

Instructions for Use

Single-use Biliary Pancreaticobiliary Scope

CL-A, CL-B

Shenzhen HugeMed Medical Technical Development Co., Ltd.

401, 501, Building 4, Haizhi Technology Park, Fortis, No. 17, Bulan Road, Xialilang Community,
Nanwan Street, Longgang District, Shenzhen, Guangdong , 518112, China

Description

Thanks for buying the Single-use Biliary Pancreaticobiliary Scope.

Before using this product, please read this Instructions for use carefully to ensure correct use.

Please keep this Instructions for use properly for consultation.

Product name:	Single-use Biliary Pancreaticobiliary Scope
Date of production:	See the label
Service life:	2 years
Compilation/revision date:	2025-03-05
Version of Instructions for use:	1.0
Contact information:	Shenzhen HugeMed Medical Technical Development Co., Ltd. Tel.: +86-755-22275866 E-mail: Info@hugemed.net
Website:	http://www.hugemed.net
	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany



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HugeMed will bear responsibilities for the safety, reliability and performance of products only when the following requirements are met at the same time:

- Assembly, extension, readjustment, improvement and maintenance must be carried out by the professionals approved by HugeMed;
- All replaced components, supporting accessories and consumables during maintenance are original or are approved by HugeMed;
- Relevant electrical equipment conforms to the requirements of MDR, FDA standards and this Instructions for use.
- Product operation is carried out in accordance with this Instructions for use.

Warranty and maintenance service

The Single-use Biliary Pancreaticobiliary Scope will be sterilized by ethylene oxide (EO) before leaving the factory, and provided in sterile packaging with a sterilization period of validity of 2 years. The Single-use Biliary Pancreaticobiliary Scope is a disposable product, so maintenance services will not be provided.

Consumables refer to disposable consumable materials that need to be replaced after each use, with no warranty period.

In case of disagreement or separate agreement on the warranty period and the above-mentioned standard warranty period between the retailer and your sales contact, please call at the HugeMed's free service hotline +86-4006901290 for consultation and confirmation. For those not confirmed by HugeMed, please contact the retailer for confirmation in time.

After-sales service company

Customer Service Department of Shenzhen HugeMed Medical Technical Development Co., Ltd.

After-sales hotline: +86-4006901290

Sales hotline: +86-755-22275866

Official website: www.hugemed.net



Warning

- This product shall be operated by professional clinicians, experts of medical electrical equipment or trained clinical medical staff in specified occasions. Personnel who operate this product shall be trained completely. Any personnel who are not authorized or not trained shall not carry out any operation.
 - Careful operation can avoid accidents!
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Foreword

1. Description

This Instructions for use (hereinafter referred to as “IFU”) describes the purpose, functions and operations of the product in detail. Before use, please carefully read and understand the IFU to ensure correct use of this product, and the safety of both patients and operators.

The IFU introduces the product with the most complete configuration, and parts of the contents may not be applicable to the product you purchased. In case of any doubt, please feel free to contact our company.

These descriptions include the precautions of how to operate the Single-use Biliary Pancreaticobiliary Scope safely, correctly, and effectively, which is conducive to reduce faults and maintenance cost, shorten the shutdown time, and improve the reliability and lengthen the service life of the instrument. It can be used not only as Instructions for use, but also as a reference manual. Therefore, this IFU must be kept beside the equipment for use at any time.

Prior to the first use, please carefully read the chapter I Safety.

2. Applicable objects

The IFU is only applicable for use by the trained clinical medical staff.

3. Figures

All figures in this IFU are only for reference, and the settings or data in figures may not be consistent with those actually displayed on the product.

4. Conventions

- ***Italic*** Bold Italic words are used in this IFU to show the sections that are quoted.
- “Dangerous”, “warning” and “be careful” and other terms are used in this IFU to prompt the dangerous information and its severity degree.

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1. Important Information – Please Read Before Use

1.1 Intended use

The Single-use Biliary Pancreaticobiliary Scope which used in conjunction with the Medical Image Processor is intended to provide direct visualization, illumination and to guide accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatobiliary system including the hepatic ducts.

Indications: Biliary strictures; Biliary stone.

1.2 Description of intended use

This product is suitable for use in hospitals or qualified medical institutions. It is only intended for use by qualified doctors who have received training in endoscopic pancreaticobiliary surgery (including ERCP) and are proficient in operating endoscopes according to the instructions for use. The intended use environments for use is the operating room and endoscope room of the hospital. The intended patients are individuals other than newborns, infants, children, pregnant women, and lactating women.

The procedures, techniques, principles, clinical applications, and risks associated with ERCP and pancreaticobiliary surgery should be thoroughly understood before using this product.

1.2.1 Absolute contraindications

1)Contraindications to ERCP (Endoscopic Retrograde Cholangio-Pancreatography);
2)Contraindications to endoscopic exploration and cannulation of pancreaticobiliary ducts (including the hepatic ducts);
3)or cases that do not fall within the scope of application. Including but not limited to: patients' inability to tolerate endoscopic examination and treatment due to poor physical conditions; failure of the duodenoscope to reach the duodenal papilla due to upper gastrointestinal obstruction; acute heart and lung diseases with unstable vital signs, and severe liver and kidney failure; coagulation disorders and hemorrhagic diseases.

1.2.2 Relative contraindications

Patients with diabetes, whether their blood sugar is normal or not, should be classified as relatively contraindicated (with poor healing ability).

1.3 The residual risks and side-effect and adverse event

Potential residual risks and side-effect and adverse event in relation to the Single-use Biliary Pancreaticobiliary Scope (not exhaustive):

Pancreatitis; Bleeding; Cholangitis; Perforation.

1.4 Device compatibility

The Single-use Biliary Pancreaticobiliary Scope is compatible with the following ancillary devices and accessories.

The Medical Image Processor HUV-02 and MS-8.

Duodenoscopes with a minimum working channel diameter of 4.2mm.

Accessory devices with a minimum working length of 2300 mm and compatible with a 1.0 mm working channel diameter.

Irrigation pumps with a maximum head pressure of 400 kPa, and a single-use check valve needs to exist in the pump tubing. Review the pump directions for use to ensure the above process limits are not exceeded and that you operate the pump properly.

