User Manual 16-2009

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Duo Camera

» The DUO Full HD control unit is a medical device combining a Full HD camera and LED light source over a single control channel. It is designed to provide local illumination of the patient's body and to capture images taken by health practitioners qualified in diagnostic procedures or surgical endoscopy procedures. «

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Chapter Overview

CONTENTS

Chapter 1 FOREWORD

Thank you for your confidence and for buying this equipment.

It is essential that you familiarise yourself with the contents of this manual. It will help you get the best out of your equipment and ensure all necessary safeguards are in place.

We have tried to make this manual as straight forward as possible to help with installation and use of the equipment. In addition, references are provided on page 37 of this manual. They look like this: [D1]. They will help you view the relevant parts of the product more easily.

Note: UDI numbers: custom products have a different UDI from the one shown on the cover of this manual. You will find it on the product label and labels on the packaging.

In this user manual, Ackermann does not use any text, brand names, pictures, figurative signs or other items liable to mislead the user or patient over the purpose, safety and performance of the device.

1.1 ASSOCIATED DOCUMENTATION

- Quick Start
- Lens user manual
- E-Ifu consulating

The Quick Start document is a simplified summary designed to help you. The only official instructions are the user manuals and the regulatory documents accompanying the medical device.

1.2 ELECTRONIC DOCUMENTATION

The instructions for use for your device can be provided in electronic format as per request on info@ackermanninstrumente.de as well, and not in printed format. If you do not get any answer immediately, please be patient, our customer service will come back to you asap.

The electronic user instructions are available in PDF format (Portable Document Format). You will need to have a PDF file read software installed to read the electronic version of the user instructions. It is important for you to have read and understood the content of the user instructions relating to the use of your device and its accessories.

! WARNING

Do not use the device without first familiarising yourself with the instructions for use.

As soon as you receive your device, you are asked to print and download all documents or sections of documents that you may need to consult in the event of an emergency, if you are unable to connect to the Internet or if your electronic display device (computer, tablet, etc.) stops working. We recommend that you visit the website regularly to check if there are any downloadable versions of your device's user instructions. Users are asked to keep documentation to hand so that it can be consulted when necessary.

All printed and electronic format documentation relating to your medical device must be kept for the device's entire service life.

Please retain all original documentation relating to the medical device and its accessories for reference at a later date. When loaning out or selling the medical device, the documentation must be provided with it.

Chapter 2 REQUIRED INFORMATION

2.1 GENERAL INFORMATION

Note: following notice is only applicable for the United States of America.

United States Federal Law restricts the use of this medical device within its territory to health professionals who are qualified, fit and certified, or to those under their control.

In the United States and Canada, the “Hospital Grade” power cord provided must be used, and it must be connected to a “Hospital Grade” power socket.

2.1.1 CONTENTS

This product comprises the following medical devices:

- ✓ One control channel
- ✓ One Full HD camera head
- ✓ One 24 mm lens (optional)
- ✓ One light cable (optional)

And the following accessories:

- ✓ One USB key with the user manual
- ✓ One EU or US power cord
- ✓ One SDI video cable
- ✓ Two light cable-device adaptors (Ackermann, Olympus and Storz fittings)
- ✓ Universal light cable adaptors, source end (Ackermann, Storz fitting) and endoscope end (Ackermann, Storz fitting) (optional)

Note: Any other consumable or accessory not sold by Ackermann will have its own manual. Please refer to it before using the product.

Keep the packaging in case you need to transport the equipment at a later date.

2.2 INDICATION FOR USE

CONTROL UNIT

The DUO Full HD control unit is a medical device combining a Full HD camera and LED light source over a single control channel. It is designed to provide local illumination of the patient’s body and to capture images taken by health practitioners qualified in diagnostic procedures or surgical endoscopy procedures (gynaecology, laparoscopy, arthroscopy, ENT, urology or spinal endoscopy).
On the camera side, the DUO Full HD enables the user to relay images to a monitor and capture photos via the camera head combined with the lens and endoscope.
On the LED light source side, the DUO Full HD has a 23,000 lux light source; this is equivalent to a 180 Watt Xenon source. Light is sent from the DUO Full HD control unit along the light cable and then to the endoscope, providing local illumination of the examination site.

CAMERA HEAD

The camera head included in the DUO Full HD unit is designed to relay the image captured at the examination site to a monitor via the control channel. It is designed for use by health practitioners qualified in diagnostics and surgical endoscopy procedures (gynaecology, laparoscopy, arthroscopy, ENT, urology or spinal endoscopy). The practitioner can also control the image settings using three buttons on the camera head: adjust the LED brightness, or zoom in/out, correct the white balance, move from flexible to rigid mode and vice versa, and capture photos. The camera head is designed for connection to the DUO Full HD control unit and to a rigid or flexible endoscope via a lens (endoscope and lens not included). The camera head is equipped with a sterile protective cover (not included) for the duration of the diagnostic/surgical procedure.

2.3 PRINCIPLE OF OPERATION

The lens, light cable (both optional) and camera head are sterilised in accordance with the manufacturer's user manual. The control unit is used outside the sterile field, unlike the proximal end of the camera head and light cable.
A compatible lens is fitted to the DUO Full HD camera head and the light cable is equipped with compatible adaptors at the two ends. The camera head and light cable are connected to the DUO Full HD control unit. The other end of the light cable and camera head are connected to the endoscope. It is recommended to use a sterile, single-use protective cover over the camera head and its cable for the duration of the procedure.

The diagnostic or surgical procedure may now be performed. The cavity is illuminated and video camera images are displayed on the monitor screen. The images may be stored on a USB key connected to the front of the DUO Full HD control unit.

2.4 USER POPULATION RECOMMENDATIONS

2.4.1 USER POPULATION

This medical device is intended for use by a skilled and capable surgeon qualified for endoscopy explorations.

This device may also be used by an assistant or nurse under the supervision of the practitioner.

This device is suitable for use in a professional healthcare facility environment.

Users must know and comply with the rules of endoscopy practice in compliance with knowledge acquired in the field and the key medical hygiene principles including cleaning, disinfection and sterilisation of MDs.

The user must wear gloves.

The user is not the patient.

The medical device can be used by any adult dental practitioner of any weight, age, height, gender and nationality.

The user must not be prone to any of the following:

- Visual impairments: any vision problems must be corrected by glasses or lenses.
- Infirmity of the upper limbs which could prevent manual manipulation of a hand-held device.
- Hearing difficulties that could prevent the user hearing audible alarms depending on medical devices;
- Difficulty in memorising or concentrating that could affect the setting of sequences or the performance of treatment protocols.

2.4.2 SPECIFIC USER TRAINING

No specific training other than initial professional training is required to use this medical software.

The practitioner is responsible for performing clinical treatments and for dangers that may arise due to a lack of skill and/or training.

2.4.3 APPLIED PART(S)

The camera and light cable are deemed to be applied parts within the meaning of the IEC 60601-1 standard. It is recommended that a sterile disposable protective cover be used on the camera regardless of the chosen sterilisation procedure and throughout the duration of the surgical procedure.

2.5 RECOMMENDED PATIENT POPULATION
2.5.1 PATIENT POPULATION

This device must be used to support the health practitioner on individuals (patients) who are suitable to undergo an endoscopy procedure.

