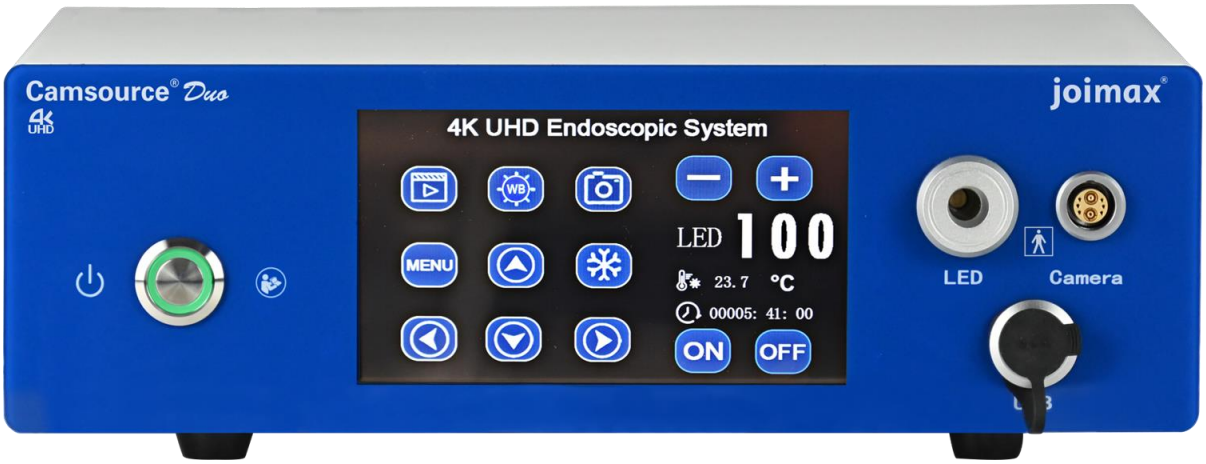
joimax®
Endoscopic Spine Experts

Camsource® Duo

Camera & Light Source System

User Manual



Combined camera and light source system with unique camera technology

Table of Content

1 Legal Notes

The manufacturer is grateful for information about any errors or inconsistencies in this document.

Due to continuous improvement of our products, we reserve the right to make technical changes that do not affect functionality and basic safety.

1.1 Liability

All procedures, notes and warnings described in this manual do not release the operator/user from his or her responsibilities regarding clinical judgment, experience and best clinical practice.

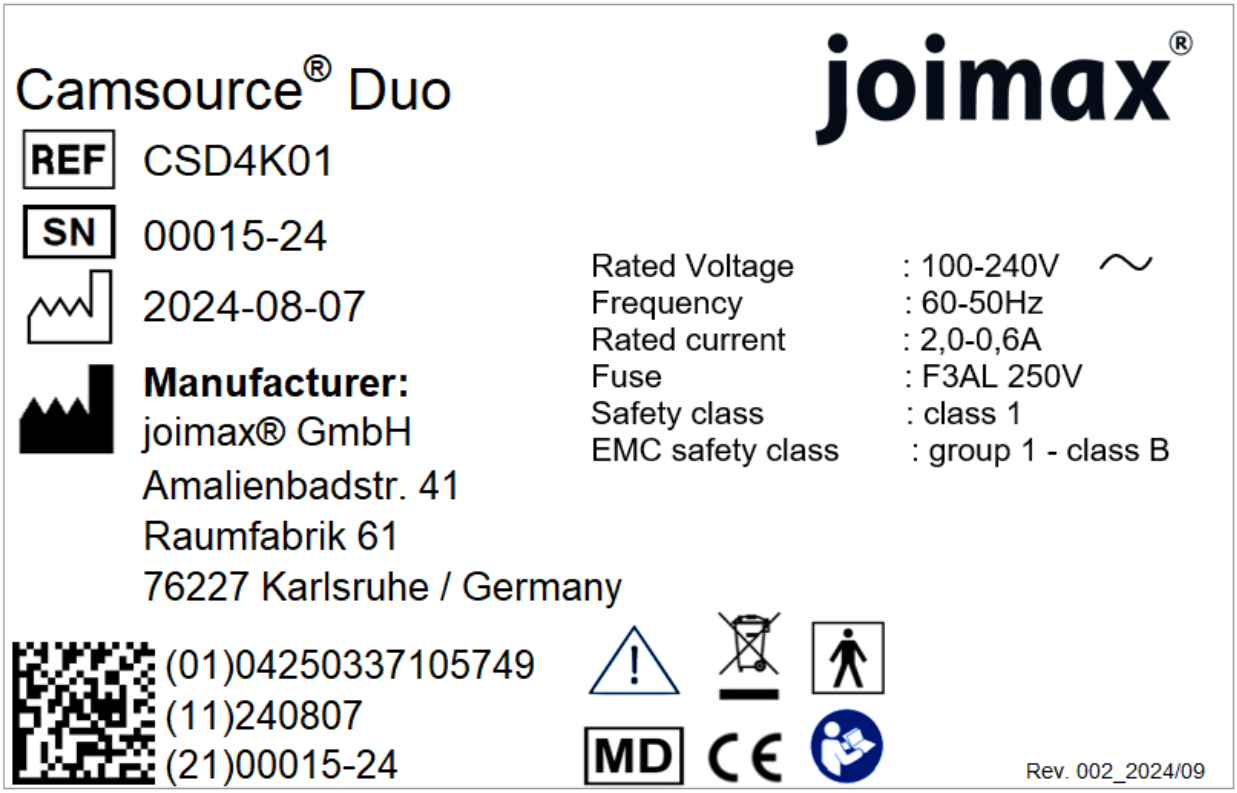
2 General Description

The Camsource® Duo is a combined camera and light source device specially designed for use in endoscopic minimally invasive surgery.
It consists of a camera control unit and a camera head with a high-resolution video sensor, on which an endoscope can be connected. The camera head is connected via cable to the camera control unit. For the light a fiber optic cable is connected to the control unit.

3 Signs and Symbols

	Please note!
	Warning!
	Separate collection of electrical and electronic devices (in accordance with directive 2012/19/EU, WEEE)
	Applied part type BF
	CE mark of the manufacturer according to MDD 93/42/EEC
	Manufacturer
	Date of manufacture
	Follow Instructions for Use
	Item number
	Serial number
	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.
	Equipotential (potential equalization)
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Keep away from rain
	Keep away from sunlight
	Non-sterile
	Medical Device

3.1 Device Label



4 Intended Purpose and Characteristics

Warning:
The device must be used only for its intended purpose described in this manual!

4.1 Intended Purpose

The Camsource® Duo is intended to provide the images of a connected medical endoscope to an external device for display or storage and provide a light source for the illumination of the surgical area, especially in minimally invasive surgical procedures.

Indications for Use

The device is intended to be used in combination with compatible endoscopes during endoscopic minimally invasive surgeries, e.g. at the spine.

Contraindications

Use of the device is contraindicated if, in the opinion of an experienced physician or according to current professional literature, the use would endanger the patient, e.g. due to the general condition of the patient, or if any other contraindications exist.

Intended Patient Population

The patient population is not restricted due to the wide application possibilities of the device. The use of the Camsource® Duo is at the discretion of the respective user on the basis of his training and experience.

Intended Users

The Camsource® Duo is intended for use by medical professionals (e.g. surgeons).
It must be operated under the supervision of qualified and authorized personnel. Users are required to be trained and familiar with the basic principles, application rules, and risks of the device in order to reliably avoid a risk to the patient, user, and others.

Intended Use Environment

The Camsource® Duo is intended for use in operating rooms.
The control unit is intended to be positioned stationary outside of the sterile patient environment, e.g. on a medical cart or table that is suitable in terms of tilting stability and weight of the device.

4.2 Characteristics

Performance Characteristics

The Camsource® Duo provides high resolution imaging (4K), especially in combination with the joimax® 4K endoscopes and the joimax® 4K flat screen monitors.
The integrated LED light source lasts about 50,000 hours and is maintenance-free. It provides constant high color temperature for an ideal and real color reproduction of anatomic structures.
Parameters can be set via an easy to clean touch panel and intuitive on screen display. In addition, the Camsource® Duo features image and video recording to an USB device directly at the device front.

Principles of Operation

The image sensor of the camera head digitizes the analog images of a connected endoscope via a 3 Chip CMOS image sensor and transmits them to the control unit. The control unit processes the images and generates a digital video stream (DVI, SDI, DP and 4K/FHD-HDMI) as signal output for a connected monitor or recording system.

An integrated LED light source generates light in the visible spectral range for illumination of the surgical area. The light is conducted from the camera control unit to the surgical area via fiber optical cable and fiber optics integrated in the connected endoscope.