Guidewires with a maximum OD of 0.89mm (0.035 in).

HugeMed recommends using a stone extractor (with an outer diameter of 2.2 Fr or 1.9 Fr).

HugeMed recommends a 200 micron laser fiber for maximum deflection and access to the pancreatico-biliary system including the hepatic ducts. A larger fiber may break and be accidentally fired inside the working channel, damaging the endoscope.

Caution

- That before each use, the compatibility of the endoscopic equipment with any accessories and/or energized endotherapy devices should be checked according to any criteria for safe use defined in the instructions for use.
 - It should be ensured that the connector can be reliably connected when endoscopic equipment is used with accessories, other me equipment and/or non-me equipment.
 - When endoscopic equipment is used with accessories, other me equipment and/or non-me equipment within a configuration for endoscopic application, the instructions of accessories, other me equipment and/or non-me equipment should be strictly followed to avoid the risks caused by their use together.
 - The applied parts of other ME equipment used within the configuration for endoscopic application to be type bf applied parts.
-

1.5 Warnings, Cautions, Notes

This chapter makes a list of basic safety information that must be paid attention to and obeyed by the users when they use the Single-use Biliary Pancreaticobiliary Scope. Other safety information that are same, similar or related to the specific operations will be showed in each chapter.

The following signal words are used throughout this IFU:



Warning

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

- Indicates special information about operating the product, or clarifies important information.
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1.6 Warning



Warning

- This product is sterilized by ethylene oxide (EO) and supplied in sterile packaging. Do not use this product if the sterile package is damaged or has been opened. Do not use this product if its label is incomplete or illegible. If it is found that the sterile package is damaged, please contact Shenzhen HugeMed.
 - Since this product is for single use only, please do not re-use, repeatedly disinfect or re-process it. Repeated use, disinfection, or processing of this product may result in product or device failure, which may lead to patient injury, illness, or death. Repeated use, disinfection, or processing of this product may pose a risk of device contamination, patient infection, or cross infection, including but not limited to the transmission of infectious diseases from one patient to another. Device contamination may lead to patient injury, illness, or death. The Company does not assume any responsibility for the consequences of repeated use, disinfection, or processing of this product.
 - Please dispose of the endoscope and its packaging in accordance with the biohazard standards or policies established by hospitals, administration departments, or the local government.
 - The conscientious doctor must be responsible for the equipment operation procedures and technology application! The trained doctors (conscientious doctors) have the rights to decide how to fully use the equipment according to the actual application conditions.
 - Before the first use, please read the IFU carefully.
 - Before using the Single-use Biliary Pancreaticobiliary Scope, the user must check it and its accessories to ensure normal and safe operation.
 - Properly install or carry the Single-use Biliary Pancreaticobiliary Scope and its supporting equipment to prevent falling, collision, strong vibration or mechanical damage caused by external force.
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Warning

- Electromagnetic field will affect the performance of the Single-use Biliary Pancreaticobiliary Scope and its supporting equipment. Therefore, equipment used near the Single-use Biliary Pancreaticobiliary Scope and Medical Image Processor and its supporting equipment must conform to the corresponding EMC requirements; otherwise faults or breakdown of the Single-use Biliary Pancreaticobiliary Scope may occur due to electromagnetic interference. Mobile phone, X ray or MRI(Magnetic Resonance Imaging) equipment are possible interference sources, and can produce high-intensity electromagnetic radiation.
 - All other equipment, for example, some similar digital interference equipment, must conform to relevant requirements in the detailed standards (such as the requirements of IEC 60950-1 on digital processing equipment and the requirements of IEC60601-1 on electrical equipment) when connecting to the Single-use Biliary Pancreaticobiliary Scope or Medical Image Processor. In addition, when additional equipment is connected to the Single-use Biliary Pancreaticobiliary Scope or Medical Image Processor, involving equipment signal input and output, its structure must conform to the system structure in accordance with IEC60601-1. The personnel responsible for connecting the equipment must ensure system operability and complete compliance with the system requirements. If there is any other problem, please consult the local equipment supplier or HugeMed's technical service center.
 - The image of the Single-use Biliary Pancreaticobiliary Scope must not be used as an independent diagnostic tool of any pathology. Physicians must interpret and substantiate any findings by other means and in light of the patient's clinical characteristics.
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1.7 Caution

Caution

- HugeMed will not bear responsibilities for any personnel injury and property loss due to the following reasons: Equipment parts are not original to HugeMed; Missing of Instructions for use; Installation, commissioning, modification, upgrade and maintenance are not carried out by the personnel authorized by HugeMed.
 - HugeMed will not bear responsibilities for those damages or events caused by use of consumables or accessories not provided by HugeMed.
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1.8 Note

Note

- Please keep this IFU beside the Single-use Biliary Pancreaticobiliary Scope for convenient
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and timely reference as needed.

- This IFU introduces the product with the most complete configuration and functions, and the product you purchased may have no certain configurations or functions.
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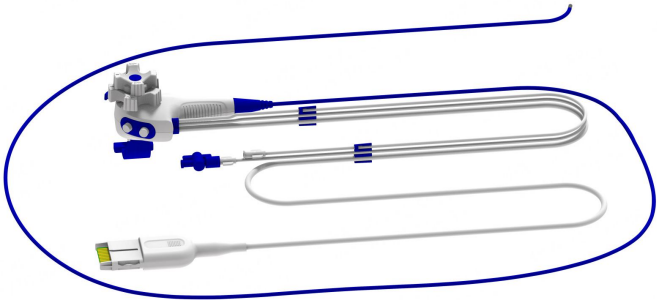


2. System Parts

Warning

- If combinations of equipment other than those shown below are used, the full responsibility is assumed by the medical treatment facility.