This medical device is designed to be used with the following patient populations:
- Children
- Adolescents
- Adults
- Elderly persons

This medical device can be used irrespectively of the patient's details such as weight, age, height, gender and nationality.

2.5.2 PATIENT POPULATION RESTRICTION

The user is the only person who can decide whether or not to treat his/her patients.

2.5.3 APPLIED PART(S)

The camera and light cable are deemed to be applied parts within the meaning of the IEC 60601-1 standard.

It is recommended that a sterile disposable protective cover be used on the camera regardless of the chosen sterilisation procedure and throughout the duration of the surgical procedure.

2.6 BASIC SAFETY IN NORMAL USE
2.6.1 NORMAL USAGE CONDITIONS

The normal usage conditions are as follows:
- Storage
- Installation
- Use
- Maintenance
- Disposal

2.6.2 BASIC PERFORMANCE

As stated in the applicable safety standard pertaining to electrical medical devices, the manufacturer has determined that the medical device does not manage basic performance.

The active part, the camera head, is held by the practitioner throughout the entire medical procedure. As a highly skilled medical expert, the practitioner can immediately detect any problems at the treatment area and react accordingly.

! WARNING

It is recommended to have a second camera or light source available in the operating theatre for use in the event that a loss or deterioration of functionality is observed in the equipment.

2.7 PRODUCT SERVICE LIFE

Repeated cleaning and sterilisation of the device will result in normal wear to the medical device.

Chapter 3 SAFETY INSTRUCTIONS

This includes information relating to the interactions, contraindications and prohibitions known by the manufacturer on the date on which this document was written.

3.1 ELECTROMAGNETIC INTERFERENCE AND ELECTROSTATIC DISCHARGE

Although this product meets standards relating to EMC, it is possible under very specific circumstances that it may cause interference to other devices, or that it may itself be affected by other devices or an unfavourable electromagnetic environment.

To avoid such situations, you are recommended:
- To ensure the electrical supply network is of good quality (particularly that all devices and trolleys are earthed);
- To keep the device away from sources of electromagnetic interference (e.g. compressor, motor, transformer, HF generator etc.).

3.2 USING ACCESSORIES NOT SUPPLIED BY THE MANUFACTURER

The medical device was designed and developed with its accessories or others offered as an option to guarantee maximum safety and performance. The use of accessories from other sources could put you and your patients at risk and could damage your medical device.

Even if the manufacturer or dealer of your accessory claims full compatibility with Ackermann equipment, it is advisable to exercise caution with regard to the origin and safety of the product offered. Look out for warning signs such as a lack of information, information in a foreign language, very attractive prices, suspect appearance, mediocre quality or premature wear.
In the event of doubt, contact an approved dealer or the Ackermann after-sales service team.

3.3 CONNECTION AND DISCONNECTION OF ITEMS FROM THE DEVICE DURING USE

- Parts of the device such as the camera or light cable may be connected and disconnected during use.
- We recommend clicking the on/off button on the rear of the device before unplugging it.

3.4 PRECAUTIONS DURING USE

- Unplug the device from the mains supply if you have no plans to use if for a few days or longer.
- To unplug the power cord, pull on the plug. Never pull on the cord itself.
- Prior to each use, make sure the device does not have any rough surfaces, sharp edges or protuberances which could lead to safety problems.
- Check the compatibility of your endoscope with the manufacturer prior to use.
- Devices which connect to the inputs/outputs must comply with the IEC 62368-1 standard.
- To prevent any errors or delays in diagnosis, you must make sure that the settings on the monitor being used are optimised for the procedure being performed, such that they will allow a clean, noise-free colour image to be obtained.
- You are recommended to use a sterile single-use protective cover on the camera throughout the procedure.
- You are recommended to set up the device on a stable surface to prevent any risk of it falling.

3.5 RESTRICTIONS

- Do not insert metal objects into the device, to avoid any risk of electric shock, fire, short-circuit or hazardous emissions.
- Do not place heavy objects on top of it.
- Do not place the device where it could be splashed with water, or in an excessively damp environment.
- Do not use corrosive or abrasive products to clean the device, but only the disinfectant liquids recommended in the chapter on “Cleaning”.
- Do not insert anything other than a light cable in the connector provided for that purpose [C2], as this may risk the optical system; the same applies to the connector designed for the camera head [C1].
- Never look directly at the light outlet or the end of the light cable when the LED is on.
- Do not place the furthest end of the light cable or the endoscope directly on the patient or on any other flammable material (sheets, gauzes, surgical drapes etc.), as it may be very hot and could result in burns.
- Do not obstruct the device’s ventilation openings.
- Not suitable for use in the presence of a flammable anaesthetic mixture with air and oxygen or nitrous oxide.
- Do not use in an oxygen-rich environment.
- Multiple-socket adaptors or extension leads must not be connected to the electromagnetic system.

3.6 CONTRAINDICATIONS

There are no known contraindications associated with the DUO Full HD (control unit and camera head). Please refer to the user manuals for other devices used during surgical endoscopy or diagnostic procedures (Gynaecology, Laparoscopy, Arthroscopy, ENT or spinal endoscopy).

3.7 PARTICULAR WARNINGS

- This device is not sterile; only the camera and lens may be sterilised.
- When connecting the light cable or camera to the control channel, do not force the connectors, as this may damage them.
- Abide by the proper usage and storage conditions (see chapter 9).
- Ensure there is sufficient airflow to prevent any overheating within the device: at least 15 cm clear all round the device. Do not cover it, and ensure that all of the device's feet are present.
- If the power cord is damaged, immediately switch off the device. It is dangerous to operate this device with a damaged cord.
- After the source has been used, when removing the fibre from its light guide, the temperature of the metal part will be very high and could cause burns.
- The light intensity at the fibre outlet may cause eye damage. Be careful handling it when the device is in use.

3.8 UNDESIRABLE SECONDARY EFFECTS

There are no known undesirable secondary effects associated with the DUO Full HD (control unit and camera head). Please refer to the user manuals for other devices used during surgical endoscopy or diagnostic procedures (Gynaecology, Laparoscopy, Arthroscopy, ENT or spinal endoscopy).

3.9 MOVING THE MEDICAL DEVICE

- The device is a mobile device, and may be moved using a trolley.

3.10 ASSEMBLY AND DISASSEMBLY OF THE PRODUCT

- The device must only be opened by a competent technician approved by the manufacturer.
- This device must not be modified without the manufacturer's authorisation. If the medical device is modified, a test and inspection must be carried out to ensure that the medical device satisfies the safety requirements.
- Only the fuses below the switch at the rear of the device may be replaced. The power should be switched off and the fuses checked and replaced if necessary; only T 1.6 A-250 V UR time-delay fuses should be used (only those marked UL/CSA).

