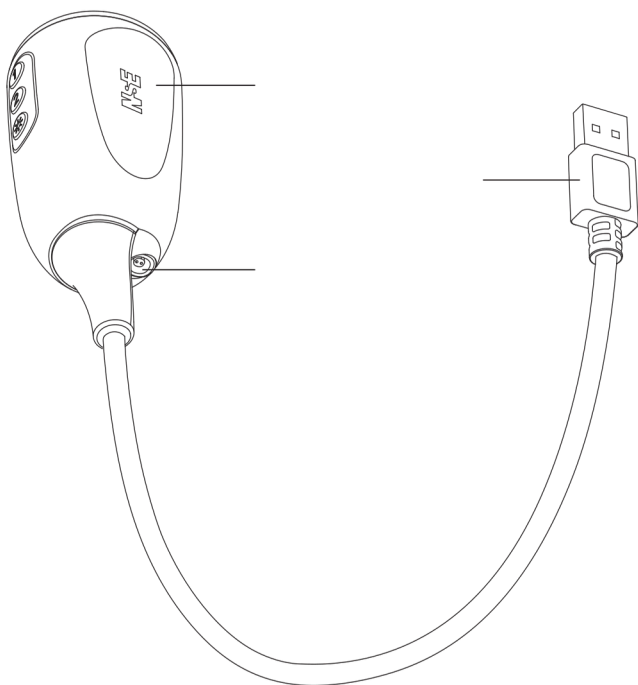


User Manual

USB3.0 HD Endoscopic Camera System



Model:6134260


Reading First

Dear customer, thank you for purchasing USB HD Endoscopic Camera System of Labomed Europe. This manual provides the information about how to use, install and maintain.

Please read this manual carefully and understand it before using the device.

- This manual should be placed on where is easy for you to get for reading at any time.
- When you don't read the manual, please put it to a place where it will not be lost or damaged.
- For safety and correct operation, the following warning marks are identified.

 Caution: Ignorance of this caution will lead to a slight damage.

 Warning: Ignorance of this warning will cause a heavy damage.

Labomed Europe b.v. reserves the right to interpret the usage of this manual.

Check the spare parts provided

When first time open the package, please check if the described spare parts are complete and in good condition. If any spare part is incomplete or damaged, please contact with your supplier.

Packing List	
Main Unit	1pc
Qualified Certificate	1pc
User Manual	1pc
Optical Adapter	1pc
LED light source	1pc

Caution:

- Please keep the packing materials well for future use.

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1 Overview

1.1 Product Name

Endo camera USB3.0, with software

1.2 Model

6134260

1.3 Product Component

Endo camera is made up of camera unit and USB cable and the camera unit contains C type lens mount, image sensor, micro controller and light source interface.

1.4 Scope

Endo camera is used with medical optical endoscope for real-time observation and recording in endoscopy and minimally invasive surgery.

The real-time video can be displayed on monitor by a computer with USB3.0 port.

1.5 Contraindication

No contraindication.

1.6 Environment Condition

Operation:

- Temperature: 5°C ~ 40°C
- Humidity: 20% ~ 80%
- Pressure: 86kPa ~ 106kPa

Storage and transportation:

- Temperature: -10°C ~ 55°C
- Humidity: 10% ~ 95%
- Pressure: 86kPa ~ 106kPa
- Long-term storage should be conducted indoor with non-corrosive gas and well ventilated.
- Transport with general vehicle. Avoid severe impact, strenuous vibration and snow rain splashed.