2.1 System chart

Table 2-1 System Chart

Diagram	Product
Single-use Biliary Pancreaticobiliary Scope	
	CL-A or CL-B
Medical Image Processor	
	HUV-02
	MS-8

Note

- The Medical Image Processor and the endoscope plug both have anti-mistake design. When inserting them, pay attention to the direction of the connector. Do not forcefully

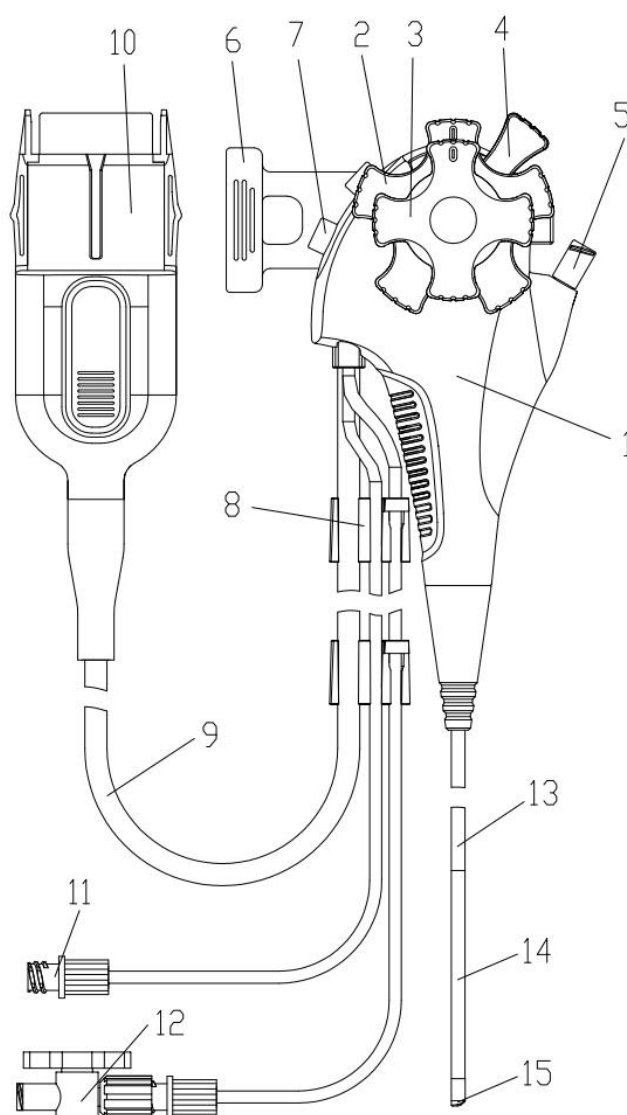
insert the connection. Forcing it when it is not in the correct position can damage the plug.

- When disconnecting the connection between the Medical Image Processor and the endoscope, pull the endoscope plug out in the opposite direction along which it was inserted.
 - To disconnect the signal cable, pull it out in the opposite direction of insertion.
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2.2 Description of the Single-use Biliary Pancreaticobiliary

Scope

The Single-use Biliary Pancreaticobiliary Scope is a single use endoscope, which is introduced within the pancreatico-biliary system including the hepatic ducts.



【Fig. 2-1】 Main features of endoscope

1) Control section: The control section contains a handle and other functional components.

2) Large-angle control knob: Turn the knob counterclockwise to bend the bending section in the upper left direction. Turn the knob clockwise to bend the bending section in the bottom right

direction.

3) Small-angle control knob: Turn the knob counterclockwise to bend the bending section in the lower left direction. Turn the knob clockwise to bend the bending section in the upper right direction.

4) Angle lock: Toggle the angle lock counterclockwise to lock the two knobs and the bending section. Partially toggle the angle lock to increase the resistance of the knob for more precise control.

5) Working channel entrance: The working channel entrance is the insertion port for accessories.

6) Connecting band: The connecting band is used to fix the endoscope.

7) Buttons: The upper one is a "Freeze/Photograph" button, and the lower one is a "White Balance" button.

8) Tube clamps: These two tube clamps facilitate the connection of the flushing tube, suction tube, and cable, and can also remove or reposition the tubes or cables.

9) Cable: The cable transmits the videos collected by the endoscope to the Medical Image Processor for processing and display.

10) Cable connector: The cable connector is used to connect the cable to the Medical Image Processor.

11) Flushing connector: The flushing connector is the connection port of the flushing tube. It clears the field of view and dilates the pancreaticobiliary duct through two dedicated flushing channels.

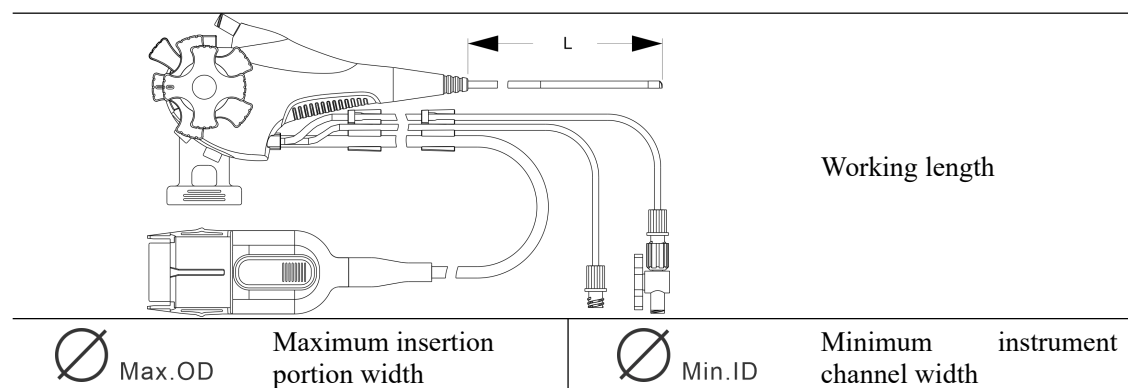
12) Suction connector (including a flow valve): The suction connector is the connection port of suction tubes and/or syringes, and contains a flow valve. Fluid can be removed through the working channel.

13) Insertion section: The insertion section includes an insertion tube, a bending section, and a distal end. The insertion tube contains a working channel (which also serves as a suction channel) and two flushing channels. The bending section can move with the movement of the knob.

14) Bending section: The bending section is a part of the insertion section that moves with the movement of the knob.

15) Distal end: The distal end is a part of the insertion section that contains a working channel outlet, two flushing channel outlets, and an imaging element.