3.11 VIGILANCE

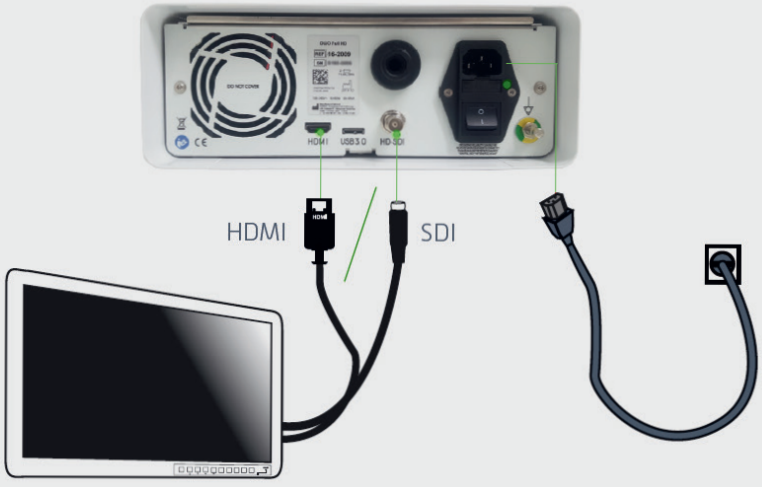
Any serious incident concerning the medical device or its accessories, with the exception of the expected secondary effects must be reported to the relevant competent authorities and to the manufacturer as soon as possible. Generally speaking, the notification period should take into account the seriousness of the incident. Consult local applicable regulations.

Manufacturer's contact details: please see page 18 (CONTACT) of the manual.

Chapter 4 INSTALLATION OF THE EQUIPMENT

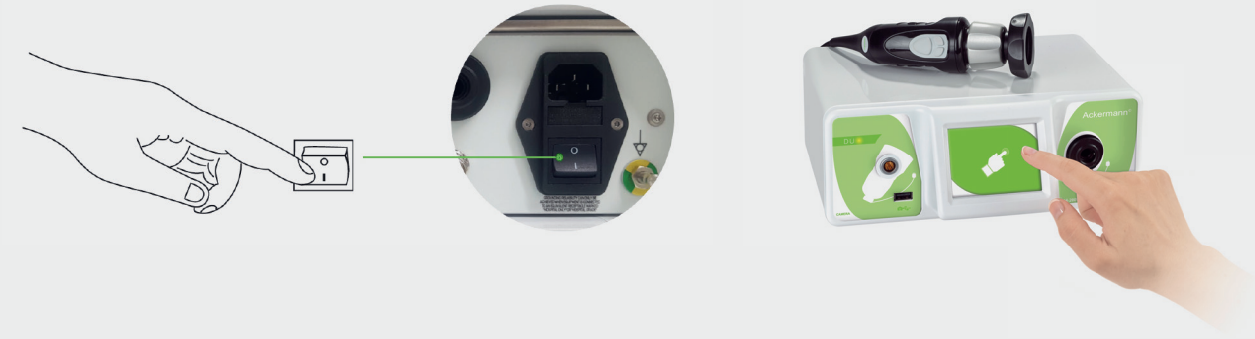
4.1 CONNECTION

- Connect the power cord to the cable connector at the rear of the device [C7] .
- Connect a video lead to one of the following video outputs: HDMI [C4] or SDI [C6].
- Connect the other end of the video lead to the monitor video input.



4.2 SWITCHING ON

- The device is fitted with a switch [S1] located on the rear of the device. The device is switched on by setting this switch to the “I” position.
- The screen on the device [L1] will then come on in standby mode; touch the screen to exit standby.



4.3 CONNECTION TO THE CAMERA HEAD AND LIGHT CABLE

- Connect the camera head connector [C8] to the control channel [C1].
- Connect the light cable to the control channel [C2]. The device has two types of connections: Ackermann (, Storz®) by default on the device.
  Olympus®, provided on the rear of the device [D1].

4.4 CONNECTION OF THE ENDOSCOPE TO THE SENSOR

- Connect the optics to the optical mount ring on the lens.
- Connect the light cable to the optics.

Chapter 5 OPERATING PRINCIPLE

5.1 STARTING

- When the device starts up you will be taken to a standby screen.
- Press the touch screen [L1] to access the main screen for your device.

5.2 MAIN SCREEN

5.2.1 WHITE BALANCE

To adjust the white balance, proceed as follows:

- Once the camera and light source are connected to the endoscope, film a white surface (e.g. white compress),
- Launch white balance adjustment:
  - . Via the interface: press the AWB button
  - . Via the camera head: perform a long press of the main button [S2]
- Continue filming the white surface until the screen displays the message “AWB OK”.
- There is also an indicator light on the device screen:
  - . White: N/A
  - . Orange: AWB in progress
  - . Green: AWB OK
  - . Red: AWB Not OK

5.2.2 FOCUSSING

- Use the focussing ring [F1] on the sensor lens to focus.
- Once the endoscope is connected and the source activated, slowly turn the ring until it is in a position where objects are seen clearly.
- Focussing from sufficient distance (d~5 cm) allows you to have sufficient depth of field for the procedure without frequent focussing being required.

5.2.3 CAPTURING PHOTOS

! CAUTION

Please note that the system does not have internal storage. If you wish to use the “Capture” function, you must provide a storage system, such as a USB key.
Note: We recommend the use of a USB key in FAT32 format.

- To capture a photo, first connect a USB key or external hard drive to the device [C3].
- An indicator light appears on the device screen, to the right of the capture button  , displaying the storage medium detection status:
  - . White: N/A
  - . Orange: Storage medium detection in progress or photo being saved
  - . Green: Detection OK or photo captured successfully
  - . Red: Error
- When the indicator is green, you can take a photo by clicking the capture button, which will have turned white  , or you can perform a short press of the main button on the camera head.
- Your photo will be saved to your storage system in .tiff format.

 Function unavailable

 Function available

Chapter 5

5.2.4 MODE SELECTION: RIGID OR FLEXIBLE

- The camera is in rigid mode by default. This mode must be used if you are using an endoscope equipped with lenses.
- If you are using a flexible endoscope equipped with optical fibre, change over to flexible mode:
  . Via the interface: press the F button
  . Via the camera head: perform a double-press of the main button [S2]
  An OSD message, represented by “F”, appears on the screen whenever this mode is active.
- To deactivate the mode, press the F button again on the interface, or double-press again on the camera head button.

F Function deactivated

F Function activated

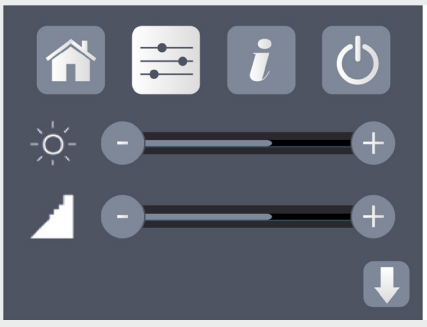
5.2.5 ADJUSTING THE BRIGHTNESS

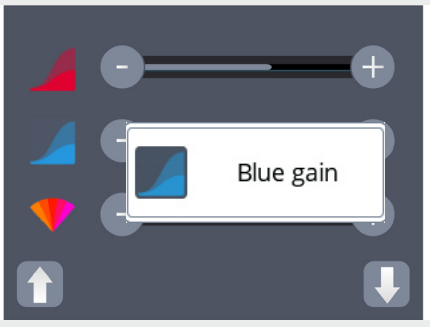
- To adjust the brightness of the light source, you can:
  . Press the + or - buttons on each side of the slider
  . Or drag the slider itself to the left or the right.
  . If the buttons are set to control the light (see 5.4.2 Settings), you can then use the left button [S3] on the camera head to reduce the brightness and use the right button [S4] on the camera head to increase it. A long press on these buttons will reduce or increase the brightness more quickly.

