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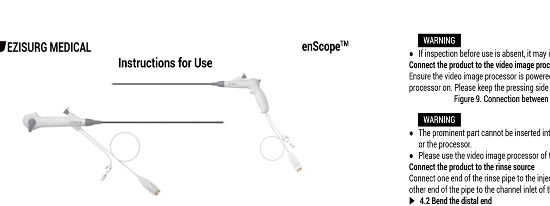
EZISURG MEDICAL

Instructions for Use

enScope™



CY-CL15R/CY-PL15R/CY-CL15S/CY-PL15S

Ezisurg Medical Co.,Ltd.

CE 0197

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Illustration

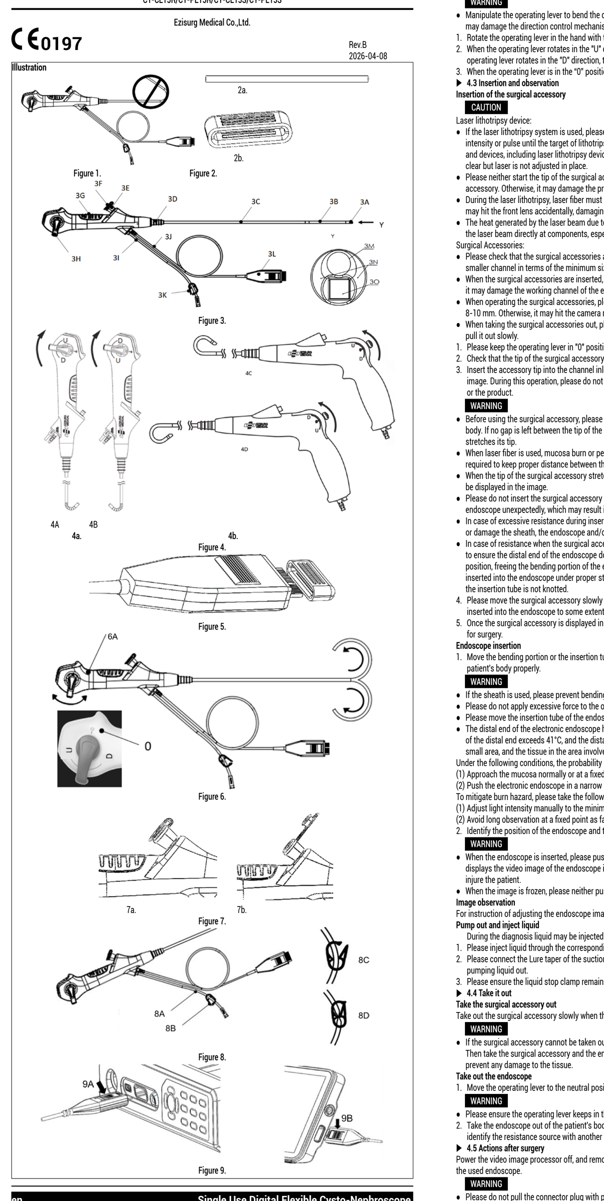

Figure 1. Figure 2. Figure 3. Figure 4. Figure 5. Figure 6. Figure 7. Figure 8. Figure 9.

en Single Use Digital Flexible Cysto-Nephroscope

Important information

Please read the following information carefully before using the product.
Please follow the warnings and cautions below when using the Single use Digital Flexible Cysto-Nephroscope (hereinafter referred to as the "Endoscope"). Additionally, the sections herein specify separate warnings and cautions.

▶ Intended use/Indications for Use
The Single Use Digital Flexible Cysto-Nephroscope is intended to be used to visualize organs, cavities and canals in the urinary tract (urethra, bladder, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

▶ Clinical Benefit
1. Provide clear images for visualization.
2. Provide working channel for diagnostic and therapeutic accessories.
3. Single-use avoiding cross-contamination and reduce cost.

▶ Intended use population
Adults only.

▶ Instruction for use
This instruction for use contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment that will be used during the procedure and use the instruments as instructed. Keep this and all related instruction for use in a safe, accessible location.
If you have any questions or comments about any information in this manual, please contact Ezisurg Medical.

▶ User qualifications
The product should be used only by professional endoscope physicians or medical staff under the supervision by professional physicians. The operators should receive sufficient clinical skill training. This document does not cover any explanation of or discussion over clinical skills.

▶ How the product works:
Working principle: Two small-sized LED lamps and one CMOS image sensor powered by the video image processor are installed on the distal end of the product. LED lamps illuminate the cavity of the human body; the CMOS image sensor converts the reflected light signal received into electrical signal, and transmits electrical signal to the video image processor via CMOS cable, the signal converter board and signal cable.