2.3 Explanation of Symbols Used



	Field of view		Temperature limitation
	Humidity limitation		Atmospheric pressure limitation
	Fragile, handle with care		Keep dry
	This way up		Stacking limit by 5
	Manufacturer		Serial number
	Date of manufacture		Use-by date
	Refer to instructions		Warning
	Medical device		Type BF applied part
	Sterilized using ethylene oxide		Do not re-use
	Single sterile barrier system		Unique device identifier
	Do not use if package is damaged and consult instructions for use		WEEE marking
	Not containing natural rubber latex	IP	Ingress protection
	Authorized representative in the European Community/European Union		CE marking

3. Instructions On Use

3.1 Inspection

3.1.1 Unpacking inspection

Before unpacking, please check the packaging box carefully to determine whether the product is damaged during transportation. If any damage is found, please immediately contact the carrier or our company.

If the package is intact, please open the outer package properly. Carefully take out this product and check its accessories one by one according to the packing list. Check the product for any mechanical damage and the completeness of items. If you have any questions, please immediately contact our after-sales service department.

Open the transport packaging of the Single-use Biliary Pancreaticobiliary Scope, take out the endoscope (still in the sterile package at this point), and perform the following visual and functional inspections:

- 1) Check the expiry date on the package of the endoscope. Do not use the endoscope if this its expiry date is exceeded.
- 2) Make sure that the sterile package is intact and free from breakage, holes or tears, etc. Do not use this product if the package is damaged or has been opened. Do not use this product if its label is incomplete or illegible.
- 3) Take out the endoscope from the sterile package, and check whether it is damaged. Do not use this product if it is damaged.
- 4) Inspect the insertion section, control section, and each functional part through visual inspection and by touching with gloved finger to ensure that no components are loose, missing, or damaged.
- 5) Visually inspect whether the insertion section is flat, smooth and free from any dents, abnormal protrusions, scratches, burrs, cracks, holes, or other abnormalities.
- 6) Turn the knob on the control section and visually inspect the bending section at the same time to ensure that the bending function is normal. The handling should be smooth and precise. When operating the knob, do not forcibly bend or straighten the bending section with an external force, otherwise, the endoscope may be damaged.
- 7) Visually inspect the cable to see whether it is kinked or damaged, and check whether the cable connector is intact.
- 8) Y-port adapter (In consideration of the operating habits of different operators, this product is also equipped with a Y-type valve accessory in the endoscope's package. This accessory is not a necessity, and the users can decide whether to use this accessory or not as the case may be).

Caution

- If some accessories are missing when you open the package, please contact the dealer or manufacturer who sold this product to you as soon as possible.
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3.1.2 Environmental requirements

The use environment of the Single-use Biliary Pancreaticobiliary Scope should meet the

requirements of *Chapter 5 Technical Product Specification*.

The use environment of the Single-use Biliary Pancreaticobiliary Scope should also avoid the existence of noise, vibration, dust, corrosive, or flammable and explosive substances, etc.

When the Single-use Biliary Pancreaticobiliary Scope are transferred from one environment to another, there may be condensation on the Single-use Biliary Pancreaticobiliary Scope due to differences in temperature or humidity. At this time, it should not be started until the condensation disappears.



Warning

- Please ensure that the Single-use Biliary Pancreaticobiliary Scope work under the specified environmental requirements; otherwise, they will not meet the technical specifications claimed in *Chapter 5 Technical Product Specification*, and may cause unpredictable consequences such as invalidation of the Single-use Biliary Pancreaticobiliary Scope.
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3.2 Operation



Warning

- Do not install and operate the product in the following locations, otherwise, fire or burns to the operator and the patient may be resulted.
 - The oxygen concentration is very high.
 - There is oxidant (such as nitrous oxide (N₂O)) in the air.
 - Flammable detergent or anesthetic.
 - There is flammable liquid nearby.
 - Do not insert the insertion section of the endoscope into the duodenum by means of the duodenoscope in the absence of a clear endoscopic field of view. Failure to comply with this warning may result in patient injuries, such as perforation, bleeding, or mucosa damage.
 - Do not perform treatment without the accessory being in the endoscopic field of view or with the distal end of the endoscope pressed against the mucosa. Failure to comply with this warning may result in patient injuries, such as perforation, bleeding, or mucosa damage.
 - Do not use the flushing tube in case of no single-use check valve to prevent back-flow. Otherwise, equipment contamination and cross-infection of patients may be resulted.
 - Do not look directly into the light emitted from the endoscope. Failure to comply with this warning may cause injuries to the eye.
 - If a Y-type valve is used, please withdraw the guide wire first, and then open the Y-type valve to ensure that the guide wire will not be pushed further to cause perforation of the human body cavity.
 - This product should not be used together with radio-frequency cutting/coagulation equipment or high-frequency equipment, such as hot biopsy forceps.
 - No changes should be made to this product.
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- An image generated from the Single-use Biliary Pancreaticobiliary Scope must not be used as an independent diagnosis of any pathology. Physicians must make the diagnosis through other means and according to the clinical characteristics of the patient.
 - Do not inject gas into the human body through the endoscope.
 - An additional set of Single-use Biliary Pancreaticobiliary Scope and Medical Image Processor should be prepared for backup use before the surgery for prevention of unacceptable risks if endoscopic equipment loses functions.
 - When inserting or removing the product from the patient's body, the movement should be gentle and slow.
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Caution

- Under the action of the duodenoscope forceps lifter, the excessive bending of the insertion section may cause breakage or kinking. Do not excessively bend the insertion section of the Single-use Biliary Pancreaticobiliary Scope with the forceps lifter.
 - If it is confirmed by X-ray that the insertion section of the endoscope is broken or kinked, please stop using the endoscope immediately.
 - Activation of a laser lithotripter or electrohydraulic lithotripter near the distal end of the endoscope may damage the distal end of the endoscope. Please refer to the laser fiber or EHL probe manufacturer's operating instructions to maintain a proper distance between the laser fiber or EHL probe and the distal end of the endoscope. Make sure that the laser fiber or EHL probe extends beyond the distal end by at least 2 mm during use.
 - Disconnecting the cable connector from the Medical Image Processor before removing the insertion section of the endoscope from the duodenoscope may result in the failure to display images from the endoscope. Before disconnecting the cable connector, the insertion section of the endoscope should be first removed from the duodenoscope.
 - Any damage to the cable connector may cause no display or abnormal display of the images. The cable and cable connector should be inspected and handled carefully prior to use.
 - If a defibrillator is used at the same time as an endoscope, it may damage the Medical Image Processor or Single-use Biliary Pancreaticobiliary Scope. Please withdraw the endoscope from the human body prior to the use of a defibrillator.
 - Patients with previous histories of gastric or biliary surgeries or narrow ducts should use this product with caution. This conditions may hinder the passage of the endoscope insertion.
 - Do not connect a wet cable connector to the Medical Image Processor, otherwise it may result in video performance degradation or system damage.
 - When there is a problem with the endoscope, please follow standard operating procedures to remove the endoscope from the duodenoscope.
 - Prior to the use of the accessories each time, check their outer surfaces to confirm that there are no rough surfaces, sharp edges or protrusions that could cause injury.
 - The distal end of the endoscope may reach a temperature of above 41°C due to the endoscopic illumination. Since the surface temperature of above 41°C may cause an
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Caution