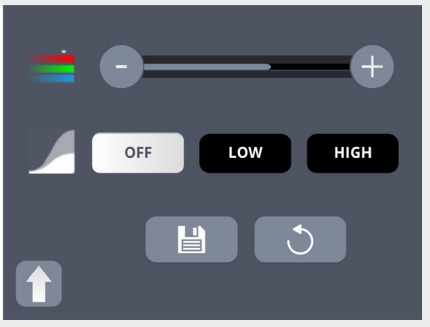
5.3 ADJUSTING THE SETTINGS

- On the header row, click the Settings button to go to the video settings screen.

- These are the available settings:
  - . Brightness
  - . Sharpness
  - . Red gain
  - . Blue gain
  - . Red phase
  - . Colour
  - . Gain







Note When you touch each icon, its name will appear on the screen to tell you which function it represents.

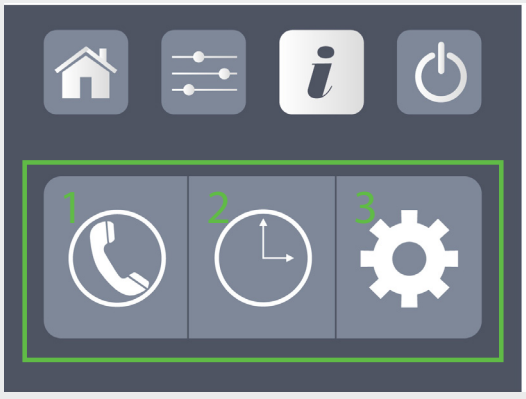
- Press the + or - buttons, or move the slider itself to adjust each setting.
- To move from one screen to another, press the / buttons
- Once they have been changed, you can save your settings by pressing the button.
- You can return the device to your last saved settings (or the factory settings if no custom settings have previously been saved) by pressing the button

Chapter 5

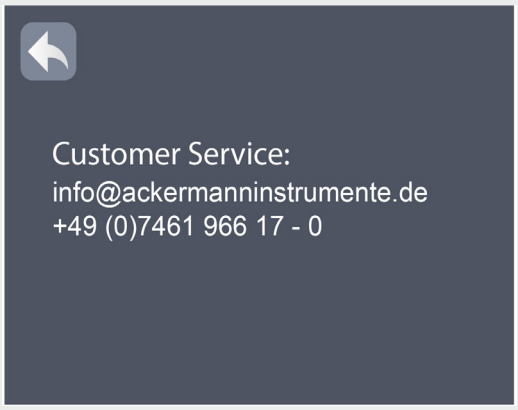
5.4 INFORMATION

➲ Press the Information button on the header row to go to the device settings and after-sales service information screen.

➲ There are three buttons on the information page:
. Contact: takes you to an information page so that you can contact our Customer Service team (1)
. Date/Time: takes you to a screen where you can adjust the date and time (2)
. Settings: takes you to a screen where you can adjust system settings (3)



5.4.1 CONTACT



SERVICE ADDRESS

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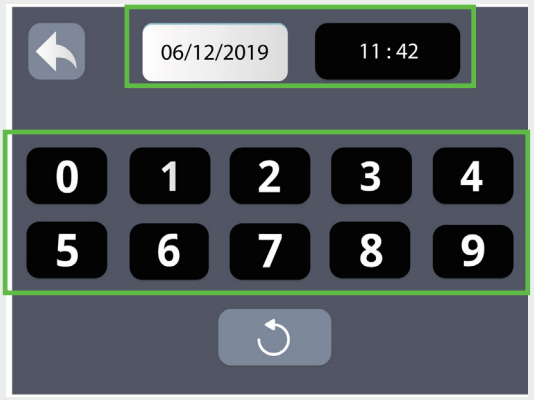
E-Mail: info@ackermanninstrumente.de
Web: www.ackermanninstrumente.de

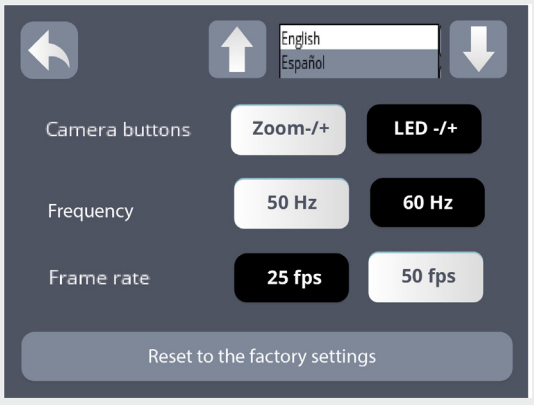
5.4.2 DATE/TIME



- To adjust the date, touch the first rectangle at the top of the screen (marked DD/MM/YYYY).
- Then press the digits to complete the date.

- To adjust the time, touch the second rectangle at the top of the screen (marked HH : MM)
- Then press the digits to complete the time.
- If you want to reset this information, press the button.

5.4.3 SETTINGS



On this screen you can set:

- The device language: FR, EN, TR, DE, IT, ES, AR, DK, NO, NL, RU, SV, JA, NL, TH, CN, PL
- Programming of the camera head buttons [S3] and [S4], namely: Zoom -/+ or LED -/+
- Frequency
- Frame speed
- Restore the device to its factory settings.

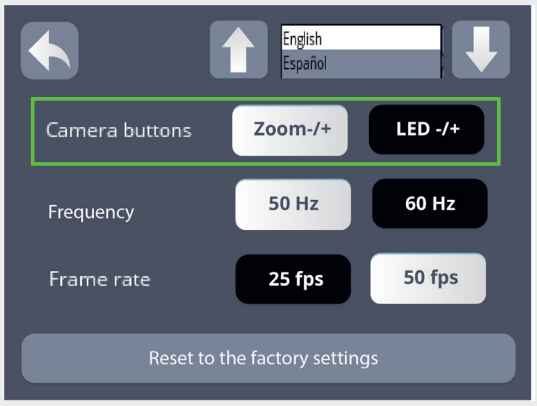
5.5 CAMERA HEAD OPERATION

5.5.1 CONNECTING THE CAMERA HEAD TO THE SYSTEM

- Connect the camera head connector [C8] to the control channel [C1]

5.5.2 BUTTON [S3] AND [S4] SETTINGS

- The Information>Settings menu includes a line with settings for the Zoom -/+ or LED -/+ buttons.
- By default the setting selected is LED -/+, but you can change it at any time to Zoom -/+ by pressing the button



5.6 SHUTTING DOWN THE DEVICE

- You are recommended to put the device into standby before switching it off. To do that, press the button provided for that purpose at the top right of the screen
- Then operate the switch on the back of the device [S1]

Chapter 6 DISINFECTION AND STERILISATION

The instructions relating to cleaning, disinfection and sterilisation protocols for accessories supplied by Ackermann have been approved for each medical device and accessory.

The local regulations in force relating to cleaning, disinfection and sterilisation protocols for accessories take precedence over the information provided by Ackermann.

6.1 CLEAN AND DISINFECTION OF CONTROL CHANNEL

- Distilled or demineralised water is recommended for the cleaning and rinsing of all devices.
- This device is not autoclavable.
- Always disconnect the device before cleaning.
- Decontamination is linked to the products, methods and/or tools selected; it remains the sole responsibility of the personnel concerned.

