Single use electronic choledochoscope Operating manual

Shenzhen HugeMed Medical Technical Development Co.,Ltd

Please carefully read this operating manual in advance before use.

HugeMed reserves the right of final interpretation of this mannual.

HugeMed reserves the right of amending this mannual, and please understand the amendment will not be further noticed again.

Version no.:A/0

Issuing date:2021/04/XX

Product information

Product name: single use electronic choledochoscope

Specifications and models: CH-M52, CH-M50, CH-M40 and CH-M32

Manufacturing date and shelf life: see the label

Medical device certificate no.:

Product's technical requirement no.:

Production licence no.: Guangdong Food and Drug Administration's Medicla Device Production Licence No. 20172951

Registrant‘s name: Shenzhen HugeMed Medical Technical Development Co., Ltd

Registrant‘s residence address: 516-1, Building 2, No. 1, Mawu Road, Baoan Community, Yuanshan Street, Longgang District, Shenzhen

Registrant’s contact information:0755-22275866

Manufacturer: Shenzhen HugeMed Medical Technical Development Co., Ltd

Residence/production address: 416-1, 516-1, Building 2, No. 1, Mawu Road, Baoan Community, Yuanshan Street, Longgang District, Shenzhen

Contact information of manufacturer:0755-22275866

[Warning]

As per the federal law of the United States, this equipment can only be sold by a doctor or following a doctor's order.

The product is sterilized by ethylene oxide (EO). Please do not use if the sterile package is damaged. If the sterile package is damaged, please contact with HugeMed.

This product is only for single use, and please do not use, disinfect or handle again. Using, disinfecting or handling again may result in failure of product or equipment, so as to further result in injury, sickness or death of a patient. Using, disinfecting or handling again may pose a risk of contamination to equipment or patient or cross-infection, including but not limited to propagate infectious disease from one patient to another. Contamination of equipment may result in injury, illness or death of a patient.

Following use, the product and its package will be handled as per policies of hospital, administrative department or local government.

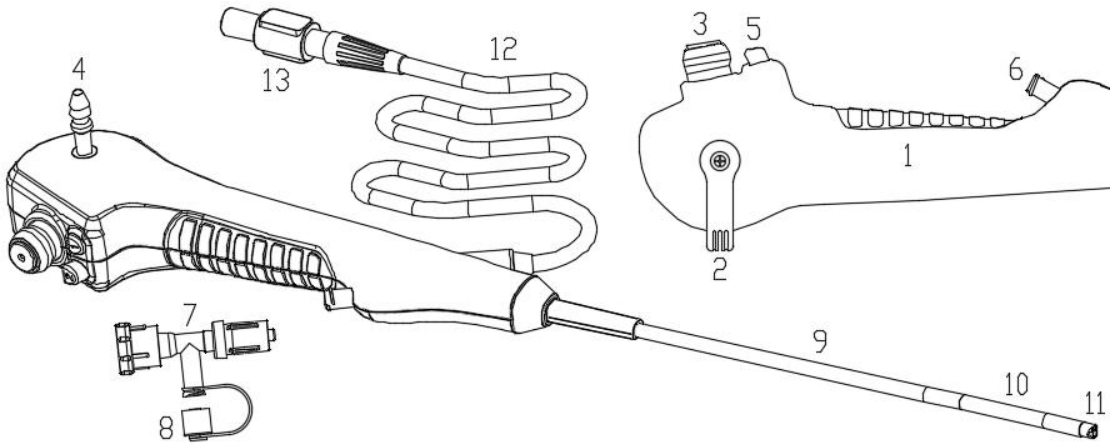
[Device description]

The single use choledochoscope (hereafter to be referred as choledochoscope or endoscope) is a sterile endoscope for single use which can convey accessories and display the video in a real-time manner when connected to the image processor.

Note

The single use choledochoscope is only compatible with the corresponding image processor of HugeMed.

