 10115 Berlin, Germany

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Ontario, L5N 3R3, Canada

Toll free fax: 1-800-482-4198 (Canada only)

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El Segundo, CA 90245-5017, USA

Thome: +1 424 218-8100, Fax: +1 424 218-8526 Toll free phone: 800 421-0837 (USA only) Toll free fax: 800 321-1304 (USA only)

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