After every use:
- Clean any possible splashes of liquid from the control unit, removing them with a lightly dampened cloth.

6.2 CLEANING AND DISINFECTION OF THE CAMERA HEAD

For the accessories listed in chapter 2, of which Ackermann is not the manufacturer, please see the relevant manufacturer's manual.

For the accessories listed in chapter 2 and manufactured by Ackermann, cleaning and disinfection guidance is given below.

Products (camera heads)	Pre-cleaning	Cleaning	High-Level Disinfection (HLD)	Drying
PLEASE SEE THE REPROCESSING SECTIONS FOR DETAILED INSTRUCTIONS	Cidezyme 0.8%	Cidezyme 0.8%	CIDEX OPA (0.55%)	STERILE SHEET
	✓	✓	✓	✓

✓ Approved method

6.3 CAMERA HEAD STERILISATION

For the accessories listed in chapter 2, of which Ackermann is not the manufacturer, please see the relevant manufacturer's manual.

For the accessories listed in chapter 2 and manufactured by Ackermann, sterilisation guidance is given below.

Products **(camera heads)**	Sterilisation									
	STERRAD®	STERIS®								
	STERRAD® 100NX	V-PRO 1	V-PRO 1 PLUS		V-PRO MAX			V-PRO 60		
PLEASE SEE THE REPROCESSING SECTIONS FOR DETAILED INSTRUCTIONS	STANDARD CYCLE, 47 MINUTES	Standard cycle	Lumen cycle	Non lumen cycle	Lumen cycle	Non lumen cycle	Flexible cycle	Lumen cycle	Non lumen cycle	Flexible cycle
	✓	✓								

✓ Approved method

Note: Ackermann devices must be cleaned and properly disinfected or sterilised in accordance with approved infection control procedures prior to use and re-use at a later date.
Any deviation from the recommended cleaning and sterilisation settings must be approved by the user.

6.4 PREPARATION PRIOR TO CLEANING

Place the devices in containers and allow to soak for a maximum of one hour in a pH-neutral (pH 6.0 to 8.0) enzymatic cleaning solution (Cidezyme 0.8% - at room temperature [20 °C ± 2 °C/60 °F ± 3 °F] for 4 minutes - or the equivalent, diluted to the appropriate concentration in accordance with the manufacturer's instructions) immediately after use to prevent blood, proteins and other contaminants from drying on the devices. Wipe the devices carefully using a disposable lint-free cloth, preferably moistened with an enzymatic cleaning solution.

! WARNING

Do not leave the device immersed in any solution (including water) for more than 60 minutes.

! WARNING

Do not use alcohol to wipe the device. To avoid damaging the device, do not apply pushing and pulling movements.

Water quality requirements: You are recommended to use distilled or demineralised water to clean and disinfect all devices.

6.5 INSTRUCTIONS ON CLEANING DEVICES

! WARNING

Wear protective gloves, clothing and a mask during the cleaning of contaminated devices.

! WARNING

Do not place cameras in an ultrasonic cleaner.

1. Immerse the device in a cold circulating water bath for 5 minutes and agitate non-rigid components.
2. Brush the exterior of the device under cold running water for 20 seconds.
3. Agitate the non-rigid components of the device and soak the device in a circulating cleaning solution containing water with 0.8% Cidezyme (ASP) at room temperature (20 °C ± 2 °C/68 °F ± 3 °F) for 4 minutes.
4. Rinse the exterior of the device with a water spray gun (below the surface in a water bath, with a static water pressure of 2 bar) 4 times for 5 seconds.
5. Rinse the external surfaces under running demineralised water for 5 seconds.
6. After cleaning, check the devices are clean and undamaged.
7. Do not use devices or accessories with visible signs of damage or which are difficult to use. Any malfunction in an accessory or device during a procedure could cause injury to the patient and other damage to the device.

6.6 STERILISATION INSTRUCTIONS

You are recommended to apply the routine sterilisation procedure for initial sterilisation and any sterilisation at a later date of all the devices. Devices may be sterilised in STERIS® V-PRO® or STERRAD® 100NX sterilisation systems using a Standard cycle. Ackermann accepts use of the following sterilisation systems to reach the desired sterility assurance level (SAL) of 10-6: STERIS® V-PRO® and STERRAD® 100NX on a Standard cycle.

Note: Prior to sterilisation, devices must be carefully cleaned and all visible organic material, blood and cleaning solution must be completely eliminated.

! WARNING

The approved sterilisation settings apply only to sterilisation equipment which is properly serviced and calibrated.

! WARNING

Any deviation from the recommended sterilisation settings must be approved by the user.

! WARNING

Ackermann recommends the use of a cleaning agent and sterilisation method to prevent unknown rates of deterioration of materials due to interactions between the material and chemical products arising from different cleaning and sterilisation processes.

6.6.1 STERRAD® 100NX STERILISATION SYSTEMS

STERRAD® sterilisation systems manufactured by Advanced Sterilization Products (ASP) exploit the combined action of hydrogen peroxide and low-temperature gas plasma to produce rapid inactivation of microorganisms at low temperature and low humidity levels. It is designed for the final sterilisation of reusable medical devices which have been properly cleaned, rinsed and dried.
The STERRAD® 100NX™ is a large steriliser with a rectangular chamber, capacity 51.2 L/26 L (usable) and two cycles - a standard cycle of approximately 47 minutes and a Flex cycle of approximately 42 minutes.

Note: These methods must only be applied to devices which have been specially designed to be compatible with STERRAD® 100NX.

! WARNING

- STERRAD® sterilisation may lead to changes in the outward appearance of devices, which do not necessarily compromise the functionality of the device.
- All devices must be carefully dried prior to loading into the STERRAD® steriliser. Loads containing moisture could cause the cycle to be cancelled.

Note:
Materials such as stainless steel and titanium are compatible with STERRAD® systems.
Please see the user guides for STERRAD® sterilisation systems to find out which other materials are compatible.

- Use only STERRAD® compatible instrument trays in the sterilisation chamber. These trays are specially designed for hydrogen peroxide vapour sterilisation.
- Use only polypropylene sterilisation packaging and/or polyolefine bags approved by the FDA. Do not use paper bags or sterilisation envelopes containing wood pulp or cotton.

Comment:
The devices judged by Ackermann to be compatible with the STERRAD® sterilisation process have been approved with a minimum of one hundred STERRAD® cycles.

6.6.2 STERRAD® 100NX INSTRUCTIONS

1. Clean and dry all devices
2. Place the devices on STERRAD® instrument trays, wrap them in an FDA-approved polypropylene sterilisation wrapping or place them in polyolefine bags. Place STERRAD® indicator strips in all trays and bags.
3. Load the STERRAD® steriliser, arranging the items in such a way that the plasma containing hydrogen peroxide can fully envelop them. Do not allow any item to touch the steriliser wall.
4. Please see the STERRAD® sterilisation system user manual for detailed instructions regarding the use of each STERRAD® device.
5. Contact STERRAD® for the most up-to-date information about sterilisation using STERRAD® 100NX sterilisation systems.