Function



Coding	Part	Function
1	Handset [A]	For holding of the product.
2	Deflector rod	For controlling the bending direction and angle of bending part. (Detailed direction is indicated in the label on the handset)
3	Drawing button	For controlling the on and off of drawing function.
4	Drawing connector	Connecting the drawing source for drawing.
5	Key 1 Key 2	Key 1: white balance Key 2: freezing/ photographing Its function can be customized on the image processor.
6	Entrance of work pass	Inserting port of accessory or connector of equipment such as syringe and injection pump. It can be connected to the T-type valve.
7、8	T-type valve	It is installed at the entrance of work pass so as to have two connectores: entrance of work pass with sealing function and function as a water-vapor connector. The water-vapor connector can be

		connected to the syringe, injection pump or other equipment to supply water, vapor and drug, etc.
9	Inserting tube [B]	Flexible inserting part which can be passively bended.
10	Bending part	It can actively bend under control of deflector rod.
11	Head end	It is located at distal end of endoscope, consisting of camera, LED and entrance of work pass.
12	Connecting wire of handset	Transmit the video signal to the image processor.
13	Connector	Connect the cable to the image processor.

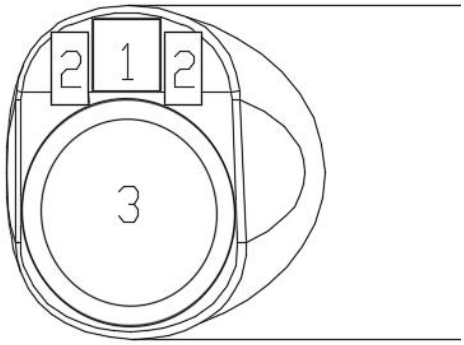
[A] The operating section of endoscope is consisted of handset and various function parts on the handset.

[B] The intubation section of endoscope is consisted of intubation tube, bending section and head end.

Operating principle

The single use electronic choledochoscope works with the image processor, and the image processor is responsible for handling its transmitted images.

This product is consisted of operation section and intubation section. The intubation section includes the work pass, which starts from the entrance of work pass of operation section and extends to the head end section for transmitting accessories, supplying water and vapor as well as for drawing. When the T type valve is not installed, the operation section contains two connectors: the entrance of work pass for transmitting accessories, and the drawing connector for connecting the drawing equipment. After installing T type valve on the entrance of work pass, one additional port is added to the operation section: a water-vapor connector for supplying water, vapor and drug.



Coding	Part	Function
1	Lens	Imaging
2	LED	Illumination
3	Work pass	Convey accessory, draw, supply water, vapor and drug

User information

This product and operation mannual are only for surgeons for pancreas and bile duct who are well-trained. Before using this product and image processor, the technology, principle, clinical application and risk related to surgeries on pancreas and bile duct structure should be fully understood.

Included items

Single use electronic choledochoscope, T type valve

[Specifications]

The specifications of single use electronic choledochoscopes of various models are listed in the following table.

Model	CY-M52	CY-M50	CY-M40	CY-M32
Field of view	120°±15%	120°±15%	120°±15%	120°±15%
Direction of view	0°±10°	0°±10°	0°±10°	0°±10°
Depth of field	3-50mm	3-50mm	3-50mm	3-50mm
Maximum size of intubation section	5.2mm±10%	5.0mm±10%mm	4.4mm±10%	3.2mm±10%
Length of intubation section	350mm±10%	350mm±10%	350mm±10%	350mm±10%
Minimum size of work pass	Φ≥2.1mm Irrespective of upper limit	2.8mm±10%	Φ≥1.2mm Irrespective of upper limit	1.2mm±10%
Bending section	210° (upwards) and 210° (downwards), with a deviation of -5% (excluding upper limit)	210° (upwards) and 210° (downwards), with a deviation of -5% (excluding upper limit)	210° (upwards) and 210° (downwards), with a deviation of -5% (excluding upper limit)	210° (upwards) and 210° (downwards), with a deviation of -5% (excluding upper limit)
Model and label	M52	M50	M40	M32
Overall length of product	610±10%mm	610±10%mm	610±10%mm	610±10%mm

[A] It cannot guarantee that the compatibility is only suitable for equipment or accessories with maximum outer diameter of intubation section.

[B] It cannot guarantee that the compatibility is only suitable for accessories with minumum inner diameter of work pass.