1.7 Safety Category

- Applied Part: Type BF
- Operation Mode: Continuous operation
- Voltage: DC 5V/0.7A supplied by computer USB3.0 port

1.8 Technical Parameters

- Image sensor type: CMOS
- Video resolution: 1920*1080, 30fps
- Interface type: USB3.0
- Optical adapter: Support all kind of C type optical adapter
- Product dimension: 45mm*45mm*80mm
- Product weight: 200±10g

1.9 Requirements for Computer

Minimum requirements for computer:











- CPU: Dual core 2.6GHz
- Operation System: Microsoft Windows10, Microsoft Windows8, Microsoft Windows7(64-bits or 32-bits)
- Memory: 4G RAM
- Screen: 1920*1080
- USB port: USB3.0

Recommended configuration for computer:

- CPU: Quad Intel Core i5 3.0GHz

- Operation System:Microsoft Windows10, Microsoft Windows8, Microsoft Windows7(64-bits or 32-bits).
- Memory:8G RAM.
- Screen:1920*1080 IPS screen.
- USB port:USB3.0.

1.10 Label and Symbol

Symbol	Explanation
	Caution! Refer to attached file.
	Type BF
	Recyclable.
	Keep away from fire.
	CE mark
	Follow instructions for use.
	Name and address of the manufacture.
	Name and address of European Representative.
	Product LOT Number.
	Product Serial Number.
IP58	Dust-protected, protected against the effects of continuous immersion in water (Maximum immersion depth and time: 1m, 1hour)

 Caution:

i. The device requires no calibration.

ii. The device contains no user repairable and serviceable parts.

iii. No modification of this equipment is allowed.

iv. Disposal

Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact your local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being.

v. The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.

vi. Manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

vii. Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (See IEC 60601-1 or clause 16 of the 3Ed. of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.

2 Product Structure

2.1 Product Diagram

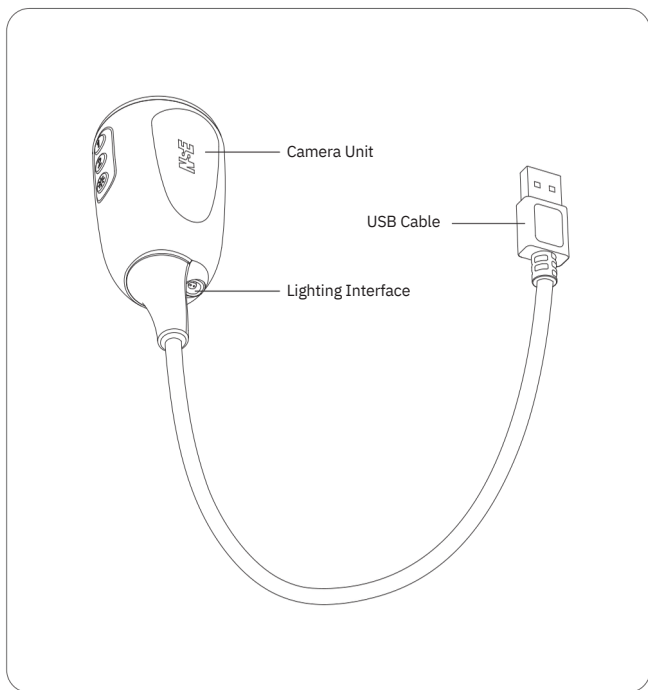


Fig. 1 Product Diagram

2.2 Button Functions

There are three buttons in the camera unit. Button ① and button ② are used for reserved functions. Button ☼ is used for LED light brightness adjustment and shut, LED light brightness can be adjusted from level 1 to level 5.