▶ Contraindications:
Contraindications apply only to applications for which the product is used for observation and diagnosis. Please do not use the product to diagnose or treat the patient suffering fever due to urinary tract infection or serious coagulation dysfunction.
Please do not use the product to diagnose or treat the patient with acute infection (acute urethritis, acute prostatitis or acute epididymitis).
Please do not use the product to diagnose or treat the patient with urinary stenosis.
For the contraindications of the product in other treatment applications (such as lithotripsy, endoscopic incision, and oncotherapy), please refer to corresponding open surgery.

▶ Adverse events
Potential adverse events related to the flexible Cysto-Nephroscope (inexhaustive).
Intraoperative pain or discomfort, hematuresis, abdominal pain, dysuria (pain and discomfort during urination), increased frequency of urination, urethra narrowing due to scar tissue formed (stenosis), and urinary tract infection (UTI).

▶ Sterilization/validity period:
The product has received ethylene oxide sterilization. Its production date and validity period are indicated on the label.

▶ Instrument compatibility
Please be confirm that the endoscopy is compatible with the ancillary equipment before using. Using incompatible equipment can result in patient injury and/or equipment damage. The models of Video image processor compatible with the endoscope are ESP30 and ESP20.

▶ Inspection before use
Before using this instrument for the first time, please inspect it according to the instructions given in Chapter 3

▶ Signal words
The following signal words are used throughout this manual:

WARNING
Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION
Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

NOTE
Indicates additional helpful information.

▶ Warnings and cautions
Follow the warnings and cautions given below when handling this instrument. This information is to be supplemented by the warnings and cautions given in each chapter.

WARNING
- The product is sterile, and is packaged with the sterile material. If the sterile package is damaged, please do not use the product.
- It is not allowed to reuse the single use product, as any of these misconducts may impair the structural integrity of the product and/or cause product fault. Consequently, it is likely to result in injury, illness or even death of the patient.
- The limited use time of this product is 4 hours, and the timing start after the device connection with the image processor and power on normally.
- Without authorisation, please do not change the institutional composition of the endoscope and the image processor used with it at will. If necessary, please contact the professional and technical personnel of Ezisurg Medical Co., Ltd.
- Please use the product within its shelf life.
- Please wear medical gloves when operating the product.
- Please do not use the product until it is confirmed that the image is clear. Otherwise, it may result in the injury of the patient, such as perforation, evulsion and bleeding.
- If the image is lost, please neither use the product nor insert any surgical accessory. Otherwise, it may result in the injury of the patient, such as perforation, evulsion and bleeding.
- Please do not push or pull the product with excessive force. Otherwise, it may result in the injury of the patient, such as perforation, bleeding, or ureteral epidermis injury. In case of any resistance when pushing or pulling the product, please identify the resistance source and take remedial measures (such as fluoroscopic examination or contrast agent injection).
- Please do not poke the side wall of the bladder or the pelvis with the tip of the product by force. Otherwise, it may result in the injury of the patient, such as perforation and bleeding.
- Please keep normal imaging when pushing or operating the surgical accessory. Otherwise, it may result in the injury of the patient, such as perforation and bleeding.
- Do not pull the laser fiber into the body of the product during the laser emitter working. Otherwise, it may cause the injury of the patient or damage the product. Please read the laser emitter manual carefully to have a good understanding of laser emission parameters. Protect eyes by wearing goggles.
- The patient leakage current will increase when the product uses any powered accessory.
- Do not look straight at light emitted from the product. Otherwise, it may damage eyes.
- The single use product has no repairable components. Please do not attempt to repair the damaged or failed product. If it is found or suspected that the product gets damaged, please do not use it any more.
- Please do not bend the insert portion of the product excessively. Otherwise, it may break or deform the insert portion.
- If the product gets damaged or fails to work during the surgery, please stop using it immediately. For more information, please refer to the section "Fault Identification and Troubleshooting". Where appropriate, it is allowed to use a new one.
- Before using the cardiac defibrillator, please take the product out of the patient's body. If the product is not taken out of the patient's body when the defibrillator is used, the current of the defibrillator may injure the patient or damage the product.
- Please do not use the product together with any high-frequency surgical device.
- Please do not use the product when it is placed close to, or stacked with, another device. If the product has to be used in misoperation. If the product has to be used, please observe it and other device to verify whether they work normally.
- The use of any accessory, sensor and cable other than those specified or provided by the product manufacturer may cause increased electromagnetic radiation or reduced electromagnetic immunity, and thus lead to misoperation.
- The portable radio frequency communication device (including antenna cable, external antenna and other peripheral components) should be located at least 30 cm (12 inches) from the video image processor (including cable designated by the manufacturer). Otherwise, it may deteriorate the performance of the equipment.
- The manufacturer will not assume liability for any interference or exposure due to the use of cable other than recommended one or the unauthorized change or modification of the product. The unauthorized change or modification of the product may disable the access of the user to operate the product.
- It is not advisable to use devices emitting radio waves other than those provided by the Company near the product, such as mobile phones, radio transceivers, mobile radio transmitters and radio-controlled toys.
- As the product emits some radio frequency energy, it may generate radio frequency interference with other medical, non-medical and radio communication devices. In order to protect such interference effectively, the product meets radio frequency emission limits under Class A Group 1 as specified in IEC 60601-1-2. However, the Company will not guarantee that it is free from interference generation in a specific installation environment.
- Type F applied components should be used as the applied components of the other medical electrical device in the product. (Please note that the leakage current of the CF device may exceed specified limits.)
- Excessive intake air or laser auxiliary gas may cause gas embolism.
- Before each use or change of view mode/setting, the operator should check to ensure real-time images (instead of stored images) with correct directions are viewed via the product.
- Medical devices used together with the product should meet applicable requirements in IEC60601-1.