6.6.3 STERIS® V-PRO™ STERILISATION SYSTEMS

STERIS® V-PRO™ low-temperature sterilisation systems from STERIS® use vaporised hydrogen peroxide (without gas plasma) to deactivate microorganisms. The compatible STERIS® V-PRO™ systems and cycles are as follows (see Table 2):

- STERIS® V-PRO™ 1
  - Standard cycle

➲ STERIS® V-PRO™ 1 PLUS
- Lumen cycle
- Non lumen cycle

➲ STERIS® V-PRO™ maX
- Lumen cycle
- Non lumen cycle
- Flexible cycle

➲ STERIS® V-PRO™ 60
- Lumen cycle
- Non lumen cycle
- Flexible cycle

! WARNING

These methods must only be applied to devices which are specially designed to be compatible with STERIS® V-PRO™.

➲ STERIS® V-PRO™ sterilisation may lead to changes in the outward appearance of devices, which do not necessarily compromise their functionality.
➲ Devices must be carefully dried prior to loading into the V-PRO sterilisation chamber. Loads containing moisture could cause the cycle to be cancelled.
➲ Ackermann recommends the use of a cleaning agent and sterilisation method to prevent unknown rates of deterioration of materials due to interactions between the material and chemical products arising from different cleaning and sterilisation processes.
➲ Use only STERIS® V-PRO™ compatible instrument trays in the sterilisation chamber. These trays are specially designed for hydrogen peroxide vapour sterilisation.
➲ Use only polypropylene sterilisation packaging and polyolefine bags approved by the FDA.
➲ Do not use paper bags or sterilisation envelopes containing wood pulp or cotton.

Comment:
The devices judged by Ackermann to be compatible with the STERIS® sterilisation process have been approved with a minimum of one hundred STERIS® cycles.

6.6.4 INSTRUCTIONS FOR THE USE OF STERIS® V-PRO™ SYSTEMS

1. Clean and prepare the devices as recommended in the Cleaning section of this user manual. Make sure the devices are fully dried.
2. Place the devices on STERIS® V-PRO instrument trays, wrap them in an FDA-approved polypropylene sterilisation wrapping or place them in polyolefine bags. Place STERIS® V-PRO indicator strips in all trays and bags.
3. Load the instrument tray into the STERIS® V-PRO™, steriliser, arranging it so that the hydrogen peroxide vapour can envelop it. Do not allow any item to touch the steriliser wall.
4. Consult the STERIS® V-PRO™ sterilisation system user manual for detailed instructions.
5. Contact STERIS® for the most up-to-date information about sterilisation using STERIS® V-PRO sterilisation systems.

6.6.5 HIGH-LEVEL DISINFECTION

Note:
High-level disinfection (minimum requirement) is recommended ONLY for “semicritical” devices which only come into contact with intact mucosa or broken skin.
High-level disinfection is NOT recommended for “critical” devices (instruments) to be used for hysteroscopy, neuroendoscopy, arthroscopy or laparoscopy.
Please see the Cidex OPA labelling for important contraindications concerning the use of Cidex OPA on devices, particularly instruments which will be used for patients affected by cancer of the bladder.

! WARNING

- Any deviation from the recommended disinfection settings must be approved by the user.
- Prior to disinfection, devices must be carefully cleaned, rinsed and dried as necessary.
- To prevent damage to devices, do not immerse them in a disinfectant solution for more than one hour.
- Ackermann recommends the use of a cleaning agent and sterilisation method to prevent unknown rates of deterioration of materials due to interactions between the material and chemical products arising from different cleaning and sterilisation processes.
- Do not mix peracetic acid based solutions with hydrogen peroxide based agents for the processing of flexible endoscopes.

MANUAL DISINFECTION

! WARNING

- Ackermann devices may be disinfected chemically (manually) using high-level disinfectant solutions containing 0.55% ortho-phthalaldehyde (e.g. Cidex OPA, a 14-day solution).
- Ackermann does not recommend the use of Cidex® PLUS or other glutaraldehyde solutions at room temperature for periods of 28 days for manual high-level disinfection, because such solutions and agents contain high concentrations of surfactants, which may dry and crystallise on devices if they are not carefully rinsed off.
- Solutions containing glutaraldehyde at a concentration of more than 2.4% must be avoided, because a higher percentage of glutaraldehyde may damage devices.

6.6.6 INSTRUCTIONS REGARDING HIGH-LEVEL DISINFECTION (HLD)

1. Place the devices in approved plastic containers. Do not soak the devices with other instruments to prevent any potential damage.
2. Prepare the disinfectant solution for use:
- 0.55% ortho-phthalaldehyde (e.g. Cidex OPA)

No activation is required. Use (Cidex) activated dialdehyde solution test strips to check that the solution is above the minimum effective concentration. Test the solution prior to every use. Note the date on which the solution was poured into the original container.

3. Fully immerse the device; you must take care to eliminate all air bubbles adhering to the surface of the immersed device.
4. Use the following disinfection conditions to carry out manual high-level disinfection:
- 0.55% ortho-phthalaldehyde (e.g. Cidex OPA)

Fully immerse the device in the Cidex OPA solution for about 5 minutes at a temperature of greater than or equal to 20 °C ± 2 °C (68 °F ± 3 °F), for no longer than 1 hour.

5. Once disinfection is complete, remove the devices from the disinfectant solution and rinse them, immersing them completely in a large quantity of sterile water (e.g. 8 litres). Keep the devices fully immersed for at least 1 minute. Rinse with a minimum 500 ml of water through all openings during each individual rinse. Repeat this procedure for a total 3 rinses by immersion. Dispose of the water between each rinse, as it will have been contaminated with disinfectant. Use fresh sterile water for each rinse by immersion. Meticulous rinsing of the devices is essential to prevent the toxic effects of any residual disinfectant solution.

Note:
Read the instructions for use provided by the manufacturer of the disinfectant for more detailed information about the use of the disinfectant solution, particularly appropriate rinsing techniques.

! WARNING

Incomplete rinsing can seriously hamper light transmission.

Chapter 7 AFTER-SALES SERVICE AND ROUTINE MAINTENANCE

7.1 MONITORING

The only preventive maintenance the medical device requires is:
- Checking of accessories
- Everyday cleaning, disinfection and sterilisation procedures.

! WARNING

Any incorrect use of the device is not covered by the guarantee. If a problem persists and the device needs to be returned to the after-sales department, make sure it is sent in its original packaging. Similarly, you are recommended to return the device in its entirety (control unit, power supply cables). Ensure your shipping form includes a not explaining the problem encountered.

7.2 AFTER-SALES SERVICE

Contact the supplier of your device. Using the services of an unapproved repairer could render your device dangerous for you and your patients.

Do not repair or modify the device without seeking the prior permission of Ackermann.

If the device is modified or repaired, specific checks and tests must be carried out to ensure that the medical device is still safe to use. In the event of doubt, contact an approved dealer or the after-sales service team at Ackermann:

- by email: info@ackermanninstrumente.de
- by telephone: +49 (0)7461 966 17 - 0
- via a request on the website: www.ackermanninstrumente.de/contact.html

Ackermann will, at the request of technical personnel working for the network of approved dealers, provide all information required to repair the faulty parts on which they may perform repairs.

