

Kettex Evision KX-02

Release date 30.1.2025)

"One good picture is better than 100 words of written text."

Our video endoscopy system in conjunction with your endoscope allows you to easily take image and video documentation for each examination



CONTENTS

Introduction	1
1. System components	2
2. First steps	3
2.1 Power On / Off	3
2.2 Attaching the adapter/camera	4
2.3 Pedal switch (working with it)	5
2. 4 Buttons on the camera body	5
2. 5 General control principles	5
3. Common working procedures	6
3.1 Preparing the exam	2 3 4 5 5 6 7
3.2 Creating an exam	7
3.3 Capturing an image	8
3.4 Video capture	9
3.5 Exview	10
3. 6 EDF Image	12
3.7 Focus Gaze	12
3.8 Focus Center	12
3.9 Opening a patient's file	13
3.10 Fiberscope settings	13
3.11 Ending the examination	14
3.12 Fullscreen mode	14
3.13 AWB	14
3.14 Brightness change	14
4. Setting assigned functions	15
5. Settings	15
6 . Safety and functional instructions	23
7. Cleaning and disinfection	29
8. Troubleshooting	30
9. Disposal	31



Introduction

This brochure aims to introduce you to the features and functionality of the Kettex Evision device, where the trade name Kettex Evision refers to the Kettex EndoscopyCam application that works with any Kettex camera. For the purposes of this brochure, we will only consider the Kettex KX-02 camera. The Kettex EndoscopyCam application is primarily used to display and document endoscopic examinations. The KX-02 camera and the EndoscopyCam software are intended for use only by qualified physicians.

The first chapter of this user manual describes what you need physically to work with the camera. The second chapter describes how to turn on the camera and the application, how to connect it to the endoscope, and what the foot switch is for. The third chapter describes the basic procedures for working with the software. The fourth chapter describes the expert setting options, which are only for real technical experts and are not needed for normal work. The fifth chapter contains instructions for work safety, and the sixth chapter provides instructions for solving possible problems.



(1)

1. Components

When working with a camera, you usually need:

- 1. Kettex KX-02 camera
- 2. Kettex EndoscopyCam software or other equivalent software

The KX-02 camera is connected to a computer with sufficient power, and the Kettex EndoscopyCam program runs on Windows 10 and higher.

1.1 Camera and cabling

The camera is connected to the computer with a USB 3 cable. The USB3 cable must be connected to the USB3 connector on the computer. Our technician will install the computer for you upon request and connect the cables. Then it is best to remember where each cable was connected and when disconnecting and reconnecting it is optimal to connect the cables where they were. With this connection, the camera and software were extensively tested.

1. 2 Kettex EndoscopyCam software

The software runs on Windows 10 and higher. The software allows you to control cameras, display images from cameras, read commands from the foot switch, save video, images and audio, etc.



(2)

2. First steps

2.1 Power On/Off

To start the Kettex EndoscopyCam application, you must first turn on the computer and wait until it starts up to the state where the computer cursor is an arrow (not a wait cursor) and when the computer is ready for further work. On the Desktop there is an icon of a Laryngoscope with a light called EndoscopyCam. You must double-click on it and wait 3-10 seconds and the application will start. The application will automatically maximize to take up the entire screen. This means that the entire system is ready for work.

If the application does not launch after double-clicking, try again - it is possible that the double-click was not correct. If you manage to launch the application 2 times, nothing happens, one instance of the application will report that the desired application is running and will close itself.

If no camera is connected, the application will write that the system is inoperable without a camera and the application will close itself.

To end the work, it is only necessary to turn off the application by clicking on the cross in the upper right corner of the application window. That is, the application is terminated like any other in the Windows system. Before that, however, it is necessary to terminate all Kettex EndoscopyCam activities - i.e., for example, stop recording video. The subsequent shutdown of the computer is done either by pressing the HW button on the computer, or via the Start menu.



(3)

2.2 Attaching the adapter/camera

The adapter on the camera serves as an optical path from the endoscope eyepiece to the camera and for attaching the endoscope eyepiece to the camera.

The eyepieces of endoscopes are standardized - i.e., for example, Storz and Wolf are the same. The eyepiece is the same for laryngoscope, fiberscope, epipharyngoscope, sinoscope or otoscope. All of these endoscopes can be attached using a locking head (coupler). The KX-02 camera complies with the C-Mount standard, so all standard couplers can be used with it.