CAUTION
- The product should only be used together with the video image processor of the Company. The connection with other device may damage the product or the operator. It is allowed to use the general medical monitor.
- Only trained doctors are allowed to operate the product. Before use, please consult relevant technical data, and medical literature related to complications and adverse events.
- Do not use the device in an aircraft.
- Please inspect whether such parts of the product and its accessories as are inserted into the human body have rough surfaces, sharp edges and protrusions that may result in safety hazards before use.
- Please use the product for the patient receiving the urinary reconstructive surgery or for the patient with known narrow ureter prudently in order to prevent the insert portion from failing to pass through the urinary system.
- Please keep the tip of the product straight when pushing or pulling the surgical accessory. Please refer to the surgical accessory manual. If the operator does not follow the manual in operation, it may result in the injury of the patient, or damage or fault of the surgical accessory and the product.
- Please do not bend the flexible insertion tube by force to prevent damage to the tube (Figure 1).
- Please only use fluid/lubricant that, as indicated, can be used for the product in the insertion tube. Please do not use any accessory that does not meet the product compatibility requirements. Otherwise, it may damage the product and/or its accessory.
- Please do not pull the signal cable by force. Otherwise, it may deteriorate system performance or damage the product.
- To prevent any safety hazard due to device failure, it is required to prepare an endoscope and a video image processor on standby so that surgery can proceed in case of device failure.
- Please dispose of the product and its package according to the regulations of the hospital, the administration and/or the local government after use.
- Before use, please inspect the compatibility between the endoscope system and any accessory and/or treatment devices according to any safety standard specified in the operation instructions.
- Please note that the bending directions are different for the standard and reverse models! For the standard deflection model, the symbol "U" should be positioned on the top and "D" on the bottom; for the reverse deflection model, the symbol "U" should be positioned on the bottom and "D" on the top.

▶ After-sales maintenance, service and parts replacement

WARNING
- The product does not contain any repairable parts. Please do not dismantle, modify or attempt to repair the product as it may injure the patient or the operator, and/or damage the product.
- The disassembly, repair, change or modification of the product by the personnel other than those of Ezisurg Medical Co., Ltd. (ESM) are beyond the warranty scope of ESM. ESM will not bear any warranty liability for those actions.

Chapter 1 Unpacking inspection

▶ Check and inspection
Inspect the transport cases and sterile packages after taking delivery to check that sterile packages are free from damage. Inspect the validity period. Do not use endoscope products whose sterile packages are damaged or that are expired. Inspect product components per the packing list (Table 1). Please do not use the products delivered in case of shortage or damage, and contact the manufacturer immediately. Please keep all packaging materials as needed when claiming compensation from the carrier.

Table 1. Product Packing List

No.	Item	Quantity
1	Endoscope	1
2	Instructions for use	1

NOTE: Insertion section protective tube is included in Endoscope as a part to protect the insertion section from bending, the protective cap is included in Endoscope as a part to protect the connector plug (Figure 2).

Figure 2. Insert portion protective tube and protective cap
2a. Insert portion protective tube 2b. Protective cap

Chapter 2 Instrument Nomenclature and Specifications

▶ 2.1 Description of structure and composition
The main components of the product are shown in the following figure3.