[Environment]

Operating environment Temperature	10-35℃（50-90℉）
Relative humidity	30-85%
Air pressure	700-1060hPa
Altitude	≤2000m
Storage and transportation Temperature	0-45℃（32-113℉）
Relative humidity	30-95%
Sterilization Sterilization method	EO (Sterilization with ethylene oxide)

[Intended use]

This product is suitable for diagnosis and treatment under endoscopic surgery for pancreas and bile duct system. The choledochoscope system is consisted of two parts: single use electronic choledochoscope and image processor.

During the endoscopic surgery of pancreas and bile duct system, the single use electronic choledochoscope can supply illumination and provide visualized images, and guide accessories for diagnosis and treatment.

The image processor is used in diagnosis and treatment of pancreas and bile duct system for receiving, handling and transmitting images from the single use electronic choledochoscope.

[Contraindications]

The contraindications for using this product include: detailed contraindications for searching and intubation in pancreas and bile duct (including hepatic duct) under endoscope.

[Warning]

·This product is not allowed to use in uncontrolled and flammable liquid or gas (e.g., detergent, anesthetic, nitric oxide and oxygen). Failing to follow this warning may result in a fire disaster or burn injury of operator and patient.

·Please do not treat if the accessory does not come into the field of view of endoscope or the distal end of endoscope is pressed on the mucosa. Failing to follow this warning may result in injury of patients, such as perforation, hemorrhage or mucosal injury.

·The function of supplying water, vapor and drug can be used only when a disposable one-way valve is installed in the external device to prevent reflux. Failing to follow this warning may result in equipment contamination or patient infection/cross infection.

·Do not look directly at the light emitted from the endoscope. Failing to follow this warning may result in an eye injury.

·After disconnecting the endoscope from the image processor, the temperature of main body of cable will be kept for a while. After pulling out the connector of cable, do not touch its end face immediately. Failing to follow this warning may result in skin burns.

·If a T type valve is used, the valve shall be opened before intalling the guide wire to avoid over-advancing the guide wire in the human body to result in perforation.

·This product is not suitable for radio-frequency cutting/freezing equipment.

·Warning: this product is not allowed to be modified.

·This endoscope system is avoided to be placed near other equipment or used in stack, or otherwise it may result in a failure. If necessary, this endoscope system and other equipment should be observed to validate that they can run normally.

·Due to illumination, the temperature of head end section of endoscope may exceed 41 ℃. Since the surface temperature exceeding 41℃ may impact the human tissue, please always ensure the distance between the end face of head end section of endoscope and mucosa of pancreas and bile duct system. Unless necessary, do not use high brightness for illumination for a long time. Unless necessary, do not observe with head end section in a fixed location for a long time.

·Before surgery, another single use electronic choledochoscope and image processor needs to be prepared for standby application.

[Precautions]

·This product can only be used with corresponding image processor, and connecting with other equipment may damage equipment or injure the operator.

·Using a laser lithotriptor or liquid-electric lithotriptor at short range may damage the distal end of endoscope. Please refer to instructions for use provided by manufaturer of laser fiber or EHL probe to understand the appropriate distance between laser fiber or EHL probe and head end section of endoscope. During use, it shall ensure that the laser fiber or EHL probe extends to at least 2mm over the head end section.

·Before removing out of intubation section of endoscope from human body, firstly pulling out cable connector will result in failure of seeing images via endoscope. Before pulling out cable connector, it shall take intubation section of endoscope out of the human body firstly.

·Any damage to cable connector may result in failure to or abnormal display of images. Before use, examine the cable and its connector and handle with care.

·Using cardiac defibrillator while using this product will damage the image processor. Please take the endoscope out of the human body before using cardiac defibrillator.

·This product shall be carefully used for patients with an operation history for stomach or bile duct or suffering from biliary stricture. These situations may impede the passing through of intubation section of endoscope.

·Please do not connect the cable connector with the image processor , or otherwise it may result in degradation of video performance or system damage.

·The portable radio-frequency communication device (including peripheral equipment such as antenna cable and external antenna) shall distance from the endoscope system (including endoscope, image processor and various connecting wire, etc.) of about 30 minutes, or otherwise, it may result in degradation of product performance.