adverse impact on the human tissues, always keep an appropriate distance between the distal end of the endoscope and the mucosa of the pancreaticobiliary duct system. Do not use high brightness for long periods of time unless necessary. Do not leave the distal end in a stationary position for observation for long periods of time unless necessary.

- When the endoscope is used with a charged endoscopic attachment, it may increase the leakage current on the patient.
 - Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should be kept at least 30 cm away from the Single-use Biliary Pancreaticobiliary Scope and Medical Image Processor, otherwise, it may cause the performance degradation of this product.
 - When using this product together with the laser lithotripsy, please wear goggles to avoid eye discomfort.
 - If any malfunction occurs during the endoscopic procedure, please stop the procedure immediately. Make sure that the angle lock is unlocked and the angle control knob is returned to its original position. Also, slowly remove the insertion section of the endoscope without touching the knob and angle lock.
 - Always watch the live endoscopic image on the screen when advancing or withdrawing the insertion cord, or when operating the controllable portion.
 - The Single-use Biliary Pancreaticobiliary Scope and Medical Image Processor should be avoided from being adjacent to or stacked with other equipment during use as such improper arrangement may lead to failure. If this is necessary, the Single-use Biliary Pancreaticobiliary Scope and Medical Image Processor and other equipment should be observed to verify that they function normally.
 - Handle the tip of the insertion part with care, and avoid contact with other objects; otherwise it may damage the device, the fragile lens surface of the tip and cause image distortion.
 - Do not apply excessive force to the controllable bending section; otherwise, the device may be damaged. Examples of improper handling of controllable bending section include: Bend the bending section directly instead of operating by the knob; operating the knob in any situation where a resistance is felt.
 - If sharp endoscope accessories such as laser fiber optics pass through when the bending section is in a bent state, it may cause damage to the instrument channel. Only when the insertion section and the controllable bending section of the Single-use Biliary Pancreaticobiliary Scope are in a straight state can the instrument channel pass through these sharp endoscope accessories.
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3.2.1 Connect the endoscope and perform the white balance

- 1) Connect the cable connector of the endoscope to the Medical Image Processor.
- 2) Connect, turn on, and use the Medical Image Processor according to the Instructions for Use.
- 3) Check whether there is an image on the monitor.
- 4) Align the distal end of the endoscope to a white object with a spacing distance of about 3-5 mm, and lightly press the "White Balance" button on the Medical Image Processor to calibrate the white balance.

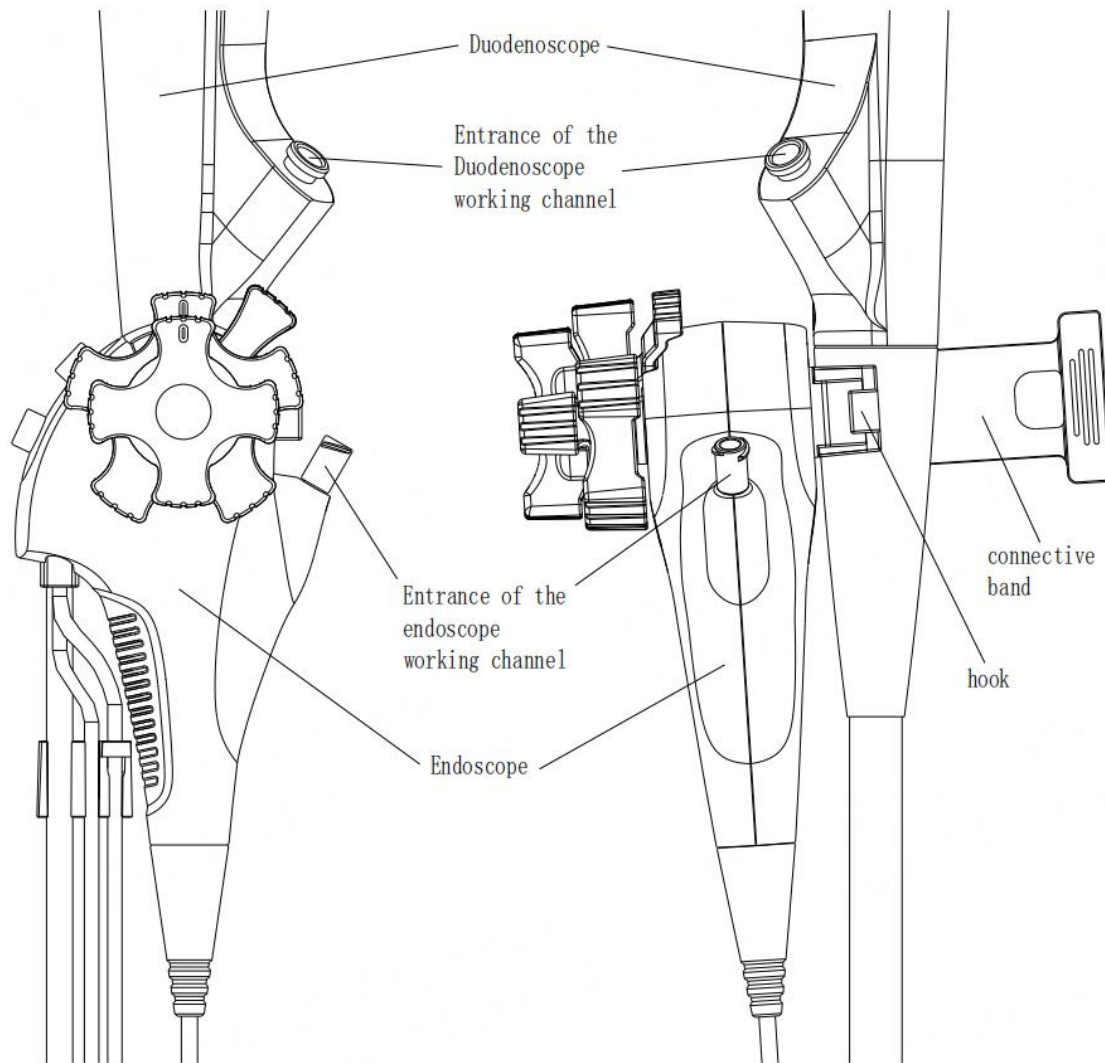
5) If the calibration fails (there is a significant obvious color difference between the object image on the monitor and the real object), perform the previous step again.