Camera KX-02



Schindler coupler



(4)

Each coupler has its own fastening mechanism. For example, the Schindler coupler has so-called autocoupling, i.e. you just need to insert the endoscope into the coupler and it will secure itself.

2.3 Foot switch

The foot switch is one of the main control devices of the KX-02 camera in combination with the EndoscopyCam software. It is operated with the foot so that the doctor has both hands free. The switch has 2 or 3 separate pedals. With this switch, you can give a command to the application during the examination, without using your hands, for example to save an image/video. The switch is connected to the computer with a USB cable, see Figure 3.



Figure 3

2.4 Buttons on the camera body

The second option to control the camera functions is the 3 buttons on the camera body. The functions on both the foot switch and the buttons are selectable (programmable), as we will mention below.

2.5 General operating principles

The following functions can be assigned to the buttons on the camera and the foot switch (equivalent to the icons on the monitor): save image/video, exview/correction of the fiberoptic grid, fullscreen, autofocus on the center of the monitor, autofocus according to the direction of view, EDF image, awb, image brightness change.



(5)

3. Common working procedures

After starting the Kettex EndoscopyCam application , the program is in the starting position as shown in Figure 4. At that moment, the camera is already capturing and displaying a live image.



Figure 4

The number and icons for selecting the type of examination - Flexi , Otoscope, Epi , Laryngoscope, Stroboscope may vary depending on the desired settings during installation. For example, the top bar may have up to five icons for switching between different types of examination. Or it may not contain any icons.



(6)

After launching the Kettex EndoscopyCam application

it is therefore possible to either switch between examination types or start expert settings (see Chapter 4 each type of examination has its own expert settings – which are locked with a password), or display the patient folder or start the examination. Switching between examination types or starting the examination is done either by tapping the icon with your finger (in the case of a touch monitor) or by clicking the mouse. Standard help/options on what to do in a given state are displayed on the right panel of the application (see Figure 4).

3.1 Preparation for the examination

Before starting the examination, the required endoscope must be attached to the adapter (see chapter 2.2) and switched to the appropriate examination type.

An optical adapter can be either fixed or variable focus. A fixed focus adapter only allows you to focus, and a variable focus adapter allows you to focus and zoom in/out.

In the case of a fixed focus adapter, the endoscope needs to be pointed at an object - preferably paper with text - and brought closer to the distance at which it will be during the subsequent examination:

Epipharyngoscopy - approx. 2cm

Otoscopy - approx. 3cm

Laryngoscopy approx. 7cm

and then focus with the adapter's focusing ring so that the text is clearly readable.

In the case of a variable focus adapter, you first need to select the desired zoom (e.g. for laryngoscopy, the smallest zoom, for the best possible view over the entire larynx) and then focus as in the previous case.

3.2 Setting up an examination

Before examining a new (or returning patient), you need to press the icon labeled "Next patient" (see Figure 3.4).



(7)

A window will appear where you need to enter the patient identification number.



The entry can be made using the touchscreen, the mouse or the keyboard. After pressing the OK button , the application enters the capture mode (Figure 6) , where it is possible to save images and videos. By pressing the Cancel button , the application returns to the previous state. Alternatively , this number can be hashed due to GDPR. If necessary, you can also enter the first name, last name, date of birth, gender. Can be set in the expert settings.

One can attach any functions mentioned in paragraph 2.5 to the pedal and buttons. We will gradually discuss how the individual functions behave.

3.3 Taking a picture

Activation by touching the icon on the screen, or short press of the pedal or short press of the camera button - The image is saved in the folder of the patient who is currently being examined under the name in the format:

ID(Patient ID) _year _month _day_hour_minute_day.jpg The name of the currently saved file is written on the right panel after the image is captured. Only one image can be saved per second.



(8)



Figure 6

3.4 Video capture

Video recording begins either by clicking the camera icon on the top bar with your mouse or finger, or by pressing the foot switch pedal for at least 2 seconds or by pressing the button on the camera for 2 seconds.

The video is saved in the folder of the patient who is currently being examined under the name in the format: ID(Patient ID) _year _month _day_hour_minute_day.avi

During video recording, the background of the "Camera" icon is colored red - see Figure 7. Clicking the "Camera" icon again, or pressing the same footswitch or the same button on the camera, will stop recording the video.