·The emission performance of this product make it suitable for industrial field and hospital (CISPR11ClassA). If used in the dwelling environment (usually needs CISPR11ClassB), this product may not be able to provide adequate protection to radio-frequency communication services. The users may need to take actions, such as moving or re-positioning equipment.

[Adverse events]

Possible complications include but not limited to

·Pancreatitis

·Perforation

·Hemorrhage

·Hematoma

·Sepsis/infection

·Cholangitis

·Allergy to contrast agent

·Mucosal injury

[How to supply]

This product is sterilized by ethylene oxide and supplied as sterile. If the package is damaged or opened, please do not use the product inside. If the label is not intact or difficult to be identified, please do not use the product.

[Equipment compatibility]

The single use electronic choledochoscope is compatible with following auxiliary equipment or accessories:

·Image processor HUV-01.

·T type valve (provided for this product)

·Its maximum pressure is 276KPa, the piping is equiped with an injection pump with male Lure fitting, and check the manual of pump to ensure the parameter is not out of specification and you can correctly use the pump.

·Accessory with minimum working length of 780mm.

·The minimum inner diameters of guiding pipe or cannula compatible with various models refer to "outer diamater of maximum intubation section" in "specification".

·The maximum outer diameter of intubation section of accessories of endoscoped compatible with various models refer to "minimum inner diameter of work pass" in "specification".

[Instruction for use]

The intended operating environments are operating room, endoscopy room, interventional radiology department or medical room of hospital.

Additional equipment required

Corresponidng image processor shall be matched when using this product.

Preparation

Out of box audit of endoscope

Open the transportation package, take out the endoscope (at this moment, it is still stored in aseptic package), and then the following visual inspection and function tests are conducted:

1. Check the shelf life on the package of endoscope, and the endoscope out of shelf life cannot be used.

2. Ensure that the aseptic package is intact without damage, hole or tearing, etc. The endoscope cannot be used if its package has any damage.

3. Take the endoscope out of the aseptic package and check whether it is damaged. The endoscope with any damage cannot be used.

4. The intubation section, handset and various function parts are visually inspected and tested by touching with a finger wearing gloves to ensure no loosening or damage of part.

5. Detect by visual inspection whether intubation section has any dimple, any hump, fracture, hole or other abnormality.

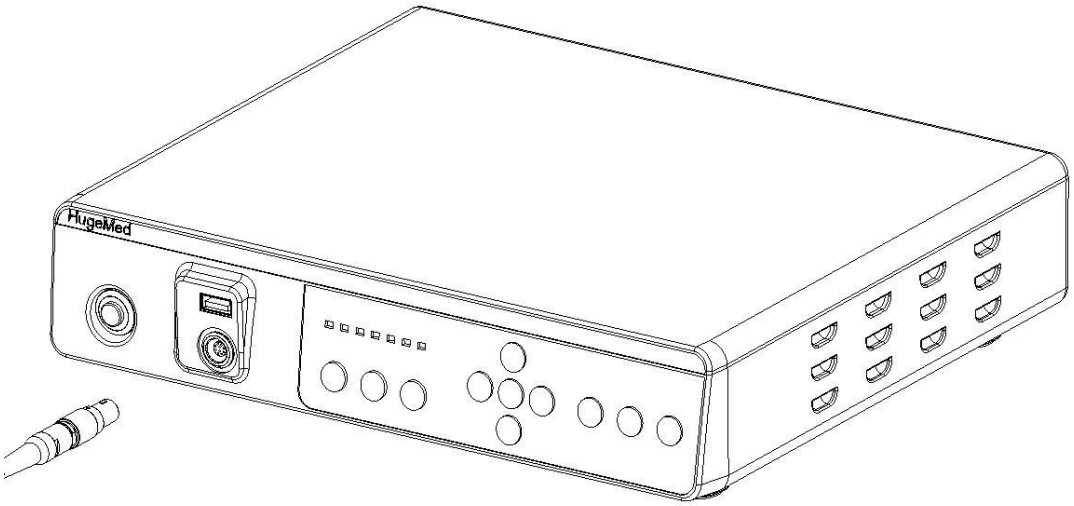
6. Lift the deflector rod on the operation section of endoscope while visually inspecting the bending section to ensure that the bending function is normal. The manipulation shall be fluent and accurate. Please do not coercively bend or correct the bending section with external force, or otherwise it will damage the product.