Caution

- During the calibration of white balance, a pure white object should be used in the case of no contact between the endoscope and the object.
 - During the calibration of white balance, the distal end of the endoscope should not be exposed at a bright place. Otherwise, the white balance calibration cannot achieve the desired effect.
 - Before each use or after a change of viewing modes / settings, the operator should check to ensure the view observed through the endoscope provides a live image (rather than a stored one) and has the correct image orientation.
-

3.2.2 Fix the endoscope and connect to the equipment

- 1) Fix the endoscope to the duodenoscope in the following manner. Adjust the orientation of the endoscope so that the direction of its knob is consistent with that of the duodenoscope, and the handle is located below the entrance of its working channel.
- 2) Fix the endoscope to the duodenoscope by the connecting band. The connecting band can be pulled outward before winding to facilitate operation.



【Fig. 3-1】 The endoscope is fixed to the duodenoscope

3) Configure the flushing pump, and then connect the flushing tube of the flushing pump to the flushing connector of the endoscope according to the Instructions for Use of the flushing pump. The pump should be come with a male connector, with an outer diameter of 3.97-4.07mm at the open end and an inner diameter is $\leq 2.90\text{mm}$.

4) Connect the suction pump can to the suction connector of the endoscope as needed according to the Instructions for Use of the suction pump, and the suction flow can be controlled by the flow valve. The pump should be come with a male connector, with an outer diameter of 3.97-4.07mm at the open end and an inner diameter is $\leq 2.90\text{mm}$.

Caution

- During the flushing operation, avoid using an excessive water pressure or water flow rate to avoid any injury to the patient.
 - If the endoscope accessory is placed in the instrument channel, the flow rate of the lavage fluid will be reduced.
 - During the suction operation, the suction volume should be reasonably controlled to avoid any injury to the patient due to excessive suction.
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3.2.3 Insertion and positioning of the endoscope

The endoscope will be inserted into the working channel of the duodenoscope which may or may not have a biopsy valve, or a guide wire used to guide through the working channel of the duodenoscope or the endoscope.

Note

- If the endoscope is inserted through the biopsy valve of the duodenoscope, it should be made sure that the biopsy valve has an opening large enough to receive the insertion section of the endoscope. Otherwise, the biopsy valve should be replaced or removed as needed, or the biopsy valve should be punctured to form such an opening.
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1) The insertion section of the endoscope is inserted into the duodenoscope after an appropriate amount of medical lubricant is applied to its insertion section.

- a. If no guide wire is used: Insert the distal end of the endoscope into the working channel of the duodenoscope by a short stroke of 2–3 cm each time to prevent the insertion section from being kinked or damaged.
 - b. If a guide wire is used: Reserve a guide wire if used in the working channel of the duodenoscope and remove other accessories (incisor, catheter, etc.). The guide wire will be threaded from the distal end of the endoscope into the working channel. The light source can be turned off as needed to better view the working channel at the distal end of the endoscope.
-

Note

- If no guide wire is used, preloaded accessories (such as biopsy forceps) should be used before inserting the endoscope into the working channel of the duodenoscope.
-

2) Deliver the endoscope into the forceps lifter of the duodenoscope.

3) Flush the flushing channel of the endoscope with saline until continuous fluid output is achieved. It can reduce the generation of bubbles during the flushing at positions such as the pancreaticobiliary duct.

4) Push the endoscope to the forceps lifter through the duodenoscope after ensuring that the forceps lifter is in a descended state.

Note

- Do not use the forceps lifter of the duodenoscope when the distal end or bending section of the endoscope is located near the forceps lifter.
-

5) Insert the distal end of the endoscope into the duodenal papilla and enter the pancreaticobiliary ampulla. This process may be achieved by means of the angle control knob of the duodenoscope and the endoscope. The angle control knob of the endoscope may be partially locked as needed.

Note

- An sphincterotomy may be required first to make sure that the endoscope can be smoothly
-

inserted into the duodenal papilla.

6) The brightness of images can be adjusted to acquire better images. (More information on adjusting image brightness can be obtained by referring to the Instructions for Use of the Medical Image Processor)

7) During the whole process, the flushing operation can be employed to reduce the influence of body fluid on the field of view. In addition to the foregoing, the suction operation can also be employed as needed. Remove all accessories from the working channel when the suction function is employed. Connect the suction pump at the suction connector, open the flow valve at the suction connector, and cover the entrance of the working channel. The suction connector can be flushed after suction operation as needed.

8) Lift or lower the forceps lifter of the duodenoscope when inserting the endoscope and using the angle control knob, so that the endoscope can pass through the pancreaticobiliary duct system to reach the target position. The angle control knob can be partially locked as needed.



Warning

- Do not excessively rotate the angle control knob used under any circumstances. When a relatively large or abnormal resistance is encountered during rotation of the knob, stop the rotation operation, otherwise, the endoscope may be damaged or patient injuries may be caused.
-

9) When the endoscope reaches the target position, the bending section can be locked by the angle lock as needed. After the bending section is locked, the bending direction of the bending section can still be adjusted through the angle control knob.