Figure 3. Structure and composition
Distal end (3A - Distal end; 3M - Working channel; 3N- LED; 3O - Camera module); Bending portion (3B - Bending portion); Insert portion (3C - Insertion tube); Operating portion (3D - Insert section protective jacket; 3E - Instrument channel port; 3F - Biopsy valve cap; 3G - Handle; 3H - Operating lever); Connecting portion (3I - Suction tube; 3J - Signal cable; 3K - Liquid stop clamp; 3L - Connector)

Table 2. Endoscope component description

Portion	No.	Name	Description
Distal end	3A	Distal end	Camera module, LED light source and working channel port are on the distal end.
	3M	Working Channel	The working channel port allows the surgical accessory/fluid to flow out of the channel.
	3N	LED	Lighting source
	3O	Camera module	Convert light signal into electrical signal
Bending portion	3B	Bending portion	The bending portion works to move the distal end by operating the operating lever.
Insert portion	3C	Insertion tube	Connect the handle and the bending portion.
Operating portion	3D	Insert section protective jacket	Prevent the joint between the insertion tube and the handle from being bent excessively.
	3E	Instrument channel port	Inlet for surgical accessory or fluid
	3F	Biopsy valve cap	The Biopsy valve cap works to prevent liquid from splashing reversely when the device is used.
	3G	Handle	The doctor holds the handle to operate the product.
	3H	Operating lever	When the operating lever rotates in the "U" direction, the bending portion moves upward. When the operating lever rotates in the "D" direction, the bending portion moves downward.
	3K	Liquid stop clamp	Stop/release the suction tube
Connecting portion	3I	Suction tube	The tube is connected to the suction pump to pump liquid out.
	3J	Signal cable	Supply power to the camera module and LED lamps; transmit the electronic signal of the image from the camera module to the video image processor.
	3L	Connector	It is connected to the video image processor.

▶ 2.2 Specifications

Environment
Transportation conditions:
Temperature: -20°C - 55°C; relative humidity: 10% RH - 80% RH; atmospheric pressure: 700 hPa - 1,060 hPa.
Storage conditions:
Temperature: -20°C - 55°C; relative humidity: 10% RH - 80% RH; atmospheric pressure: 700 hPa - 1,060 hPa.
Working conditions:
Temperature: 10°C - 40°C; relative humidity: 30% RH - 75% RH; atmospheric pressure: 700 hPa - 1,060 hPa.
Product Specifications
The Product Specifications and catalog number are as follows

Table 3. Product Specifications

	Item	Index
Basic parameters	Distal end diameter	5.2 mm(15.6 Fr)
	Max. outer diameter of insertion portion	5.6 mm(16.8 Fr)
	Insertion tube outer diameter	5.0 mm(15 Fr)
	Minimum working channel width	≥2.2 mm(6.6 Fr)
	Working length	380 mm
	Field of view (diagonal angle)	120°
	Direction of view	0°
	Depth of field	2 mm-100 mm
	Output resolution	1280pixel×720pixel
	Bending angle	Upper/lower bend: 210 °
General specifications	Shock-proof type	N/A
	Shock-proof degree	Type BF applied part (insert portion) when connected to the video image processor
	Safety degree when used with flammable anesthetic mixture with air or flammable anesthetic mixture with oxygen or nitrous oxide	A device that should not be used with flammable anesthetic mixture with air or flammable anesthetic mixture with oxygen or nitrous oxide
	Ingress protection against feed fluid	IPX7 for insert portion, IPX2 for handle
	Shelf life	3 years

Table 4. Product Models

No.	Catalog number	Working length	Manipulating direction	Holding mode	Remarks
1	CY-CL15R	380 mm	Reverse type	Vertical holding	LED lighting, resolution 1,280×720; outer diameter of distal end: 5.2mm(15.6 Fr), inner diameter of channel:2.2mm (6.6 Fr)
2	CY-CL15S	380 mm	Standard type		
3	CY-PL15R	380 mm	Reverse type	Horizontal holding	
4	CY-PL15S	380 mm	Standard type		

Figure 4. Schematic Diagram of the Product Model
4a. CY-CL15S /CY-CL15R 4b. CY-PL15S/CY-PL15R
4A-Standard type; 4B-Reverse type;4C-Standard type;4D-Reverse type

▶ 2.3 Accessory specification
Specification of surgical accessory:
1. Outer diameter of accessory: ≤ 2 mm.
Please note that in addition to complying with the above size requirements, compatible accessory also need to hold a CE certificate to ensure its compliance of lunched on the EU market

Chapter 3 Preparation and Inspection

▶ 3.1 Inspection before use
Remove the protective cap
Please remove the protective cap of the connector plug before use (Figure 5. Protective cap of the connector plug).
Visual inspection and internal connection inspection