Key Components

Control Unit	Camera Head	Optic coupler
		
The control unit of the system receives the digital images of the camera head and processes them to a digital video stream and provides video outputs for the connection of monitors and/or recording systems. It includes a glass front with control elements for adjustment of device and image settings. The control unit provides an integrated LED light source, which generates light in the visible spectral range.	The camera head, as the applied part of the system, digitizes the endoscopic images and transmits the video signal to the camera control unit via cable. It has 4 buttons that enable various settings and functions.	The optic coupler allows the endoscopic camera to be connected to an endoscope with ocular connector and the endoscope image to be focused.

4.3 Clinical Benefits

The application of minimal invasive surgical methods is favorable compared to open surgery in terms of the following clinical benefits: help gain easy access to the pathological site thus reducing the surgical duration, smaller incision/less trauma, preservation of stabilizing structures, less scarring, less pain, faster recovery time/reduced hospitalization time and improved quality of life.

Endoscopic spinal surgery clearly profits from an endoscopic camera system in terms of the following clinical benefits: real-time visualization of the surgical area within the patient's body, convenient observation of the images captured by the endoscope on a monitor, reduced duration of the surgical intervention, the patient is less exposed to anesthetics and the surgeon is less physically demanded.

5 Scope of Delivery

After delivery of the Camsource® Duo, the packaging must be checked for external damage. If any components are damaged or missing, please contact joimax® customer service.

Item number	Item description		
CSD4K01S	Camsource® Duo System **List of components:**		
	Item number	**Item description**	**Quantity**
	CSD4K01	Camsource® Duo Control Unit	1
	CSD4K01CO	Camsource® Duo Camera Head Ocular	1
	CSD4K01COV	Optic Coupler	1
	CSLC0250	Fiber optic cable	2
	CSLC0250.L1	Fiber Optic Cable Adapter joimax®/Wolf	2
	JHDMI0020	joimax® HDMI Cable	1
	JMUSBS10	joimax® USB Flash Drive 16GB	1
	n/a	Instructions for Use	2

6 Safety and Warning Notes

6.1 General Safety and Warning Notes

Warning:
This device must be used by trained professionals only!

Warning:
Never touch the patient and any signal input or output connectors on the device at the same time!

Warning:
Installation of the device on a medical trolley with multiple socket-outlet leads to the establishment of a ME system and can lead to a reduced level of safety. The requirements regarding ME systems of IEC 60601-1 must always be observed.

Warning:
The device is not intended for use in explosive areas (e.g. in the presence of anaesthetic gas).

Warning:
Keep these instructions for use in a conspicuous place near the device!

Warning:
Read this manual carefully before first use. Protect yourself, patients, and third parties from damage by defective devices or improper operation!

Warning:
Mechanical stress, such as from falling, can damage or destroy the device!

Warning:
Never use the device with the housing open.

Warning:
Always make sure blood circulation is not impaired when positioning and sedating the patient.

6.2 Additional Notes regarding the Light Source

Warning:
Do not stare into the light source opening or onto surfaces reflecting the light beam. The intense light may cause temporary loss of vision.

Warning:
High-energy light can lead to increased temperature at the light-emitting surface of a connected endoscope. In invasive applications, direct tissue contact might lead to unintended tissue effects. Direct tissue contact is to be avoided and continuous irrigation of the surgical area is recommended.

6.3 Additional Notes regarding Electrosurgical Equipment

Warning:
If the device is used stacked in combination with electrosurgical devices, always position the device above the electrosurgical unit. Ensure that cables of active electrosurgical accessories are not positioned close to the camera control unit or the camera head cable.

Warning:
Never touch the connected endoscope with an activated electrosurgical electrode.

6.4 Additional Notes regarding MRI (Magnetic Resonance Imaging) and CT (Computer Tomography)

Warning:
Do not use the Camsource® Duo during MRI or CT scans.
Due to energetic interactions of magnetic fields and X-rays with the material of the endoscope and camera head, the optical and electrical components of the Camsource® Duo may be damaged. Unforeseeable side effects and visual disturbances may occur.

6.5 Residual Risks and Undesirable Side-Effects

When using the product, residual risks exist and may lead to the following side effects for patient, user or third parties: electric shock, burns, transfer of pathogens, uncoordinated tool orientation, an abortion of the surgery, change of the technique or misinterpretation of anatomical structures.

7 Installation and Commissioning

Warning:
Examine the device, the accessories, and all electrical connections for function and damage prior to use! Defects in cables, connectors, housings or loose parts can impair performance and safety and must be rectified immediately!

***Warning*:**
The Camsource® Duo and the camera head must be cleaned and disinfected before first use according to the cleaning instructions.

Warning:
This device must be installed and commissioned by authorized personnel only. Improper installation could cause damage to the user, the patient, or others, and might damage the device or other medical equipment.

Warning:
Place the device in a way that allows easy disconnection from the mains.

Warning:
The ambient temperature must not exceed 40° C (104° F) during operation.

Warning:
Place the control unit on a clean, flat surface. Ensure that you keep sufficient space behind the device for efficient airflow. Make sure that a minimum distance of 15 cm (6”) is maintained between the back of the device and other objects. All ventilation openings must not be obstructed.

The device is recommended to be installed in the joimax® endoscopic trolley.

Keep the original packaging for possible shipment of the device!

The device and all accessories must be checked immediately upon receipt for completeness and obvious damage. Damages may be claimed only if the manufacturer is notified immediately (within a 24-hour period).

7.1 Connection of the Device

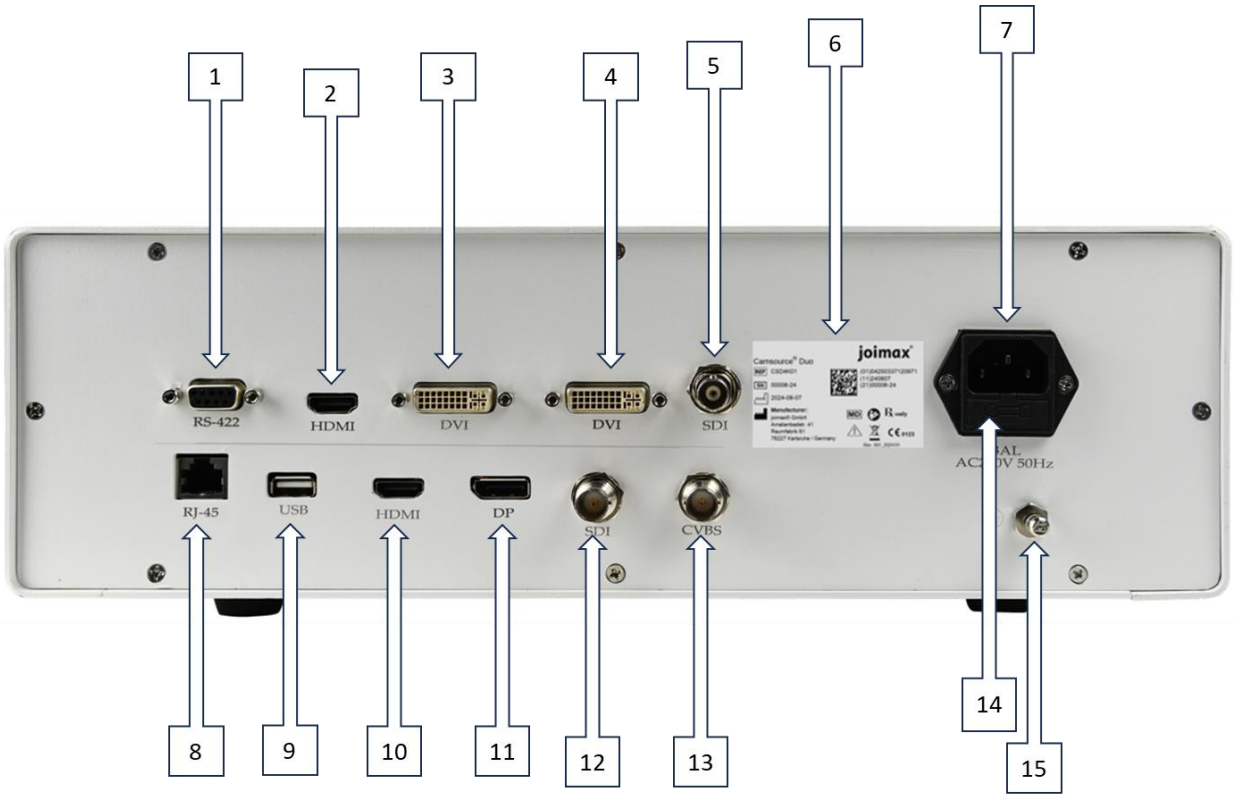
Warning:
To avoid the risk of electric shock, this equipment must always be connected to potential equalization and a power supply with protective earth!

