Kettex Development s.r.o.
Na Pěšině 465/6, 184 00 Praha 8
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INSTRUCTIONS FOR USE

KETTEX EVISION – SOFTWARE

PRODUCT INFORMATION

Name
Kettex EVision – Software

Medical device class
I

Intended use
Kettex EVision – Software is a medical device serving to display, save and scan digitised images in the form of pictures of video from a compatible endoscopic camera.
This medical device allows the image to be processed in order to improve its contrast and the visibility of the structures.

Indication
Kettex EVision – Software is intended for diagnostic uses, not for use during surgeries.

This software tool is specifically designed for use in combination with a compatible Kettex EVision – Endoscopy Cam camera.

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 Kettex EVision – Software fails, the doctor must be able to complete the examination through the endoscope lens without using this device.

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

PROCEDURE

1. Start the Kettex EVision – Software
2. Select appropriate endoscopic examination

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3. Start the examination
4. Take the image/video
5. Modify the image as appropriate
6. Stop the examination procedure
7. Deactivate Kettex EVision – Software

The Kettex EVision – Software operating procedure is described in more detail in the Kettex EVision system user manual, which was delivered together with your Kettex EVision – Software.

USE IN COMBINATION WITH OTHER DEVICES

Kettex EVision – Software is intended for use in combination with a compatible endoscopic camera. Full HD Endoscopy Cam KX-01 is an ideal solution for this purpose.
Kettex EVision – Software requires the Windows 7–64 b operating system or higher.
Kettex EVision – Software reads commands from a foot pedal switch.
Kettex EVision – Software is designed for data reading from any standard-design endoscope.

All other systems used in combination with Kettex EVision – Software 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 (residual risks)

- Particular attention must be paid to the correct examination setting.
- Before use, check the performance of this software, correct focusing and credible colours.
- The PC must not run any other application during the examination or Kettex EVision – Software might run inadequately slowly.
- No other software must be running on the background of the computer with the running Kettex EVision – software in order to prevent inadequate slowing down.
- If the user suspects the image is not credible, they must complete the examination through the endoscope lens.
- Use the optimal software setting for the examination as identified by a qualified technician during installation.
- If the user has doubts as regards the setting (calibration) performed by the qualified technician, they may reset (recalibrate) the parameters by following instructions in the software user manual. The manufacturer shall not be held responsible for calibration performed by any person other than the technical personnel authorised by the manufacturer.
- The software must be installed by qualified technical staff authorised by the manufacturer.
- If the fibroscope is replaced, the system must be recalibrated for correction of the fibroscopy grid.

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OTHER IMPORTANT INFORMATION

The computer on which Kettex EVision – Software is installed must be secured against unauthorised use. If the folder with the patient data is exported to the local network, all the other computers having access to the folder must also be secured against unauthorised use.

MEANING OF THE SYMBOLS ON THE PRODUCT

Symbol	Meaning
CE	CE conformity mark according to the MDR
	Warning! Consult instructions for use!
	Manufacturer
SN	Serial number
MD	Medical device

MANUFACTURED BY

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

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

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CE