

# **Single-use Choledochoscope**

## **Instructions for Use**

Shenzhen HugeMed Medical Technical Development Co., Ltd

Please read the Instructions for Use of the product carefully before use.

HugeMed reserves all the rights for the final explanation of the Instructions for Use.

HugeMed reserves the right to modify or change information within the Instructions for Use without further notice.

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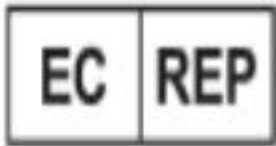


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# 1. Important Information - Please Read Before Use

This system comprises a single-use choledochoscope and an image processor. Please read these safety instructions carefully before using the system. The Instructions for Use are subject to change without prior notice. A copy of the latest version can be provided as required. Please note that these instructions do not constitute an explanation or discussion of clinical procedures. These instructions involve only basic operations of the single-use choledochoscope and image processor and operation-related precautions.

Prior to the initial use of the single-use choledochoscope system and image processor, the operator should be adequately trained in the use of the clinical endoscope and familiar with the intended use, warnings, and precautions described in the Instructions for Use. For the purpose of the Instruction for Use, the term "endoscope" refers to a single-use choledochoscope, which includes multiple series. The Instructions for Use applies to the endoscope and image processor and provides system-related information.

## 1.1. Intended use

The product is intended for the diagnosis and treatment of the pancreatic ductal system in endoscopic surgery. A single-use choledochoscope system is comprised of a single-use choledochoscope and an image processor.

A single-use choledochoscope is used to provide illumination and intuitive images in endoscopic surgery of the pancreatic ductal system and serves as a guide to diagnosis and management with accessories.

The image processor is used in the diagnosis and treatment of the pancreatic ductal system to receive, process, and transmit video sequences from the single-use choledochoscope.

## 1.2. Contraindication

1. Specific contraindications for pancreatic duct (including hepatic duct) probing and intubation under an endoscope;

Note: This choledochoscope should be used without interference of environmental and other factors and operated in strict accordance with the instructions.

## 1.3. Clinical advantages

The choledochoscope is designed to be disposable to minimize the risk of cross-contamination.

## 1.4. Warnings and precautions

**Do not use this product in the presence of flammable liquids or gases (such as detergents, anesthetics, nitric oxide, and oxygen) that are beyond control. Failure to follow this may result in fire or burns of the operator and patient.**

• **Do not perform treatment until the accessory appears in the endoscopic view or when the**

distal end of the endoscope is pressed against the mucous membrane. Failure to follow this may result in patient injuries, such as perforation, bleeding, or mucosal damage.

- Water, air, and drugs can only be delivered when the external device is installed with a single-use unidirectional valve to prevent backflow. Failure to follow this may result in device contamination or patient infection/cross-infection.
- Do not look directly into the light emitted from the endoscope. Failure to follow this may cause injuries to the eye.
- Temperature of the cable will remain for a period of time after disconnecting the endoscope from the video processor. Do not touch the connector immediately after unplugging the cable connector. Failure to follow this may cause skin burn.
- A Type T valve, if used, should be opened before the guide wire is loaded to avoid perforation due to excessive length of the guide wire inserted into the patient's body.
- This product does not apply to radio frequency cutting/coagulation devices.
- **Warning: Do not make changes to this product.**
- Use of this endoscope system adjacent to or stacked with other devices should be avoided as this may cause malfunctions. If such use is necessary, this endoscope system and the other devices should be observed to verify that they are operating normally.
- The distal end of the endoscope may reach temperatures above 41°C as a result of endoscopic illumination. An appropriate distance must always be kept between the distal end face of an endoscope and the mucosa of the pancreatic ductal system as the surface temperature above 41°C is associated with an adverse impact on human tissue. Prolonged high-brightness illumination should be avoided unless necessary. Do not leave the distal end in a stationary position for observation for a long time, unless necessary.
- Prepare a stand-by single-use choledochoscope and video processor before surgery.
- This product can only be used in conjunction with the corresponding video processor and may damage the device or cause injury to the operator when connected to other devices.
- Use of a laser lithotrite or hydroelectric lithotripter at close range 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 when in use.
- Unplugging the cable connector prior to removal of the insertion portion of the endoscope from the human body will cause it unable to see videos/images from the endoscope. The insertion portion of the endoscope should be withdrawn from the human body before unplugging the cable connector.
- Any damage to the cable connector may cause no display or abnormal display of videos/images. Cables and cable connectors should be inspected and handled carefully prior to use.
- Use of this product together with a cardiac defibrillator will damage the video processor.

Please withdraw the endoscope from the human body prior to the use of a defibrillator.

- Patients with a previous history of gastric or biliary surgeries or narrow ducts should use this product with caution. This may hinder the pass-through of the insertion portion of the endoscope.

- Do not connect a wet cable connector to the video processor, as it may cause video performance degradation or system damage.

- Portable RF communications equipment (including peripheral equipment such as the antenna cable and external antenna) should be at least 30 cm away from the endoscope system (including the endoscope, video processor and connecting wires, etc.), otherwise, it may cause performance degradation of the product.

- The emission characteristics of this device 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 product 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.

- The endoscope is single-use and must be handled and disposed of in accordance with generally accepted standards of medical practice for such devices to avoid contamination before insertion.

- Please wipe the surface of the image processor with rubbing alcohol before and after use.

- Federal (USA) Law restricts this device for sale to or on the order of a physician.

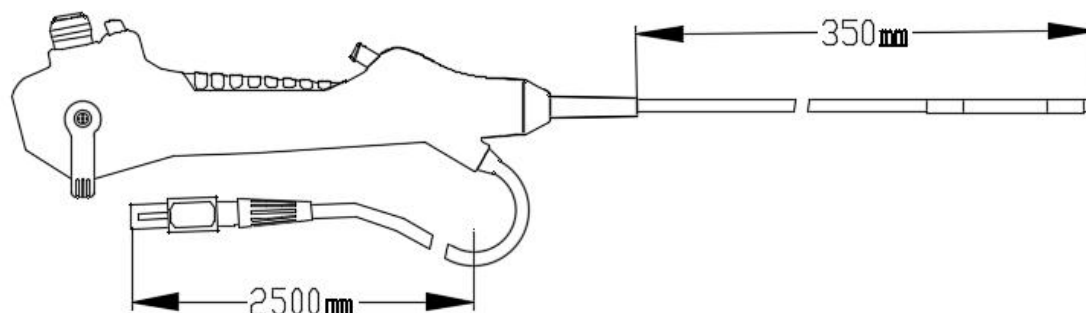
- Do not attempt to clean, sterilize, and reuse Single-Use choledochoscope on another patient as it is a single-use device, the re-use may lead to infection.