After pressing the "Camera "icon (or pressing the footswitch or button), the video must sometimes be synchronized and merged with the audio track, if audio was recorded. After synchronization is complete, the application goes to the state of Figure 8 - equivalent to the initial state of Figure 6.



(9)



Figure 7



Figure 8

3.5 Exview

The system supports contrast rendering of red. The rendering is automatically turned off and to turn it on, you must press either the middle icon on the toolbar or step on the middle pedal. That is, unless a tool with the fiberscope flag is selected. In that case, this icon is not present.



(10) Instead, there is a correction of the fiberoptic grid.



Figure 9



Figure 10



(11)

3.6 EDF Image

Captures the entire z-stack of images to the debug directory for further processing in the full scope of the fluid lens.

3.7 Focus Gaze

With a predefined webcam, face tracking is started and the camera focuses on the place where the user is looking in the image.



3.8 Focus Center

The camera focuses on the center of the image when you press the icon, foot pedal, or button on the camera.

3.9 Opening a file to a patient

Clicking on the "Folder" icon will open the patient's folder in Windows Explorer, with all of their saved files, i.e. both images and videos.

3.10 Fiberscope settings - fiberscope grid correction

If the application has a Fibroscope examination set, then in



(12)

recording mode you can set whether the scanning will be corrected.

In principle, the fiberscope is composed of a small number of optical fibers. The raw image transfer from the fiberscope by the camera shows an optical grating, which is very disturbing for the examination. This grating can be removed (corrected) in software. The correction has one parameter – off/on. See figure 10 and 11.

The procedure for working with a fiberscope is that first the fiberscope is connected to the camera, then it is focused on an object, and finally the correction button is turned on (or the foot pedal is used) and the grid disappears.



Figure 11

3. 11 End of examination

The investigation can be easily terminated by clicking the red "End" icon. This will return the application to its initial state - see Figure 4.

3.12 Fullscreen mode

Whenever necessary, the application can be switched to



(13)

fullscreen mode, i.e. to a state where only the image from the endoscope is visible and no icons, help, etc.

Setting the fullscreen mode is done by double-clicking on the monitor. This can be done at any time except when you are in expert settings mode. You can exit fullscreen mode by double-clicking on the monitor again. The second option is to hook the fullscreen to the foot pedal or the KX-02 camera button.

3.12 AWB

One push auto white balance according to the image.

3.13 Brightness change

Changes the desired image brightness for aexp algorithm.

4. Setting the assigned functions

KX-02 command definition			×
First Icon/Pedal	Second Icon/Pedal	Third Icon/Pedal	
Save Image/Video	ExView / Grid Red	• AF gaze	Serial USBPort
	EDF Image	EDF Image	COM5 👻
	Focus on Demand	Focus on Demand	
	Full Screen Mode	Full Screen Mode	unknown Send
	AWB	AWB	
	Brightness	Brightness	\$CAM1.ENABLED=1
First Cam Button	Second Cam Button	Third Cam Button	{10000 50000} \$LENS.CURRENT = 1000 {16141614}
Save Image/Video	Save Image/Video	Save Image/Video	{16141614}
EDF Image	ExView / Grid Red	• AF gaze	Command Cams Available
Focus on Demand	EDF Image	EDF Image	none
Full Screen Mode	Focus on Demand	Focus on Demand	
• AWB	Full Screen Mode	Full Screen Mode	
 Brightness 	AWB	• AWB	Sensitivity X: 2 Sensitivity Y: 4
	Brightness	Brightness	Sensitivity X: 2 Sensitivity Y: 4
	Close		

In this dialog, you can assign individual functions to individual footswitches and buttons on the camera. See 5.8)



(14)

5. Settings

For the sake of completeness, this chapter will briefly discuss the system settings, which can only be done by a specialist during system installation. Changing the settings changes the internal parameters of the system. Access for a regular user is blocked by a password.

The settings are accessed by holding your finger on the screen when you are not in investigation mode. A context menu will pop up.