10) If a guide wire is already used, it may be removed from the working channel of the endoscope as appropriate to enhance control of bending performance.

3.2.4 Remove the endoscope from the duodenoscope

1) Make sure that the angle lock is unlocked, and restore the angle control knob to the initial position to avoid any damage to the tissue and the working channel of the duodenoscope during endoscope withdrawal.

2) Remove the accessories (if any) from the endoscope.

3) Withdraw the endoscope back to the working channel of the duodenoscope.

4) Turn off the lighting source by the button on the front panel of the Medical Image Processor.

5) Withdraw the insertion section of the endoscope from the duodenoscope.

6) Loosen the connecting band and remove the endoscope from the duodenoscope.

7) Disconnect the flushing connector and suction connector from the endoscope as needed.

8) Disconnect the cable connector from the Medical Image Processor.

9) Dispose of the used product in accordance with relevant requirements.

3.2.5 Safely end the operation of this product

Please follow the steps below if you need to end the operation of this product during use:

1) Remove the accessories (if any) from the endoscope, and then remove the endoscope from the

duodenoscope.

- 2) Check the endoscope for any missing or abnormal components to ensure that no foreign object is left in the patient's body.
- 3) Turn off the Medical Image Processor by pressing the power button on the front panel of the Medical Image Processor. If the indicator light is off, it indicates the Medical Image Processor is turned off. Turn off the switch on the back of the Medical Image Processor. If the indicator light is off, it indicates that the Medical Image Processor is powered off.
- 4) Disconnect the cable connector from the Medical Image Processor.

4. Maintenance

The Single-use Biliary Pancreaticobiliary Scope is supplied in a sterile state, and disposable only.

4.1 Cleaning and Disinfection

The Single-use Biliary Pancreaticobiliary Scope is disposable, not used twice.

4.2 Environmental requirements

This product is transported and stored after packaging. This product should be stored in a clean, well-ventilated, cool, and dry environment that is free from any corrosive gas. Do not store this product in direct sunlight.

If this product is not packaged and transported as required, or the storage environment does not meet the requirements, or if drops, falls, collisions or any other abnormality occur during use, this product will be damaged, or become moldy and foggy, the tube body will be collapsed, and the sealing performance will deteriorate, etc. As a consequence, it will result in phenomena like abnormality of image performance, which will cause wrong diagnoses and other hazards to patients.

The specific environmental requirements are shown in Table below:

Table 4-1 Environmental requirements for storage, transportation and operating

		CL-A / CL-B
Operating	Temperature	5°C - 40°C
	Relative humidity	30% - 80% (non-condensing)
	Atmospheric pressure	70KPa - 106KPa
Storage	Temperature	-40°C - 55°C
	Relative humidity	30% - 93% (non-condensing)
	Atmospheric pressure	70KPa - 106KPa
Transportation	Temperature	-40°C - 55°C
	Relative humidity	30% - 93% (non-condensing)
	Atmospheric pressure	70KPa - 106KPa

4.3 Product disposal

To avoid possible infection or other microbial risks after the use of the Single-use Biliary Pancreaticobiliary Scope, please dispose of the endoscope and its package according to the relevant standards or policies of the hospital, administrative department, or local government.

Or you can contact the dealer or manufacturer who sold this product to you for more relevant information.

4.4 Available product information

The electronic IFU is available on the website:

<https://hugemed.net/Products/SingleUseEndoscope-Gastroenterology-SingleuseBiliaryPancreaticobiliaryScope.html>

Find the download center at the bottom of the page, where “Instructions for Use of Single-use Biliary Pancreaticobiliary Scope ” is shown. Click it to download IFU.

Other information about the product is available on the website:

<https://hugemed.net/Products/SingleUseEndoscope-Gastroenterology-SingleuseBiliaryPancreaticobiliaryScope.html>

5. Technical Product Specification

Table 5-1 Technical Parameters of Single-use Biliary Pancreaticobiliary Scope

Category	Items	Specification
Optical system	Field of view	in the air 120°±10%
	Viewing direction	0°± 3°
	CMOS pixel	400 * 400
	Depth of field	3-50 mm
Insertion part	Controllable bending part	90°, the lower deviation is -10%, unlimited upper deviation.
	Maximum width of the insertion portion	3.5 mm ± 10%
	Minimum width of the working channel	1.2 mm ± 10%
	Working length	2140 mm ± 3% (CL-A) 2000 mm ± 3% (CL-B)
Sterilization	Sterilization method	EO (Ethylene Oxide Sterilization)

Please note that if the insertion part is not kept straight, the bending angle of the controllable bending part will be affected.

6. Troubleshooting

If there any serious incidents occurred, contact with Hugemed, we will report to European Union as described in its own procedures which compliant with MDR. The hospital can report to the European Union followed its own procedures too.

When troubles or failures other than those listed in the following table are observed, turn off the Medical Image Processor and turn it on again. If the problem still cannot be resolved, please contact HugeMed for repairing.

Table 6-1 Troubles shooting

There is no live image on the left side of the screen but the user interface shows up on the display.	
Cause	Action
The endoscope is not or poorly connected with the Medical Image Processor.	Disconnect and then reconnect the Single-use Biliary Pancreaticobiliary Scope and the Medical Image Processor
There are communication problems between the Medical Image Processor and the Single-use Biliary Pancreaticobiliary Scope.	Turn off the processor by pressing and holding the ON/OFF button for at least 1 second. When the it is off, restart it by pressing and holding the ON/OFF button again.
The endoscope is damaged.	Replace the endoscope with a new one.
The image display is dark.	
Cause	Action
The optical path of the endoscope and the Medical Image Processor is not connected.	Disconnect and then reconnect the Single-use Biliary Pancreaticobiliary Scope and the Medical Image Processor
The light source of the Medical Image Processor is not turned on.	Turn on the light source of the Medical Image Processor .and adjust the brightness as appropriate
The brightness level of the light source is too low.	Adjust the brightness of the light source as appropriate
The light source is damaged.	Use a backup system and contact the manufacturer.
The endoscope is reused, which exceeds the limit of "single use"	Replace the endoscope with a new one.
The image shown on the left side is frozen.	
Cause	Action
A communication error has occurred in the system	Turn off the Medical Image Processor by pressing and holding the ON/OFF button for at least 1 second. When the it is off, restart it by pressing and holding the ON/OFF button again.
The current image has been frozen.	Unfreeze the image.
The endoscope is damaged.	Replace with a new one.

