

# Kettex EVision

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"One good image tells more than hundreds of words"

Our videoendoscopy system together with your endoscopes allows you to create an objective image/video documentation very easily for every examination.

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# Introduction

In this brochure we would like to introduce our system Kettex EVision, show its features and the way how to operate it. Kettex EVision is the videoendoscopy system for displaying and storing endoscopic examinations.

In the first section we show the parts of the system, how to connect it and disconnect it. In the second section we show how to switch on/off the system, how to attach any endoscope and what is the footswitch good for. In the third section we describe the basic workflows. In the fourth section we describe expert setting which should be modified just by experts and not by common users. In the fifth section there are safety and operational instructions. In the last (sixth) section we describe troubleshooting.

# 1. Parts of the system

System Kettex EVision consists of several parts:

1. Camera Kettex KX-01 or Kettex KX-01-OR
2. software Kettex EVision SW

System Kettex EVision is connected to the computer with enough computational power and the Kettex EVision SW runs on Windows 7 - 64b and higher. Neither the computer nor MS Windows system is not a part of the Kettex EVision system. The footswitch is not part of the Kettex EVision medical device.

## 1.1 Camera and cable

The camera is connected by USB3 cable to the computer. USB3 cable can be up to 3 meters long and it is usual that it has a blue connector. USB3 cable must be connected to the USB3 connector on the computer side. The system Kettex EVision will be installed by our technician and he will connect all the cables properly. If you are going to disconnect cables anytime please remember which cables were connected to which connectors. When you reconnect the cables, please use the same cables to the same connectors. If you use different connectors, we cannot guarantee the proper functionality.

## 1.2 Software Kettex EVision SW

The application needs system Windows 7 - 64b or higher to run. Software allows you to control the camera, acquire image, display image, enhance image, read the footswitch commands, save images, videos, sound.

## **2. First steps**

### **2.1 Switch on/off**

As the first step you need to run the computer and wait until it is ready. If you have OS Windows 8 or higher you need to run Desktop as the very first step. After that double-click on the icon of the laryngoscope with the name of the application Kettex EVision SW. Wait one to three second until the application launches. It starts in maximized window automatically. Now the system is ready to run.

If the application doesn't launch, try to double-click again. If you launch the application in two instances, the second instance of the application will display the message "The application already runs" and terminates itself.

If there is no camera connected, it will display the message "No camera connected" and terminates itself.

For switching the application off please use the red cross in the top right corner. If you capture the video at this moment, the capturing will be finished automatically.

Switching off the system should be finished by switching off the computer. Never use "Sleep" or "Hibernate".

When you switching off the computer there is no special care needed for cameras or footswitch.

### **2.2 Attaching the endoscope**

The coupler is a part of optical path from endoscope to the camera and the camera lock (which is a part of the coupler) is used to fasten the eyepiece of the endoscope to the coupler.

The eyepieces of the endoscopes have the same shape - it is standardized - and all the famous brands use the standard i.e. STORZ, WOLF, Olympus. The eyepiece are the same for laryngoscopes, fibroscopes, epipharyngoscopes, sinoscopes and

otoscopes. All the endoscopes can be fastened by the couplers lock. See image 1a, fastened endoscope see image 1b.



(a)



(b)

*Image 1: (a) camera and coupler with lock (b) fastened epipharyngoscope*

Fastening the endoscope is easy. You need to press 2 levers against each other (viz image 2), the lock is released. Attach the endoscope and release the levers. The endoscope is locked no and you can just rotate the endoscope and nothing else.

It is recommend to use a disposable sterile drapes (sleeves) to cover the camera and coupler. Sterile drapes form a barrier around camera and its cable, ensuring maximum longevity of camera. For best results, follow the instructions provided by the drape manufacturer.



Image 2

## 2.3 Footswitch

The footswitch is the most important control part of the system. It is operated by a foot to keep both hands free for patient examination. The footswitch has three pedals. Using the footswitch you can command the application to save image/video, change the brightness of the live image or to enhance vessels.

The footswitch is connected to the computer by USB cable - see Image 3.



Image 3

### 3. Common workflow

**If you launch the application**, you will see it in the starting state - see Image 4. In this state the camera acquire images and the application displays it.

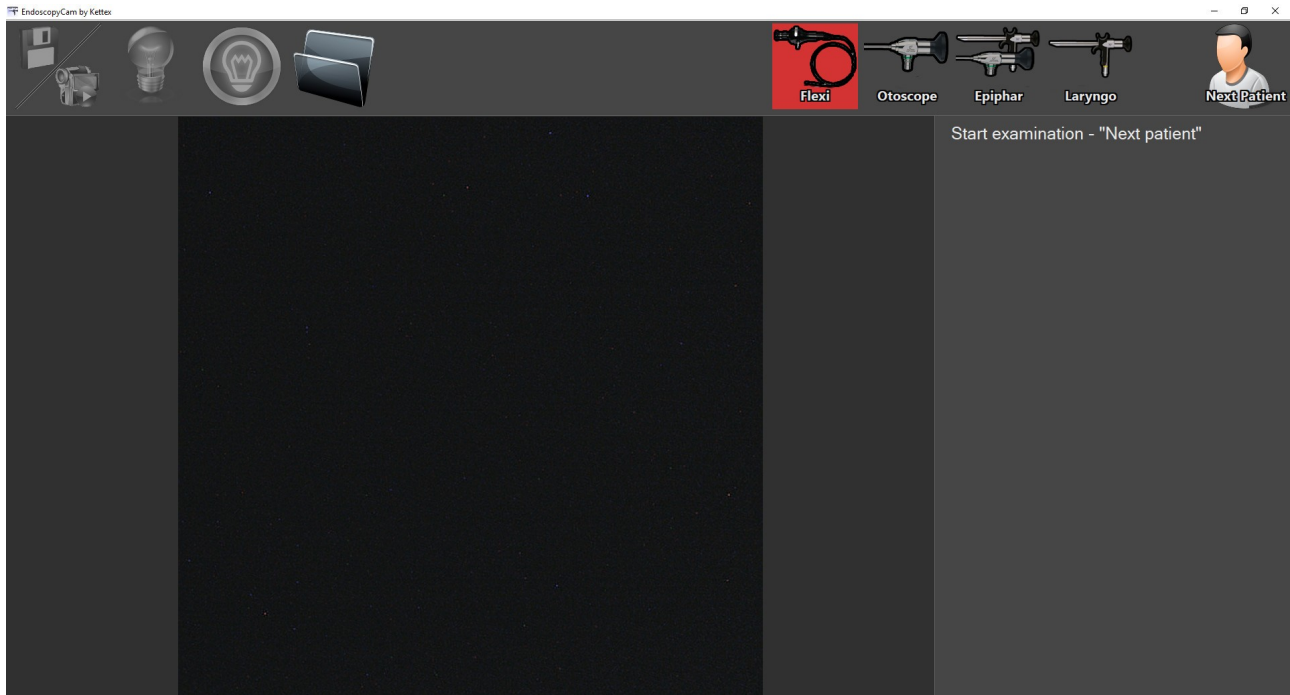


Image 4

The number of icons for the type of examination - FLEXI, Otoscope, EPIPHAR, Laryngoscope, Stroboscope may differ according to the initial setting during the installation. The toolbar can contain upto five icons to switch between the types of examination. Or it needn't contain a single icon.