The first option is "Tool Definition" . After selecting this option, the following dialog will appear:

Basic setting					×
	Language	English 🔻			
Left:	1 Middle:	2 Right:	3	Use Only 2 Pedals	
			Cams available:daA2448-70uc		
Camera Type	KX-02 👻	KX-02 🔻	KX-02 💌	KX-02 🔻	Don\'t use ▼
Resolution	1224x1024 🔻	1024x1024	1920×1080 🔻	2048x2048 🔻	•
FPS	25 👻	25 🔽	25 💌	25 🝷	-
Behavior	1 - Fibroscope 🔻	2 - Normal 💌	2 - Normal 🔻	2 - Normal 🔻	2 - Normal 🔻
Hints	1.0 6.0	4.0 2.0	3.0 3.0	4.0 5.0	1.0 1.0
		r			
			KX-02 Setting		
Camera Icon					
Icon Text	fibroscope	sinoscope	uni	laryngo	
		ОК	Cancel		



(15)

Where it is possible to change:

1) application language

2) footswitch activation values – the footswitch is actually a keyboard and each pedal is actually pressing one letter/number. There are many types of footswitches and each gives different values. Here you can set the correct values so that yours works.

3) how the camera will be pinned to the given icon

4) what resolution and framerate will the camera have?

5) how will the given camera behave (normal, fibroscope)

6) in the dialog, you can change the appearance of the application toolbar - you can set which icons with which texts will appear there and which connected camera will be turned on on a given icon, or whether a given position will be inactive.

7) what inscription will the camera have?

8) the KX-02 settings icon is dedicated to setting the assignment of functions to individual controls

Te Deseguing with the second s

The second option, "User Settings," opens:

Where the user can set some user parameters after pressing the "Edit" button . The settings are unique for each endoscope - i.e. they may differ.



(16)

We can set: white balance – either manually or automatically, camera offset – the de facto location in the chip from which the live image will be taken. The resolution used (e.g. FullHD) is always smaller than the actual size of the chip. We can also select image inversion and whether the microphone will be recorded. We can also select a location on the disk where patient data will be stored and we can also modify the strength of the fibroscopic grid correction. More details in the following settings: Advanced settings.

Third option "Advanced settings (for experts only)"

It is for expert users only and is not recommended to run. All parameters and settings are accessible here.



Exposure and Gain Settings

Exposure means how long an individual image is exposed, gain is the amplification of the signal in the image - the equivalent of the ISO value in a camera. These parameters therefore affect how many frames the camera provides per second (how smooth the image is), how bright it is and how much noise it contains.



(17)

The higher the exposure, the brighter the image, but the fewer frames per second the camera takes. The higher the gain, the brighter the image, but the more noise it contains. For exposure and gain, there is an option to set the setting to "Auto", and both values are dynamically adjusted according to the Autorefer and AutoMax values.

Autorefer and AutoMax settings

Both values affect exposure and gain when Auto is selected - i.e. exposure and gain are set automatically. Autorefer is the value that the application tries to reach by setting exposure and gain. The higher the value, the brighter the result of automatic exposure and automatic gain should be.

AutoMax is the maximum exposure value that is allowed for automatic exposure.

White balance

Halogen, xenon or LED light can be used as a light source for the endoscope. Each source has a different color of light and when pointing at a white object, a color different from white is visible. Therefore, in order for the color display to be correct, it is necessary to perform white calibration. Either manually or automatically. **Automatic correction** is done by pointing the endoscope at a white object and pressing the "Auto white balance" button. The white color is automatically corrected within three seconds . "Manual white correction" is set with three sliders so that the white matches the white.

Color calibration

This is a very advanced function that no user should do on their own. Otherwise, there is a risk of absolute color inaccuracy, potentially malfunctioning of other parts of the processing and display of the entire system. Using color correction, curves can be set for each color and for intensity. See Figure 12.



(18)

SetDef

The application itself sets the preset values for Flip, Gamma, Saturation and Sharpness.

Gamma

The slider allows you to adjust the gamma correction of the image.

Offset X, Offset Y

Cameras do not always use the entire chip for imaging, so this offset can be used to tell which part of the chip to use. This affects which part of the endoscope's eyepiece is visible.

Flip horizontal/vertical

The orientation of the image can be changed to match the orientation in the real environment. This is done by focusing the endoscope on the letter and changing the flips so that the letter is correctly oriented.



