

INSTRUCTIONS FOR USE

FULL HD ENDOSCOPY CAM KX-02_KYMO

MEDICAL DEVICE INFORMATION

Name

Full HD Endoscopy Cam KX-02_Kymo



Fig. 1. Medical device Full HD Endoscopy Cam KX-02_Kymo

UDI

UDI-DI

08594200760069

Basic UDI-DI

8594200760CAMKX-KymoGR

Class

Class I medical device according to 2017/745 (MDR)

Intended purpose of use

The intended purpose of the Full HD Endoscopy Cam KX-02_Kymo video endoscopic medical device is digitization the image visible in the eyepiece of the endoscope and its subsequent display on the PC. The medical device allows image manipulation to improve contrast. Medical device is intended for outpatient care.

Indication

The device is intended for diagnostic purposes.



The Full HD Endoscopy Cam KX-02_Kymo is specifically designed for use in combination with the compatible Kettex EVision – Software.

Contraindication

There are no known contraindications to this medical device.

User Qualifications

The intended user is a physician or healthcare professional experienced in endoscopic procedures who has been properly trained by the manufacturer or a person designated by the manufacturer.

KX-02_Kymo medical device , the doctor must be able to complete the examination through the endoscope eyepiece without using this device.

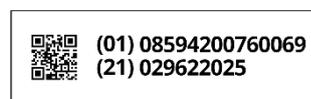
Target patient population

Patients undergoing endoscopic examinations.

MEDICAL DEVICE IDENTIFICATION

Fig.1 Illustrative image of the label on the medical device Full HD Endoscopy Cam KX-Kymo

UDI MD IPX7 SN 029622025



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LIFETIME

The expected lifespan is 8 years, provided that the Full HD Endoscopy Cam KX-02_Kymo medical device is not mechanically damaged and the rules of storage and use according to the intended purpose are followed.

WORKING PROCEDURE

1. Before use

- Visual inspection of the device, including the cable, for cleanliness and undamaged condition.
- Check the basic functions of the device; if any malfunction is discovered, the device must not be used.
- Connecting the endoscope to the camera lock, connecting the light source. Checking for correct connection.
- Installing camera drivers. Ensuring driver compatibility with Windows OS.

2. Performing the examination with an emphasis on maintaining the correct image orientation.

- During the procedure, the user must not touch the patient or other medical equipment in the patient environment.
- **It is necessary to work with the camera with increased caution to minimize the risk of the camera slipping out of your hand.**

3. End of examination

- Blinding the camera, placing it in the holder.

KX-02_Kymo medical device is described in more detail in the Kettex EVision system user manual. The user manual is supplied with the Full HD Endoscopy Cam KX-02_Kymo medical device .

By disconnecting (pulling out) the USB connector, the device is disconnected from the network (from power).

USE IN COMBINATION WITH EVISION

The USB Endoscopy Cam is connected via a USB port to a computer, which may or may not be a medical grade PC with an operating system. The computer must have software compatible with the Endoscopy Cam installed, the software representing an ideal combination with the Full HD Endoscopy Cam KX-02_Kymo is Kettex EVision – Software .

A coupler compatible with the C-Mount standard is connected to the USB Camera , optical path . A standard endoscope , either rigid or flexible with a light source, is further connected to the coupler.



All other equipment used with the Full HD Endoscopy Cam KX-02_Kymo medical device must meet the safety and efficiency requirements for performing endoscopic examinations. Special emphasis is placed on the safety and efficiency of cooperating electrical equipment.

WARNINGS

- To avoid risk, the computer for the camera must be connected to a power supply with protective earthing.
- The Full HD Endoscopy Cam KX-02_Kymo medical device can only be connected to medical electrical equipment that complies with IEC 60601-1 and IEC 60601-1-2.
- Connecting the device to another non-medical device is only possible if this device is powered by a separating transformer intended for healthcare.
- **During the examination, there must be no contact between the patient and the Full HD Endoscopy Cam KX-02_Kymo medical device .**
- Do not use the product in environments with high humidity (above 85%).
- Do not use the product in an environment with flammable gases or in an environment with an increased oxygen concentration.
- **It is strictly forbidden for anyone to interfere with the installation, especially the electrical installation.**
- **It is strictly forbidden to remove the insulation from the USB cable or the silicone insulation from the camera.**
- Modifications to this device are prohibited.
- Do not modify this device without authorization from the manufacturer.
- In the event of modification of this device , appropriate inspections and tests must be carried out to ensure continued safe use of the device .

NOTICE

- In the event of any problems with the Full HD Endoscopy Cam KX-02_Kymo , or any unusual behavior, it is necessary to stop using the device immediately.
- KX-02_Kymo medical device may only be used by a qualified, trained user.
- **Before use, it is necessary to check the correct orientation of the image by a routine test on a known sample.**
- The device can only be used with standard endoscopes.
- The device is very sensitive to mechanical shocks; dropping it can damage it.
- **During the examination, contamination of the camera with body fluids should be avoided as much as possible. In case of contamination of the camera with body fluids, the camera should be disinfected with sterilizing wet wipes.** If an increased risk of contact with fluid is expected, a disposable protective cover should be used for the camera.
- **It is necessary to avoid contact of the device with any liquid (especially contact of the uncovered USB connector).** In case of such contact, it is necessary to immediately turn



off the camera, dry it from the outside and leave it to dry thoroughly. Then it is necessary to check the functionality of the camera .