**When you launch the application** you can switch between types of examination or launch the expert setting (see Section 4 - every type of examination has its own expert setting), or you can open the patient's folder or start the examination. You can switch between the different type of examination by touching the appropriate icon on the toolbar. You can start the examination the similar way. Common help / possibilities to do in current state you can see at the top-right corner of the application - see Image 4, under the top toolbar .

### **3.1 Before examination**

Before the examination you need to attach the appropriate endoscope to the coupler (see section 2.2) and switch on the correct type of examination in the application. .

You can have a coupler with fixed zoom or a coupler with optical zoom 2x. A coupler with fixed zoom allows you just focus image, the zoomable adapter allows you to focus and to change the zoom.

In the case of fixed zoom coupler you need to aim it to some object - paper with text is optimal - and focus it to the object at proper distance for every type of examination:

Epipharyngoscopy - cca 2cm

Otoscopy - cca 3cm

Laryngoscopy - cca 7cm

In the case of zoom coupler you need to select desired zoom factor (for example for laryngoscopy you need smallest zoom factor, for epipharyngoscopy you need the biggest zoom factor) and afterwards continue with focusing as with fixed zoom coupler.

**3.2 Starting examination** Before starting examination of the new patient (or returning patient) you need to touch an icon on the toolbar with the icon "Next patient" - see Image 3,4. Dialog window will appear, where you need enter the ID of the patient - see

Image 5.

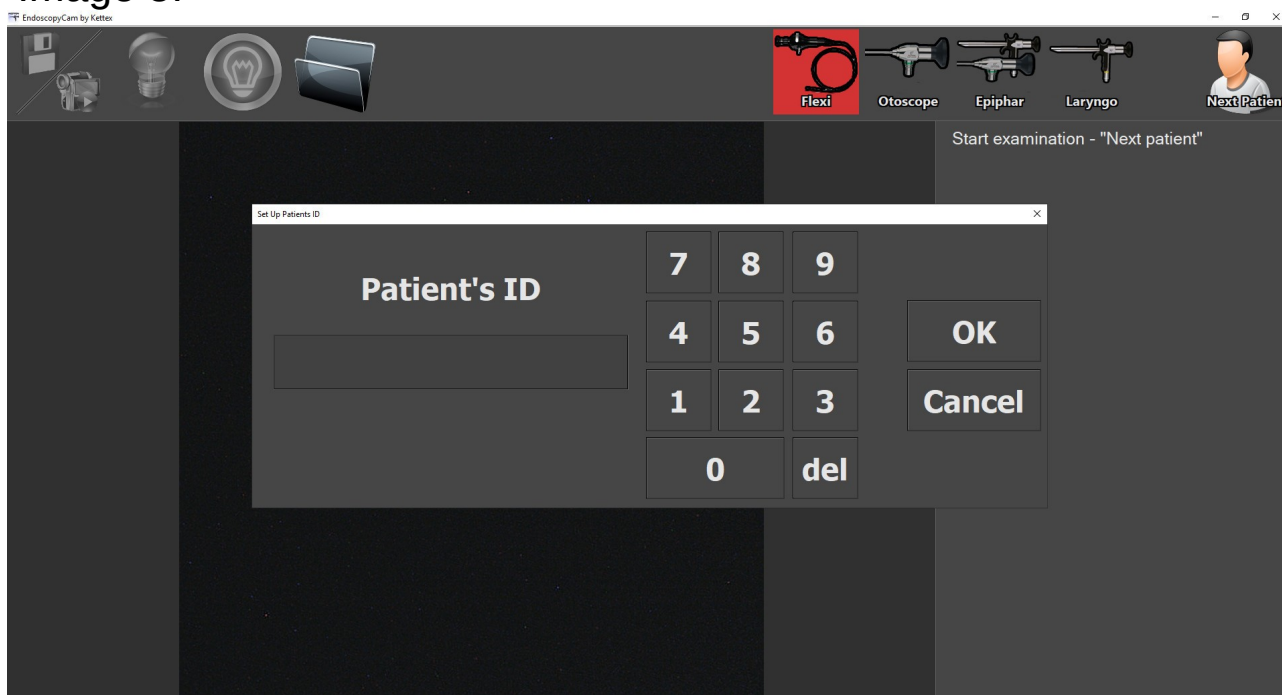


Image 5

You can set the ID of the patient by the touch screen or by mouse or keyboard. After pressing button **OK**, the application goes to the acquisition mode (see Image 6), when you can capture images and save videos. When you press button **Cancel** application goes to the previous state.

### 3.3 Capturing image

You can capture image by the your foot - short step on the left pedal of the footswitch. The image is saved to the patients folder which is examined right now. The filename has following format:  
ID(„ID of the patient“)year\_month\_day\_hour\_minute\_second.jpg  
for example ID33434396\_2014\_01\_12\_07\_35\_02.jpg

The filename of just captured and saved image is written to the right pannel. You can save just one image per second. If you need save images with shorter period, please use video capturing.

### 3.4 Capturing video

Start capturing video by mouse click (or touch) the the first icon on the toolbar. Or you can alternatively use the left pedal of the footswitch - if you press it and hold for at least 3 seconds the application will start video capturing as well.

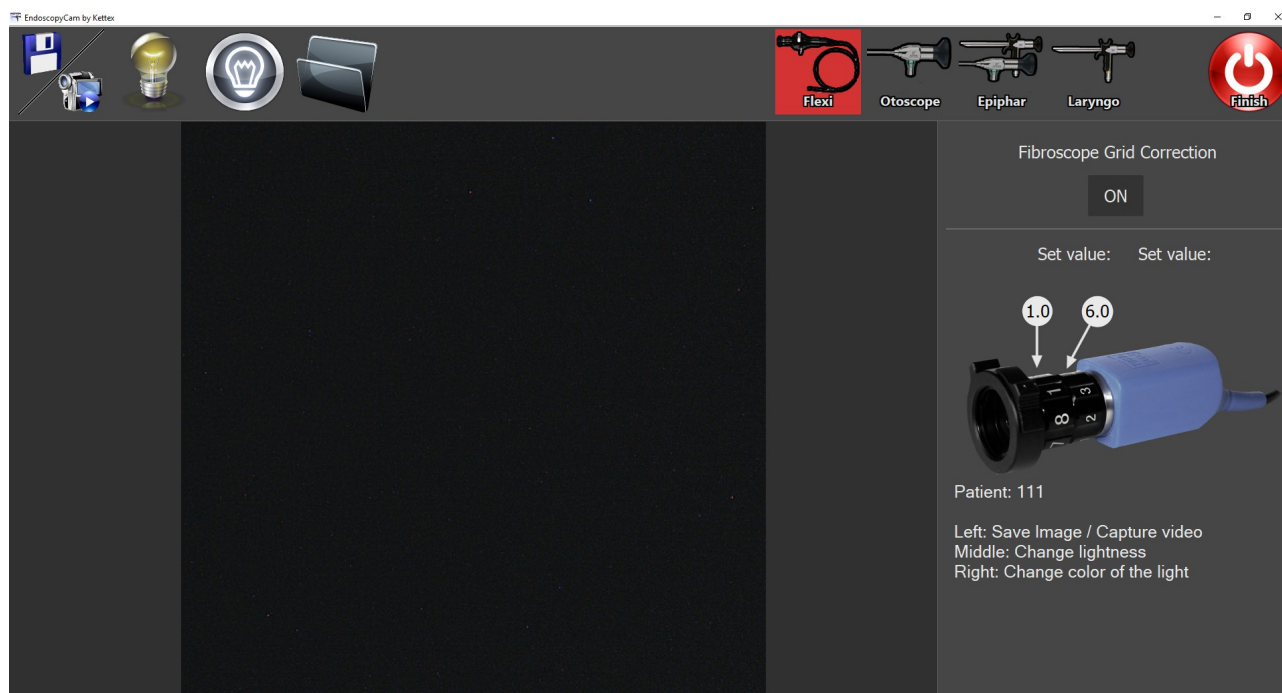


Image 6

The video is saved to the patients folder which is examined right now. The filename has following format:

ID(„ID of the patient“)year\_month\_day\_hour\_minute\_second.jpg  
for example ID33434396\_2014\_01\_12\_07\_35\_02.avi

During the capturing of the video capturing is the icon is changed to red - see Image 7. If you click the camera icon on the toolbar again (or step on the left pedal of the footswitch) the capturing is finished.