Low picture quality	
Cause	Action
Light is reflecting on the screen.	Move the monitor to a position where no direct light is shining on the screen.
Ambient light is too strong.	Decrease the brightness of the ambient light.
Dirty/damp screen.	Wipe the screen with a clean cloth.
The surface of the imaging element at the distal end is contaminated	Inject more lavage fluid. If the lens cannot be cleaned in this manner, withdraw the endoscope, and wipe the imaging element at the distal end by using a cotton swab dipped with 70% ethanol or isopropanol.
It is difficult to insert an endoscopic accessory through the channel.	
Cause	Action
Working channel is blocked.	Flush the working channel with sterile saline using a syringe. If it is impossible to clear the working channel, prepare a new endoscope.
Endoscopic accessory is too big.	Check that the accessory used is of the recommended size.

Appendix 1. Electromagnetic Compatibility

Caution:

The Single-use Biliary Pancreaticobiliary Scope meets the electromagnetic compatibility requirements of IEC 60601-1-2 standard and IEC 60601-2-18 standard.

The user should install and use the device as per the electromagnetic compatibility information provided in the accompanying documents.

Portable and mobile RF communication equipment may affect the performance of the Single-use Biliary Pancreaticobiliary Scope, so avoid strong electromagnetic interference when using it; therefore, please do not use it near mobile phones, microwave ovens, etc.

Guidance and manufacturer's declaration are detailed in the attachment.

Warning:

Use of the Single-use Biliary Pancreaticobiliary Scope adjacent to or stacked with other equipment should be avoided. If such use is unavoidable, it is necessary to monitor and verify that it can operate well under the configuration for its use.

Class A equipment is intended for use in an industrial environment or professional healthcare environment, and it may be potentially difficult to ensure electromagnetic compatibility in other environments including residential or home environments as a result of conducted disturbance and radiation disturbance of the Single-use Biliary Pancreaticobiliary Scope.

Except for cables sold by the manufacturer of the Single-use Biliary Pancreaticobiliary Scope as spare parts for internal components, the use of accessories and cables other than those specified may result in increased emissions or reduced immunity of the Single-use Biliary Pancreaticobiliary Scope.

No.	Name	Cable length (m)	Shielded or not
1	Handle cable	2.0	yes

The following RF emitters may be a source of electromagnetic disturbance: diathermy, electrocautery, WPT, 5G, EAS and RFID. Please avoid to be exposed to these potential electromagnetic disturbance sources.

RFID and EAS may be concealed in the environment, if electromagnetic disturbance appeared, please check the potentially sources in the surrounding one-meter area.

Do not use the device near active HF surgical equipment and the MRI room.


Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Single-use Biliary Pancreaticobiliary Scope, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and manufacturer's declaration - electromagnetic emissions		
The Single-use Biliary Pancreaticobiliary Scope is intended to be used in the following specified electromagnetic environment, and the purchaser or user thereof should ensure that it is used in such an electromagnetic environment.		
Emission Test	Compliance	Electromagnetic environment - guidance

RF emissions CISPR 11	Group 1	The Single-use Biliary Pancreaticobiliary Scope only uses radio frequency energy only for its internal functions. therefore, its RF emissions are low and there is little chance of interference with nearby electronic equipment.
RF emissions CISPR1	Class A	The Single-use Biliary Pancreaticobiliary Scope is suitable for use in non-domestic establishment and in establishment that is not directly connected to a low voltage power supply network which is for domestic power supply.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not Applicable	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Single-use Biliary Pancreaticobiliary Scope is intended to be used in the following specified electromagnetic environment, and the purchaser or user thereof should ensure that it is used in such an electromagnetic environment.			
Immunity test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 KV contact discharge ± 2 KV, ± 4 KV, ± 8 KV, ± 15 KV air discharge	± 8 KV contact discharge ± 2 KV, ± 4 KV, ± 8 KV, ± 15 KV air discharge	Floors should be made of wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should at least reach 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 KV For power supply lines ± 1 kV For Input/ Output lines	± 2 KV For power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode voltage ± 2 kV common mode voltage	± 0.5 kv, ± 1 kV differential mode voltage ± 0.5 kv, ± 1 kv, ± 2 kV common mode voltage	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 IEC 61000-4-11	0% of UN for 0,5 cycles and phase angles of 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315 0% of UN for 1 cycle and phase angles of 0° 70% of UN for 25 / 30 cycles and phase angles of 0° 0% of UN for 250 / 300 cycles	0% of UN for 0,5 cycles and phase angles of 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315 0% of UN for 1 cycle and phase angles of 0° 70% of UN for 25 / 30 cycles and phase angles of 0° 0% of UN for 250 / 300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the endoscopy image processor requires continued operation during power mains interruptions, it is recommended that the endoscopy image processor be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m (50/60 Hz)	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the alternative current mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Single-use Biliary Pancreaticobiliary Scope is intended for being used in the electromagnetic environment specified below. The customers or users of the Single-use Biliary Pancreaticobiliary Scope should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should not be used closer than the recommended separation distance to any part of the Single-use Biliary Pancreaticobiliary Scope, including the cable. The separation distance should be calculated from the corresponding formula of transmitter frequency. Interference may occur near the device marked by the following symbols. 
Note 1: At 80MHz and 800MHz frequency, adopt formula of higher frequency range			
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and human body.			
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 taken into consideration. If the measured field strength in the location where the Single-use Biliary Pancreaticobiliary Scope is used exceeds the applicable RF compliance level above, the Single-use Biliary Pancreaticobiliary Scope should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Single-use Biliary Pancreaticobiliary Scope.			
b The field strength should be lower than 3V/m within the entire frequency range of 150 KHz~80 MHz.			

Appendix 2. Packing list

If you find that the items are inconsistent with this information, please contact the manufacturer.

No.	Name of component	Quantity	Note
1	Single-use Biliary Pancreaticobiliary Scope	1	
2	Y-port adapter	1	
3	Instructions for Use Single-use Biliary Pancreaticobiliary Scope	1	