- For the user or patient, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

## 2. System Description

This system comprises a single-use choledochoscope and an en image processor.

### 2.1 System components - single-use choledochoscope



The single-use choledochoscope is available in 4 models: CH-M50, CH-M52, CH-M40 and CH-M32

#### 2.1.1 Specifications

Models	CH-M52	CH-M50	CH-M40	CH-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	3-50 mm	3-50 mm	3-50 mm	3-50 mm
Diameter of insertion tube	Φ5.0 mm	Φ5.0 mm	Φ4.2 mm	Φ3.1 mm
Maximum insertion portion width	5.2 mm±10%	5.0 mm±10%mm	4.4 mm±10%	3.2 mm±10%
Insertion portion length	350 mm±10%	350 mm±10%	350 mm±10%	350 mm±10%
Minimum insertion channel width	Φ≥2.1 mm No upper limit	2.8mm±10%	Φ≥1.1 mm No upper limit	1.2mm±10%
Bendable portion	210° upward and 210° downward with a deviation of -5% (exclusive of the upper limit)	210° upward and 210° downward with a deviation of -5% (exclusive of the upper limit)	210° upward and 210° downward with a deviation of -5% (exclusive of the upper limit)	210° upward and 210° downward with a deviation of -5% (exclusive of the upper limit)
Total product length	605mm	605mm	605mm	605mm

It cannot be ensured that the instrument combination applying only to the minimum insertion channel width is compatible.

It cannot be ensured that the instrument combination applying only to the maximum insertion portion width and working length is compatible.

#### 2.1.2 Operating environment and storage & transportation environment

Operating environment	5-40°C
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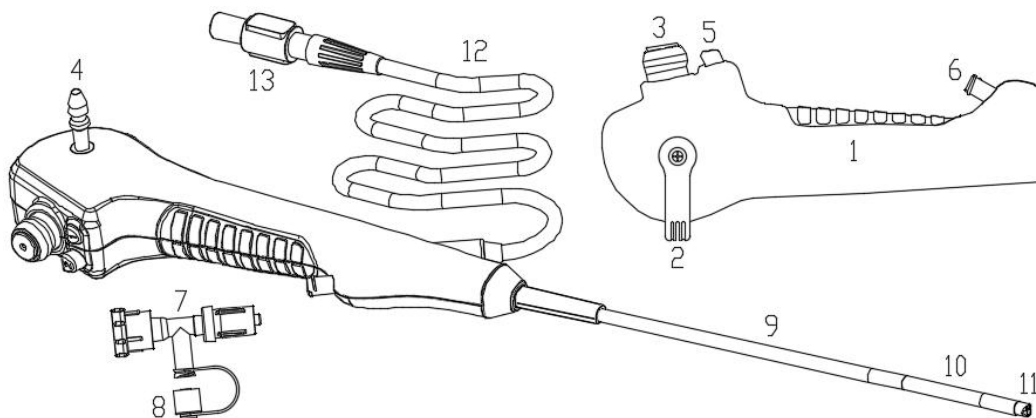
Temperature	
Relative humidity	≤93
Air Pressure	700-1060 hPa
Altitude	≤2000 m
<b>Storage and Transport</b>	
Temperature	0-45°C (32-113°F)
Relative humidity	30%-95%
Sterilize	
Sterilizing Method	EO (ethylene oxide sterilization)

### 2.1.3 Product compatibility

- HugeMed recommends a 200 micron laser fiber for maximum deflection and access to the kidney. A larger fiber may break and be accidentally fired inside the working channel, damaging the endoscope.
- HugeMed recommends using a stone extractor (with an outer diameter of 2.2 Fr),
- HugeMed recommends using a biopsy forceps (with an outer diameter of φ1.0mm),
- Endoscope can only be used in conjunction with the image processor produced by HugeMed.
- Compatible accessories

**Sharp accessories, such as laser fibers, can cause damage to the working channel if passed when the scope is deflected—pass these instruments only when the scope is not deflected (straight).**

### 2.1.4. Single use choledochoscope

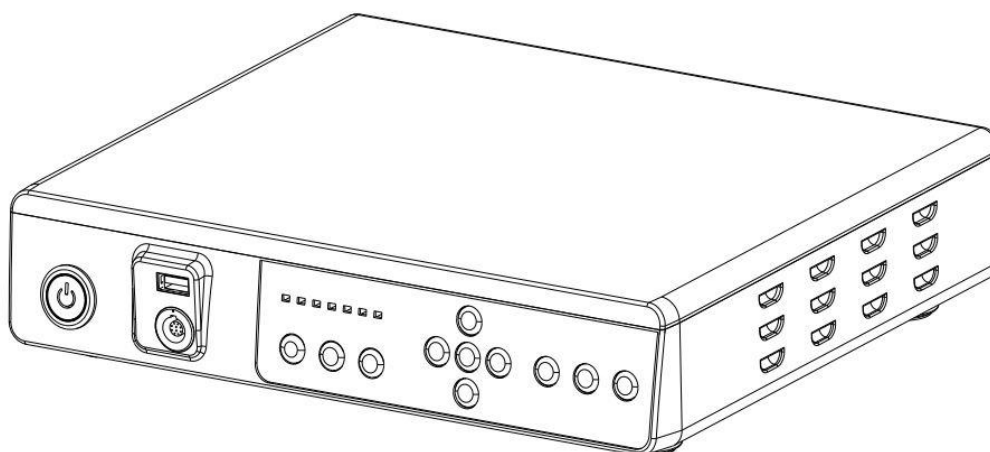


No.	Component	Function
1	Handle	Used to hold the product.
2	Lever	Used to control the bending direction and angle of the bendable portion. (Specific directions are marked on the handle)
3	Suction button	Used to control the opening and closing of the suction function.
4	Suction joint	Used to connect to the suction source for suction.

5	Button 1 Button 2	Button 1: Short press for photographing and long press for recording Button 2: Freezing Its function can be customized on the video processor.
6	Working channel entry	It is an insertion port for accessories or a connector for the syringe, syringe pump or other devices, to which Type T valve can also be connected.
7	Type T valve	It is installed at the entry of the working channel to divide it into two connectors: a working channel entry with a sealing function and a water/air supply connector. The water/air supply connector can be connected to a syringe, a syringe pump, or other devices for water, air, and drug supply.
8	Luer tip cap	It is used to cover the water/air supply connector on Type T valve for sealing.
9	Insertion tube	A flexible insertion portion that can be passively bent.
10	Bendable portion	Active bending can be enabled under the control of the lever.
11	Distal end	It is located at the far end of the endoscope, and comprises the camera, LED, and working channel exit.
12	Cable	Used to transmit the video signal to the video processor.
13	Cable connector	Used to connect the cable to the video processor.