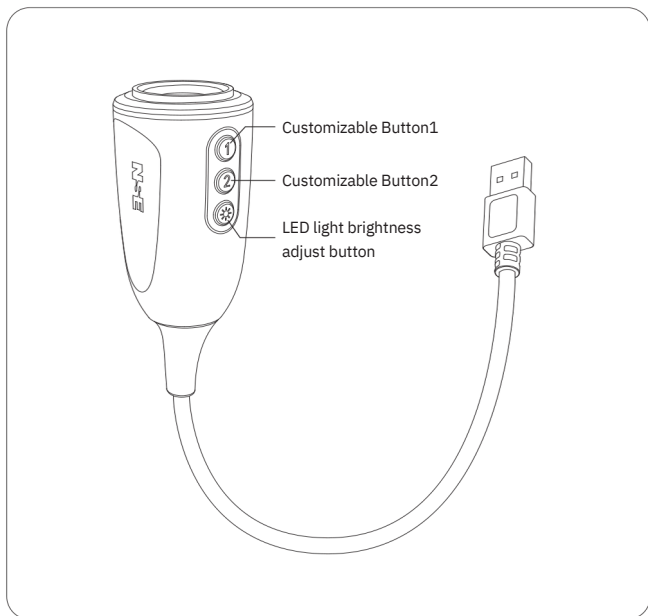


Fig.2 Buttons

3 Installation and Operation Instructions

3.1 Installation

The product needs to be installed before using. Please follow the steps as below:

- a) Take out the lens cap from the camera unit, then connect the C type optical adapter to the lens mount (C-Mount) located in the camera unit, clockwise rotate it to tighten it up.
- b) Open the lock of the optical adapter, connect the endoscope, and release the lock to fix it.
- c) Connect the self-locking connector of LED light to the lighting interface in camera unit, and connect the other end of the LED light to endoscope, clockwise rotate it to tighten it up.

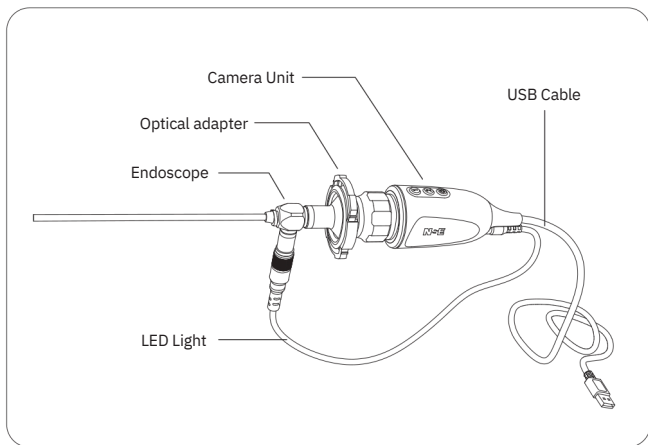


Fig.3 Product Installation

⚠ Caution: There is a red dot in the self-locking connector of LED light, please make sure it is aligned to the red dot in the lighting interface in camera unit when connecting LED light.

⚠ Caution: The LED light is the application component connected to the endoscope.

3.2 Operation Instructions

After the installation of endoscope, please connect the Endo camera to the USB3.0 port of computer.

After connecting to computer, the operation system will install the driver automatically, if the driver is installed correctly, you will see our product in device manager->imaging devices.

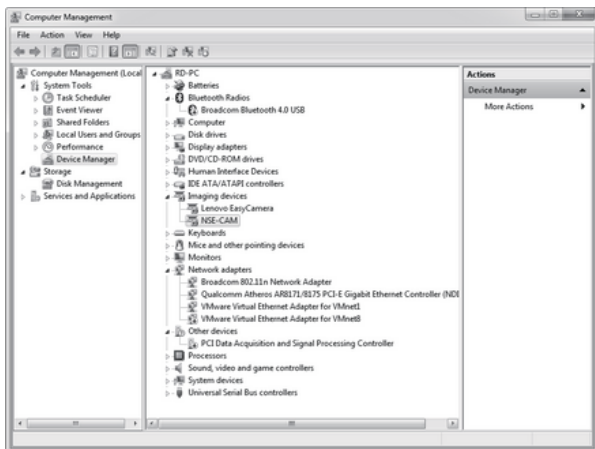


Fig.4 View Device

Open the specific software to real-time view and record the image under endoscope. After opening the specific software, you can use the LED light brightness adjust button to adjust output brightness.