WARNING
- If inspection before use is absent, it may injure the patient or damage the product and its accessories.
1. Inspect the surface of the flexible insertion tube by feeling the tube with fingers to ensure the surface is free from burr.
2. Inspect whether the bending portion has extruded metal parts.
3. Inspect whether the distal end has contamination and damage traces such as dent, hump, crack or hole visually.
4. Inspect the handle, the operating lever and the Instrument channel port. Ensure parts are free from looseness, bending or damage.
5. Inspect whether the signal cable and the signal plug have damage or contamination visually. Inspect whether the electrical contact in the signal plug has corrosion traces.
6. Hold the bending portion with one hand gently, and push, pull and rotate the distal end with the other hand slowly to check that the connection between the bending portion and the distal end does not get loose.
7. Hold the insertion tube with one hand gently, and push, pull and rotate the bending portion with the other hand slowly to check that the connection between the insertion tube and the bending portion does not get loose.

▶ 3.2 Inspection of bending and rotating operations

WARNING
- If the operating lever gets loose and/or moves unstably, or if the bending portion rotates unstably, the bending mechanism may be abnormal. In this case, please do not use the product because the bending portion may not be straightened, which may result in injury, bleeding and/or perforation of the patient.

CAUTION
- Please do not straighten or bend the bending portion by force when operating the operating lever. Otherwise, it may damage the direction control mechanism.
1. Hold the product (holding area as shown in Figure 6. Schematic diagram of bending operation,6A –Holding part) with one hand, and operate the operating lever up and down slowly until it stops. Check the bending portion rotates smoothly and correctly, and that it can rotate to the maximum angle.
2. Operate the operating lever slowly to check that the bending portion restores to the approximately straight position.

▶ 3.3 Channel inspection

CAUTION
- The product is known to resist the following fluid types: blood, urine, normal saline, contrast agent and water-based lubricant.
1. Check that the Biopsy valve cap is in closed state, as shown in Figure 7a.
2. Open the Biopsy valve cap, as shown in Figure 7b, allowing the device to pass through the small hole in the center of the cap and into the channel.

Figure7. Schematic diagram of working state of the biopsy valve cap
7a. Closed state of the biopsy valve cap 7b. Open state of the biopsy valve cap

3. The instrument channel port of the endoscope is compatible with three-way or locking valves equipped with male Luer lock connectors.

▶ 3.4 Suction tube inspection

Figure 8. Suction Tube (Release/Stop)
8A-Suction tube ;8B-Liquid stop clamp;8C-Release position;8D-Stop position

- Adjust the liquid stop clamp to the stop position when the Suction tube is not working
- Adjust the liquid stop clamp to the release position when the Suction tube is working
- The Biopsy valve cap is closed when the liquid stop clamp is working (as shown in figure 7a)

▶ 3.5 Endoscope image inspection
1. Ensure the video image processor is powered off. Then connect the product to the video image processor, and power the processor on.
NOTE: For detailed connection information, please refer to the "Connection" in the "Operation and disposal" section.
2. Check that LED lamps light up, and that the camera module works normally.
3. Check that LED lamps have effective light intensity control function.
NOTE: For detailed light intensity control information, please refer to the "Unpacking inspection, &appearance & functions" section in the "Instructions for Use of the Video Image Processor".

Chapter 4 Operation and disposal

▶ 4.1 Connection

WARNING
- If inspection before use is absent, it may injure the patient, or damage the product and its accessories.

Connect the product to the video image processor.
Ensure the video image processor is powered off. Then connect the product to the video image processor, and power the processor on. Please keep the pressing side of the connector plug facing upward.

Figure 9. Connection between the connector plug of the endoscope and the video image processor
9A-Press;9B-Press

WARNING
- The prominent part cannot be inserted into the groove if they are not aligned. Insertion by force may damage the endoscope or the processor.
- Please use the video image processor of the company. Otherwise, it may damage the product.

Connect the product to the rinse source
Connect one end of the rinse pipe to the injector, or the gravity feeding bag, or the discharge port of the pump, and connect the other end of the pipe to the channel inlet of the product (or to the fluid port of the Irrigation and locking valve).

▶ 4.2 Bend the distal end

WARNING
- Manipulate the operating lever to bend the distal end. Do not straighten or bend the bending portion by force. Otherwise, it may damage the direction control mechanism.
1. Rotate the operating lever in the hand with the thumb to bend the distal end.
2. When the operating lever rotates in the "U" direction, the distal end and the bending portion move upward. When the operating lever rotates in the "D" direction, the bending portion moves downward (Figure 6).
3. When the operating lever is in the "0" position, the bending portion moves back to the approximately straight position.