Just after command "quit capturing" (see above), the video must be synchronized sometimes and mix with sound track alternatively. When synchronization finishes the application goes to the state (see Image 8) which is equivalent to the initial state - Image 6.

### 3.5 Exview

The system supports blue light contrast. Exview is disabled apriory, so if you want to switch it on you need to click (touch) the second left icon on the toolbar or step on the middle pedal of the footswitch.

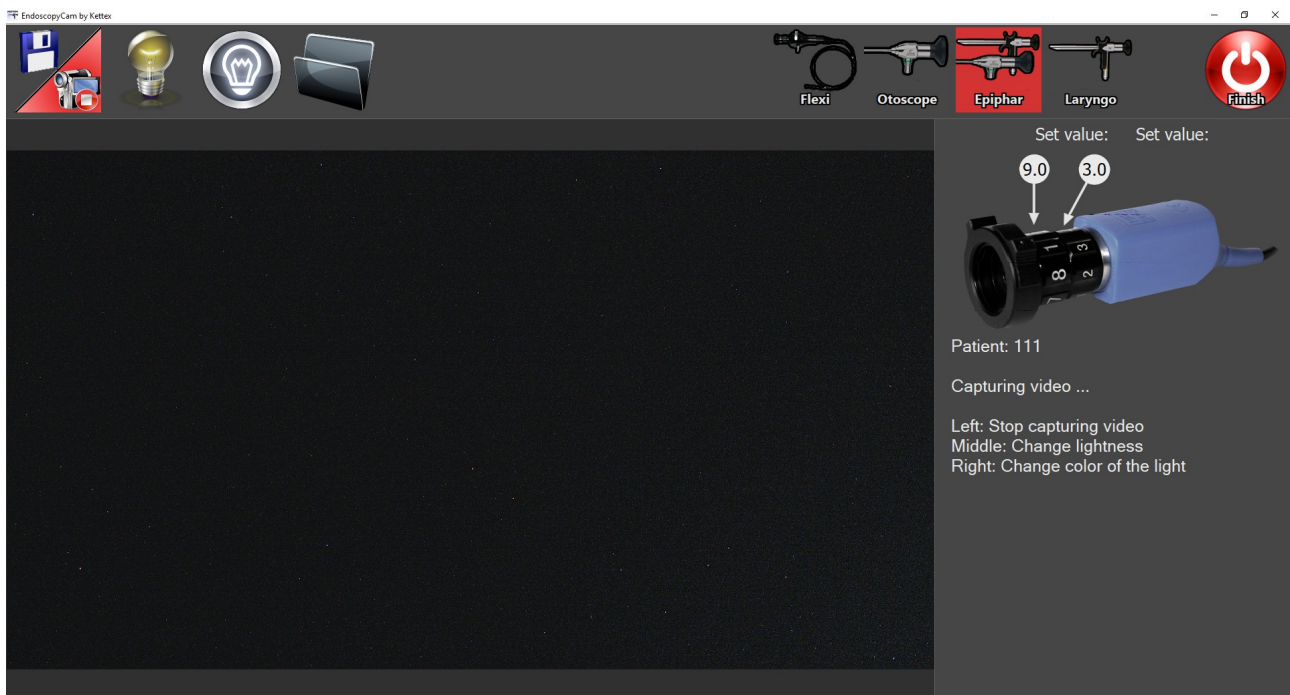


Image 7

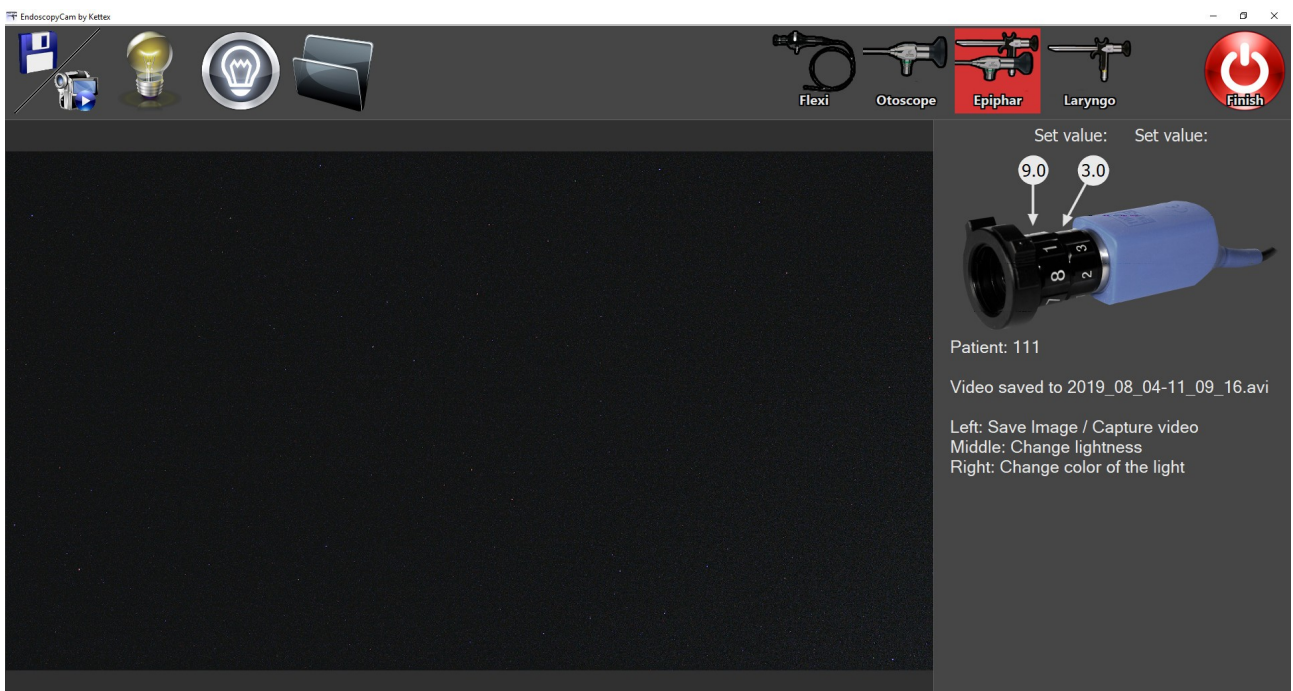


Image 8



Vessels highlighting has two different modes.