7. Visually inpsect whether the cable is kinked or damaged, and check whether the cable connector is intact.

8. If consider using the T type valve, visually inspect it and confirm its seal ring is opened.

Connect the image processor and check the image

1. The cable connector of endoscope is connected to the image processor (hereafter to be referred as schematic diagram, please be subject to the material object of image processor matched).



2. Connect the image processor and boot up as per the instruction of it.

3. Check whether there is a image shown on the screen.

White balance

The white balance is corrected as per the following mehod:

1. Align the head end of endoscope to the white object with a distance of about 3-5mm, and press lightly the button for white blance for correction.

2. If fail to correction (there is a significant color difference between the image shown on the screen and the material object), the previous step will be implemented again.

Note: during white balance correction, ensure using a while object and the endoscope is not allowed to touch this object.

Note: during white balance correction, the head end of endoscope is not allowed to exposed to bright light. Otherwise, the correction of white balance cannot achieve an ideal effect.

Connect to drawing source and T type valve

1. If there is a need to use drawing function, the drawing source can be

connected to the drawing connector on the operation section of endoscope, and the button for drawing can control the on and off of drawing function.

2. If there is a need to use the function for supplying water, vapor and drug, the T type valve can be connected to the entrance of work pass. When using the water-vapor connector of T type valve, the cap of Lure fitting on the water-vapor connector can be removed and then the Lure fitting can be connected to the syringe, injection pump or other equipment. When using the entrance of work pass of T type valve, rotary knob on the T type valve is counterclockwisely rotated to make the seal ring inside the valve open and the accessory pass through from the entrance of work pass.

Note: without a single one-way valve to prevent reflux, do not connect the re-used injection pump or other equipment to the water-vapor connector. Otherwise, it may result in equipment contamination and cross-infection of patients.

Intubation and position of endoscope

1. After an appropriate amount of lubricant for medical use is coated on the intubation section of endoscope, the intubation section is inserted into the catheter, orifice of laparoscope, percutaneous approach or catheter of other endoscopes.

Note: if the endoscope is inserted via a cannula, please ensure it has a large enough opening to accommodate the intubation section of endoscope.

Note: the maximum outer diameters of accessories compatible with of endoscopes of various models refer to "minimum inner diameter of pass work" in "specification".

Note: if necessary, the image quality can be improved by adjusting brightness (For more information about adjustment of brightness, please refer to instruction for use of corresponding image processor).

Note: wash the front end of camera len with a function of supplying water and vapor to clean the field of view. If necessary, it also considers to be conducted via the drawing function. During drawing, all accessories of work pass are taken out, the drawing source is connected to the drawing connector, press the drawing button for drawing (at this moment, if the entrance of work pass is connected to the T type valve, the seal ring on the T type valve shall be in a closed state. If the water-vapor connector on the T type valve is not connected to the equipment, the cap of Lure fitting on the water-vapor connector shall be installed on the water-vapor connector). If necessary, the water, vapor and drug can be supplied after drawing.

2. Deliver the endoscope to the target location of the pancreas and bile duct system. During this process, the bending orientation and angle of bending section can be adjusted with the deflector rod on the operation section.

3. The contrast agent can be injected into the body via the work pass of

endoscope to realize the perspective observation under a X-ray device. The drawing function shall suspend to use during injection of contrast agent.

Note: the work pass shall be rinsed with normal saline after using contrast agent. Otherwise, it may result in failure to pass through the work pass, and also may result in the reduction of maximum bending angle of the bending section.

Insert the accessory into the endoscope

1. Prepare an accessory for intended use as per the instruction for use of this accessory.

2. While observing real-time vedio and operating endoscope, pass the accessory via the entrance to the work pass of endoscope. If using the T type valve, counterclockwisely unscrew the rotary knob on the T type valve to make the seal ring open and then pass the accessory through the middle hole.