▶ 4.3 Insertion and observation
Insertion of the surgical accessory

CAUTION
Laser lithotripsy device:
- If the laser lithotripsy system is used, please select a system with adjustable intensity or pulse options. Adjust laser intensity or pulse until the target of lithotripsy is displayed clearly in real time. Please do not start any surgical accessories and devices, including laser lithotripsy device, if no image is displayed clearly. Please suspend the surgery if the image is clear but laser is not adjusted in place.
- Please neither start the tip of the surgical accessory nor stretch it to the tip out of the sheath when inserting the surgical accessory. Otherwise, it may damage the product and/or its surgical accessory.
- During the laser lithotripsy, laser fiber must stretch out of the channel outlet by 8-10 mm before the surgery. Otherwise, it may hit the front lens accidentally, damaging the product.
- The heat generated by the laser beam due to high temperature will weaken the intensity of components. Please do not point the laser beam directly at components, especially plastic components.

Surgical Accessories:
- Please check that the surgical accessories are labeled to be intended for the endoscope with ID of 2.0 mm/6.0 Fr. or with smaller channel in terms of the minimum size.
- When the surgical accessories are inserted, please check that the moving part of the forceps keeps closed state. Otherwise, it may damage the working channel of the endoscope.
- When operating the surgical accessories, please ensure the moving part of the forceps extends out of the channel outlet by 8-10mm. Otherwise, it may hit the camera module accidentally, damaging the product.
- When taking the surgical accessories out, please ensure the moving part of the surgical accessories keep closed, and then pull it out slowly.
1. Please keep the operating lever in "0" position before inserting the accessory.
2. Check that the tip of the surgical accessory has been closed or retracted into the sheath (if any).
3. Insert the accessory tip into the channel inlet. Operating slowly to bring it into the channel until the tip is displayed in the image. During this operation, please do not shake the handle to ensure stable image and avoid any damage to the patient or the product.

WARNING
- Before using the surgical accessory, please ensure the tip of the endoscope does not contact the inner wall of the patient's body. If no gap is left between the tip of the endoscope and the inner wall, perforation may be caused when the device stretches its tip.
- When laser fiber is used, mucosa burn or perforation may be caused due to heat caused by laser beam. Hence, it is required to keep proper distance between the laser fiber outlet and the mucosa.
- When the tip of the surgical accessory stretches out of the distal end of the endoscope by about 2.5 mm, the accessory will be displayed in the image.
- Please do not insert the surgical accessory by force or suddenly as the accessory may stretch out of the distal end of the endoscope unexpectedly, which may result in injury, bleeding and/or perforation of the patient.
- In case of excessive resistance during insertion, please stop insertion as excessive force of insertion may injure the patient, or damage the sheath, the endoscope and/or the accessory.
- In case of resistance when the surgical accessory is pushed into or pulled out of the endoscope, please check image first to ensure the distal end of the endoscope does not contact any tissue, and then ensure the operating lever is in the neutral position, freeing the bending portion of the endoscope from bending. Besides, please ensure the surgical accessory is inserted into the endoscope under proper state. That is, the stone retrieval basket of the accessory should keep closed and the insertion tube is not knotted.
4. Please move the surgical accessory slowly and pay close attention to the video image in real time when the accessory is inserted into the endoscope to some extent as it is just displayed in the image.
5. Once the surgical accessory is displayed in the image, please operate the operating lever to bend the tip and the accessory for surgery.

Endoscope insertion
1. Move the bending portion or the insertion tube to approach the patient and operate slowly to insert the product into the patient's body properly.

WARNING
- If the sheath is used, please prevent bending in the sheath.
- Please do not apply excessive force to the operating lever.
- Please move the insertion tube of the endoscope to approach the urethral orifice and push it slowly to prevent tube bending.
- The distal end of the electronic endoscope has strong illumination capacity, which may rise temperature. If the temperature of the distal end exceeds 41°C, and the distal end keeps quite close to the mucosa, intense light will be centralized in a small area, and the tissue in the area involved will be heated due to long illumination on the surface or even be burned.

Under the following conditions, the probability of burn hazard will rise:
(1) Approach the mucosa normally or at a fixed point and observe it for a longer time;
(2) Push the electronic endoscope in a narrow lumen.
To mitigate burn hazard, please take the following measures:
(1) Adjust light intensity manually to the minimum as required to make observation clearly.
(2) Avoid long observation at a fixed point as far as possible.
2. Identify the position of the endoscope and the bending angle of the distal end in the image.