## 2.2 System component – image processor

### Model of Image Processor: HUV-01



### 2.2.1 Technical parameters

Display	
Default resolution	1024*768
Screen ratio	4:3
Image output	No less than 1024*768
Start-up time	≤10 s
Storage method	USB flash drive/mobile hard disk formatted to FAT32
Power	



Power requirements	100-240 V~50/60 HZ 35 VA
Protection against electric shock	Class I, Type BF applied part
Operating environment	
Temperature	5-40°C
Relative humidity	≤93% RH
Atmosphere pressure	70-106 kPa
Altitude	≤2000 m
Storage and Transport	
Temperature	0-45°C
Relative humidity	30%-95% RH
Outline dimension	
Width	240 mm
Length	300 mm
Height	60 mm
Weight	1.2 kg
Connections	
USB connection	USB 2.0
S-video connection	Optional
DVI connection	Optional

## 2.2.2 System menu



### Functions of main menu

Function	Range of adjustment
Colour Mode	M0, D65 and LED1 are available
Red Gain	Optional from 0 to 100 with an initial value of 50
Green Gain	Optional from 0 to 100 with an initial value of 50
Blue Gain	Optional from 0 to 100 with an initial value of 50
AGC Type	Mean or peak
Sharpness	Available from 0 to 15

3D Denoise	Available from 0 to 3
Gamma Level	Available from 0 to 15
Zoom In	Available from 0 to 1
Record Source	Optional lens, CVBS-IN
CVBS Mode	Available in PAL, NTSC
Language	Available in both Chinese and English

## 3. Pre-use Inspection

This system must be inspected in accordance with the following rules before use. Moreover, the inspection should be performed in accordance with the Instructions for Use and the rules for other devices used in conjunction with the endoscope.



- The software copyright of the video processor is owned by our company, and no organization or individual is allowed to tamper, copy or exchange it by any means or in any form without permission.
  - HUV-01 Image Processor must be connected to the endoscope produced by HugeMed. HugeMed assumes no responsibility for any damage or incident caused by connecting to endoscopes not manufactured by HugeMed.
  - When HUV-01 Image Processor is used with energized endoscopes or endoscope accessories not manufactured by HugeMed, patient leakage currents may be additive.
  - When the endoscope connected to HUV-01 Image Processor loses its function, it should be withdrawn from the body of the patient immediately and disconnected from HUV-01.
  - Do not use this product in the presence of high-frequency electrosurgical equipment, as it may cause patient injuries or equipment damage.
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### 3.1 Inspection of packaging integrity

3.1.1 Before use, please check whether the outer packaging of the endoscope is complete and whether the product model and specifications are consistent with those on the label.

#### Warning

- Do not use the endoscope if its sterile barrier or packaging is damaged.
- The endoscope has been sterilized with ethylene oxide, with the expiration date printed on each layer of packaging. Do use products beyond the expiration date in clinical practice.
- Do not open the bag or box with knives or other sharp tools.

### 3.2 Open package inspection

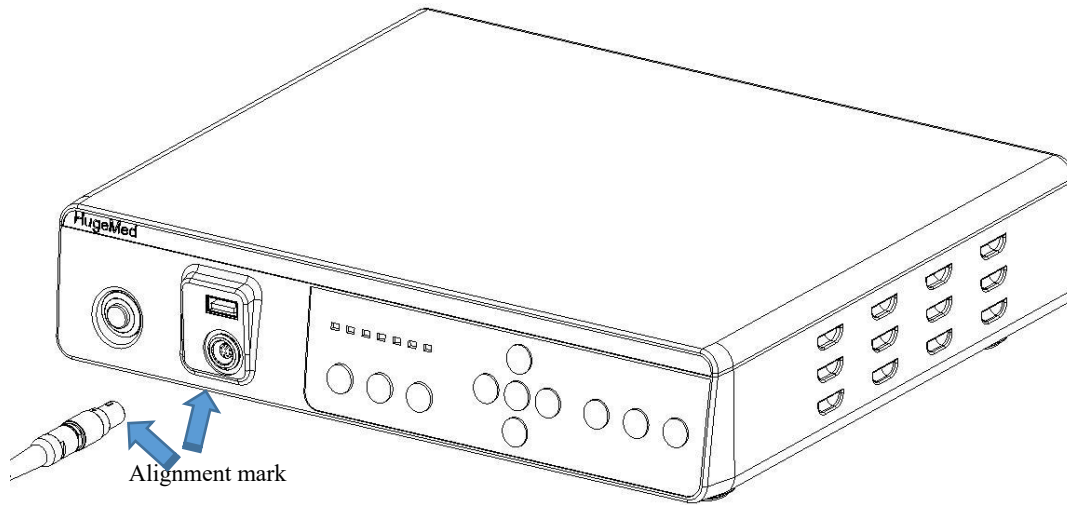
Check for shipping damage or other damages, such as rough surfaces, sharp edges or protrusions, which may harm the patient.

### 3.3 Installation, connection and inspection

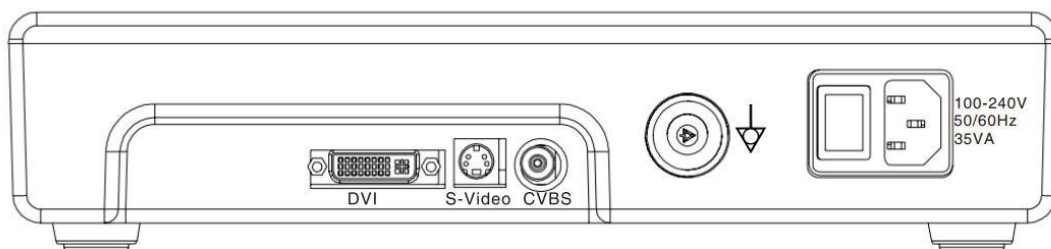
#### Warning

- Do not look directly into the distal end of the endoscope while inspecting the light source as this may cause eye injury.

3.3.1 Connect the endoscope power connector to the matching endoscopy video processor and press the power button. Both the power indicator and the endoscope image will be displayed on the monitor.