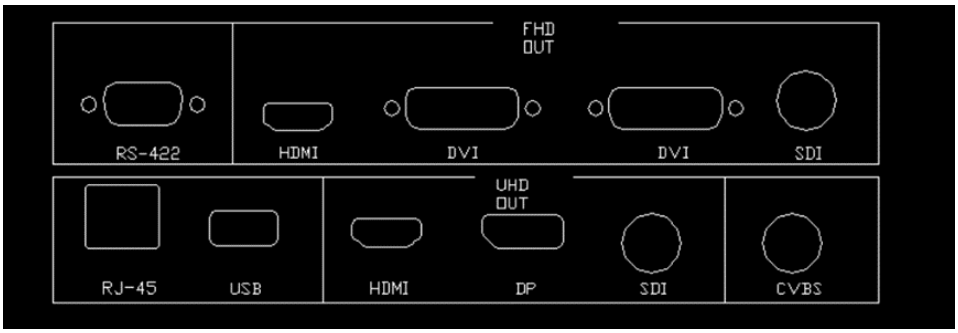
Warning:
Only joimax® accessories (cables etc.) may be used for connection!

Warning:
Always keep cables out of passage areas in order to reduce the risk of stumbling.

Warning:
Make sure all connectors are free of coarse soiling before insertion.

Warning:
Before connecting and launching the system, all components must be visually inspected for integrity. Damaged parts must be replaced. This must be done by experts.





1.	RS-422 socket	9.	USB Socket
2.	FHD HDMI output	10.	4K HDMI output
3.	FHD DVI video output	11.	Display Port output
4.	FHD DVI video output	12.	4k SDI Output
5.	SDI video output	13.	CVBS Output
6.	Device label	14.	Fuse Holder
7.	Mains connection (IEC C14 connector)	15.	POAG (equipotential bonding)
8.	RJ-45 Socket		

16	Fiber optic cable connector
17.	Camera head connector
18.	USB port for USB storage

1. Connecting the Equipotential Grounding to the Appropriate Link

Warning:
The device must always be connected to potential equalization and a supply network with protective earth.

Respect the requirements of section 8.6.7 of IEC 60601-1 regarding medical electrical systems.

Connect the potential equalization plug to the grounding via appropriate cable.

2. Connecting the Device to Mains Supply

Warning:
Always connect the device to a buffered power supply and make sure that the nominal voltage and power values are respected.
Check the power supply cable prior to use!

Use the original power cord to connect the power inlet with the mains supply.

3. Connecting an External Display

Connect the video cable of the display to the corresponding output connector of the control unit (SDI, DVI, DP, HDMI).

4. Connecting the Camera Head Cable and Fiber Optic Cable to the Control Unit

Unscrew the black sealing cap from the plug of the camera head cable. Make sure that the plug is in the correct position (red dot on plug and socket). Connect the Plug to the socket. The Camera Head Cable must be connected before switching the device on, otherwise there will be no picture. If this happens, switch the device off with the cable plugged in and switch it on again.

Insert the plug of the Fiber Optic Cable into the socket until it snaps into place.

7.2 General Safety and Warning Notes

Warning:
This device must be used by trained professionals only!

Warning:
Never touch the patient and any signal input or output connectors on the device at the same time!

Warning:
Installation of the device on a medical trolley with multiple socket-outlet leads to the establishment of a ME system and can lead to a reduced level of safety. The requirements regarding ME systems of IEC 60601-1 must always be observed.

Warning:
The device is not intended for use in explosive areas (e.g. in the presence of anaesthetic gas).

Warning:
Keep these instructions for use in a conspicuous place near the device!

Warning:
Read this manual carefully before first use. Protect yourself, patients, and third parties from damage by defective devices or improper operation!

Warning:
Mechanical stress, such as from falling, can damage or destroy the device!

Warning:
Never use the device with the housing open.

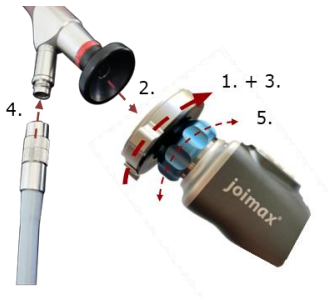
Warning:
Always make sure blood circulation is not impaired when positioning and sedating the patient.

7.3 Connection of an Endoscope

Warning:
For optimal color rendering, white balance must be performed after every change of the endoscope.

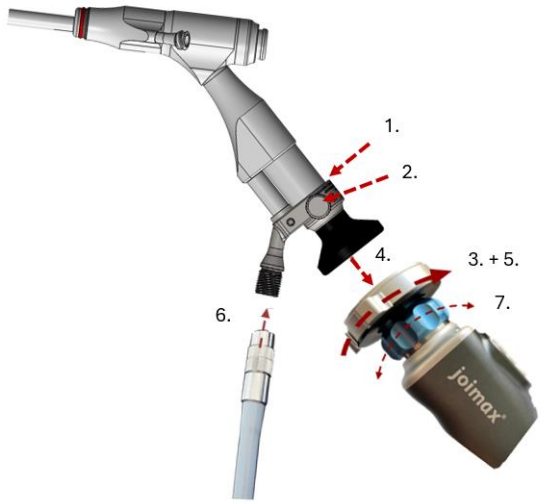
Standard Ocular Connector

1. Open the ocular coupling.
2. Insert the endoscope into the coupling.
3. Release the ocular coupling.
4. Screw the fiber optic cable onto the light connector.
5. Focus the endoscopic image manually by using the focus ring.



Combo Connector with Combo Optic Adapter

1. Connect the Combo Optic Adapter to the Combo endoscope.
2. Tighten the fixing screws on both sides.
3. Open the ocular coupling.
4. Insert the endoscope into the coupling.
5. Release the ocular coupling.
6. Screw the fiber optic cable onto the light connector of the Combo Optic Adapter.
7. Focus the endoscopic image manually by using the focus ring.



7.4 Sterile Preparation of the Camera Head

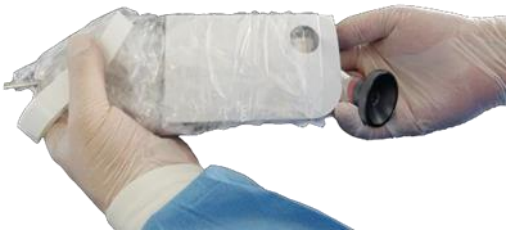
The Camsource® Duo camera head can be sterilized according to the reprocessing instructions in this user manual. Alternatively they can be used with a sterile cover without the need for sterilization between several consecutive applications.

Warning:
The camera head cable must be operated in a sterile condition.

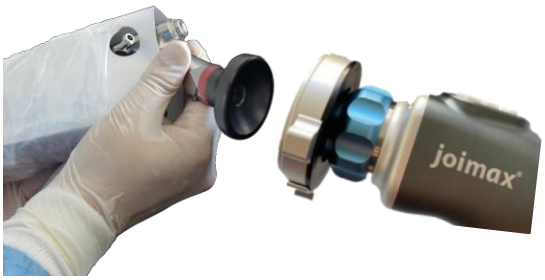
The camera head cable can be used with a sterilized cover. For this purpose, the Camsource® Camera Cable Cover (CSCC1223/CSCC1324US) is recommended.
The Camsource® Camera Cable Cover is sterilized using ethylene oxide and delivered in sterile packaging.

If the camera head are used non-sterile with a sterile cover, joimax® recommends storing the camera head between consecutive operations in the camera head mount attached to the endoscopic trolley or the drawer.

1. The sterile nurse inserts the hand with the endoscope into the sterile cover.



2. While the sterile nurse holds the endoscope, the non-sterile nurse attaches the camera head to the endoscope.



3. The sterile nurse now seals the cover around the endoscope via the adhesive strip.

4. The non-sterile nurse now pulls the telescopically folded cover over the camera head cable towards the control unit.

5. Check the endoscope for proper connection.

7.5 Functional Tests

After correct wiring of the control unit, start the connected display according to its respective instructions for use, then start the Camsource® Duo.

Adjust the output of the Camsource® Duo via the various available image settings until a satisfactory image is displayed.

Warning:
Check live image quality prior to every use.

7.5.1 Behaviour in the Event of Malfunctions

In the event of malfunction of the device or changes in its performance that may affect safety (e.g. deviations from the permissible operating conditions) have the faults corrected immediately.