3. Slowly pass through the accessory to observe the real-time vedio, and after the accessory come into the field of view, adjust its orientation to 6 o'clock. If necessary, the perspective image under the X-ray device can be observed.

4. After the accessory is extended from the distal end of endoscope and the distal end of accessory is guided to the target position, the intended operation can be conducted.

Note: when using an EHL probe, degeneration or disappearance of image can occur during activation of probe. If the image disappears, please disconnect the cable connector of endoscope to image processor, and connect them again.

Note: if inserting the accessory into the endoscope is blocked, ensure that the deflector rod on the operation section of endoscope is located near the initial position so as to keep the bending section originally straight.

Note: ensure that the accessory passes through the work pass in the right manner, e.g., when the disposable biopsy forceps comes into the work pass, the forceps shall be kept in a closed state. Otherwise, it may result in accessory's failure to pass through the work pass, and even damage of work pass and accessories.

Note: if there is still resistance, please slightly pull back the endoscope and then slightly advance accessories. Then advance the endoscope again after the accessory passes through the resistance point.

Take out the accessory from endoscope

1. During observation of videos, withdraw the accessory to the head end section. If using the T type valve, keep the seal ring open when withdrawing the accessory.

2. Withdraw the accessory from the endoscope. If there is resistance, investigate clearly the source of resistance at first before continuing to

withdraw the accessory.

3. The accessory may be taken out and replaced during the process.

Taking out of endoscope

Taking out the endoscope following steps below:

1. Ensure that the deflector rod is located at the initial position for avoidance of tissue injury.

2. Take out the accessory from endoscope.

3. Take out the endoscope from the catheter or orifice of laparoscope (if appropriate).

4. Press the button on the front panel of image processor to turn off the LED light.

5. Disconnect the drawing source, injection pump or other equipment (if necessary) from the endoscope.

6. Disconnect the cable connector from the image processor.

7. Handle with the endoscope following the instruction below.

End the operation of endoscope in a safe manner

End the operation of endoscope following the procedure below:

1. Take endoscope and accessory out of the patient.

2. Check whether the endoscope has any loss or abnormal part, and ensure there is no foreign matter left inside the patient.

3. Disconnect the cable connector from the image processor.

4. Press the power button on the front panel of image processor to turn off the image processor, and going out of indicator light means that the image processor is power off. Interrupt the image processor via the switch on the back of image processor, and the going out of indicator light means outage of image processor.

Discarding

In order to avoid potential infection or risk from other microorganisms following use of the product, discard the single use electronic choledochoscope in the following manner:

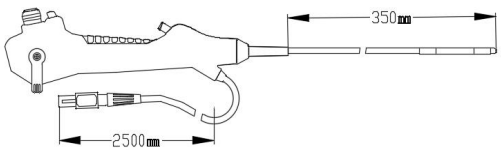
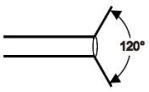
The product following use may contains harmful microorganisms, which must be stored in a container with a symbol of harmful microorganisms. Untreated subtances with biohazard are not allowed to handled with unclassified household wastes. The substances with biohazard must be disinfected before handling, or delivered to the an institution designated by the local government and hospital and dedicated for handling of this kind of wastes.

[Customer service]

This product is a disposable product, and Shenzhen HugeMed Medical Technical Development Co.,Ltd dose not provide a maintenance service for it.

If there is any question during using this product, please contact with Shenzhen HugeMed Medical Technical Development Co.,Ltd.

[Symbol]

	Working length
∅Max.OD	Maximum outer diameter of intubation section
∅Min.ID	Minimum inner diameter of work pass
	Field of view
	The product with sterile barrier system or package damaged is not allowed to be used.
	Free of natural latex
	Applied part of BF model
	Manufacturing date: YYYY-MM-DD
	Expiry date: YYYY-MM-DD
STERILE EO	Sterile product, sterilized by EO.
	It is a disposable product, and please do not re-use it.
	Manufacturer
SN	Serial number
	Warning
	Refer to the instruction for use.
Rx Only	Medical items with prescriptions

	Temperature limit: the temperature shall be 0-45 ℃ (32-113 ℉) during storage and transportation.
	Humidity limit: the relative humidity shall be 30-80% during storage and transportation.