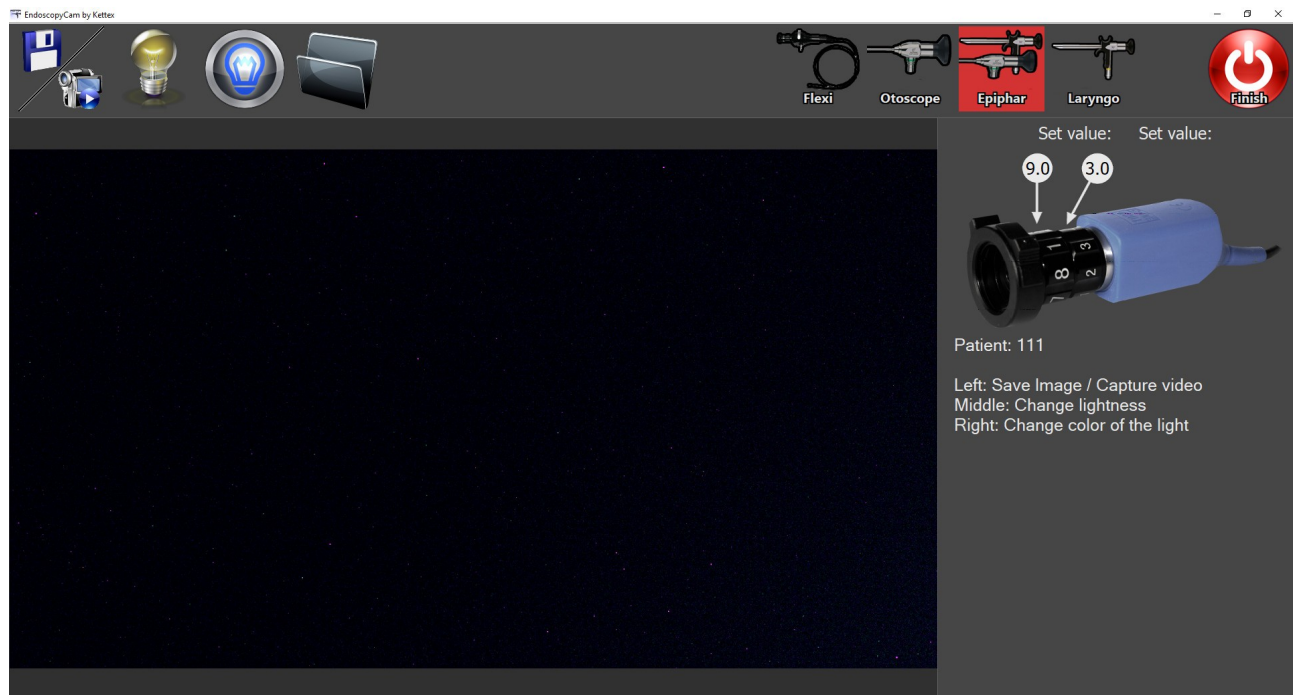


Image 9

### 3.6 Lightening / darkening image

During the examination the mean brightness of the image is preserved. Despite one would like to darken/ lighten the image sometimes. It can be done easily using the right pedal of the footswitch or the third left icon on the toolbar.

All the icons are changing in the cycle this way



Desired image should be darker



Original brightness



Desired image should be lighter

### 3.7 Open the patients folder

Clicking (touching) the "Folder" icon will open the MS Explorer with the patients data (images and videos). If you are not in the capturing mode the application will ask you for patients ID at first.

### 3.8 Fibroscope setting

If you have fibroscope examination allowed in your application (see Image 4 - icon FLEXI is present), you can set the fibro grid correction parameter in the capturing mode.

The basic problem is, that fibroscope contains the grid of optical fibres. So the raw image from the fibroscope shows the grid which is really unpleasant. We can get rid of this grid using our software correction. There is one parameter that must be set up ON/OFF. See Image 12.

Well, the workflow is as follows: a) attach the fibroscope to the coupler b) focus on the object with grid c) set up the correction parameter to optimal correction visually.

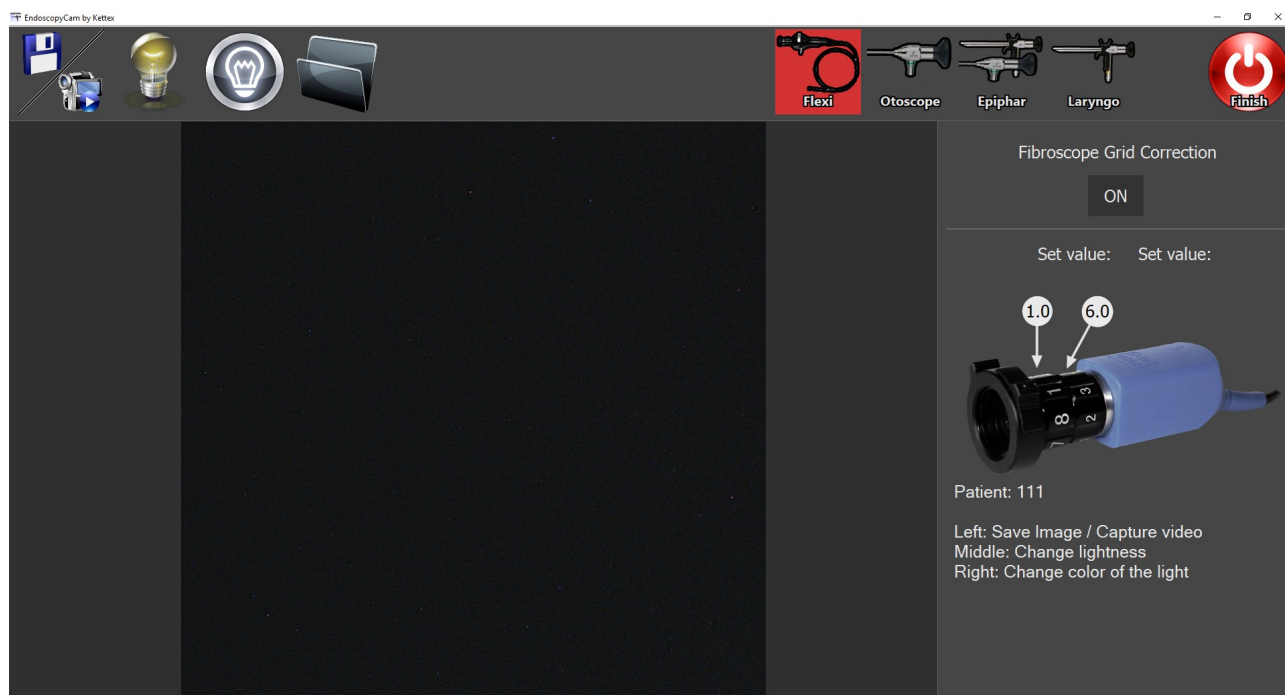


Image 12

### 3.9 Finish the examination

You can finish the examination by clicking (touching) the red icon on the toolbar with text "Finish". The application will change its state to the initial one - see Image 4.

## 4. Fullscreen mode

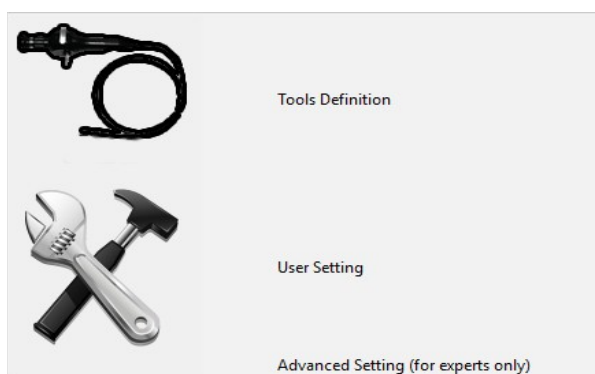
Anytime it is possible to switch the application to the fullscreen mode, i.e. to the state when all the hints, icons etc. are hidden and you can see just the image from endoscope.