WARNING
- When the endoscope is inserted, please push it following the principles of anatomy. Please ensure the image processor displays the video image of the endoscope in real time while the distal end of the endoscope is pushed. Otherwise, it may injure the patient.
- When the image is frozen, please neither push nor bend the endoscope.

Image observation
For instruction of adjusting the endoscope image, please refer to the Instructions for Use of the Video Image Processor.
Pump out and inject liquid
During the diagnosis liquid may be injected or pumped out
1. Please inject liquid through the corresponding port of the Irrigation and locking valve, as shown in Figure 3.
2. Please connect the Lure taper of the suction tube to the pump, and keep the liquid stop clamp in the release position when pumping liquid out.
3. Please ensure the liquid stop clamp remains in the stop position when the suction tube is not working.

▶ 4.4 Take it out
Take the surgical accessory out
Take out the surgical accessory slowly when the tip of the accessory is switched off and/or retracted into the sheath.

WARNING
- If the surgical accessory cannot be taken out of the endoscope, please switch off the accessory or retract it into the sheath. Then take the surgical accessory and the endoscope out simultaneously while observing the endoscope image. Please prevent any damage to the tissue.

Take out the endoscope
1. Move the operating lever to the neutral position, leaving the distal end of the endoscope to restore to the straight state.

WARNING
- Please ensure the operating lever keeps in the neutral position when the endoscope is taken out of the patient's body.
2. Take the endoscope out of the patient's body slowly while paying close to the image. In case of any resistance, please identify the resistance source with another imaging means before the endoscope is taken out.

▶ 4.5 Actions after surgery
Power the video image processor off, and remove the connector plug of the endoscope from the image processor. Dispose of the used endoscope.

WARNING
- Please do not pull the connector plug with power. Otherwise, it may damage the device.

▶ 4.6 Disposal
Please dispose of the product, its accessory and packaging material according to the regulations of the hospital, the administration and/or the local government.

WARNING
- The shelf life of the product is 3 years. Please do not use the product if it is expired.
- Please do not litter the abandoned endoscope and its accessory as they will pollute the environment. Instead, please hand over the medical waste to the agency designated by the local environmental protection administration for proper disposal.

Chapter 5 Troubleshooting

▶ 5.1 Image distortion or no image

WARNING
- In case of image distortion or no image during surgery, please stop pushing the endoscope and stop inserting, pushing or operating the device in the channel. Otherwise, misoperation may injure the patient or damage the endoscope. Carry out troubleshooting following the steps below:

(1) Disconnect the endoscope and the video image processor.
(2) Ensure the data cable and the connectors of both the endoscope and the video image processor are in good condition.
(3) Ensure the signal cable and the connector of the endoscope, and the data cable and the connector of the video image processor are clean and dry.
(4) Re-connect the product to the video image processor securely.
(5) Check real-time image. If no image is displayed, please implement Step (6).
(6) Power the video image processor off.
(7) Then power the video image processor on, and check real-time image again. If no image is displayed still, please implement Step (8).
(8) Please stop using the endoscope and pull it out following the steps below:
1) Move the operating lever back to the neutral position, leaving the distal end to restore straight state. Check the bending status of the endoscope in the image.
2) Take the endoscope out of the patient's body slowly. In case of any resistance, please identify the resistance source in the image before continuing to take out the endoscope.
3) Abandon the endoscope and use a new one to complete the surgery.
- If LED lamps on the distal end are damaged, please abandon the endoscope and use a new one to complete the surgery.

▶ 5.2 Bending control failure

WARNING
- In case of control failure, please stop pushing the endoscope, and stop inserting, pushing or operating the accessory in the working channel. If direction control fails, please stop using the endoscope following the steps below:

(1) Move the operating lever back to the neutral position.
(2) Check that the insertion tube is in straight state through the image.
(3) If the insertion tube is still bent, please straighten the tube tip with the operating lever while paying close attention to the image.
(4) Check that the insertion tube is straightened with the fluoroscope or other imaging means.
(5) Pull the endoscope out of the patient's body slowly. Monitor the pulling process in the dot fluorescent image or with other imaging means. In case of resistance, please identify the resistance source before continuing to pull the endoscope, and take remedial measures.

▶ 5.3 Working channel/suction channel blockage

WARNING
- When the device is inserted with blockage or suction fails, please do not push the device or pump out liquid for force. Instead, please stop working immediately, and take the following measures.

(1) Clean the working channel/suction channel with a brush, or rinse the channel with an injector filled with sterile water or saline.