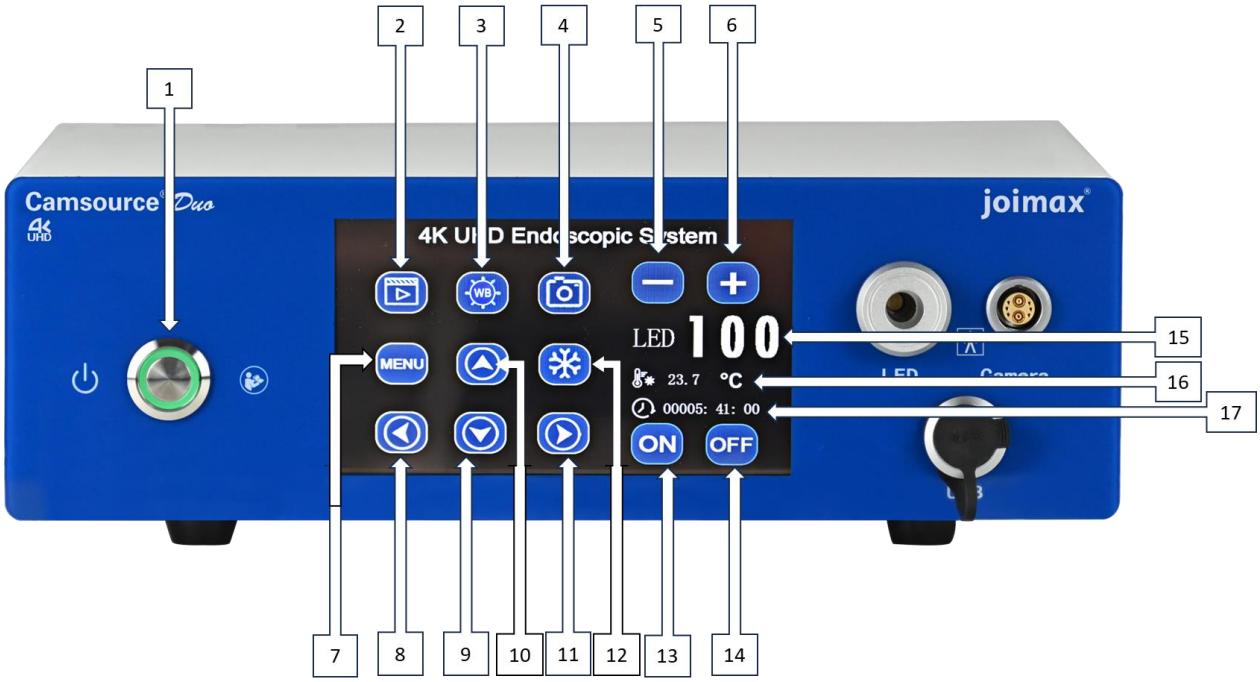
The Camsource® Duo can be switched off at any time by using the power switch as an emergency stop switch.

Proceed as follows in case of malfunctions:

1. Immediately remove the endoscope from the patient.
2. Inspect the Camsource® Duo and perform a functional test.
3. Contact the joimax® technical support.
4. Report any serious incident to joimax® GmbH and the competent authority having jurisdiction in your locale, see Chapter 18.

8 Operation

8.1 Control Elements



1.	Button “Power” with status LED	10.	Button “Up”
2.	Button “Video Recording”	11.	Button “Right”
3.	Button “WB” (White Balance)	12.	Button „Freeze“
4.	Button “Snapshot”	13.	Button “ON” (Light Source)
5.	Button “Minus” (Light Source)	14.	Button “OFF” (Light Source)
6.	Button “Plus” (Light Source)	15.	LED Status
7.	Button “MENU”	16.	Device Temperature
8.	Button “Left”	17.	Running Time
9.	Button “Down”		

8.2 Starting the Device

Warning:
Make sure that the device is turned on only after checking the power connector and after ensuring that the device is completely wired.

Warning:
Before each use and after every change of device settings, always make sure a live image and no still image is displayed!

The booting sequence may take a few seconds to complete.

1. Connect the power cord and press the “Power” button at the frontside of the device to boot it. The LED of the button lit green.
2. Press the “Power” button again to turn the device off.

8.3 Shutting Down the Device

1. The control unit is shut down by pressing the "Power" button at the front of the control unit. The LED of the "Power" button turns off.
2. Press the "Power" button again to restart the device.

8.4 Activating / Deactivating the Light Source

Switching the light source on and off in short intervals reduces the LED life considerably. Please avoid this if possible.

1. Press the button "ON" at the device front. The light source is turned on.
2. Press the button "OFF" to switch the light source off.
3. Press "+/-" to adjust the light intensity (0 – 100)

8.5 Performing White Balance

Warning:
For optimal color rendering, white balance must be performed after every change of the endoscope.

Warning:
Make sure to keep the endoscope directed towards the white surface until the white balancing has been completed.

To find the optimal white point, it may help to vary the distance between the distal end of the endoscope and the white object while performing the white balance. The white surface should not reflect. A piece of white paper or gauze is recommended.

White balance is necessary to ensure a lifelike color reproduction in case of different lighting conditions, varying optical circumstances and generally after changing endoscopes.

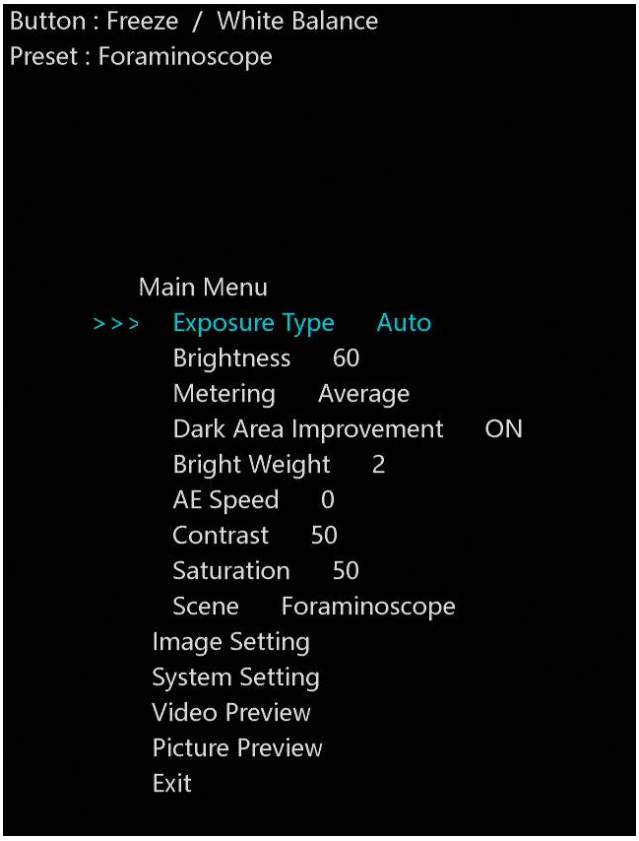
1. Connect an endoscope to the camera head.
2. Switch the light source on.
3. Press the button "WB" at the device front while holding a pure white surface in front of the distal end of the endoscope at a distance of 1 – 3 cm (approx. ½ - 1¼").
4. Check that a satisfactory live image is displayed.

8.6 Changing Settings

To enter a settings menu, press the “MENU” button on the device front:

The following menus are displayed on the screen:

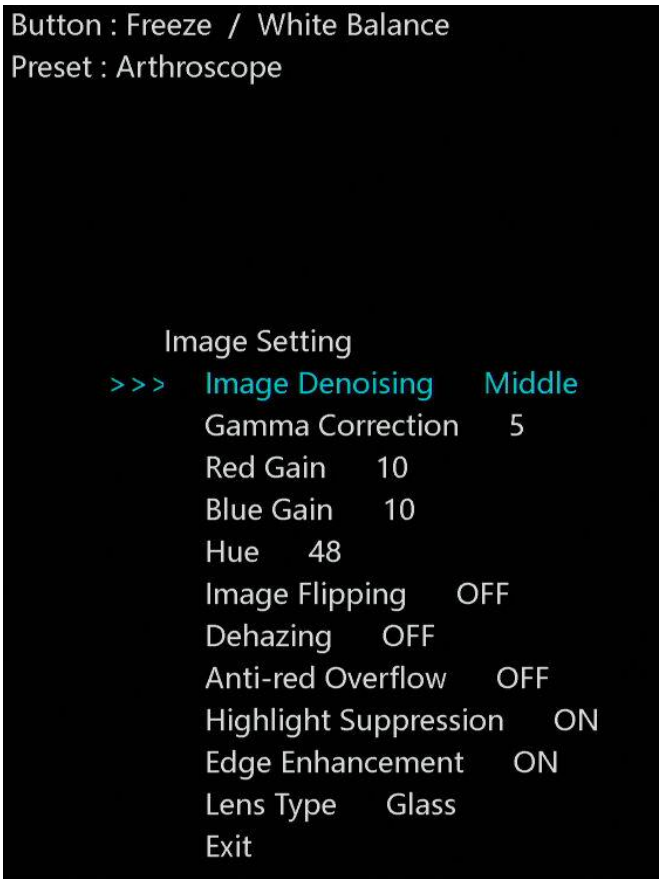
Main Menu



with the following settings:

Exposure Type	**Auto/Manual**
Brightness	**40-80**
Metering	**Average/Center/Around/Global**
Dark Area Improvement	**ON/OFF**
Bright Weight	**2 – 10**
AE Speed	**0 – 10**
Contrast	**40 – 80**
Saturation	**30 – 70**
Scene	**Foraminoscope/Laparoscope/Fiberscope/Arthroscope/ Otorhinoscope/Laryngoscope/Intrauterine Uroscope/Foraminoscope/PreSet1/PreSet2/PreSet3**