The fullscreen mode can be switched on by doubleclick on the image. You can do it anytime except in the expert mode. You can return from the fullscreen mode just by doubleclicking the monitor again.

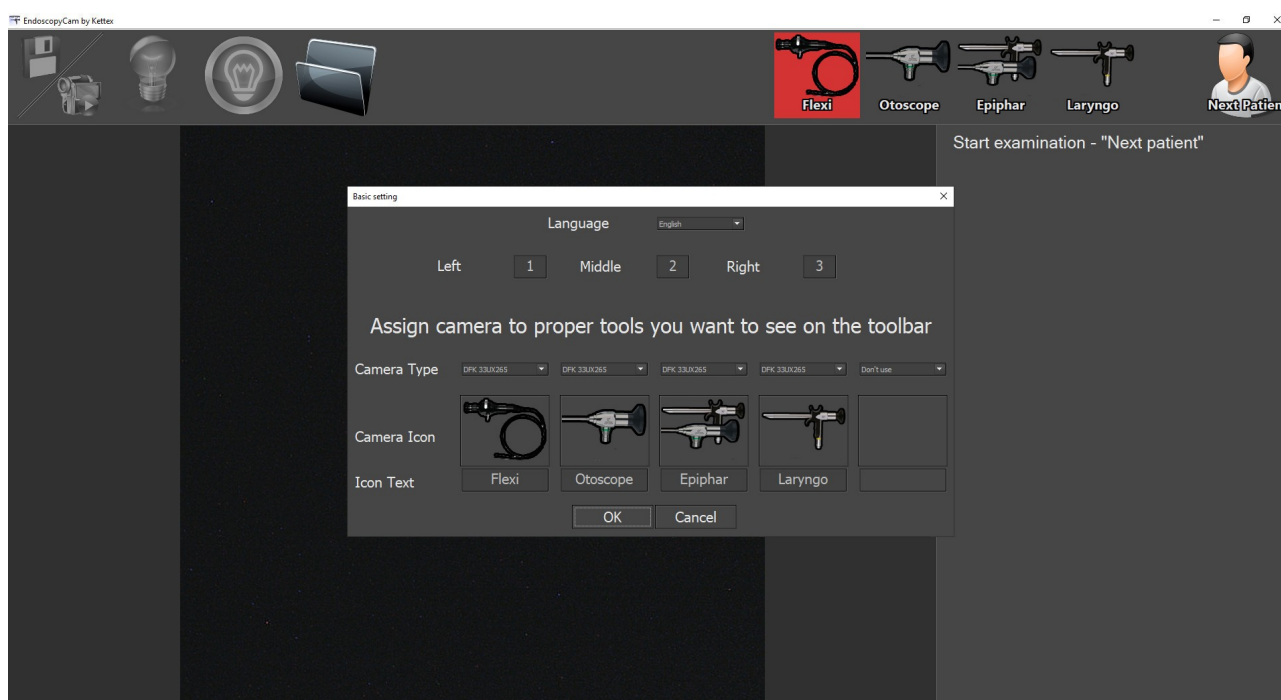
## 5. Setting

This section contains setting of the system for the brochure completeness. But this setting should be used just by our expert, not by a regular user. This setting allows you to change internal parameters of the system and should be set up during the installation and it is protected by a password.

You can enter the setting from the initial mode of the application by holding the finger (or right mouse click) on the screen. On this action the context menu will appear.



**First option „Tools definition“** If you choose this option following dialog appears.

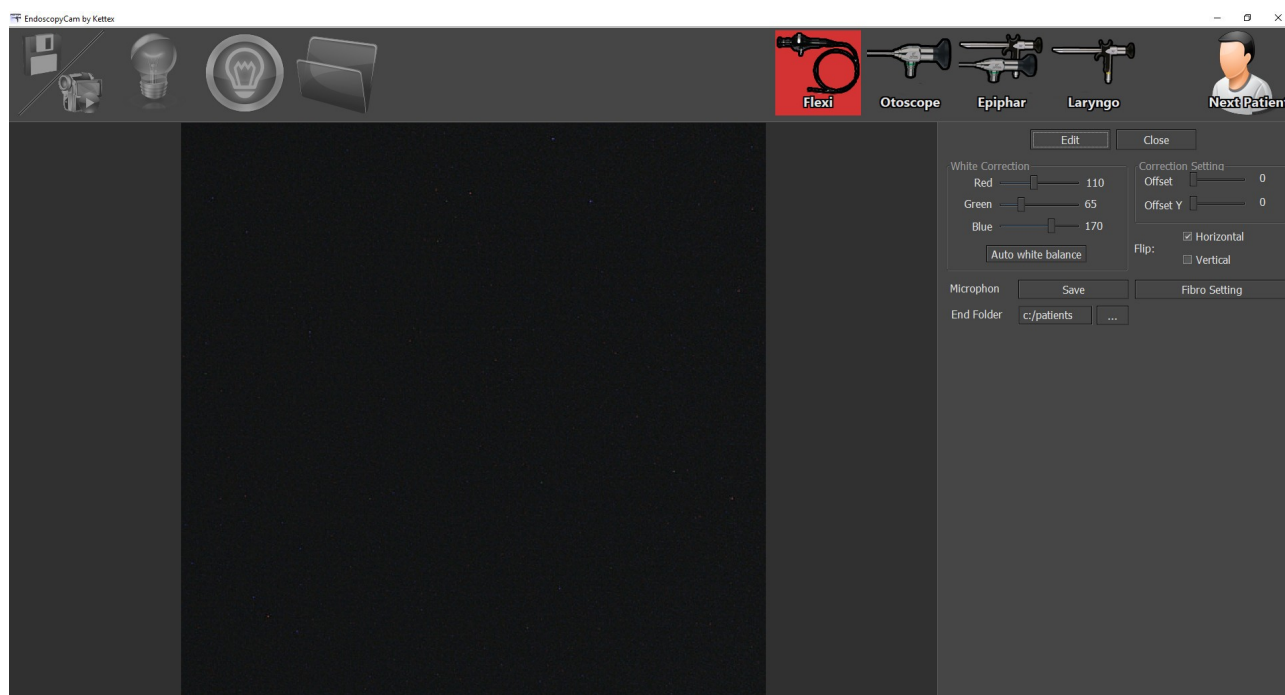




Where you change:

- 1) language of the application
- 2) activation values of the footswitch. Every type of footswitch has its own. The footswitch is the small keyboard in fact and if you press any pedal it send some letter/digit to the systém.
- 3) you can change the design of the toolbar – including number of icons that will appear on the toolbar, what images will be displayed and what text, what camera and what resolution corresponds with every single icon.