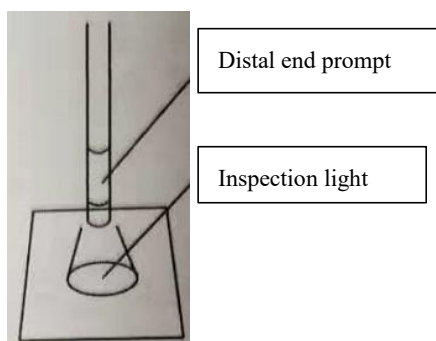


**Schematic diagram for connection between the endoscope and HUV-01 Image Processor**

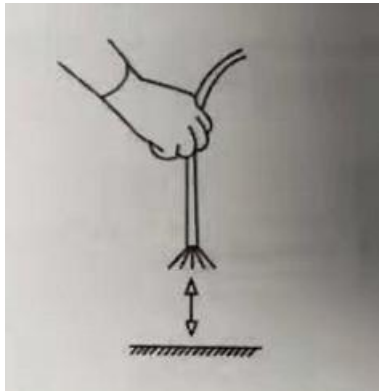


**Connection between the monitor (display device) and HUV-01 Image Processor**

3.3.2 Confirm that there is a beam of light emitted from the end of the endoscope (dual LED)



3.3.3 Point the distal end of the endoscope at the object to be measured and move it between 3-50 mm. Verify on the monitor that the image quality and brightness of the object to be measured are basically stable.



Note:

- Please refer to "White Balance Calibration" in case of abnormal color of endoscopic image.

3.3.4 Observe the distal tip of the endoscope by aligning it to the palm of your hand to ensure that the endoscopic image is free from noise, blur or other abnormalities.

### 3.4 Inspection of the bending function of endoscope

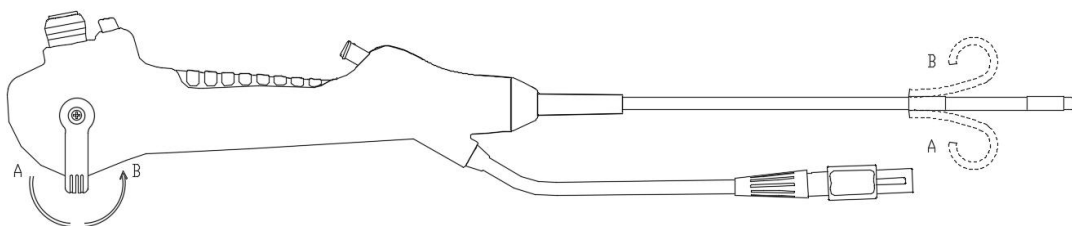
The following inspections should be performed when the bendable portion is in a straight line.

#### Warning

- Bending function abnormality may occur if the bending control lever slides with a clicking sound or the bendable portion does not achieve a smooth bending. In this situation, an endoscope should not be used because abnormalities may occur during the surgery.

3.4.1 Slowly slide to bend the control lever and confirm that the bendable portion is bent smoothly and normally and can achieve the maximum bending amplitude.

3.4.2 Slide the bending control lever to bend the bendable portion upward and downward respectively



3.4.3 Slowly slide the bending control lever to the neutral position and confirm that the bendable portion can be smoothly restored to a nearly straight line.

### 3.5 Inspection of the suction function

Skip this inspection if suction is not required.

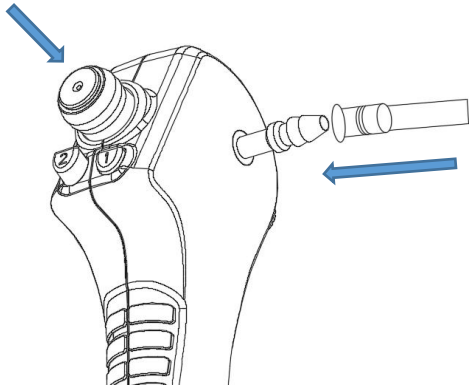
#### Warning

- Do not continue to use the endoscope if the suction valve cannot work properly as continued suction may occur, leading to patient injury.

Note:

- The pressure of the negative-pressure device system should be less than 70 kpa.

3.5.1 Connect the pipeline of the vacuum system to the suction joint and adjust the suction pressure to the level that should be reached during surgery.



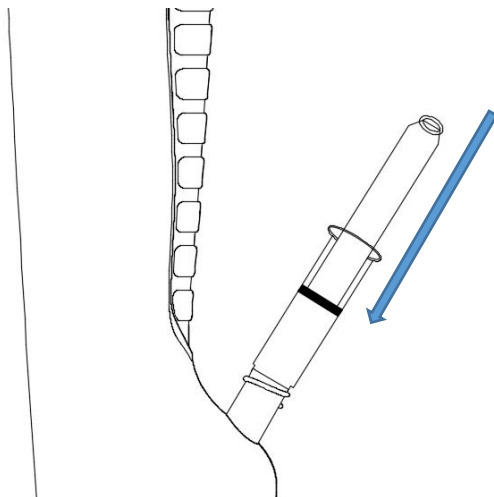
3.5.2 Immerse the distal tip into sterile water and press the suction valve. Confirm that the bottle of the water sucking device can enable continuous water absorption.

3.5.3 Release the Air Suction button, confirm that the air suction stops and that the Air Suction button returns to its original position.

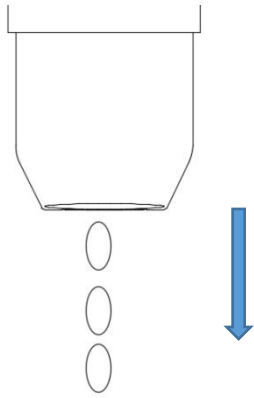
3.5.4 Take the end of the arthroscope out of water. Press the Air Suction button to suction for a few seconds so that all water in the pipeline is removed.

### 3.6 Inspection of the working channel

3.6.1 Insert a syringe filled with sterile water into the working channel port of the endoscope and press the plunger.



3.6.2 Confirm that the injection is flowing out from the end of the endoscope.



**Warning** ⚠

- The syringe must remain perpendicular to the working channel port when inserting into it. Otherwise, the device will be damaged.

**Caution:**

- The syringe must be entirely inserted into the working channel port for the purpose of proper operation.

### 3.7 Inspection of other therapy accessories

**Warning** ⚠

- The compatibility between the endoscope and any accessories should be inspected according to [Compatible Equipment and Accessories] before each use to ensure safety use.
- The head of endo-therapy accessories such as biopsy forceps must be closed at the time of insertion, otherwise the working channel will be damaged and parts will fall off.
- Do not insert endoscopic accessories forcibly in case of any difficulty in their insertion. Forcible insertion can result in damage to the working channel and detachment of endo-therapy accessories.
- The endo-therapy accessory must be inspected for abnormalities in appearance or operation before use and should be replaced in time if any.

3.7.1 Endo-therapy accessories are inserted from the working channel port and pushed slowly to ensure that the accessory can extend smoothly from the distal-end working channel port.

### 3.8 White balance

**Warning** ⚠

- A pure white object should be used when performing white balance calibration, but it should never come into contact with the endoscope.
- The distal tip of the endoscope should not be exposed to an external light source whilst performing white balance calibration. Otherwise, white balance calibration may end in failure.

