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INSTRUCTIONS FOR USE

FULL HD ENDOSCOPY CAM KX-02

MEDICAL DEVICE INFORMATION

Name
Full HD Endoscopy Cam KX-02

Fig. 1. Full HD Endoscopy medical device Cam KX-02

UDI
UDI-DI
08594200760052

Basic UDI-DI8594200760CAMKX-02S9

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

Intended purpose of use
Intended purpose of the video-endoscopic medical device Full HD Endoscopy Cam KX-02 is a digitalization of the image visible in the eyepiece of the endoscope and its subsequent display on a PC. The medical device allows manipulation of the image for better contrast. The device is intended for use in ambulances and for use during operations.

Indication
The device is intended for both diagnostic purposes and for use in operations.
Full HD Endoscopy Cam KX-02 is specifically designed for use in combination with compatible Kettex software 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.
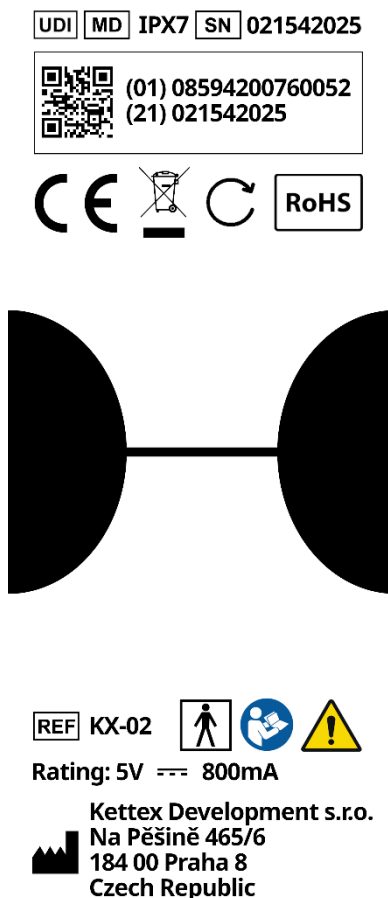
In case of malfunction of the Full HD Endoscopy medical device Cam KX-02, the doctor must be able to complete the examination through the eyepiece of the endoscope without using this device.

Target patient population

Patients undergoing endoscopic examinations or endoscopic procedures.

MEDICAL DEVICE IDENTIFICATION

Fig.1 Illustrative image of the label on the Full HD Endoscopy medical device Cam KX-02

| UDI | MD | IPX7 | SN | 021542025 |

(01) 08594200760052
(21) 021542025

CE ☒ ↻ RoHS

REF KX-02

Rating: 5V ⎓ 800mA

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LIFETIME

The expected lifespan is 8 years, assuming no Full HD Endoscopy medical device Cam KX-02 is mechanically damaged and the rules of storage and use according to the intended purpose of use will be 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.

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

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

USE IN COMBINATION WITH EVISION

The USB camera 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 Endoscopy compatible software installed. Cam , a software that represents an ideal combination with Full HD Endoscopy Cam KX-02 is Kettex EVision – Software .

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

All other devices used with the Full HD Endoscopy medical device Cam KX-02 must meet the safety and efficiency requirements for performing endoscopic examinations. Particular 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 medical device Full HD Endoscopy Cam KX-02 can only be connected to medical electrical equipment complying 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 medical device. Cam KX-02.**
- 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 case of any problems with the Full HD Endoscopy Cam KX-02, or any unusual behavior, you must stop using the device immediately.
- The medical device Full HD Endoscopy Cam KX-02 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 pattern.**
- 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. Excessive 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 **in use (especially when connected to an endoscope that is inserted into the patient's body) and connected to an electrical power source** .
- To reduce possible electromagnetic or other mutual interference between the device Full HD Endoscopy Cam KX-02 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 product is damaged, Kettex EVision – The 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
- Chip : Sony CMOS Pregius IMX548
- 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

STORAGE CONDITIONS

- The product can only be stored and used within a 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

- Storage and use of the product is only possible within the temperature range of 0–30 °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

Device requires regular maintenance carried out in the form of regular safely technical controls (BTK) once every 2 years .

For safe implementation routine maintenance carry out actions according to parts this one instructions Cleaning and disinfection 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 be done only 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
$C \epsilon$	CE marking of conformity according to MDR
	Read the instructions for use
	Attention (warning)
	Manufacturer
SN	Serial number
REF	Catalog number
MD	Medical device
	Type BF application part
RoHS	Restricted use of hazardous substances
	Product disposal instructions
	Designed for repeated use

UDI	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 medical device Full HD Endoscopy Cam KX-02 , 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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