Chapter 6 Essential Performance

The essential performance of the endoscope is as follows:
(1) Be able to display real-time images.
(2) Be able to display image with the correct orientation.
(3) There is no noise in image which can affect doctor's diagnosis, noise may manifest as grains or specks, horizontal or vertical stripes, flickering, and snowy screen.

Chapter7 Electromagnetic compatibility

CAUTION
- For this equipment, special precautions regarding electromagnetic compatibility (EMC) must be taken, and it must be installed and used in accordance with the electromagnetic compatibility information specified in this manual.
- This product conforms to the relevant requirements of the IEC 60601-1-2 standard electromagnetic compatibility.
- Portable and mobile radio frequency communication devices may hinder the normal operation of the medical endoscope image processor or the electronic endoscope. Please use the processor and the endoscope under the recommended electromagnetic environment.
- The use of accessories and cables (energy converters) other than those sold as spare parts for the product may increase electromagnetic emission or lower electromagnetic immunity. The product contains the cable below:

Table 5. Cable Information

Cable name	Length
Signal cable (a part of the endoscope catheter)	2.5 m

- The product should not be used when it is placed close to, or stacked with, another device. If the product has to be used, observe it to check that it works normally in the configuration.

Table 6. Declaration of Compliance (Electromagnetic Emission)

Manufacturer's Declaration – Electromagnetic Emissions		
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions (CISPR 11)	Group 1	The equipment 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 environment.
RF emissions (IEC/CISPR 11)	Class A	The equipment is suitable for use in all establishments, other than non-domestic or domestic establishments directly connected to the public low-voltage power supply network that supplies buildings used.
Harmonic emissions (IEC 61000-3-2)	Not Applicable	
Voltage fluctuations flicker emissions (IEC 61000-3-3)	Not Applicable	

Table 7. Declaration of Compliance (Electromagnetic Immunity)

Manufacturer's Declaration – Electromagnetic Immunity		
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Immunity test	Compliance Level	Electromagnetic environment-Guidance
Electromagnetic discharge(ESD) (IEC61000-4-2)	± 8 kV Contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air	Floors should be made of wood, concrete or ceramic tile that hardly produces static. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electromagnetic fast transient/ burst (IEC61000-4-4)	± 2 kV for power supply lines ± 1 kV for signal lines	Mains power quality should be that of a typical commercial (original condition feeding the facilities) or hospital environment.
Surge (IEC61000-4-5)	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines (IEC61000-4-11)	0% U_T, 0.5 Cycle (At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% U_T, 1 cycle 70% U_T, 25/30 cycles Single phase: at 0° 0% U_T, 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment with highly reliable service. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field (IEC 61000-4-8)	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity fields from RF wireless communications equipment (IEC 61000-4-3)	Refer to next table	Portable and mobile RF communications equipment should be used no closer to any part of the product
Proximity magnetic fields (IEC 61000-4-39)	134.2 kHz, PM, 2.1 kHz, 65 A/m 13.56 MHz, PM, 50 kHz, 7.5 A/m	The sources of proximity magnetic fields should be used no closer than 0.15 m to any part of the product
Conducted RF (IEC 61000-4-6)	3 Vrms, 150 kHz~80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2√P d=1.2√P 80 MHz to 800 MHz d=2.3√P 800 MHz to 2.7 GHz 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey(a), should be less than the compliance level in each frequency range(b). Interference may occur in the vicinity of equipment marked with the following symbol.
Radiated RF (IEC 61000-4-3)	3 V/m 80 MHz ~2.7 GHz	

NOTE
1: U_T is the AC mains voltage before application of the test level.
2: At 80 MHz and 800 MHz, the higher frequency range applies.
3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
4: To established the proximity threshold 0.15 m for Proximity magnetic fields, the IEC Subcommittee (SC) 62A considered the types of proximity magnetic field disturbance sources expected:
– induction cooking appliances and ovens operating at frequencies up to 30 kHz;
– RFID readers operating at both 134.2 kHz and 13.56 MHz;
– electronic article surveillance (EAS) systems;
– security systems;
– equipment used for position detection (e.g. in catheter labs);
– wireless power transfer charging systems for electrical vehicles that operate in the frequency range of 80 kHz to 90 kHz.
These frequencies and applications are representative examples based on sources of magnetic field disturbances in use at the time of publication of the collateral standard IEC 60601-1-2:2014+A1:2020.

a. 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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the equipment.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended minimum separation distances:
Nowadays, many RF wireless equipment have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. This Systems has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014+A1:2020. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and this Systems as recommended below.

Table 8. Recommended minimum separation distances

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Manufacturer Information

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