3.8.1 Press the Power button of the endoscopy video processor, connect it to the corresponding

endoscope and press the power switch of the video processor. When the distal end of the endoscope is directed at the white object, the white balance button on the video processor screen or the handle button with the white balance function should be gently pressed for white balance calibration.

3.8.2 Repeat the above steps in case of calibration failure.



## 4. Use of Endoscope

The endoscope can only be operated by qualified medical personnel under the supervision of a physician, and operators must receive clinical and technical training on the endoscope. The endoscope should be connected to the endoscopy video processor before use, as shown below:

- (1) Check whether the signal connecting line is intact in appearance;
- (2) Refer to the operating instructions of the endoscopy video processor and prepare to connect the endoscope.
- (3) Connect HUV-01 to the signal connecting line;
- (4) Connect the endoscope to the signal connecting line.

Press the Power button to start the host machine.

### Warning

- This device cannot be used together with the high-frequency electric knife or argon plasma for possible device damage or patient injury.
- The endoscope cannot be withdrawn in advance in the following situation. Otherwise, the patient will be injured.
  - When an accessory extends from the distal end; or
  - When the bendable portion is bent to a certain angle.

### 4.1 Insertion of endoscope

#### Warning

- Do not use excessive force in either the left or right directions at the time of endoscope insertion as this may cause injury to the patient.
- Do not slide the bending control lever forcibly as this may impose an excessive load on the steel wire, leading to stretching or breaking of the steel wire and affecting the bending function.

#### Caution

- The insertion tube should be lubricated with medical lubricants before endoscope insertion to minimize friction produced when inserting the endoscope into a patient's body.
- Whether there is an appropriate stand-by device that can be used immediately in the event of malfunction.

4.1.1 When the distal bendable portion of the endoscope is placed in a neutral and non-angular position, the choledochoscope is inserted into the pancreatic duct through the incision with the hand not holding the handle of the operation portion. Be sure to observe the real-time video displayed on the monitor when the choledochoscope enters the patient's body.

4.1.2 The bending control lever is used to control the bending angle at the distal end and guide the distal end to go deeper into the pancreatic duct for observation.

## 4.2 Suction

Skip this step if this function is not required.

### Warning

- Excessive suction pressure may cause mucosal aspiration or injury.
- Make sure that Type T valve is closed at the time of pumping. If not closed, the effect of the endoscope suction system will be reduced.
- Do not press the suction valve for a long time during the suction process.

4.2.1 Connect the catheter of the negative-pressure device system to the suction joint of the endoscope, and adjust the suction pressure to the level that should be reached during surgery.

4.2.2 Tighten the Type T valve, press the suction button, and operate the suction system.

## 4.3 Injection or flushing of drugs

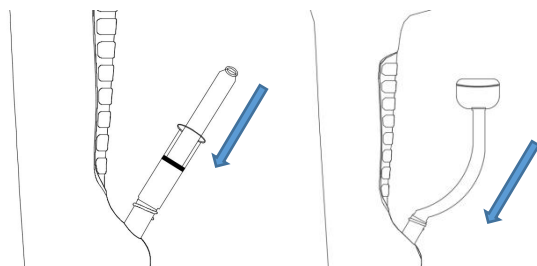
Skip this step if this function is not required.

### Warning

- The liquid will be sucked into the bottle of the vacuum system if the Suction button is pressed during liquid delivery.

4.3.1 Confirm that the suction function is closed.

4.3.2 Insert either syringe or infusion set into the working channel port.



## 4.4 Insertion of the therapy accessories into the endoscope

### Warning

- Do not insert the therapy accessories forcibly or abruptly, as the accessories will extend from the distal end of the endoscope abruptly, which could cause patient injury.
- If therapy accessories are used, it is necessary to keep the bendable portion of the endoscope in a straight line and make the distance between the distal end of the endoscope and the mucosa greater than the minimum visible distance of the endoscope.
- Do not operate the endoscopic accessory if the position of the accessory cannot be seen in the endoscopic image, as it could cause device damage

4.4.1 Please refer to [Compatible Accessories] in the Instructions for Use for the selection of endoscopic accessories.

4.4.2 Withdraw the endoscope back to the bendable portion in a natural straight line, with the bending control lever kept still.

4.4.3 Inspect whether the head of the therapy accessory is closed, and then slowly insert it into the working channel port.

4.4.4 Observe the real-time video displayed on the monitor when the therapy accessory reaches the distal-end working channel, and slowly push the accessory forward from the distal end. Fix the accessory devices to keep fixation.

4.4.5 Operate the bending control lever to slowly move the distal end to the expected position for surgery.

## **4.5 Withdrawal of the accessories**

### **Warning**

- The bendable portion should be kept in a straight line when the endo-therapy accessory is withdrawn, otherwise it may cause equipment damage or patient injury.
- Make sure that the endoscopic therapy accessory to be withdrawn is completely retracted to the working channel.
- Do not withdraw the endoscopic therapy accessory if its end is not closed. because it may cause patient injury or device damage.

4.5.1 Put endoscopic accessories back into the working channel after they have been used.

4.5.2 Ensure that the control lever is in the neutral position, and then slowly withdraw the endo-therapy accessories from the working channel.

## **4.6 Withdrawal of the endoscope**

### **Warning**

- The patient should be examined carefully if there is blood on the surface of the insertion portion when the endoscope is withdrawn from the patient's body.
- The endoscope cannot be withdrawn from the patient's body with excessive force in case of non-smooth removal, which may result in patient injury.

4.6.1 Observe the real-time endoscopic video displayed on the monitor and operate the bending control lever to slowly withdraw the endoscope from the patient's body.

4.6.2 Withdraw the endoscope and disconnect it from the endoscopy video processor.

## **4.7 Post-use inspection of endoscope**

Inspect the withdrawn endoscope for any missing part or other abnormalities to ensure that there is no foreign object left in the patient's body.

#### **4.8 Post-use disposal of endoscope**

The used endoscope is considered infected and must be handled according to local guidelines, rather than using infected medical equipment with electronic components. This product is intended for single use only, and should not be reused.

#### **4.9 Post-use disposal of endoscopy video processor**

Surfaces of the endoscopy video processor that has been used should be wiped with alcohol.

## 5. Others

### 5.1 Shelf life

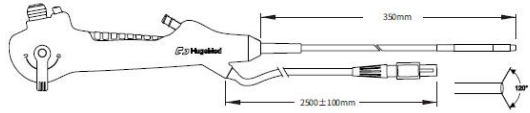
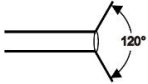











The date of manufacture and expiration date should be indicated on the label, and the aseptic shelf life is 3 years.