Attachment A

A1.1 Classified as per types of electric shock protection: applied by the host;
A1.2 Classified as per extents of electric shock protection: applied part of BF type;
A1.3 Classified as per protection level to feed liquid: conventional device;
A1.4 Classified as per degree of safety when used under the flammable anesthetizing gas mixed with air or oxygen or nitrogen oxide: equipment which cannot be used under the flammable anesthetizing gas mixed with air or oxygen or nitrous oxide;
A1.5 Classified as per operation mode: continuous operation mode;
A1.6 Rated voltage and frequency of equipment: not applicable;
A1.7 Input power of equipment: not applicable
A1.8 Whether the equipment has a applied part which protects against defibrillation and discharging effect: not applicable;
A1.9 Whether the equipment has a signal output or input part: not applicable;
A1.10 Permanently installed equipment or non-permanently installed equipment: non-permanently installed equipment;
A1.11 Classification of electromagnetic compatibility: in compliance with Class A in Group 1 of GB4824-2019;

[AttachmentB: Electromagnetic Compatibility]

Note

- The single use electronic choledochoscope complies with requirements related to electromagnetic compatibility in YY0505 and GB9706.19 standards.
- Users shall install and use according to the electromagnetic compatibility information provided in the random document.
- The portable and mobile RF communication devices may impact the performance of the single use electronic choledochoscope, and avoid strong electromagnetic interference when using it, e.g., near the mobile phone and microwave oven;
- Details of guidance and statement from the manufacturer refer to attachments.
- Slight water ripple phenomenon may occur during the EMC test, which does not impact the acutal use and performance effect of the product.

Warning

- The single use electronic choledochoscope shall not be near other equipment or used in stack, and if it must be so, it shall be observed and validated that it can be normally run under the configuration for use.
- The Class A equipment is proposed to be used in the industrial environment, since the single use electronic choledochoscope transmits disturbance and radiate disturbance, guaranteeing electromagnetic compatibility in other environments may pose a potential difficulty.
- Except the cable sold by the manufactuerer as the replacement part of single use electronic choledochoscope, using additionally unspecified accessories and cables may result in increasing of emission or reduction of noise immunity of single use electronic choledochoscope.

Serial number	Name	Length of cable (m)	Whether is shielded
1	Cable to handset	2.5	NO

Guidance and statement of manufacturer-electromagnetic emission		
The single use electronic choledochoscope is intended to use in the following specified electromagnetic environments, and the purchaser or user of it shall ensure it can be used under such an environment:		
Emission test	**Conformance**	**Electromagnetic environment-guidance**
GB4824 RF emission	Group 1	The single use electronic choledochoscope can use RF engery for its internal function. Thus, its RF emission is very low, and may not generate any interference to nearby electronic equipment.
GB4824 RF emission	Class A	The single use electronic choledochoscope is suitable for non-domestic facilities and all facilities not directly connecting to the domestic residential public low voltage power supply network.
Gb17625.1 Harmonic emission	Not applicable	
GB17625.2 Voltage fluctuation/scintillant emission	Not applicable	

Guidance and statement from the manufacturer-electromagnetic immunity			
The single use electronic choledochoscope is intended to use in the following specified electromagnetic environments, and the purchaser or user of it shall ensure it can be used under such an environment:			
Immunity test	**IEC60601 test**	**In compliance**	**Electromagnetic**
Electrostatic discharge (ESD) **GB/T17626.2**	±6kV contact discharge ±8kV air discharge	±6kV contact discharge ±8kV air discharge	The ground shall be covered with woodiness, concrete or ceramic tiles, and if the ground is covered with synthetic materials, the relative humidity shall be less than 30%.
Electrical fast transient burst **GB/T17626.4**	±2kV to power wire ±1kV to input/output line	Not applicable	Not applicable
Surging **GB/T17626.5**	±1kV difference-mode voltage ±2kV common-mode voltage	Not applicable	Not applicable
Sagging, short interruption and change to voltage on the power supply of input wire **GB/T17626.11**	<5%U_T, lasting for 0.5 cycles (On U_T, sagging for >95%) 40%U_T, lasting for 5 cycles (On U_T, sagging for 60%) 70%U_T, lasting for 25 cycles (On U_T, sagging for 30%) <5%U_T, lasting for 5s (On U_T, sagging	Not applicable	Not applicable