Before using, you can target endoscope to white object like white paper and long press button (⊗) to auto-adjust white balance parameters.

After using, please close the PC software, then unplug the Endo camera and keep it in the packing box.

⚠ Caution: Endo camera can only be connected to the USB3.0 port for normally use

⚠ Caution: Please refer to the software user manual, and you can view the software version by the ABOUT menu.

⚠ Warning: Please do not directly sight the LED light beam in short distance.

⚠ Warning: Please do not disassemble the product and spare parts like LED light etc. Any malfunction or failure, please stop using it and contact with your distributor or directly to the manufacturer.

4 Product Cleaning and Maintenance 4.1 Cleaning Methods

a) Suggested to use the sterilized cotton immersed in 70% aldehyde or isopropyl made detergent or 75% made medical alcohol to wipe the product surface, and please to wipe the glass gently.

b) The USB interface should be mounted by cap when cleaning.

c) Using the distilled water to wash the product and using the dry soft fabric to dry the product surface.

⚠ Warning: Do not touch the lens or use the hard objects to scrub the lens.


⚠ Caution: Please clean Endo camera and keep it in packing box if long-time no use.

⚠ Caution: Please keep Endo camera dry after cleaning.

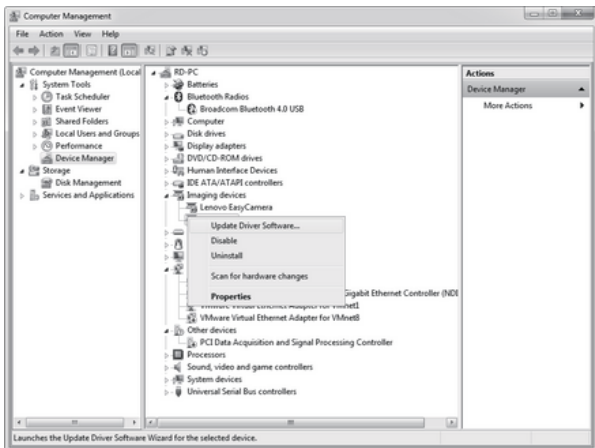
⚠ Warning: Please make sure Endo camera used with sterile cover, while using. Endo camera in minimally invasive surgery.

5 Troubleshooting

5.1 Fail to Install Driver

After you connect the Endo camera to the computer correctly, the software can't open the camera device, or there is a yellow mark  in the device icon in computer device management. Please refer to the following steps:

- Please make sure connect Endo camera to the USB3.0 port.
- Please use the following operation to update system drive:



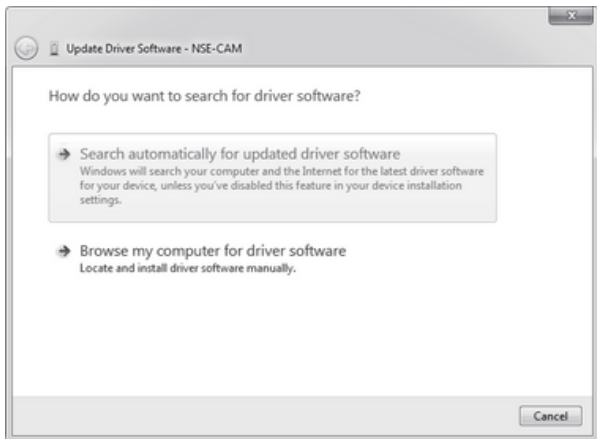


Fig.5 Update Driver

- Please try to reconnect Endo camera

5.2 Video Interruption

The connection between Endo camera and computer may loose, causing the video interruption, please reconnect Endo camera to computer.

5.3 Video is not smooth

Please make sure the using computer configuration is above the minimum requirements.

5.4 Image is fuzzy

Please adjust the focus of the optical adapter to get a clear image.

5.5 There is dark spot in image

Please check the endoscope, optical adapter and the camera surface are clean, if they are dirty, please use the soft fabric to clean gently.