- Disconnecting the device from the computer may only be performed by a technically trained person.
- Do not expose the device to direct sunlight or other strong light sources. Excessively intense light can damage the camera sensor.
- Handle the device with the utmost care, do not pull on the cable and avoid any other intentional deformation of the cable.
- Do not handle the product near an open flame or high voltage source.
- **In extreme conditions, the camera temperature can reach up to 45°C.**
- The device is not sterile, nor is it intended for subsequent sterilization. **Soaking it in a sterilization solution or placing it in an autoclave will destroy it.**
- The device must not be cleaned or otherwise maintained while it is **in use (especially when connected to an endoscope that is inserted into the patient's body) and connected to an electrical power source** .
- To limit possible electromagnetic or other mutual interference between the Full HD Endoscopy Cam KX-02_Kymo and other devices, use technical means to minimize them.
- The device does not have an alarm system, but the device will turn off, the user is informed about this
- If the device is damaged, Kettex EVision – Software will not start and the device cannot be used.
- Do not place the device in a way that would make it difficult to disconnect the device
- Before each use or after changing the viewing modes/settings, the user should check that the view observed by the endoscope provides a live image (not a recorded image) and that the image is in the correct orientation.
- The device must not be installed and used in the presence of explosive gas concentrations in the area of use of HF-powered endoscopic devices.
- Before each use of the device, the user should check compatibility with devices used at the same time, such as a light source or endoscope, safe use is according to the Workflow.

TECHNICAL PARAMETERS

- Dimensions : max. dimension 3 meters cable length, 100 mm, 40 mm, 40 mm
- Weight : max. 400g including cable
- Connectivity : USB3 PC/W11
- Native resolution : 2448×2048 pixels, 720x540 pixels
- Chip : Sony CMOS Pregius IMX548, Sony CMOS IMX 287
- Control : three buttons A, B, C (all active only when pressed)
- Protection: IPX7
- Altitude: 3000m above sea level
- Attachment part : the entire body of the device, see Fig. 1
- Accessories: the device has no accessories



EMC

THE CHAPTER WILL BE ADDED BASED ON EMC TEST RESULTS

STORAGE CONDITIONS

- The product can only be stored in the temperature range of 0–40 °C at a relative non-condensing humidity of up to 85%.
- The product must not be exposed to static discharges and for long-term storage (over 14 days) it is necessary to store the product in an antistatic bag.

CONDITIONS FOR OPERATION

- The product can only be used in the temperature range of 0–24 °C at a relative non-condensing humidity of up to 85%.
- The device must not be exposed to static discharges.

CLEANING AND DISINFECTION

- Cleaning and disinfection must not be performed while the device is in use (especially if it is connected to an endoscope that is inserted into the patient's body).
- Before cleaning and disinfecting, it is necessary to turn off the computer and monitor and disconnect it from the power source.
- Cleaning and disinfection may only be carried out by a qualified person.
- The camera and adapter must be cleaned at least once a week using a damp disinfectant wipe.
- The camera eyepiece should be cleaned at least once every 2 months. Before each use, it is necessary to check the cleanliness of the eyepiece.
- It is prohibited to use ethanol-based substances or other flammable substances to clean the camera body.
- In case of accidental contamination, it is necessary to perform a thorough cleaning again with a damp cloth with disinfectant. It is necessary to prevent the disinfectant from getting on the camera connector. It is also advisable to take care not to get dust on the adapter optics and remove any dirt with a cotton swab soaked in 80% ethanol.
- We disinfect the surface of the device only when it is switched off, and we disinfect the surface of the cables using common chemical procedures using approved products, e.g. MIKROZID, SAGROSEPT, GIGASEPT® INSTRU AF, GIGASEPT FF, etc.

MAINTENANCE

The device requires regular maintenance in the form of regular safety and technical inspections (BTK) once every 2 years.

To safely perform routine maintenance, perform the tasks according to the Cleaning and Disinfection section of this manual with the prescribed frequency: the camera and adapter must be cleaned at least once a week, the camera eyepiece must be cleaned at least once every 2 months, and the eyepiece must be checked for cleanliness before each use. Maintenance must only be performed by a qualified person.

DISPOSAL

Current European Union legislation, implemented in all member states, requires that electrical and electronic equipment be disposed of separately from other waste. This includes electrical equipment including accessories such as cables, electronics. In the event of disposal of this product, please follow the rules in force in the Czech Republic.

EXPLANATIONS OF GRAPHIC SYMBOLS ON THE PRODUCT LABELLING

| Symbol | Meaning of the symbol |
|---|---|
|  | CE marking of conformity according to MDR |
|  | Read the instructions for use |
|  | Attention (warning) |
|  | Manufacturer |
|  | Serial number |
|  | Catalog number |
|  | Medical device |
|  | Type BF applied part |
|  | Restricted use of hazardous substances |
|  | Product disposal instructions |

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|--|----------------------------------|
| A circular arrow icon representing a recycling or repeated use symbol. | Designed for repeated use |
| The UDI (Unique Device Identifier) symbol, consisting of the letters "UDI" inside a square border. | Unique medical device identifier |

MANUFACTURER

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SERVICE ORGANIZATION

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In the event of any serious adverse event occurring in connection with the Full HD Endoscopy Cam KX-02_Kymo medical device , please contact the manufacturer via email : info@kettex.cz and also the competent authority of the Member State.

More information can be found on the website: www.kettex.cz

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