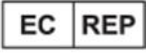









### 5.2 Customer service

The single-use choledochoscope is intended for single use only, for which maintenance services are not supported by Shenzhen HugeMed Medical Technical Development Co., LTD.

If you have any questions in the use of this product, please contact Shenzhen HugeMed Medical Technical Development Co., LTD.

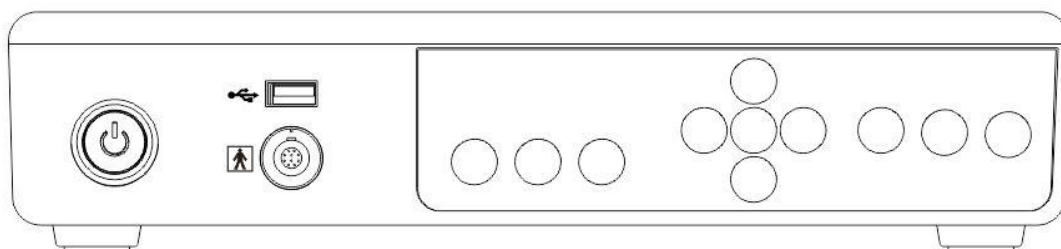
### 5.3 Symbols and description

	Working length
	Field of view
	Do not use if package is damaged and consult instructions for use.
	Type BF applied part
	Date of manufacture: followed by YYYY-MM-DD
	Expiration date: followed by YYYY-MM-DD
	Sterile product, sterilized with EO.
	For single use only. Do not reuse.
	Manufacturer
	Serial number
	Warning
	See the Instructions for Use
	Prescription

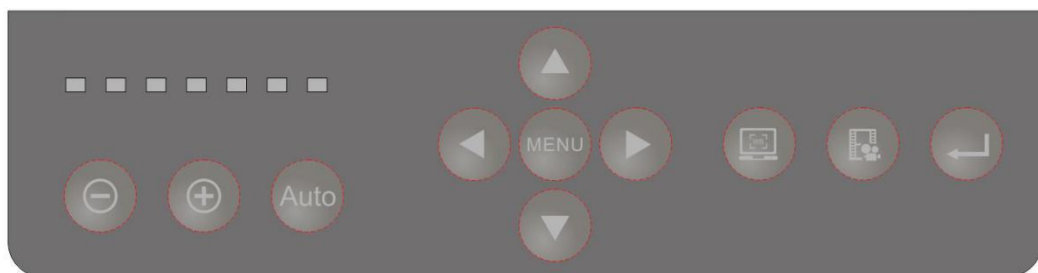
	UDI code
	Medical device
	Authorized representative
	Date of manufacture
	CE mark: indicates that the device complies with the EU 2017/745
	Temperature limit
	Humidity limitation
	Atmosphere pressure limitation
	Keep dry: indicates a medical device that needs to be protected from moisture.
	This symbol indicates the correct upright position of the transport package
	Staking limit by number
	Contain no natural rubber latex

# Appendix A Operating Instructions for HUV-01 Image Processor

## A.1 Introduction to the function of HUV-01



Button control panel of HUV-01 Image Processor



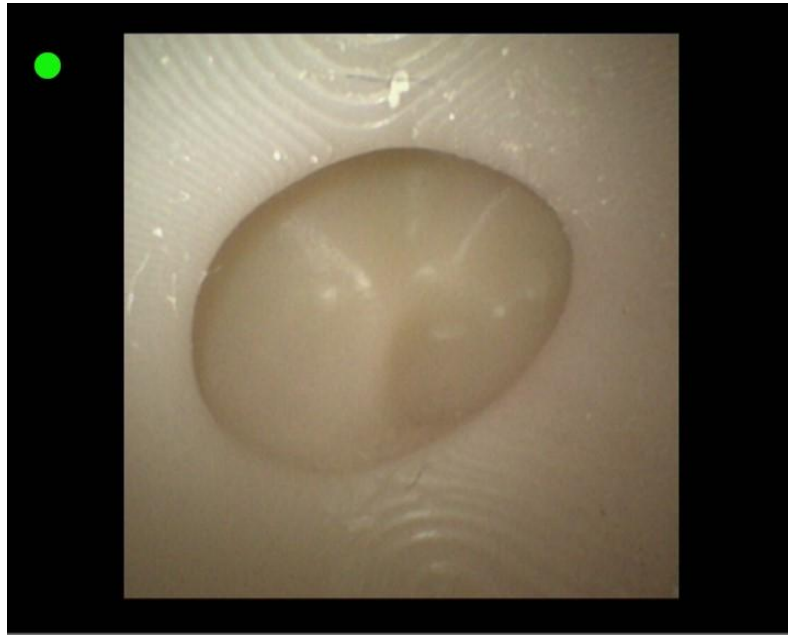
Button control panel of HUV-01

### A.1.1 Button function

Buttons	Power button	OK button	Record button	Freeze/Photographing button	White balance button	Menu button	Auto	+	-
Symbol									
Function	Power the device on/off	Exit the menu setting interface	Save the video	Freeze and save the image	White balance function	Enter the menu setting interface	Adjust the light output to maximum	Increase light output	Decrease light output



### A.1.2 Home screen



Press the Power button to start HUV-01, then the Power button will light up, and the machine will automatically enter the home screen mode, as shown in 『Figure 4-2.





**[ Figure 4-2 ] Home screen mode**

(1) There will be a green dot displayed in the upper left corner of the screen when a USB flash drive or mobile hard disk has been connected to the HUV-01, otherwise, the green dot will not be displayed, the host machine will not perform any processing, and nothing is displayed on the interface.


(2) Photographing: Enter the home screen mode, press the Photography button  on the button control panel, and there will be a freezing  prompt in the lower left corner of the screen and a blinking red circle around the green dot in the upper left corner of the screen, indicating that the image has been saved, which will be named after the time when the video is saved

(3) Recording: After pressing the Record button  on the control panel, there will be a green dot flickering at the upper left corner of the screen, indicating that video recording has started. Press the Record button  on the control panel again to end the video recording. There will be a prompt displayed on the screen that the video has been saved. Saved videos will be named after the time when the video is saved.

(4) Freezing: Enter the home screen mode, press the Photography button  on the button control panel, there will be a freezing  prompt that the real-time image has been frozen in the lower left corner of the screen, and a flashing red circle around the green dot in the upper left corner of the screen indicating that the image has been saved. The saved images and videos will be named after the time when the image/video is saved.

(5) White balance: Point the distal end of the corresponding endoscope handle to the white



reference object, and press the white balance button  on the control panel. After the white balance has been achieved, the color of the images displayed on the screen will return to normal.

(6) Press the menu setting button  on the control panel to enter the main interface menu mode, as shown in 『Figure 4-3』 .