Added filter – Sharpness (Sharpening postprocessing) The image can be either software sharpened or



(19)

unsharpened. Sharpening enhances blurred edges. You can adjust both the strength of sharpening and the level of detail to be emphasized. The level of detail means whether fine or coarse details should be emphasized.

Sharpness Settings	×
None UnS Power	1
Details	3.50
Close	

Denoising

An image captured with non-zero gain contains noise. Denoising can remove it without damaging the data – tissue structures. It is possible to have denoising turned off, turned on automatically or set it manually, where the slider is used to set the strength of denoising - i.e. how much noise will be removed. With greater strength, stronger noise but also more fine structures will be removed. There is also the option of automatic mode, where the strength of denoising is set by the software itself according to the degree of amplification.

Saturation

It is possible to set the saturation of the image. A setting of 100 is the maximum possible saturation. A setting of 0 is a black and white image.

Fibro Setting

It is possible to adjust the correction strength of the fiberoptic grating when correction is turned on.

Encrypt ID

If the switch is turned on in all places where the ID is used when saving (directory name, file name), the hash key is used, which is recorded in the database.cgpass file, which is accessible (decoded) only after the user logs in to the Windows system.



(20)

Use Metadata

In addition to entering the ID, you can also enter your first name, last name, date of birth, and gender. This data is then saved together with the ID in the database.cgpass file.

GDT Setting

The program can communicate with the server using the GDT protocol. GDT is a German standard for ZP clientserver communication. Pressing this button will bring up the communication settings.

DICOM+PACS

The program can save data to dicom files and communicate and save to a dicom server. The program can read metadata from a dicom worklist. Pressing the button will call up the communication settings.

Destination directory

The location on the disk where data for all patients is stored, the so-called root directory. Data for an individual patient is then stored at the address target directory/patient ID/

Sounds

The application can make sounds when capturing an image, video, etc. The sounds can be turned on or off.

Hot Pixels

In the case of permanently overlit pixels, they can be corrected separately with this function.

Microphone

When this option is enabled, audio is recorded along with the video.



(21)

Eyepiece trimming

By setting the cropping, the cropped part will be colored white when saving, which is suitable for subsequent printing.

Command camera test

It allows you to test the correctness of the command camera settings for controlling the focus function by sight and adjust the camera if necessary.

6. Safety and functional instructions

device is safe in all respects. When working with the camera, please pay attention to the following points:

1) End of examination – After disconnecting the endoscope, attach the camera to the camera holder or otherwise cover its optics. This is to prevent dust from settling in the optical path, as dust in the optical path can greatly degrade the image in future examinations.

2) USB Cable – if you accidentally disconnect it, the camera will stop showing live images and the application will close. In this case, it is important to connect the camera to the same connector it was previously connected to.

Safety precautions

In case of any problems with the device, i.e. the device starts to behave abnormally, stop using it immediately. The doctor must be able to complete the examination using only the eyepiece.

Carefully inspect the camera including the cable before each use and if you find any visible damage, do not use it. Use in such a case is strictly prohibited as it could expose the patient to unacceptable risk.



(22)

Do not use the camera in an environment with high humidity. Never use the device in an environment with flammable gases or in an environment with an increased concentration of oxygen. Repairs to the device, except those explicitly mentioned in the manual, must be carried out only by the manufacturer.

Excessive light can damage the camera sensor. Direct exposure to sunlight or other super bright light sources, whether in the visible or invisible spectrum, can damage the camera sensor. Use a camera mount to store the camera.

Handle the camera with care. Do not intentionally squeeze, pull, or bend the cable leading from the camera.

The camera and accessories are very sensitive to mechanical shock. Dropping the camera or coupler on the floor may damage it.

Before each use of the camera, check that the basic functions are working. If not, do not use the camera.

Also check that the image is in the correct orientation. Use the camera only with endoscopes with a standard eyepiece.

If you have any doubts about the authenticity of the image, complete the examination using only the eyepiece.

Warning

The camera temperature can reach up to 46 degrees Celsius in extreme conditions .



(23)

Principles for installation and subsequent use required to comply with IEC/EN 60601-1

The camera during normal operation in cooperation with other electrical devices. If you combine this device with other means, the requirements of the standard should be observed

IEC/EN 60601-1. Please follow the recommendations from clause 16 of IEC/EN 60601-1 relating to medical devices (systems) - in particular the technical requirements.