If the above operation can't solve your problem, please contact the after-sales service.

6 EMC Information

⚠ Caution: Endo camera is complying with IEC 60601-1-2:2014 standard.

⚠ Caution: Users should install and operate according to EMC information provided in the accompanying documents.

⚠ Caution: Portable and mobile RF communications equipment may affect Endo camera performance, please avoid the use of strong electromagnetic interference, such as near mobile phones, microwave ovens.

⚠ Caution: Guidelines and manufacturer's statement detailed in the annex.

⚠ Warning: The device or system should not be close to or stacked with other equipment or if you must be close to stacked to use, should observe to verify normal operation can be configured.

⚠ Warning: Class A equipment is intended for use in industrial environments, for Endo camera's conductive disturbance and radiation interference, potential dangers may appear in other environments to satisfy electromagnetic compatibility.

7 After-Sales Service

Endo camera is warranted to be maintained by us, we give one year guaranty time. During the guaranty period we will provide free repairing service and replaced spare part.

The service life of the product is 5 years.

Warranties are void and do not apply if:

1. Damage caused by error operating or using without following instruction manual (any application beyond the usable range).
2. Damage caused by repair or modified inspection that not operated by our service engineer.
3. Damage caused by natural hazard such as fire, flood, earthquake or thunder

If there is any malfunction please contact manufacturer or supplier for services.

⚠ Caution: Warranties will not be applied if the device is disassembled.

Appendix A EMC Information

Guidance and manufacturer's declaration – electromagnetic emissions		
The Endo camera is intended for use in the electromagnetic environment specified below. The customer or the user of the Endo camera should assure that it is used in such an environment.		
emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group I	The Endo camera uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The Endo camera must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – Electromagnetic immunity


Endo camera is intended for use in the electromagnetic environment specified below. The customer or the user of Endo camera should assure that it is used in such an environment.

Immunity test	IEC 60601 test voltage	Compliance level	Electromagnetic environment – guidance
Electro-Static discharge (ESD) IEC 61000-4-2	±8 kV Contact discharge ±15 kV Air discharge	±8 kV Contact discharge ±15 kV Air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical Fast Transient IEC 61000-4-4	±2kV to power supply line ±1kV to input/output line	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	N/A	Mains power quality should be that of a typical commercial or hospital environment.

<p>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</p>	<p><5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s 50Hz,60Hz 3A/m</p>	<p>N/A</p>	<p>Mains power quality should be that of a typical commercial or hospital environment. If the user of the Endo camera requires continued operation during power mains interruptions, it is recommended that the Endo camera be powered from an uninterruptible power supply or a battery.</p>
<p>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</p>	<p>50Hz,60Hz 3A/m</p>	<p>50Hz:30A/m 60Hz:30A/m</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p>
<p>NOTE U_T is the a.c. mains voltage prior to application of the test level.</p>			

Guidance and manufacturer's declaration – Electromagnetic immunity

Endo camera is intended for use in the electromagnetic environment specified below. The customer or the user of UC-100 should assure that it is used in such an environment.

Immunity test	IEC 60601 test voltage	Compliance voltage	Electromagnetic environment – guidance
<p>RF Immunity IEC61000-4-3</p>	<p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Endo camera, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommend isolation distance</p> $d = 1.2 P \sqrt{f}$ $d = 1.2 P \sqrt{f} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 P \sqrt{f} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,c should be less than the compliance level in each frequency range.d Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Endo camera is used exceeds the applicable RF compliance level above, the UC-100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME EQUIPMENT.

d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

The recommend isolation distance between Portable and mobile RF communication equipment and Endo camera

The Endo camera is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [it can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Endo camera as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter /W	Separation distance according to frequency of transmitter /m		
	150 kHz ~ 80 MHz $d = 1.2 \sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2 \sqrt{P}$	800 MHz ~ 2,5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



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