7.3 FAULTS AND WARNINGS

WARNING		POSSIBLE CAUSE	ACTION TO TAKE
ON CONTROL UNIT	ON MONITOR		
Light cable disconnected	No light cable	Light cable missing	Connect a light cable
Camera disconnected	Camera head disconnected + target on screen	No camera	Connect the camera
AWB indicator red	AWB Not OK	White balance failed	Restart white balance adjustment
USB indicator red	USB Not OK	Problem saving to USB	Remove then reconnect the USB key Next, try a different USB key If the message persists, contact the manufacturer
LED temperature	LED Overheating	LED problem	Contact the manufacturer

! CAUTION

The equipment must be disinfected prior to return for repairs.
When returning the equipment, check its condition and note down any anomalies on the shipping form as necessary. Confirm those anomalies to the carrier by recorded letter within 48 hours. If equipment shipped by us suffers damage during transport, the total cost of repairs will be billed to the carrier if exceptions have been communicated within the deadline, otherwise such charges will be billed to the addressee.

Chapter 8 ELECTROMAGNETIC COMPATIBILITY

All the information below is based on the requirements of standards to which the manufacturers of electrical medical devices must adhere (as stated in standard IEC 60601-1-2).

The medical device complies with the electromagnetic compatibility standards in force. However, the user must make sure that any electromagnetic interference does not create an additional risk, such as radio-frequency transmitters, or other electronic devices.

This chapter contains the information required for you to install and use your medical device in optimum conditions in terms of electromagnetic compatibility.
The different medical device leads must be kept away from each other.

Sometimes mobile telecommunication devices such as mobile phones can interfere with the medical device. The recommended separation distances in this chapter must therefore be strictly observed.

The use of accessories of transducers and cables other than those specified or sold by Ackermann as replacement parts, may have as a consequence an increase of emission or decreased immunity of the medical device and result in inadequate operation.

8.1 CABLE LENGTH

Cables and accessories	Maximum length	Test type	In compliance with:
Mains cord Universal light cable Camera cable	< 3 metres	RF emission	CISPR 11, Class B
		Harmonic current emissions	IEC 61000-3-2
		Voltage fluctuations and flicker	IEC 61000-3-3
		Electrostatic discharge immunity	IEC 61000-4-2
		Radiated, radio-frequency, electromagnetic field immunity	IEC 61000-4-3
		Electrical fast transient/burst immunity	IEC 61000-4-4
		Surge immunity	IEC 61000-4-5
		Immunity to conducted disturbances, induced by radio-frequency fields	IEC 61000-4-6
		Power frequency magnetic field immunity	IEC 61000-4-8
		Voltage dips, short interruptions and voltage variation immunity	IEC 61000-4-11

8.2 RECOMMENDED SEPARATION DISTANCES

The medical device is designed to be used in an electromagnetic environment in which interferences caused by RF radiation are controlled.

The user or installer of the medical device can help prevent any electromagnetic interference by applying a minimum distance, according to the maximum power of the radio-frequency transmission equipment.

! CAUTION

You should avoid using this device alongside other devices or stacked with them, since that could cause incorrect operation. If such use is necessary you should carefully observe this device and the other devices to check that they are operating normally.

8.3 ELECTROMAGNETIC EMISSIONS

The medical device is designed for use in the electromagnetic environment described in the table below. The user and/or installer must therefore ensure that the medical device is used in the environment described below.

Emission test	Conformity	Electromagnetic environment – comments
Electromagnetic radiation disturbance (Radiated emissions) (CISPR 11)	Group 1	The medical device uses RF energy for its internal operation.
Disturbance voltage at power terminals (Conducted emissions) (CISPR 11)	Class B	Professional healthcare facility environment and home healthcare environment.
Harmonic current emission (IEC 61000-3-2)	Conforming	
Voltage variations, voltage fluctuations and flicker (IEC 61000-3-3)	Conforming	

8.4 MAGNETIC AND ELECTROMAGNETIC IMMUNITY

The medical device is designed for use in the magnetic and electromagnetic environment described in the table below. The user and/or installer must ensure conformity of the electromagnetic environment.

Immunity test	Test level as per IEC 60601	Conformity level	Electromagnetic environment / comments
Electrostatic discharge (ESD) (IEC 61000-4-2)	± 8 kV contact ± 2, 4, 8,15 kV air	± 8 kV contact ± 2, 4, 8,15 kV air	Professional healthcare facility environment and home healthcare environment
Electrical fast transient/burst (IEC 61000-4-4)	± 2 kV for electrical supply lines ± 1 kV for ports	± 2 kV for electrical supply lines ± 1 kV for ports	Professional healthcare facility environment and home healthcare environment
Surges (IEC 61000-4-5)	± 0.5 and 1 kV differential mode ± 0.5, 1 and 2 kV common mode	± 0.5 and 1 kV differential mode ± 0.5, 1 and 2 kV common mode	Professional healthcare facility environment and home healthcare environment
Magnetic field at rated industrial frequency (IEC 61000-4-8)	30 A/m	30 A/m	Professional healthcare facility environment and home healthcare environment
Voltage dips, short interruptions and voltage variations (IEC 61000-4-11)	0% UT for 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle 70% UT For 25 cycles at 50 Hz For 30 cycles at 60 Hz Single phase: at 0°	0% UT for 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle 70% UT For 25 cycles at 50 Hz For 30 cycles at 60 Hz Single phase: at 0°	Professional healthcare facility environment and home healthcare environment.

ELECTROMAGNETIC IMMUNITY, RADIO-FREQUENCIES

The medical device is designed for use in the magnetic and electromagnetic environment described in the table below. The user and/or installer must ensure conformity of the electromagnetic environment.

Immunity test	Test level		Conformity level	Electromagnetic environment - Guide
CAUTION: RF portable communication devices must not be used (including peripheral devices such as antenna cables and external antennas) closer than 30 cm (12 inches) from any part of the medical device, including the cables specified by the manufacturer. Otherwise, the performance of those devices could be impaired.				
Radiated radio-frequency electromagnetic fields (IEC 61000-4-3)	Home healthcare	10 V/m 80 MHz at 2.7 GHz 80% MA at 1 kHz	10 V/m 80 MHz at 2.7 GHz 80% MA at 1 kHz	Professional healthcare facility environment and home healthcare environment.
	Professional healthcare	3 V/m 80 MHz at 2.7 GHz 80% MA at 1 kHz	3 V/m 80 MHz at 2.7 GHz 80% MA at 1 kHz	
Nearby fields emitted by wireless RF communications devices (IEC 61000-4-3 provisional method)	9 V/m 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz		9 V/m 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	Professional healthcare facility environment and home healthcare environment.
Conducted disturbances, induced by RF fields RF (IEC 61000-4-6)	Home healthcare	3 V 150 KHz at 80 MHz 6 V in ISM band and band ranging from 0.15 MHZ to 80 MHZ, including amateur radio band 80% MA at 1 KHz	3 V 150 KHz at 80 MHz 6 V in ISM band and band ranging from 0.15 MHZ to 80 MHZ, including amateur radio band 80% MA at 1 KHz	Professional healthcare facility environment and home healthcare environment.
	Professional healthcare	3 V 150 KHz at 80 MHz 6 V in ISM band and band between 0.15 MHz and 80 MHz 80% MA at 1 KHz	3 V 150 KHz at 80 MHz 6 V in ISM band and band between 0.15 MHz and 80 MHz 80% MA at 1 KHz	