To guarantee the safety of the user and the patient, use only components and spare parts recommended and specified by the manufacturer.

Pay attention to what products and how to use them together with this device-

Only active medical devices that have the appropriate certificate (declaration of conformity) and are provided by the manufacturer for such use may be placed in the patient environment.

Electrical equipment outside the patient environment must comply with safety requirements according to the relevant ISO standards.

The patient environment according to IEC / EN 60601-1 is defined as the area around the patient with a radius of 1.5m.

When selecting system components, the following basic safety requirements should be met:

1. After installation of a medical device or after its modification, the leakage current should be measured to ensure that the limit values according to EN 60601-1 are not exceeded. The leakage current can be reduced by a transformer separating the device from the mains, or a protective earth can be installed on the device.



(24)

2. Connecting the camera to a non-medical device – such a device must be placed outside the patient environment (at a distance of more than 1.5m from the patient) and must be powered by a separating transformer intended for healthcare.

3. Connecting a medical device with a non-medical device used in a room with non-medical use via a long cable is possible if a galvanic isolator is used between the medical and non-medical equipment.

If the camera is connected to other equipment or is used in a manner other than specified above, it may increase the risk of leakage current passing through the patient.

If a hub is used, it should not be placed on the floor. Connecting the system to other medical/non-medical devices requires new analysis and safety checks to verify compliance with the requirements of IEC/EN 60601-1.

Any modification of the medical system contrary to these instructions may unacceptably increase the risk of leakage current and will cause an increase in risk to the patient.

Do not touch the patient or other equipment in the patient environment during the examination.

Other general instructions – must be followed under all conditions

In general, working with the device is further conditioned by several important points that must be met.

The manufacturer assumes no responsibility for any negative events caused by failure to follow the following instructions.



(25)

6.1 Installation may only be carried out by a trained technical worker of the manufacturer/distributor (TP). It is strictly forbidden for anyone not authorized to interfere with the installation, especially interfering with the electrical installation.

6.2 It is necessary to work with the camera with increased caution, especially when examining a patient, to minimize the risk of the camera slipping out of your hand. It is also necessary to prevent the camera from hitting any object. To store the camera between uses, it is necessary to use a secure place or a camera holder with a VESA adapter supplied by the manufacturer.

6.3 It is not permitted to disconnect the USB camera from the computer by a technically untrained person.

6.4 Any reinstallation of the system and system settings may only be carried out by a designated company technician, either on site or via remote administration.

6.5 When setting the parameters of the Kettex EndoscopyCam application, leave the settings to the company's technical staff. The company is not responsible for the functionality of the application if it is incorrectly set by a person other than TP.

6.6 When inserting the endoscope into the head lock, pay special attention to the correct position. Check the functionality by a routine test on a known sample.

6.7 When recording videos, make sure to end the recording properly. This will prevent the entire disk from filling up prematurely.

6.8 The computer on which the Kettex EndoscopyCam application is running must be secured against use by



(26)

unauthorized persons. Therefore, it is necessary to password protect the computer so that no unauthorized person has access to patient information. If a directory with patient data is exported to a local network, it is necessary to password protect all computers to which the directory is exported.

6.9 While the computer with the Kettex EndoscopyCam application is being used for examination or surgery, the computer must not be used for other user applications to avoid slowing down the computer. No background program must be installed on the computer with the Kettex EndoscopyCam application that could slow down the Kettex EndoscopyCam application.

6.10 It is necessary to clean the eyepiece of the camera head with a cotton swab and alcohol once every 2 months. It is necessary to ensure the cleanliness of the endoscope used – both the eyepiece and the tip of the endoscope. It is necessary to visually check the amount of light emitted by the light guide cable or portable light source once every 2 months. In case of a decrease in the luminous flux, it is necessary to either replace the light guide cable or the lamp or recharge the portable light source.

6.11 When changing the light style (LED-halogen-xenonmetal halide) or changing the endoscope, it is necessary to recalibrate the system using expert settings.

6.12 When changing the fiberscope, it is necessary to recalibrate the fiberscope grid correction system.

6.13 When using the camera, it is necessary to pay attention to safety, handle the cable with care, do not kink it, do not let the camera hang by the cable. Before each examination, the cable must be visually inspected and the system must not be used in case of visible wear.