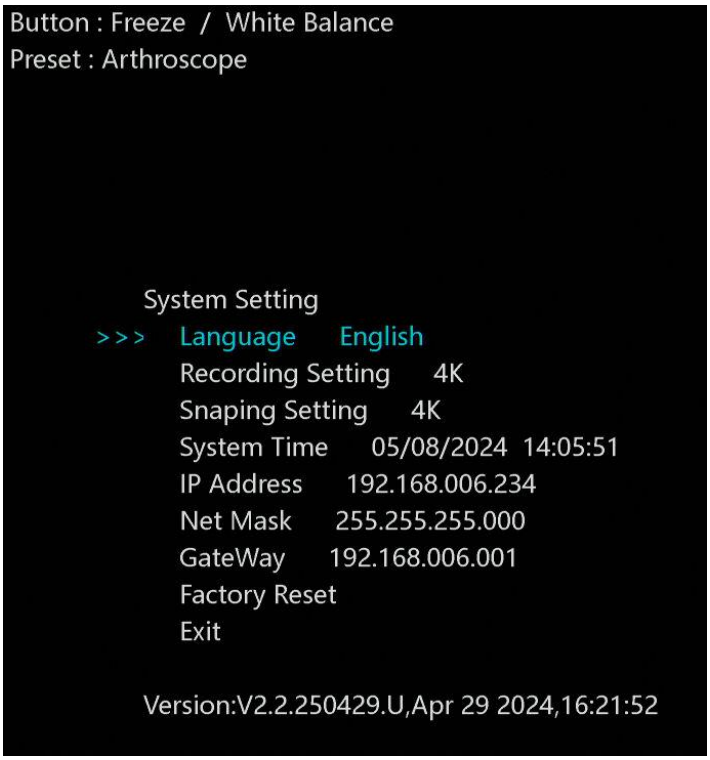
Image Setting



with the following settings:

Image Denoising	**Off/Low/Middle/High**
Gamma Correction	**0 - 10**
Red Gain	**0 - 20**
Blue Gain	**0 – 20**
Hue	**40 - 60**
Image Flipping	**ON/OFF**
Dehazing	**ON/OFF**
Anti-red Overflow	**ON/OFF**
Highlight Suppression	**ON/OFF**
Edge Enhancement	**ON/OFF**
Lens Type	**Glass/Fiberoscope**

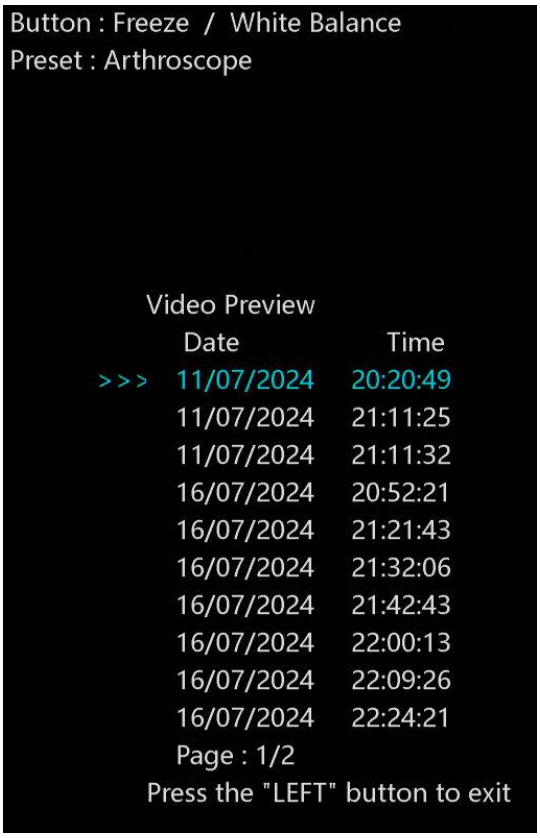
System Settings

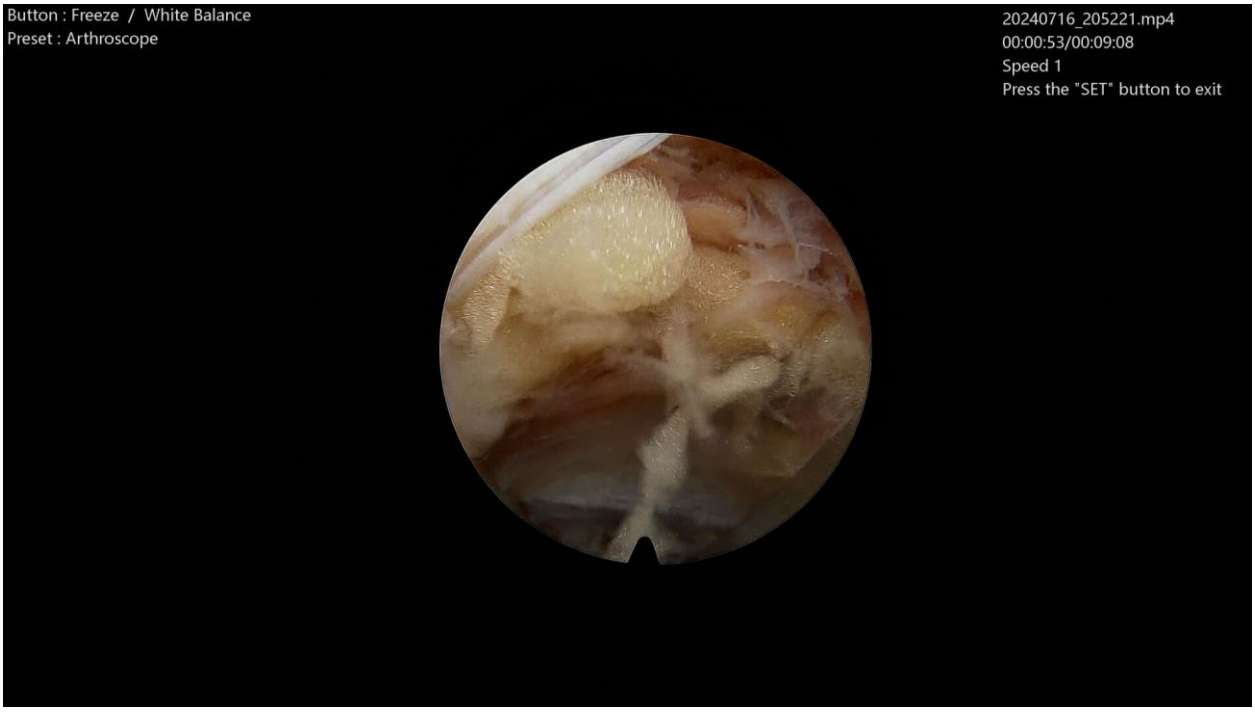


with the following settings:

Language	**English/Chinese**
Recording Setting	**720p/1080p/4K**
Snaping Setting	**720p/1080p/4K**
System Time	**Set System Time**
IP Address	**Set IP Address**
Net Mask	**Set Net Mask**
GateWay	**Set GateWay**
Factory Reset	**Set to Factory Settings**
Version	**Current Software Version**