### **A.1.3 Main interface menu**


- 1) Colour Mode: Three color schemes are preset, including M0, D65 and LED1.
- 2) Red Gain: Adjust the value of the red component of the image.
- 3) Green Gain: Adjust the value of the green component of the image.
- 4) Blue Gain: Adjust the value of the blue component of the image.
- 5) AGC Type: Mean or peak AGC. The mean AGC is mainly based on the mean brightness of the full image, while the peak on the number of overexposed points.
- 6) Sharpness: It is used to adjust image resolution and edge sharpness. The higher the value is, the sharper the image and the higher the noise will be.
- 7) 3D Denoise: It is used to reduce image noise, the higher the value is, the stronger the denoising effect will be. 0 means the denoising function is disabled.
- 8) Gamma Level: It is used to adjust the image contrast. The higher the value, the higher the contrast enhancement.
- 9) Zoom In: Value 0 indicates no image magnification, and value 1 and value 2 are optional. See 4.1.5 Image Magnification Settings.
- 10) Border Type: Value 0 means the default border, and values available for border setting are 1-6. See 4.1.4 Border Switch Settings.
- 11) Record Source: Record source selected corresponds to the image screen of the endoscope handle or the external video input screen.
- 12) CVBS Mode: PAL and NTSC are available.
- 13) Language: Switch between Chinese or English in real time.




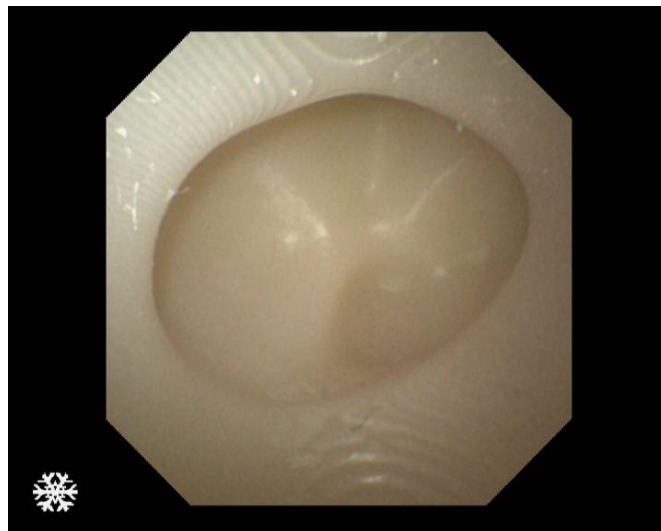
**【Figure 4-3】 Main interface menu mode**

#### A.1.4 Border switch settings

(1) The border is switched in the main interface menu mode by pressing the down arrow

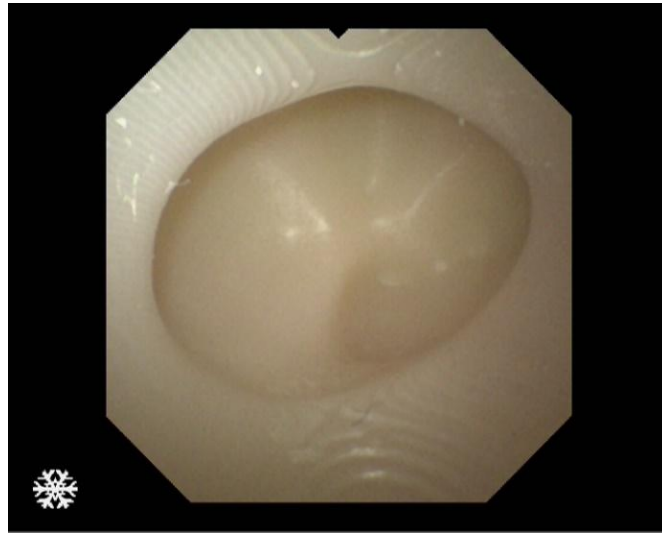
button  to select Border Type in the main interface menu and pressing the right arrow

button  to set the image border to type 1, as shown in 『Figure 4-4』 .



**【Figure 4-4】 Border Type 1**

(2) Press the right arrow button  to set the image border to type 2, as shown in 『Figure 4-4.1』 .



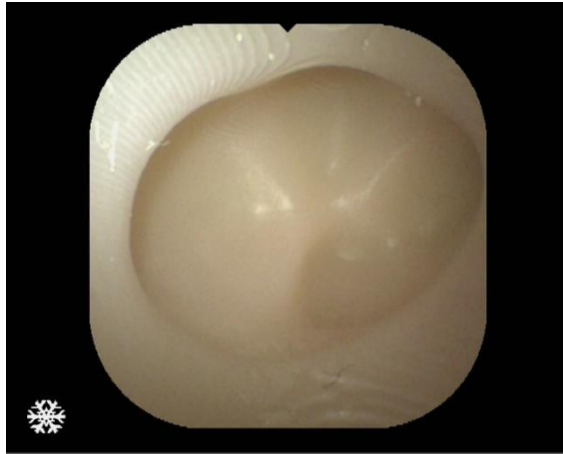
**【Figure 4-4.1】 Border Type 2**

(3) Press the right arrow button  to set the image border to type 3, as shown in **【Figure 4-4.2】** .



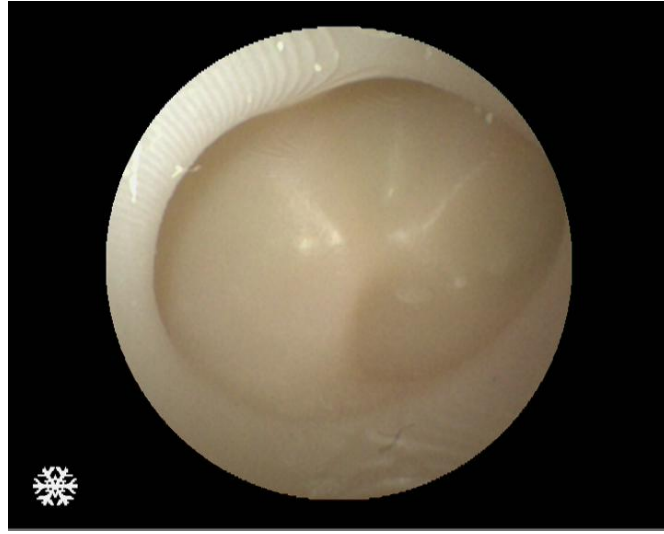
**【Figure 4-4.2】 Border Type 3**

(4) Press the right arrow button  to set the image border to type 4, as shown in **【Figure 4-4.3】** .