Chapter 9

TECHNICAL SPECIFICATIONS

CONTROL UNIT

- Automatic white balance
- Video outputs:
  - 1 HDMI
  - 1 HD-SDI/3G-SDI
  - - 1 USB 3.0 micro B
- Recommended USB key format: FAT32
- Compatible light cable types: Ackermann, Storz® and Olympus®
- Electronic shutter
- Automatic thermal protection system
- Brightness equivalent to 180 Watt Xenon light source
- Manual brightness adjustment
- Anti-blinding function with light cable detection
- LED technology
- Up to 50,000 hours LED service life
- Colour temperature: 5,000 K
- Brightness, sharpness, red and blue gain, red phase and colour settings adjustments
- Gain: Off / Low / High
- Settings displayed on screen
- “SAVE” function to store settings
- “RESET” function to restore factory settings
- Digital zoom up to 2.5x
- Integral (USB) Full HD image recorder / .tiff format
- Touch screen with intuitive interface
- 17 languages
- Dimensions (W x H x D): 260 x 100 x 215 mm
- Weight: 1900 g
- Protection type: IPX0 (no water resistance)
- Electrical supply: 100 - 240 Vac / 50 - 60 Hz
- Electrical power consumption: 85-95 VA
- Two T1.6 A - 250 V fuses (UL/CSA marked only)
- Continuous operation

CAMERA HEAD

- 1 CMOS Exmor RTMnology 1/2" Full HD sensor
- 2 programmable buttons
- Automatic or adjustable electronic shutter (1/50 to 1/100,000)
- Resolution: 1920 x 1080 p
- Definition: 1080 lines
- Active pixel area: 1920 x 1080
- Cable length 2.99 metres
- Dimensions (D x H): 130 x 47 mm
- Weight (camera only): 150 g
- Protection type: IPX7 (waterproof)

Lens (option)

- 24 mm HD lens
- C-mount, instrument holder with locking mechanism
- Weight: 87 g
- Protection type: IPX7 (waterproof)

Environment

- Electrical safety: Class 1 devices, applied parts of CF type
- Operating temperature: +10 °C / +40 °C
- Transport temperature: -10 °C / +45 °C
- Storage temperature: +10 °C / +40 °C
- Atmospheric pressure for operation, transport and storage: 700 hPa to 1060 hPa
- Complies with international standards IEC 60601-1; IEC 60601-2-18; IEC 60601-1-2: IEC 60601-1-6 and NF EN ISO 15223-1
- IEC 62471: risk group 2
- Not suitable for use in the presence of a flammable anaesthetic mixture containing air, oxygen or nitrous oxide.

Chapter 10

DISPOSAL AND RECYCLING

This device bears a recycling symbol in accordance with European Directive 2002/96/EC concerning Waste Electrical and Electronic Equipment (WEEE).
By correctly disposing of this device you will help prevent any harm to the environment and to human health.
The  symbol present on the device or in the accompanying documentation shows that this product cannot under any circumstances be processed as domestic waste. It must therefore be disposed of at a waste centre designated for the recycling of electrical and electronic equipment.
For disposal, please comply with current rules concerning waste disposal in the country of installation.
To obtain further detailed information about the processing, salvage and recycling of this device, please contact your nearest retailer who will tell you how to proceed.

Chapter 11 REGULATIONS AND STANDARDS

11.1 APPLICABLE STANDARDS AND

This medical device complies with the essential requirements of European Directive 93/42/EC and European Regulation 2017/745. It was designed and manufactured in accordance with an EN ISO 13485-certified quality assurance system. This equipment is designed and developed in compliance with Electrical Safety standard IEC 60601-1 in force.
The information in this user manual is based on the requirements of standards to which the manufacturers of medical devices must adhere (as stated in standard IEC 62366-1).

11.2 MEDICAL CLASS OF THE DEVICE

The medical device is a class I device according to European Directive 93/42/EC and European Regulation 2017/745.

11.3 MANUFACTURER'S RESPONSIBILITY

Failure to comply with the recommendations provided by the manufacturer in this document and those supplied subsequently in written, electronic or whatever other form will render the warranty null and void. The manufacturer shall be released from any liability, including for direct or indirect injuries to persons or damage to property and the environment. Furthermore, the managers of the facility, customers or collaborators shall be held liable for any damage and/or accidents and/or deterioration of patients' or operators' health or of the surrounding environment.

11.4 SYMBOLS

S Button
L Indicator light
C Connector
I Label (under the product)
F Lens

Symbol	Description
	Complies with European Directive 93/42/EC and European Regulation 2017/745
	Read user manual before use
	T UL/CSA time-delay fuses
	Potential equalization
	Video output ports and auxiliary control output port
	Protective ground (earth)
REF	Order number
SN	Serial number
	For medical devices, this symbol appears alongside the name and address of the year of manufacture. The latter is denoted by four figures.
	For medical devices, this symbol appears alongside the name and address of the manufacturer.
	Data input and auxiliary output
	CF type device
	Electronic or electrical equipment marketed aft er 13/08/2005. This symbol indicates that this product must not be processed with domestic waste.
	Please read the user manual.
	Upper and lower temperature limit of the medical device
	Humidity range within which the medical device can be safely exposed.
	Atmospheric pressure limit. Indicates the range of atmospheric pressure within which the medical device can be safely exposed.


L1
C1
C2
C3
DU
CAMERA
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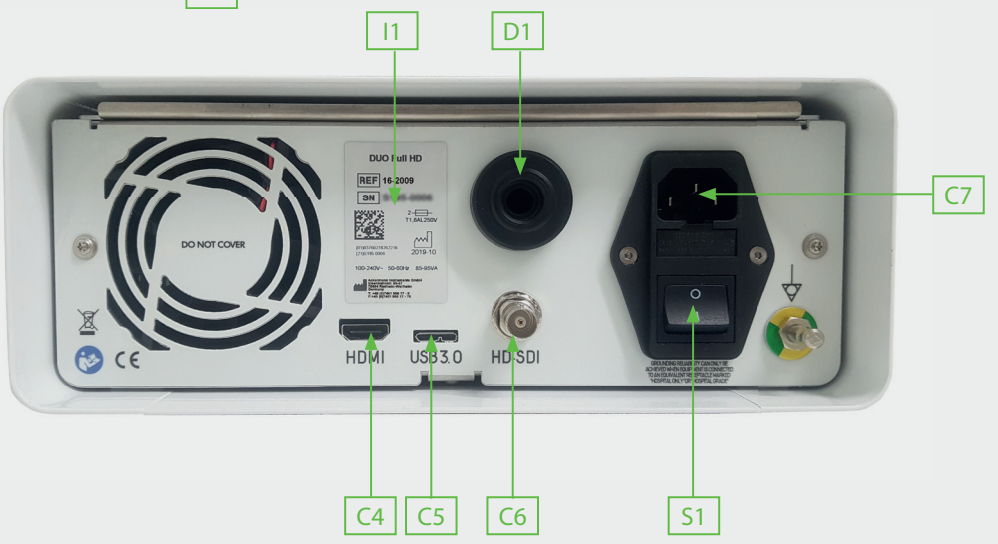
LED


I1
D1
C7
C4
C5
C6
S1
DUO Full HD
REF 16-2009
DO NOT COVER
HDMI
USB3.0
HD-SDI


F1
S4
S2
S3


C8

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