**The second option „User setting“** opens simple user setting dialog.

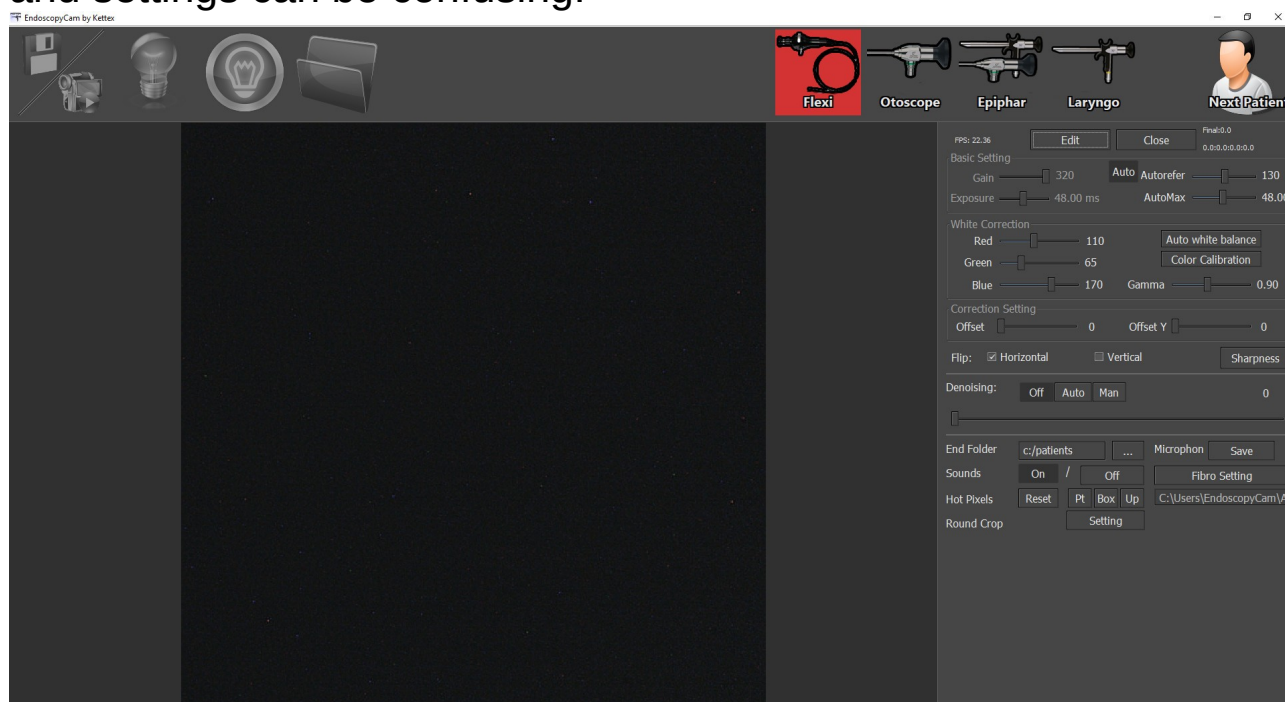


User needs to press button „Edit“ at first and can set some user params afterwards. The setting is unique for all endoscopes – i.e. it can differ for all the tools.

We can set following things: white balance correction – manual or automatical, camera offset - ROI of the chip where from is the live image taken. We can select flip of the image horizontal/vertical. We can select whether the sound from microphone will be captured.

## The last option „Advanced Settings (for experts only)“

This setting should be launched just by experts and we don't allow for users to run it, because the access to all the system parameters and settings can be confusing.



The setting is grey apriory to avoid random change of the params. Pres button “Edit” to enable params edit or press “Close” to leave the dialog.

## Setting gain and exposure

Exposure time means for how long will opened the shutter for each image. Gain means amplification of the signal - it is equivalent of ISO in the photography. These parameters has major influence how many images will be captured per second (how fluent the image will be) and how bright and noisy it is.

Longer exposure means brighter image but less number of images per seconds. Bigger gain makes the image brighter but more noisy.

Exposure and gain has the option "Auto" to have these values set automatically according to the values Autorefer and Automax.

## Setting Autorefer and AutoMax

Both values influenced exposure and gain when the value Auto is selected for them - gain and exposure will be set up automatically. Autorefer is an value of the mean intensity of the image. Higher value means brighter image. The application tries to reach selected brightness by changing the camera exposure and gain.

AutoMax is the maximal value of the exposure that can be used for automatic brightness setting.

## White balance

You can use halogen, LED, xenon light source for the endoscope. Every light source has different spectral profile. This causes that if you aim the light to the white desk you will see yellow desk using the halogen light source. All the other colors are shifted this way as well. But we want to recognize colors correctly. White Balance correction is the way how to do that. There are two options: a) manual b) automatical white balance. So you can tune parameters manually or let the application the job itself. For **automatical white balance correction** you need to aim the endoscope to the white (gray) object and press the button "White balance". After that please wait 5 seconds and the application will change R,G,B gains to make the grey, grey again.

## Color Calibration

Is an extensive method for setting correct colors. Cannot be done without extensive knowledge of color theory. Do not use it. You can set any curve for any color component and even for intensity profile. For details please see Image 13.

## Gamma

You can set the gamma correction by the slider

## Offset X, Offset Y

If the whole chip is not used for image capturing, you can change the ROI of the chip, that is used for image capturing.

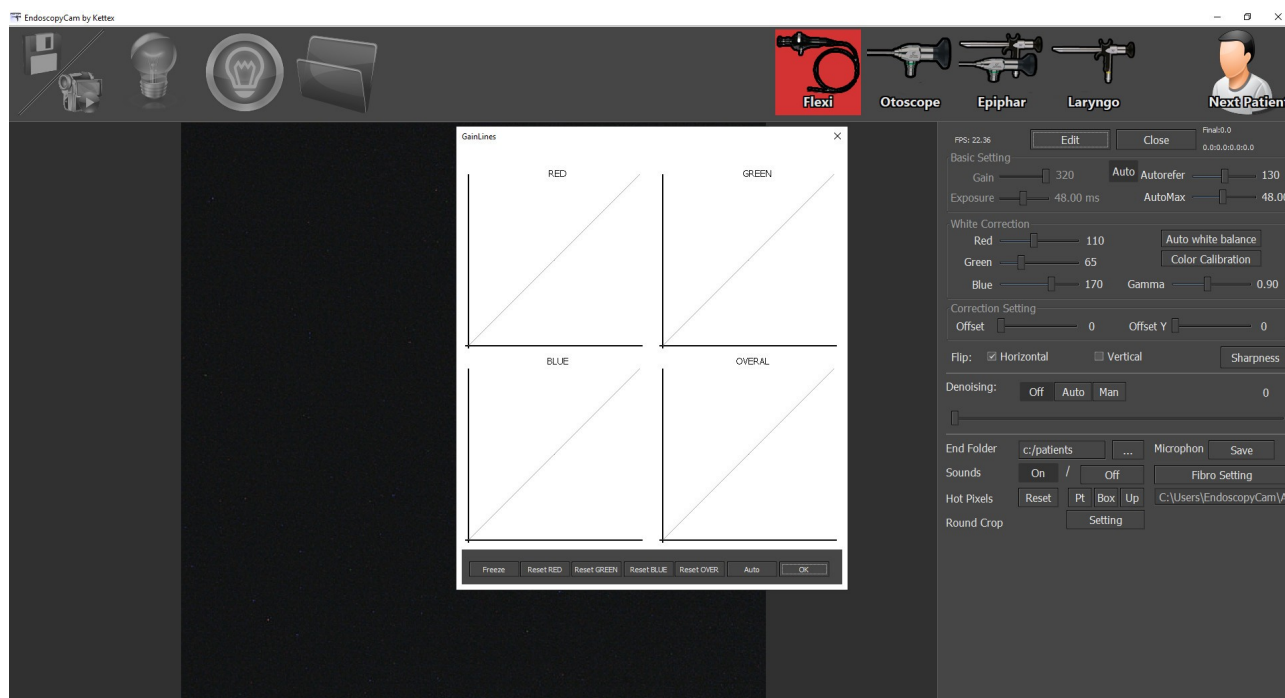


Image 13

## Flip horizontal / vertical

You can flip the image using this feature.