Video Preview

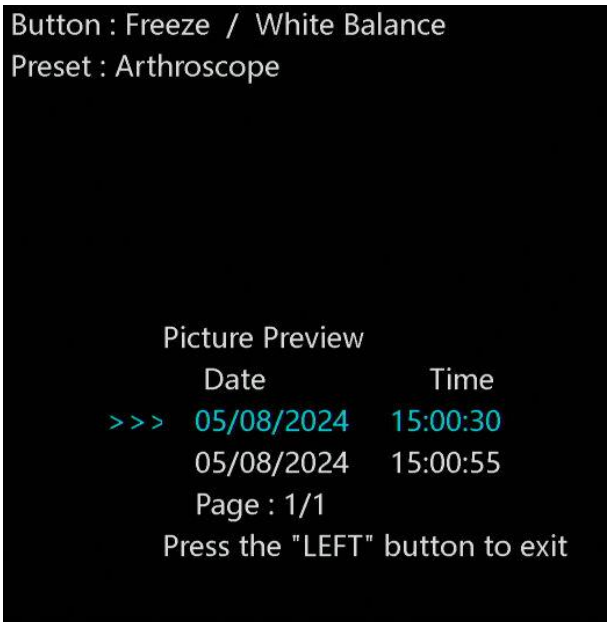


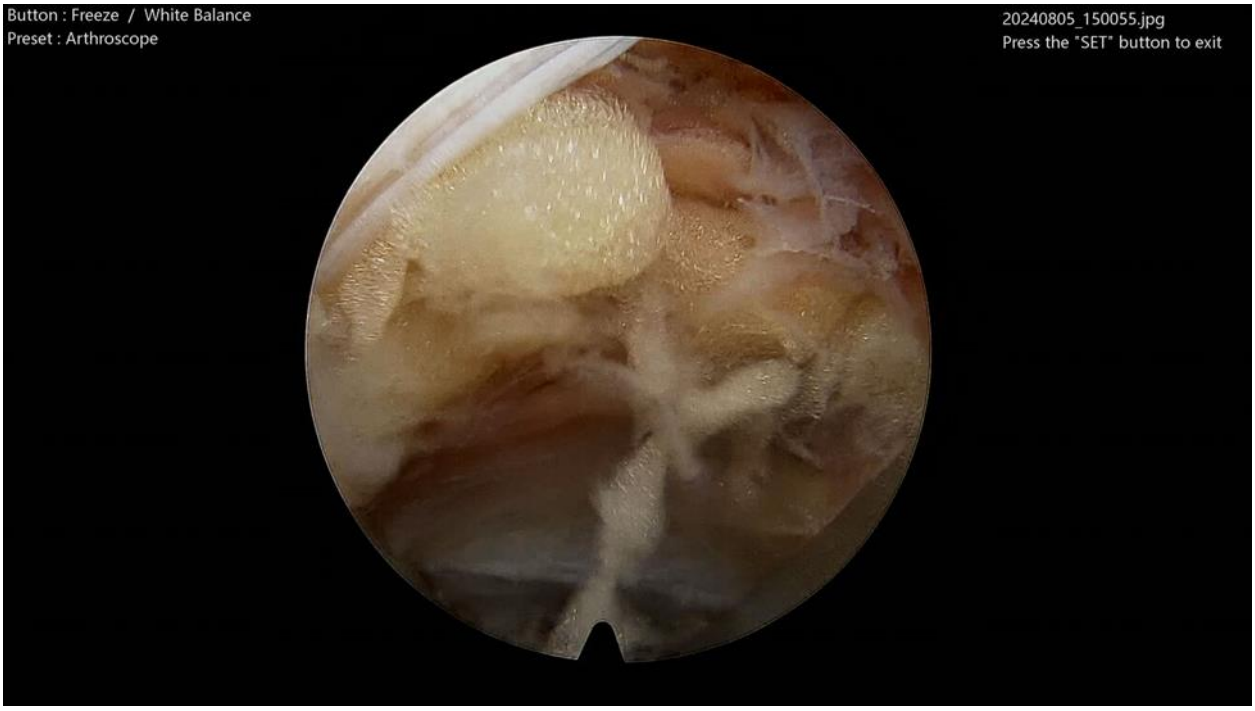


with the following settings:

Speed **1/4 - 2**

Image Preview





Individual parameters are selected via the “Up” and “Down” buttons.
The selected setting can then be adjusted with “left” and “right”.

8.7 Taking a Snapshot / Video

The Camsource® Duo does not provide any internal storage. To take a snapshot, a USB storage must be connected. The connected USB storage must be FAT32 formatted.

The camera can make a snapshot of the currently displayed endoscopic image and store it as a JPEG file directly on a connected USB storage.

To save a snapshot, press the "Snapshot" button with USB storage connected and ready to use.

To save a video, press the "Video" button with USB storage connected and ready to use.

9 Processing

Warning:
The Camsource® Duo and the camera head must be cleaned and disinfected before first use.

Warning:
The Camsource® Duo Control Unit is not suitable for sterilization!

Warning:
Before cleaning or disinfection, turn off the device and disconnect it from the power source. Also, disconnect it from all other devices connected to a power source.

Warning:
Check the device and all accessories after processing and prior to every use for damage and for proper operation.

Always respect locally applicable regulations and hygiene procedures of the hospital.

9.1 Cleaning and Disinfection of the Control Unit

Warning:
Ensure no liquid enters the Camsource® Duo Control Unit during cleaning and disinfection.

Warning:
Before cleaning or disinfection, disconnect all components from the Camsource® Duo Control Unit and disconnect the control unit from its power source.

Warning:
In case of severe soiling, the front panel of the control unit can be carefully cleaned with a cotton swab soaked in alcohol. Do not use any sharp objects for cleaning!

For effective wipe disinfection of the Camsource® Duo Control Unit, use of Mikrozid® sensitive wipes (Schülke & Mayr) is recommended by joimax® GmbH.

Pay particular attention to the connectors at the front of the control unit and the plugs of the handpieces. Make sure to let them dry thoroughly before connecting any components.

The surfaces of the Camsource® Duo Control Unit can be cleaned and disinfected with a suitable mild varnish- and plastic-friendly cleaning and disinfectant detergent using the following procedure:

1. Turn off the device.
2. Disconnect the camera head and from the control unit and disconnect the control unit from the power supply.
3. Seal the USB port at the device front with the attached plug.
4. Apply the cleaning detergent onto a sponge or soft cloth and wipe the exterior surfaces of the device repeatedly.
5. Wipe off the cleaning agent with a sponge or soft cloth moistened with clean water.
6. Dry the device surface with a clean and lint free cloth.

9.2 Cleaning, Disinfection and Sterilization of the Camera Head, Optic Coupler and Fiber Optic Cable

Warning:
Do not clean and disinfect the Camsource® Duo Camera Head Ocular (CSD4K01CO) with a optic coupler (CSD4K01COV) being attached. Always unscrew the optic coupler from the camera head and process the optic coupler separately.

Warning:
Ensure no liquid enters the camera head connector sealing cap during cleaning and disinfection.

Warning:
The camera head are not suitable for ultrasonic cleaning.

Warning:
Immediately after use (within a maximum of 2 hours), coarse soiling must be removed from the camera head with running water or a disinfectant solution.

For quick cleaning and disinfection between several consecutive applications with a sterile cover, it is recommended to perform a simple wipe disinfection or rapid disinfection following the steps below:

1. Disconnect the camera head from the control unit and from the endoscope.
2. Unscrew the optic coupler and the fiber optic cable
3. Screw the sealing cap tightly onto the plug of the camera head cable.
4. Apply the cleaning detergent or disinfectant onto a sponge or soft cloth and wipe the exterior surfaces of the camera head repeatedly.
5. Wipe off the cleaning agent with a sponge or soft cloth moistened with purified water.
6. Properly dry the camera head.

It is recommended to thoroughly clean and disinfect the camera head at least once a week following the instructions below:

9.2.1 Pre-Treatment

Warning:
To remove soiling manually, use a soft brush or a clean soft cloth designed exclusively for this purpose. Never use a metal brush, steel wool or any sharp objects for cleaning.

Warning:
Do not use abrasive cleaners, waxes or solvents for cleaning.

1. Disconnect the camera head from the control unit and from the endoscope.
2. Unscrew the optic coupler and the fiber optic cable.
3. Screw the sealing cap tightly onto the plug of the camera head cable.
4. Rinse the camera head with purified water (Temp. < 35° C/95° F). Push each button at least three times during rinsing.

9.2.5 Sterilization

Warning:
The camera head must be sterilized before first and every use if they are used without a sterile cover.

Warning:
The Camsource® Duo Camera Head Ocular (CSD4K01CO) must only be sterilized using plasma sterilization! Note the markings on the camera head.

Warning:
Uncleaned camera head must not be sterilized as the effectiveness of the sterilization is only guaranteed after cleaning and disinfection. Make sure the camera head are clean before sterilization!

Warning:
Other autoclave settings and cycles than specified may have negative effects on the sterilization result and the function of the camera head.

Warning:
Please note that overloading the sterilizer may reduce the sterilization result. Also, in case of overload there is the possibility of undesirable condensation, which increases the formation of corrosion on camera head. Observe the manufacturer's instructions for maximum loading of the sterilizer.

It is the responsibility of the user to carry out the recommended sterilization procedures with regard to achieving the desired or required sterilization effect.

Applicable national legal regulations must be observed.

It is not recommended to use other sterilization methods (such as flash sterilization, hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization).

The STERRAD® sterilization system may cause cosmetic changes to some optic coupler components.

The Camsource® Duo **Camera Head Ocular (CSD4K01CO)**, Optic Coupler (CSD4K01COV) and Fiber Optic Cable (CSLC0250) can be sterilized using the following procedures:

PLASMA STERILIZATION
STERRAD® STERILIZATION SYSTEM Comply with STERRAD® Advanced Sterilization Products instructions. The camera head is compatible with the STERRAD® 100NX DUO Cycle.

9.2.6 Storage

After sterilization, the camera head must be stored dry and dust-free in the sterilization packaging.