(27)

6.14 The system may only be stored and used within the temperature range of 0 Celsius to +40 Celsius at a relative non-condensing humidity of up to 85 %.

6.15 It is necessary to avoid exposing the camera and cable to static discharges and for long-term storage (more than 14 days) it is necessary to store the camera in an anti-static box or bag.

6.16 It is forbidden to use alcohol-based substances or other flammable substances to clean the camera body. Do not handle the camera near an open flame or high voltage source.

6.17 The computer to which the camera is connected must be connected to the electrical network through a surge protector with protection parameters equal to or better than 2 MOPPs . The same protection must also be used for connecting the touch monitor in the system.

6.18 It is strictly forbidden to remove the insulation from the USB cable or the silicone insulation of the camera.

6.19 Contact between the patient and the camera or their bodily fluids should be avoided. If the camera is contaminated with bodily fluids, the camera should be disinfected with sterilizing wet wipes. If the camera is likely to come into contact with fluids, a disposable plastic camera cover should be used.

6.20 The camera should not come into contact with liquid, especially the exposed USB connector. If such contact occurs, the camera should be turned off immediately, the outside should be dried and the camera should be allowed to dry. The camera should then be checked for proper operation.



(28)

6.21 The device must not be operated when any component is malfunctioning.

6.22 The device may only be used by a trained user.

6.23 Before using the device, it is necessary to visually check its functionality, follow all safety instructions during use, and use the device only if the user is able to successfully complete the examination or procedure, even through the eyepiece in the event of a system malfunction.

6.24 When investigating, use the optimal settings determined during installation by the company's technician.

6.25 Before using the system, it is necessary to check the functionality, safety, and reliability every time – check the correct orientation of the camera, the correct focus, the color fidelity, the correct seating of the endoscope lock, and the cleanliness of the endoscope. In the event of any or partial malfunction, the system must not be used. Connected peripherals such as a footswitch, touch monitor, etc. also require a functionality test.

7. Cleaning and disinfection

Before cleaning and disinfecting, please turn off the computer and unplug it from the power source, as well as the monitor. If the computer is connected to the network via a cable, unplug the cable as well.

Cleaning and disinfection of the device must only be carried out by a qualified person in the following manner.

It is necessary to wipe the adapter and camera at least once a week with a damp cloth. with a disinfectant wipe.



(29)

The device is not manufactured sterile and should not be sterilized. Any attempt to soak it in a sterilization solution or place it in an autoclave will destroy it.

In case of accidental contamination, it is necessary to perform a thorough cleaning again with a moistened wipe 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 alcohol (80%), otherwise the quality of the image captured by the camera may deteriorate.

8. Troubleshooting

Problem: The application cannot be launched. **Solution:** Wait at least ten seconds and if the application does not launch, try double-clicking the Kettex EndoscopyCam application again. If the application still does not launch, wait one minute and if the application still does not launch, contact support.

Problem: The application reports that it cannot be launched without a connected camera, or some icons for various examinations have disappeared.

Solution: Exit the application, check the USB cable connection to the camera and to the computer, or disconnect and reconnect the USB cable. Relaunch the application. If the problem persists, contact support.

Problem: The foot switch app control does not work. **Solution:** Exit the application, check the USB cable connection to the footswitch and to the computer, or disconnect and reconnect the USB cable. Relaunch the application. If the problem persists, contact support.



(30)

Problem: Audio recording doesn't work when recording video

Solution: Check the expert settings to see if audio recording is enabled.

Check if your microphone is disabled or muted in Windows.

Problem : The application "crashed", performed an incorrect operation, and was automatically terminated. **Solution:** Contact technical support.

In case of any unspecified situation, please contact technical support.

9. Disposal

Current European Union legislation, implemented in all member states, requires that electrical and electronic equipment marked with this symbol be disposed of separately from other waste. This includes electrical equipment including accessories such as cables,



electronics, etc. In the event of disposal of such a product, please follow the rules in force in the Czech Republic. The symbol displayed on electrical and electronic equipment applies only to current members of the EU.



(31)

Manufacturer and Technical Support:

Kettex Development sro On the Path 465/6 184 00 Prague 8 phone: 728 526 720 email: support @ kettex.cz

Kettex KX-02

Category I medical device.

CE