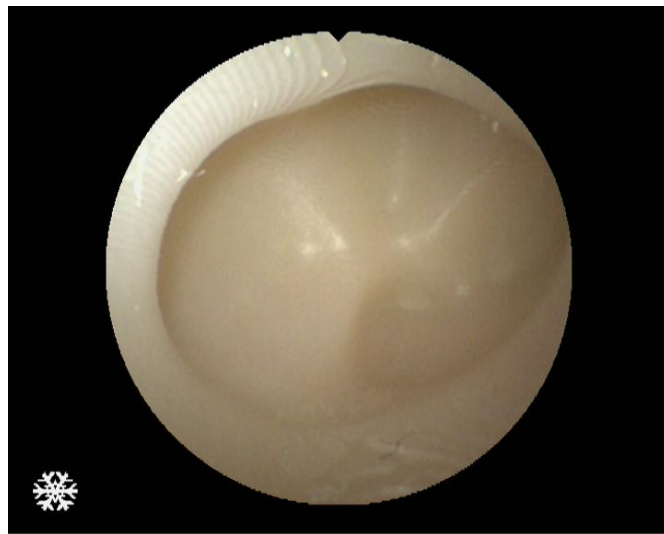
**[Figure 4-4.3] Border Type 4**

(5) Press the right arrow button  to set the image border to type 5, as shown in [Figure 4-4.4] .





**[Figure 4-4.4] Border Type 5**

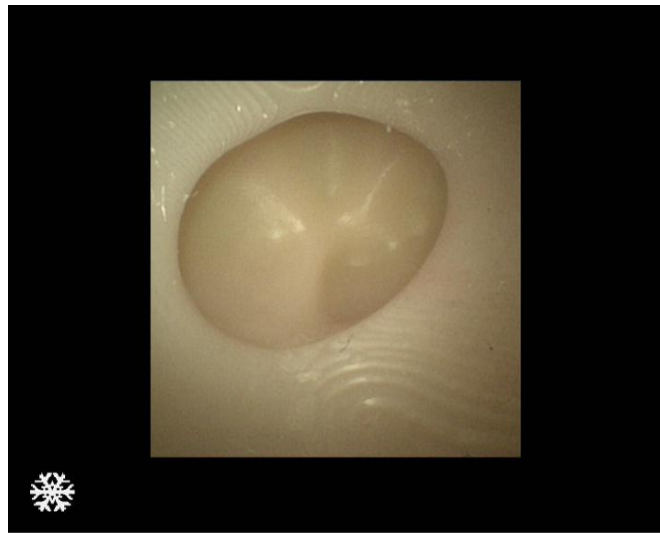
(6) Press the right arrow button  to set the image border to type 6, as shown in [Figure 4-4.5] .




**[Figure 4-4.5] Border Type 6**

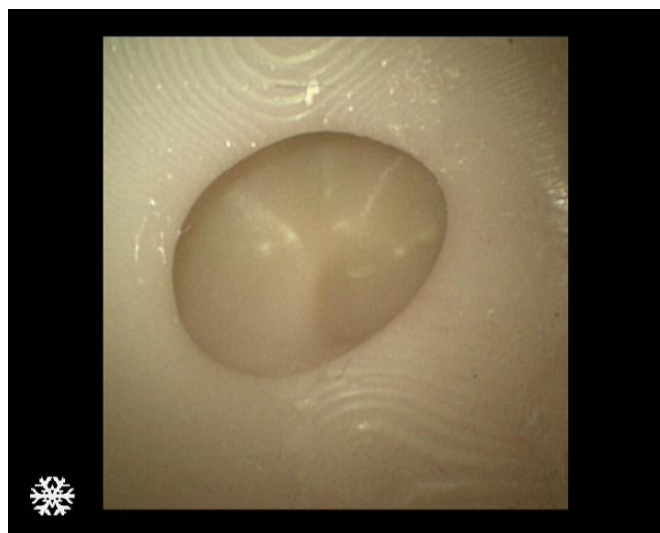
### A.1.5 Image zooming setting

(7) Image zooming and switching are performed in the main interface menu mode by pressing the down arrow button  to select "Zoom In" in the main interface menu and pressing the right arrow button  to set the image zooming to 0, as shown in 『Figure 4-5』 .



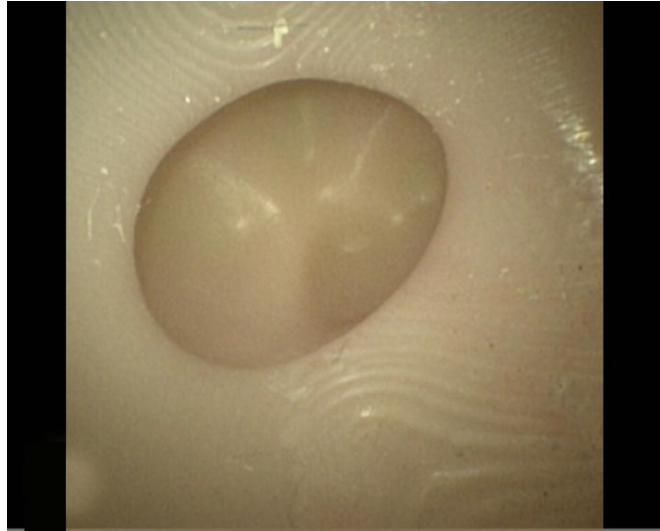
【Figure 4-5】 Zoom in 0

(8) Press the right arrow button  to set the image zooming to 1, as shown in 『Figure 4-5.1』 .



【Figure 4-5.1】 Zoom in 1

(10) Press the right arrow button  to set the image zooming to 2, as shown in 『Figure 4-5.2』 .





『Figure 4-5.2』 Zoom in 2

#### A.1.6 Language setting

(11) The language is set to Chinese by default, as shown in 『Figure 4-6』 .



『Figure 4-6』 Chinese mode

(12) Language is switched in the main interface menu mode by pressing the down arrow button  to select Language in the main interface menu and pressing the right arrow button  to set the language to English mode, as shown in 『Figure 4-6.1』 .



**[Figure 4-6.1] English mode**

The electronic IFU is available on the website:

<http://www.hugemed.net/Product/Single-use-Endoscope/Single-use-Choledochoscope>

Then click the green menu “Manuel download” the eIFU will show on the website.



## **Appendix B Safety Classification**

### **B.1 Classification of equipment**

B.1.1 Degree of protection against electric shock: BF applied part

B.1.2 Non-permanently installed equipment

B.1.3 The electrical insulation diagram is as shown in Figure A.1.

B.1.4 Degree of safety application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide: Equipment cannot be used in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

B.1.5 Type of operation mode: Continuous operating device

B.1.6 Electromagnetic compatibility classification according to CISPR 11:2016, IDT: Group 1 Class A.

REVISION HISTORY			
Version	Overview of Revision Content	Revision by	Effective Date
1.0	Add New	W. Weitzel	2021.08.17