9.3 Reusability

Warning:
When selecting cleaning agents and disinfectants, make sure they do not contain the followings substances:

- *organic, mineral, and oxidizing acids (minimum admitted pH-value 5.5)*
- *lyes (maximum admitted pH-value 8.5, neutral/enzymatic cleaner recommended)*
- *organic solvents (for example: acetone, ether, alcohol, benzene)*
- *oxidizing agents (for example: peroxide)*
- *halogens (chlorine, iodine, bromine)*
- *aromatic, halogenated hydrocarbons*
- *heavy metal salts*
- *oils*
- *acids*

Warning:
Do not expose the camera head to temperatures above 138° C/280° F.

Warning:
The lifetime of the camera head is limited, because they are subject to natural wear and aging. Inappropriate handling, e.g. overloading, unsuitable cleaning agents, high temperatures, etc., may reduce the lifetime of the equipment.

The manufacturer recommends a preventive maintenance after 50 reprocessing cycles. If appropriate care is taken and the above procedures are used, the camera head can be reprocessed at least 150 cycles. Any further re-use or the use of damaged and/or contaminated instruments is in the responsibility of the user.
In case of any doubt about product quality we recommend to return the camera head for inspection or for replacement to joimax®.

10 Technical Data

General	
Power supply	100 – 240 V AC , 50 / 60 Hz
Current consumption	2.0 - 0.6 A
Fuse	F3AL 250V
Weight	9.20 kg
Dimensions	Control Unit (W/D/H): 330 × 340 × 110 mm Camera Head (W/D/H/L): 35 x 110 x 40 x 2960 mm
The system is completely closed for access by the user during intended use. The Camsource® Duo software is embedded into the control unit and the system does not provide any network functionality. Therefore no requirements concerning hardware or special IT security measures are necessary to run the software as intended.	
Operating conditions	
Operating temperature	+10 °C to +35 °C / +50 °F to +95 °F
Relative humidity	30% to 75%, non-condensing
Atmospheric pressure	70 – 106 kPa (0 – 3000 m)
Transport and storage conditions	
Temperature	-25 °C to +70 °C / -13 °F to +158 °F
Relative humidity	10% to 90%
Atmospheric pressure	50 – 106 kPa
Special conditions	Keep the device dry and protected from sunlight.
Safety	
Protection class	I
Applied standards	
IEC 60601-1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2013, IEC 60601-2-18:2009, IEC 62304:2015, IEC 62366-1:2016	
Camera	
Digital video output	DVI, SDI, HDMI, DP
Resolution	DVI, SDI,HDMI: 1920 x 1080 pixels DP, SDI, HDMI: 3840 x 2160 pixels
Documentation	
Functions	Capture of image and video files
Image formats	JPEG
Video formats	MP4
Storage	USB 2.0 port for USB storage
Applied part	
Classification	Type BF (according to IEC 60601-1)

11 EMC Notes

Warning:
The Camsource® Duo mandates special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

Warning:
Use of accessories and cables other than those specified or provided by the manufacturer of this equipment may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning:
Use of this device adjacent to or stacked with other devices should be avoided, because it might result in improper operation. If the endoscopic camera must be used in a stacked configuration or adjacent with other electronic devices, this device and the other devices must be observed to ensure normal operation.

Warning:
This product may emit radio frequency energy and, if not installed and used according to the instructions, may cause harmful interferences to other devices in the vicinity. If this product interferes with other devices, the user is encouraged to try the following in order to correct the interference:

- *Increase the distance between interfering components.*
- *Consult the manufacturer of the other device for help.*

Warning:
Portable RF communications equipment should be used no closer than 30 cm (12”) to any part of the Camsource® Duo. Otherwise, the performance of this equipment might be impaired.

This equipment has been tested and found to comply with the requirements regarding electromagnetic compatibility (EMC) according to IEC 60601-1-2:2014 (Ed.4). The customer or user of the Camsource® Duo has to ensure that it is operated in such environments.

The Camsource® Duo is suitable to be used in combination with RF surgical equipment. The device was tested according to IEC 60601-2-2, BB.4 and can withstand the emissions produced by such equipment.

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 group 1, class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The Camsource® Duo is suitable for use in professional healthcare facility environments according to IEC 60601-1-2:2014 (Ed.4).

Phenomenon	Compliance	Electromagnetic environment – guidance
Conducted and radiated RF emissions	Group 1	The Camsource® Duo uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class A	The Camsource® Duo is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic distortion	Not applicable	
Voltage fluctuations and flickers	Not applicable	

Guidelines and Manufacturer's Declaration - Electromagnetic Immunity

The Medical Endoscopy Camera System is intended for use in the electromagnetic environment specified below. The purchaser or user shall ensure that it is used in this electromagnetic environment.

Immunity test	IEC60601 Experimental Levels	level of compliance	Electromagnetic Environment - Guidelines
electrostatic discharge GB/T 17626.2	±6kV contact discharge ±8kV air discharge	±6kV contact discharge ±8kV air discharge	The floor should be wood, concrete or ceramic tile, and if the floor is covered with synthetic material, the relative humidity should be less than 30%.
Electrical fast transient pulse group GB/T 17626.4	±2kV to power line ±1kV to input/output lines	±2kV to power line inapplicable	Grid power should be of a quality typically used in commercial or hospital settings
(electrical) surge GB/T 17626.5	±1kV line to line ±2kV line to ground	±1kV line to line ±2kV line to ground	Grid power should be of a quality typically used in commercial or hospital settings
Power input line Voltage transient, Short interruptions and voltage variations GB/T 17626.11	<5% UT for 0.5 cycles (on UT, >95% transient drop) 40% UT for 5 cycles (on UT, 60% transient drop) 70% UT for 25 cycles (on UT, 30% transient drop) <5% UT for 5s (>95% transient drop on UT)	<5% UT for 0.5 cycles (on UT, >95% transient drop) 40% UT for 5 cycles (on UT, 60% transient drop) 70% UT for 25 cycles (on UT, 30% transient drop) <5% UT for 5s (>95% transient drop on UT)	The grid power supply should be of a quality typically used in a commercial or hospital setting. If the user of the medical endoscopy camera system requires continuous operation during power interruptions, an uninterruptible power supply (UPS) or battery power is recommended for the medical endoscopy camera system.
industrial frequency magnetic field (50Hz) GB/T 17626.8	3A/m	3A/m	The IF magnetic field shall be characterized by IF magnetic field levels typical of sites in a typical commercial or hospital environment.

Note: UT is the AC grid voltage before applying the experimental voltage.

Guidelines and Manufacturer's Declarations - Electromagnetic Immunity

<table>
<tr><td colspan="4">The Medical Endoscopy Camera System is intended for use in the electromagnetic environment specified below. The purchaser or user shall ensure that it is used in this electromagnetic environment.</td></tr>
<tr><td>immunity test</td><td>IEC60601 test level</td><td>level of compliance</td><td>Electromagnetic Environment - Guidelines</td></tr>
<tr><td>radio-frequency conduction (RFCC)
GB/T 17626.6

radio-frequency radiation
GB/T 17626.3</td><td>3V (RMS)
150kHz~80MHz

3V/m
80MHz~2.5GHz</td><td>3V (RMS)

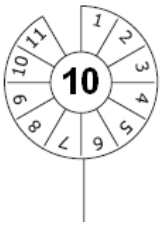
3V/m</td><td>Portable and mobile RF communications equipment should not be used closer to any part of the product including cables than the recommended isolation distance, which should be calculated using a formula corresponding to the frequency of the transmitter.
Recommended isolation distance
$d=1.2\sqrt{p}$
$d=1.2\sqrt{p}$ 80MHz~800MHz
$d=2.3\sqrt{p}$ 800MHz~2.5GHz
Style:
P - Transmitter supplied by the transmitter manufacturer
The maximum output rating of the shooter to
Watts (W) units.
d-Recommended isolation distance in meters (m)
The field strength of a fixed RF transmitter, as determined by a survey of the electromagnetic field house[a] , should be lower than the compliance level in each frequency range[b] .
Interference may occur in the vicinity of equipment marking the following symbols.
  </td></tr>
<tr><td colspan="4">Note 1: At 80 MHz and 800 MHz frequencies, the formula for the higher band should be used.
Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by breathing and reflections from building , objects and humans.</td></tr>
<tr><td colspan="4">Fixed transmitters such as: base stations for wireless (cellular/cordless) telephones and terrestrial mobile radio, amateur radio,
The field strength of AM and FM radio broadcasts, as well as television broadcasts, etc., cannot be predicted accurately in theory. For the purpose of evaluating fixed
The electromagnetic environment of the RF transmitter should be considered the survey of the electromagnetic field house. If the field strength of the site where the medical endoscope camera system is located is measured to be higher than the above mentioned
RF compliance level, then the medical endoscopic camera system shall be observed to verify that it can function properly. If abnormal performance is observed, additional measures
It may be necessary, for example, to reorient and reposition the product.
[b]The field strength should be less than 3V/m over the entire frequency range of 150KHz~80MHz.</td></tr>
</table>

12 Service / Maintenance

Warning:
Do not use the device during service activities.

joimax® GmbH recommends performing a function and safety inspection at regular intervals according to EN 62353 or to other corresponding country-specific regulation.