## Additional filter – Sharpness

Postprocessing refocusing

This is the way how to refocus the image by the application. Using this slider you can select which level of details is interesting for you and how much do you want amplify the details. The drawback of the refocusing is that it amplifies noise as well. There are two filters which can be chosen - UnS and GuF. GuF should be used alone, UnS can be used with the System Sharpness.

### System Sharpness

This is refocusing which is proceeded by camera itself, earlier than the image gets to the computer. This refocusing procedure enhances image edges with the highest level of details.

### System Brightness

This changes the brightness independtly on Autoreference just

before the image comes to computer. It is processed by internal FPGA just in the camera.

## **Denoising**

When you capture the image with non-zero gain it contains the noise. Denoising (noise reduction) can remove it while it doesn't damage the data – tissue structures. You can switch off the denoising, set it to auto behavior or tune it manually, where the slide means the power of the denoising – that means how strong edges will be considered as the noise. If you overshoot the parameter, it will remove more noise, but it can remove some structures as well.

## **Folder**

You can specify the parent directory of the patients data - it means the place on disc which will be used as a root directory for all the patients folders.

## **Sounds**

The application can make sounds when capturing image/video or ending the examination. You can switch on/off this feature.

## **Hot Pixels**

You can correct hot pixels of the camera.

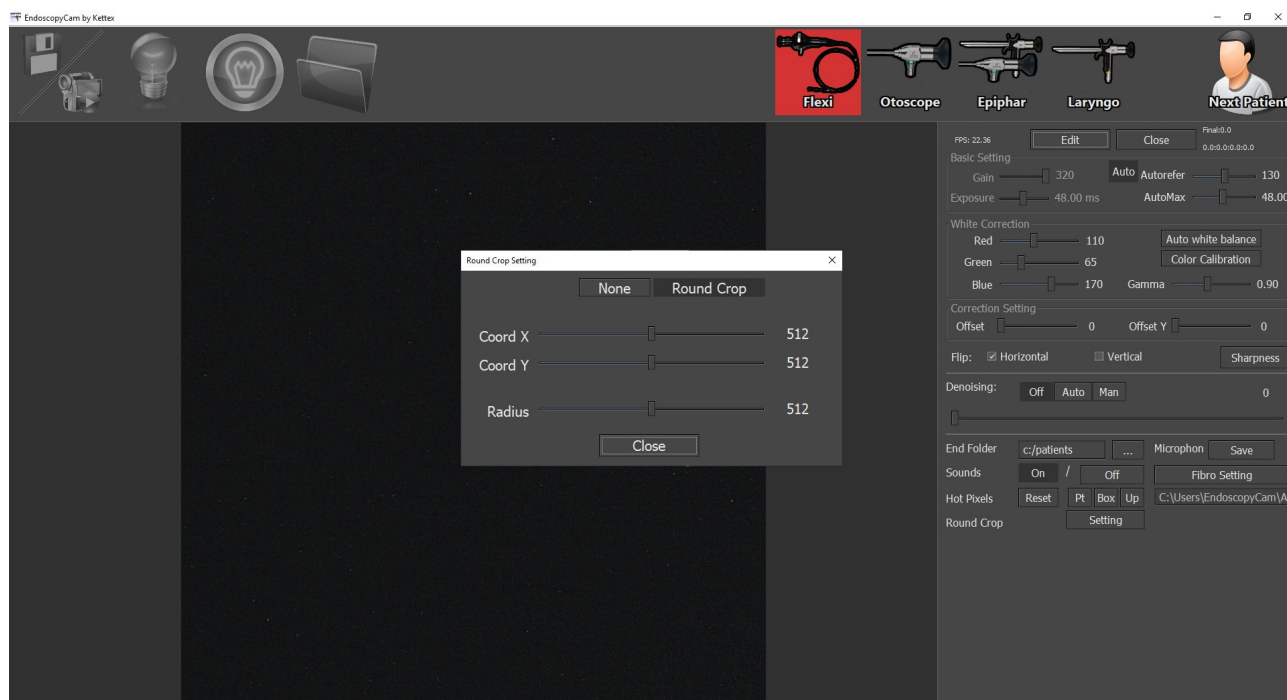
## **Microphone**

This option allows you to capture the sound together with video.

## **Round crop**

If you set round cropping the round part of the image will be set to white color, which is useful for image print.





## 6. Safety and operational instructions

The system is safe from any point of view.

If you work with camera pay attention to:

- finishing the examination. When you detach the endoscope please push back the blind end to prevent dust degradation of the coupler.
- USB cable. If you unplug it by an accident, the camera will stop providing live image.

### Safety precautions

In case of any problems and not proper operation of the device, stop using the product. Doctor must be able to finish diagnosis using the ocular only.

Do not use the camera in high humidity environment.

Never use the device in the environments of flammable anesthetic gases or oxygen rich environment.

Repairs to the device, other than those specified in this instruction, can be performed only by manufacturer.

Camera during normal use works in conjunction with other electrical devices in medical system. When combining or modifying medical system, requirements of IEC/EN 60601-1 should be fulfilled. Please follow the recommendations from Clause 16 of IEC/EN 60601-1 related with medical systems.

To guarantee the safety of the user, the patient and others, use only accessories and spare parts specified by the manufacturer of this product. Other accessories or spare parts can cause the emission of increased electromagnetic radiation or reduce immunity against interference.

Too much intensive light can damage the camera image sensor. Direct exposure to sunlight or radiation of other bright light sources in the range of visible or ultraviolet light will cause permanent damage to the camera image sensor.

Use camera holder for storing camera.

Handle with care. Do not squeeze, pull and bend the cable of camera head.

Camera and its accessory is very sensitive to mechanical shock. Dropping camera or coupler on the floor could cause its mechanical damage! Run through the checks before each use. Do not use products which are damaged, incomplete or have loose parts.

Before each use, check to ensure the view observed through the endoscope provides the correct image orientation.

## **Warning**

The the temperature of the camera can reach up to 46 degree celsia.

## **Installation tips to meet EN 60601-1 requirements**

Camera is designed to work in conjunction with other electrical devices in medical system. The combination of the medical system can only be performed by qualified person. Installation of medical systems and their modifications during normal use are permitted with caution to requirements. Legal requirements and Clause 16 of EN 60601-1 technical requirements have to be fulfilled.

In addition to this operating instruction also follow the instructions of the product used in combination with this product.

In the patient environment may be located only medical electrical devices provided by the manufacturer for such use. Electrical equipment outside the patient environment must meet certain safety requirements according to IEC or ISO. Patient environment in accordance with IEC / EN 60601-1 is defined as the area around the patient of distance 1.5 m.

