INSTRUCTIONS FOR USE

Full HD Endoscopy Cam KX-01

PRODUCT INFORMATION

Name
Full HD Endoscopy Cam KX-01

Medical device class
I

Intended use
Full HD Endoscopy Cam KX-01 is a video-endoscopy medical device used for digitisation of the image that is visible through the endoscope lens and displayed on the screen of a PC. The product allows the image to be processed in order to improve its contrast.

Indication
Full HD Endoscopy Cam KX-01 is intended for outpatients care only, not for use during surgeries.

The product can be used in combination with the compatible Kettex EVision – Software.

Contraindications
No contraindications of this medical device are known.

User qualification
The intended user is a medical doctor or other healthcare professional experienced in endoscopic procedures who has been properly trained by the manufacturer or by a person or entity authorised by the manufacturer.

If the Full HD Endoscopy Cam KX-01 fails, the doctor must be able to complete the examination through the endoscope lens without using this medical device.

Target patient population
Patients of any age or gender undergoing endoscopic examination.

PROCEDURE

1. **Before using the device**
   - Inspect the camera visually to make sure that the product, along with the cable, is clean and defect-free.

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- Test the camera's basic functions. Do not use the camera if any fault is detected.
- Connect the endoscope to the camera lock, connect the light source. Inspect the correct connection.
- Install the camera drivers. Make sure the drivers are Windows OS compatible.

2. **Examination procedure** with emphasis on maintaining the correct image orientation.

- Do not touch the patient or any other medical instrumentation in the patient's environment during the examination
- **Be very careful when operating the camera in order to minimise the hazard that the camera would slip out of your hand**

3. **Examination procedure termination**

- Blind the camera and put it into the holder with the VESA adapter

The Full HD Endoscopy Cam KX-01 operating procedure is described in more detail in the Kettex EVision system user manual, which was delivered together with your Full HD Endoscopy Cam KX-01.

USE IN COMBINATION WITH OTHER DEVICES

The USB camera Full HD Endoscopy Cam KX-01 should be interfaced, via an USB port, to a computer, which may or may not be a medical device with an operating system. The computer must be fitted with software compatible with the Kettex Endoscopy Cam KX-01. Kettex EVision – Software represents ideal software for this purpose.

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

All other systems used in combination with the Full HD Endoscopy Cam KX-01 must satisfy all requirements for safety and efficiency required for endoscopic examinations. Safety and efficiency of the cooperating electrical systems are crucial in this respect.

WARNINGS

- To avoid associated risks, the computer must be connected to the grid with protective grounding.
- The electrical system(s) to which the Full HD Endoscopy Cam KX-01 is connected must comply with IEC 60601-1 and IEC 60601-1-2.
- **Avoid contact between the KX-01 Full HD Endoscopy Cam and the patient during any examination.**
- Do not use the camera in a very humid (RH >85%) environment.
- Do not use the camera in an environment with flammable gases or with an elevated oxygen concentration.
- **The installation must NOT be modified or repaired by any unauthorised person! This applies, in particular, to the electrical parts including wiring.**

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- **Do NOT remove insulation from the USB cable or the silicone insulation from the camera!**

CAUTION

- If any Full HD Endoscopy Cam KX-01 related problem arises, including any unusual behaviour of this product, stop using the camera immediately!
- The Full HD Endoscopy Cam KX-01 must be operated by a trained user.
- **Make a tentative test on a known sample before use to make sure that orientation is correct.**
- The medical device must be used in combination with a standard-design endoscope.
- The medical device is very sensitive to mechanical impacts. It may be destroyed if it falls on the floor or another hard surface.
- **Take all measures to avoid camera contamination with body fluids during an examination. A camera contaminated with body fluids must be disinfected with wetted sterilization wipes.** Wrap the camera in a disposable cover if an increased risk of product contact with body fluids is expected.
- **Take all steps to prevent contact of the product (the non-covered USB connector in particular) with any fluid.** If, nevertheless, the camera gets into contact with a fluid, switch off the camera immediately, dry the outer surface and allow the camera to dry completely. Then test the performance of the dry camera**.**
- The camera must be disconnected from the computer by trained technician, approved by the manufacturer.
- Do not expose the product to direct sunlight or to the light of other intense light sources. Too intense light may damage the sensor in the camera.
- Handle the camera with utmost care, do not pull the cable and avoid any cable deformation.
- Do not handle the product near open flames or a high-voltage source.
- **The camera temperature can reach up to 45°C in extreme conditions.**
- The product is not sterile and is not designed for subsequent sterilization. **The product will be destroyed if it is put into a sterilization solution or autoclaved.**
- Do NOT clean the product or perform any maintenance **while in use (in particular, while interfaced to an endoscope that has been introduced into the patient's body) and connected to a power supply system.**
- Use technical means to minimise any electromagnetic or other interferences between the Full HD Endoscopy Cam KX-01 Full and other instruments.

STORAGE

- The medical device must be stored at a temperature between 0°C and 40°C, humidity (non-condensing) must not exceed 85%.
- Avoid exposing the product to static discharges. Put the product into an antistatic bag for long-term (>2 weeks) storage.

CLEANING AND DISINFECTION

- Do not clean or disinfect the product while in use (especially while interfaced to an endoscope which had been introduced into the patient's body).
- When going to clean/disinfect the product, switch off the computer with the monitor first and disconnect it from the power supply system.
- The product must be cleaned/disinfected by a qualified person.
- The camera and adapter must be cleaned with a moist disinfecting wipe once a week as a minimum.
- The camera lens must be cleaned once in 2 months as a minimum. Make sure the lens is clean prior to any use.
- Do not use cleaning solutions based on ethanol or any other flammable liquid!
- If the product has been inadvertently contaminated, clean it thoroughly with a moist wipe with a disinfectant. Prevent the disinfectant from getting onto the camera connector. See to it that no dust deposits on the optical elements. Use a wetted swab to remove any impurities.

DISPOSAL

Applicable EU legislation, implemented by all Member States, requires that waste electrical and electronic equipment is disposed of separately from other waste. This covers electrical equipment together with the accessories such as cables and electronics. Dispose this device in compliance with the rules valid in the member state where the device will be disposed.

MEANING OF THE SYMBOLS ON THE PRODUCT

Symbol	Meaning
$C\,\epsilon$	CE conformity mark according to the MDR
📖	Consult instructions for use
⚠	Warning
🏭	Manufacturer
SN	Serial number
REF	Product number
MD	Medical device
🚶	Type BF applied part

MANUFACTURED BY:

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If any serious product-related adverse event is encountered, please contact the manufacturer by email on: info@kettex.eu . Also inform the Member State's competent body.

For additional information please visit Company website: www.kettex.eu

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