The Camsource® Duo is low maintenance. Regardless of the Camsource® Duo being low maintenance, regular service can contribute to early detection of defects and faults and, thus, extend the operating life of the devices.



Next inspection

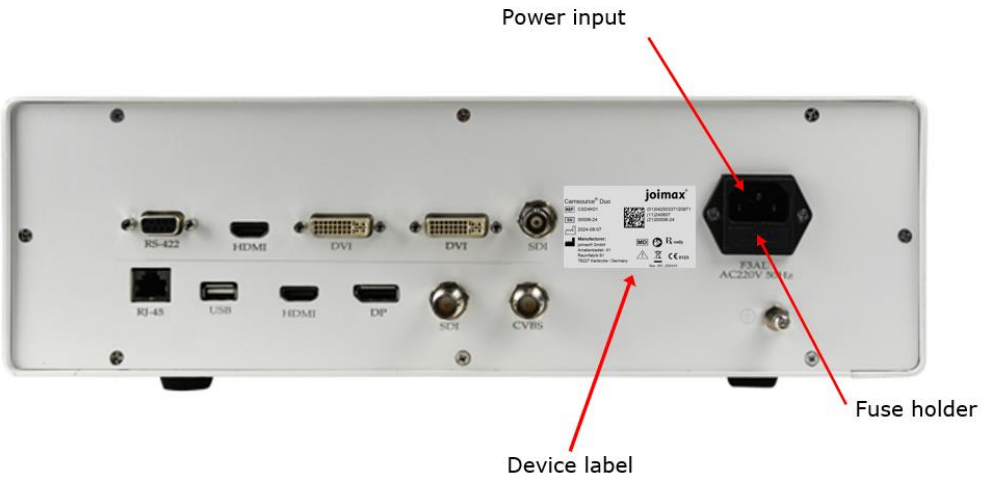
An operating life of 5 years is specified for the Camsource® Duo Control Unit. Any use beyond this depends on the results of the safety inspections. The operating life of the camera head is verified for up to 150 sterilization cycles. Any further re-use or the use of damaged and/or contaminated instruments is in the responsibility of the user. The lifetime of the optic coupler depends on the applied method of cleaning, disinfection and sterilization.

joimax® GmbH recommends an inspection to be performed at least once a year. The inspection should be documented with an inspection-label on the device.

12.1 Replacing the Fuse

Warning:
Always observe the specifications on the device label and follow the instructions below when replacing the fuse. Non-observance may result in malfunction of the device and possible injury.

Warning:
Always disconnect the device from the power supply when performing service activities.



1) Unplug the power cord from the control unit.
2) Open the fuse holder.
3) Check the type of replacement fuse on the device label and replace the defective fuses.
4) Plug the power cord into the control unit.
5) Turn on the device via the power switch at the device front and check the function of the device.

13 Troubleshooting

Problem	Possible cause	Possible solution
No operation	No power supply	Check power supply connection Check main fuses
	Device is not switched on	Switch on the device
	Defective device	Contact joimax® customer service
No image	Device is not switched on	Switch on the device
	Incorrect cabling on device and monitor	Inspect correct cabling
	Incorrect monitor settings	Inspect selected input source
	Defective video cable	Inspect integrity and replace video cable
	Device is not detected by monitor	Disconnect and reconnect the camera head to the device
	Defective camera head/device/monitor/optical cable	Contact joimax® customer service
Image is dark	Endoscope/optic coupler/camera head lens is dirty or damaged	Clean endoscope/optic coupler/camera head lens
	Fiber optic cable is not properly connected	Inspect connection of fiber optic cable
	Brightness is set too low at the device/monitor	Increase the brightness of the device/monitor
	Device is overheating	Ensure cooling fan is not blocked
Image blurry	Endoscope/optic coupler/camera head is dirty	Clean endoscope/optic coupler/camera head lens
	Optic coupler is not properly focused	Check the attached endoscope and the connected optic coupler
		Refocus connected optic coupler
Color bar pattern is displayed	No camera head is connected	Connect a camera head to the control unit
	Connected camera head is defective	Contact joimax® costumer service
Picture shows an unnatural color	White balance of the camera was not performed	Perform white balance
	Color settings of the device are incorrect	Adjust colors at the device
	Color settings of the monitor are incorrect	Adjust colors on monitor
		Contact joimax® costumer service
Image artifacts during use of RF surgical equipment	RF surgical equipment cables are routed too close to the camera head cable or control unit	Increase the distance between RF surgical equipment cables and camera head cable and control unit
	RF surgical equipment is activated in direct contact with the endoscope or working tube	Only activate the RF equipment when not in contact with the endoscope or working tube
Others		Contact joimax® costumer service

14 Warranty

Warning:
Do not open the Camsource® Duo. Unauthorized opening, repair, or modification of the device releases joimax® GmbH from any liability for the operating safety of the device and results in any claims becoming void, even during the warranty period.

Warning:
In case of return of equipment or accessories, original packaging material must always be used!

Warning:
To protect your staff and the joimax® GmbH employees, please clean the unit and its accessories and disinfect it before sending it.
Should this be impossible due to temporal constraints, please prepare the unit as much as possible and label it accordingly.

The warranty period for the *Camsource® Duo* depends on the legal regulations of the specific country and on agreements in the purchase contract.
In addition, the details in our general terms and conditions apply.

To facilitate quick processing of service requests and repairs, we ask you to send the product with the following information:

- Model/Item number (REF)
- Serial number (SN)
- A description of the error as accurate as possible
- Invoice of the device if available
- Contact person for questions

15 Consumables / Accessories

Warning:
Only the consumables/accessories from joimax® GmbH listed below are to be used with the Camsource® Duo. Use of accessories and cables other than those specified or provided by the manufacturer may result in improper operation.

Warning:
Make sure to follow the instructions for use of accessories to be used with the device (e.g. monitors, recording systems etc.).

Consumables

All consumables are provided by joimax® GmbH. Replacements for all consumables can be ordered from joimax® GmbH or via the respective local joimax® distributor.

Item number	Item description
CSCC1223	Camsource® Camera Cable Cover Disposable, telescopic folded, with perforation and adhesive tape, L 230cm / W 12.5cm
CSCC1324US	Camsource® Camera Cable Cover (US Version) Disposable, telescopic folded, with perforation and adhesive tape, L 244cm / W 13cm

Accessories

Item number	Item description
ADAPTC1	Combo Optic Adapter for combo-endoscopes and ocular camera head
JMUSBS10	joimax® USB Flash Drive 16GB
JDVI0020	joimax® DVI Cable, L 200 cm
JHDMI0020	joimax® HDMI Cable
JBNC0020	joimax® BNC Cable, high-flexible, double shielded / L 200 cm

16 Compatibility

Any endoscope with standard DIN ocular connector can be connected to the Camsource® Duo.

Detailed information regarding joimax® endoscopes and accessories can be found in the joimax® product catalog.

For further information and new products directly contact the joimax® customer service or your joimax® representative.

17 Disposal of the Device

Warning:
This symbol indicates that medical devices must be disposed of separately from household waste. Dispose of electrical waste in accordance with the applicable national and local regulations.

Warning:
This symbol must be affixed to the waste container or the device when discarding it.

Dispose of packing material, unless it is contaminated, in accordance with national and local regulations.

According to the implementation of European law into national laws and regulations, you are obliged to properly dispose of medical devices.

Discard used and contaminated medical devices at a collection point of an appropriate disposal carrier. "Medical waste" is classified according to dangerous goods law (for transportation) by UN number UN 3291.

18 Incidents Reporting

Any serious incident that has occurred in relation to the device should be reported to joimax® GmbH and the competent authority having jurisdiction in your locale.

Please notify us at the following telephone number:

For the US	**+1 949-859-3472**	**(24-hour availability)**
For all other countries	**+49 (0)721 25514 – 999**	**(24-hour availability)**

Thank you for your support!

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MANUFACTURER

joimax® GmbH
Amalienbadstrasse 41,
RaumFabrik 61
76227 Karlsruhe, Germany

Phone +49 (0) 721 255 14-0
E-Mail info@joimax.com
Web www.joimax.com

IN USA DISTRIBUTED BY

joimax®, Inc.
140 Technology Drive, Suite 150
Irvine, CA 92618, USA

Phone +1 949 859 3472
E-Mail info@joimaxusa.com
Web www.joimax.com

joimax® Asia
Rykadan Capital Tower,
135 Hoi Bun Road,
Kwun Tong, Hong Kong

Phone +852 29116418
E-Mail asia@joimax.com
Web www.joimax.com

joimax® ASEAN
Regus Vision Exchange
2 Venture Drive, Level #24-01 - #24-32
Singapore 608526

Phone +65 6914 9227
E-Mail asia@joimax.com
Net www.joimax.com