When selecting the system components basic safety requirements shall be fulfilled:

1. After medical system installation or modification, leakage currents shall be measured to ensure that the limit values according to EN 60601-1 are not exceeded. Leakage currents can be reduced by means of separating transformer or additional protective earth terminal to system ground.
2. To connect the camera with non-medical devices, the nonmedical device must be placed outside patient environment (in distance above 1.5 m the non-medical devices have to be powered through a medical separating transformer.
3. To connect the medical devices with a non-medical device in



non-medically used room through a long cable, a separation device should be used between the devices and the non-medical device.

When camera is used with other equipment, leakage currents may be additive causing hazard to the patient.

If a multiple socket-outlet is used, it shall not be placed on the floor.

Connection of additional medical, non-medical devices or multiple socket outlets to medical system requires re-analysis and safety checks on compliance with the requirements of IEC/EN 60601-1.

Any modifications of medical system contrary to this operating instruction, could result in exceeding allowable safe limits of leakage currents and will cause hazard to the patient.

During the treatment, do NOT touch the patient and other devices in patient environment.

**Next general instructions - must be respected all the time**

The company is not responsible for any undesirable events caused by not respecting of following instructions.

6.1 The installation can be done only by trained technician of the manufacturer or distributor. It is strictly prohibited to modify installation by anyone else, especially modification of the electrical parts.

6.2 It is necessary to handle camera with maximal care especially when the patient is diagnosed or treated and therefore minimize camera slip. You have to use camera holder for camera storing or well secured place.

6.3 It is not allowed to disconnect the camera from computer by not properly trained person.

6.4 The system re-installation or expert setting can be done only by company technician (manufacturer's or distributor's technician) on place or by distant access.

6.5 For parameters setting of the Kettex EVision application (calibration) please follow the instructions or let the setting on the trained technical. We are not responsible for wrong functionality caused by improper settings by non-trained stuff.

6.6 When you attach the endoscope to the coupler you need to take extra care to proper position of the camera and endoscope. The proper position must be checked on the well known pattern before examination.

6.7 If you capture videos, take extra care to proper ending of the saving video. You can avoid wasting space on your HDD.

6.8 Computer running Kettex EVision SW must be secured against unauthorized person use. Please use password for computer logging in to avoid unauthorized access to personal patients data. If you export the patients folder anywhere you need to secure all the computers where from you have access to the folder as well.

6.9 When the Kettex EVision SW is used for the patients diagnostics or treatment, no other computation demanding application can be run to prevent computer slow down. More over it is mandatory to avoid installation of application running on the background which can slow down the computer as well (like anti-virus, DropBox ... etc).

6.10 It is necessary to clean the ocular of the coupler at least once per 2 months by cotton wool and 80% alcohol. Moreover it is necessary to check at least once per 2 months the amount of light coming from lightguide and or portable lightsource. In the case that the amount is low you need to replace the lightguide or to charge the portable light source.

6.11 When you change the light source you need to re-calibrate the white balance by user setting.

6.12 When you change fiberoscope you need to switch on/off the fibroscopic grid correction with the new fiberoscope to let the system autocalibrate the grid.

6.13 When using camera you need to take care about cable, not to bend it, pull it and don't let the camera hang. You need to check the camera and the cable visually before every single use. When you find some damage it is strictly prohibited to use it.

6.14 The system can be stored and used in the range 0-40 degrees Celsius and the non-condensing humidity up to 85%.

6.15 You need to avoid camera exposition to electrostatical charges and you need to use antistatic bag for long term storing.

6.16 It is prohibited to clean the camera body by alcohol based or other flammable substances. Don't take camera to the neighbourhood of the fire or high voltage source.

6.17 Computer serving the camera must be attached to the power source just by overvoltage protection with parameters equal or better than „APC Performance SurgeArrest PF8VNT3“. The same protection must be used on the touchscreen monitor, otherwise you increase the risk for the patient.

6.18 It is strictly prohibited to remove USB cable isolation or silicon camera isolation. If this happen our company is not responsible for camera functionality or any undesirable events.

6.19 It is desirable to avoid the contact between camera and patient or his/her body fluid. In the case of contamination by body fluids it is necessary to clean the camera propely – check section Cleaning. In the case one can expect the camera contact with body fluid it is desirable to use single use plastic sleeve for the camera.

6.20 You have to prevent the contact between the USB connector and any fluid. In the case there is such a contact, you have to switch off the camera and computer immediately and let the connector dry. You need to check all the functionality before the next use.

6.21 The device cannot be used if any of its part is not working properly.

6.22 The device can be used only with well trained user.

## 7. Cleaning and disinfection

Before the cleaning and disinfecting please turn off the computer and disconnect the camera.

Cleaning and disinfecting of the device should be performed by qualified personnel and following the steps outlined below.

The device is not designed to be sterilised! Any attempt at sterilization of the device will result in permanent damage. By sterilization we mean sterilization in lotion or autoclave.

It is needed to clean the coupler and the camera by wetted doily with disinfection. When the camera is contaminated accidentally please do the thorough cleaning by the doily again. Please prevent the dust degradation of the coupler. You can remove the dust from the optical path using 80% ethanol and cotton wool sticks.

Do not use autoclave or disinfection by placing camera to any fluid - any fluid or a steam will damage the camera and the warranty will be void in that case.

## 8. Troubleshooting

**Problem:** Cannot launch the application

**Solution:** Wait for ten seconds and try to launch the application again. If it doesn't launch again hold on for one minute. If nothing changes, please email/call the technical support.

**Problem:** The application said that it cannot run without any camera connected - or some icons disappeared from the toolbar.

**Solution:** Quit the application and check the USB cables of your camera(s). If it doesn't help, please re-connect both connectors - on the camera and computer side. If the problem persists please email/call the technical support.

**Problem:** Footswitch doesn't work properly.

**Solution:** Quit the application and check the USB cable. If it doesn't help, please re-connect the connector. If the problem persists please email/call the technical support.

**Problem:** The application doesn't save any sound for the video.

**Solution:** Check the expert setting whether there is enabled sound capturing. Check whether the microphone is muted or disabled in the MS Windows. If the problem persists please email/call the technical support.

**Problém:** Application "died", it makes invalid command and it was terminated automatically by the MS Windows.

**Solution:** Email/call the technical support.

## 9. Disposal of used product

The current EU-wide legislation, implemented in each member state, requires that all electrical and electronic equipment marked with this symbol is disposed separately of other waste. This includes electronic devices or electrical accessories such as cables, electronics, etc. When disposing of such products, please follow the advice of your local authorities. The symbol shown on electrical and electronic products only applies in current EU member states.



If any unspecified problem appears, please email/call the technical support.

**Kettex Development s.r.o.**  
**Na Pěšině 465/6, 184 00 Praha 8**  
**IČ: 03267016**  
**DIČ: CZ03267016**  
**email: [info@kettex.eu](mailto:info@kettex.eu)**  
**web: [www.kettex.eu](http://www.kettex.eu)**



## **Producer and Technical support:**

Dr. Filip Krolupper Ph.D  
Mirovická 40  
182 00 Praha 8  
Czech Republic  
tel: +420 728 526 720  
email: [filip.krolupper@gmail.com](mailto:filip.krolupper@gmail.com)

## **Kettex KX-01, KX-01-OR**

Active medical device Class I.



**Kettex Development s.r.o.**  
**Na Pěšině 465/6, 184 00 Praha 8**  
**IČ: 03267016**  
**DIČ: CZ03267016**  
**email: [info@kettex.eu](mailto:info@kettex.eu)**  
**web: [www.kettex.eu](http://www.kettex.eu)**