	for >95%)		
Power frequency magnetic field (50/60Hz) **GB/T17626.8**	3A/m	3A/m（50/60Hz）	The power frequency magnetic field shall have the characteristics of power frequency magnetic field in typical places under commercial or hospital envrionments.
Note: U_T refers to the alternating voltage before applying the test voltage			

Guidance and statement from the manufacturer-electromagnetic immunity			
The single use electronic choledochoscope is intended to use in the following specified electromagnetic environments, and the purchaser or user of it shall ensure it can be used under such an environment:			
Immunity test	**IEC60601 test electrical level**	**In compliance**	**Electromagnetic environment-guidance**
RF transmission GB/T17625.6	3Vrms 150kHzto80MHz	3Vrms	The distances from portable and mobile RF communication devices to any part of the single use electronic choledochoscope (including the cable) shall not be shorter than recommended isolation distances. This distance shall be calculated with an equation corresponding to the frequency of transmitter. **Recommended isolation distance**
RF radiation GB/T17626.3	3V/m 80MHzto2.5GHz	3V/m	$d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHzto800MHz $d=2.3\sqrt{P}$ 800MHzto2.5GHz Where, *p* is the maximum rated output power as per the transmitter provided by its manufacturer, in the unit of watt (W), d is the recommended isolation distance, in the unit of meter (m). [b] The field strength of fixed radio-frequency transmitter is determined by survey[a] of an electromagnetic place, and each radio-frequency range[b] shall be lower than the electrical level in compliance. The interference may occur near the equipment with the following marks. 
Note 1: for frequencies of 80MHz and 800MHz, the equation of the higher frequency band is adopted. Note 2: these guidances may not be suitable for all cases, the electromagnetic propagation is			

impacted by absorption and reflection by buildings, objects and human bodies.
a For fixed transmitters, e.g., base stations of air (cell/cordless) telephone and ground mobile radio, amateur radio, AM and FM radio broadcasting as well as television broadcasting, their field intensities cannot be accurately and theoretically predicted. The survey of electromagnetic place shall be considered for assessing the electromagnetic environment of fixed radio-frequency transmitter. If the field intensity where the single use electronic choledochoscope is located is measured higher than the suitable electrical level in compliane of radio frequency, this single use electronic choledochoscope shall be observed for once to validate it can normally run. If abnormal performance is observed, the supplement measure may be necessary, e.g., readjust the direction or location of this single use electronic choledochoscope. b Within the whole frequency range of 150KHz ~ 80MHz, the field intensity shall be less than 3V/m.

Recommended isolation distance between portable and mobile radio-frequency communication devices and this single use electronic choledochoscope

This single use electronic choledochoscope is intended to use in an electromagnetic environment with disturbance of radiofrequency radiation controlled. As per the maximum rated output power of communication device, the purchaser or user of single use electronic choledochoscope can prevent the electromagnetic interference by maintaining the minimum distance between the portable and mobile radio-frequency communication equipment (transmitter) and the single use electronic choledochoscope as recommended below.

The maximum rated output power of transmitter/W	**Isolation distance/m corresponding to different frequencies of**		
	150kHz～80MHz $d=1.2\sqrt{P}$	**80MHz～800MHz** $d=1.2\sqrt{P}$	**800MHz～2.5GHz** $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

The equations in the corresponding transmitter frequency list can be used to identify the maximum rated output power of transmitter and recommended Isolation distance d in the unit of meter (m), the p here is maximum rated output power of transmitter provided by its manufacturer in the unit of watt (W).

Note 1: for frequencies of 80MHz and 800MHz, the equation of the higher frequency band is adopted.

Note 2: these guidances may not be suitable for all cases, the electromagnetic propagation is impacted by absorption and reflection by buildings, objects and human bodies.