About This Manual

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Product Model: EG-UR5

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- All installation operations, expansions, changes, modifications and repairs of this product are conducted by SonoScape authorized personnel.
- The use or application of the product or the use of parts or accessories is approved by SonoScape.
- The electrical installation of the relevant room complies with the applicable national and local requirements.
- The product is used in accordance with the instructions for use.

Documentation

Understand the meanings of the following items clearly before reading this manual.

Item	Meaning
	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
	Indicates a potentially hazardous situation which, if not avoided, may result in malfunction or damage of the system.
NOTE	Indicates precautions or recommendations that should be used in operating the system.
	Indicates a potentially biological hazardous situation which, if not avoided, may result in disease transmission.

Item	Meaning
Boldfaced Word	Indicates controls on the control panel, or on-screen objects such as menu items or keys.

Contact Information

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1 Safety

This chapter describes important information for operating this endoscope. To ensure the safety of both the operator and patient, please read the relevant details in this chapter carefully before using this endoscope.

The operator should be thoroughly familiar with the precautions provided in this manual. Otherwise, the manufacturer is not responsible for the effects on safety, reliability and performance of the endoscope.

1.1 Intended Use

The ultrasonic gastrovideoscope (hereinafter called endoscope) is intended to provide endoscopic images for the examination and diagnosis of the upper gastrointestinal tract and to perform the ultrasound examination and diagnosis of the upper gastrointestinal sub-mucosa and the surrounding organs.

The endoscope should be used in the medical institution. The operator of the endoscope should be a physician or a medical staff supervised by a physician, both of whom have received sufficient training in clinical endoscopy technology.

- The endoscope is intended for adults.
- Strictly follow the intended use to operate the endoscope. Otherwise, it may result in personal injury or damage to the endoscope.

Federal law restricts this device to sale by or on the order of a physician. Please read the user manual carefully prior to use.

1.1.1 Indications

The endoscope can be used for the following indications:

- TN staging of upper digestive tract malignant tumors
- Upper digestive tract submucosal lesions
- Biliary and pancreatic system diseases
- Other diseases: gastric and duodenal ulcer, esophagual and gastric varices, gastric malignant lymphoma, duodenal papilla diseases, etc.

1.1.2 Contraindications

During clinical examination, the following contraindications should be specially paid attention to:

Relative contraindications

- Mild cardiopulmonary diseases (such as mild cardiac dysfunction, sinus tachycardia, atrial fibrillation and other mild arrhythmia)
- Severe hypertension
- Giant diverticulum of esophagus or esophageal varices
- Severe esophageal, spinal column and thorax deformity

Absolute contraindications

- Severe cardiopulmonary diseases (such as severe cardiac dysfunction, severe pulmonary dysfunction and severe arrhythmia)
- Shock or other severe patients
- Suspected or confirmed upper digestive tract perforation or perforation acute phase
- Mental disorders and non-cooperated patients
- Acute phase of gastric and esophageal chemical burns

1.2 Product Compatibility

The endoscope is used with the image processor (HD-550/HD-550Exp/HD-550Pro/HD-550S/HD-510/HD-500Plus), light source (VLS-55Q/VLS-55T/VLS-51T/VLS-51D) and ultrasound system (P60 Exp/P60/P60 Pro/P60 CV/P60S/P60 VO) provided by the manufacturer.

1.3 Safety Precautions

Read and understand all precautions in this manual before attempting to use the endoscope. Keep this manual with the endoscope at all times. Periodically review the procedures for operation and safety precautions.

1.3.1 Electrical Safety

- If any qualifications for an operator are developed by the medical administration or other official institutions, the operator should meet the qualification requirements. Otherwise, only the medical staff approved by the hospital safety administrator or by the person who is in charge of the department can perform endoscopy.
- Only the personnel authorized or trained by the company is allowed to maintain the endoscope. Any unauthorized personnel should not assemble or disassemble the device.
- If hospital administrators or official institutions (such as endoscopic academic institutions) have established an application standards for endoscopy and endoscopic treatment, follow the standards.
- Do not use the system with flammable anaesthetics (category AP) or flammable anaesthetics with oxidants (category APG).
- Evaluate the property, purpose, benefits and risks (including medical risks, unknown risks and the possibility) thoroughly before performing endoscopy. Perform endoscopy only when benefit outweigh risks.
- Make a detailed explanation to the patient about the benefits and risks of the endoscopy and endoscopic diagnosis, as well as the methods to be applied.
- Only perform endoscopy with the patient's consent.
- Evaluate potential benefits and risks at all times during endoscopy and endoscopic diagnosis. Stop the endoscopy immediately and take appropriate measures when risks outweigh benefits.
- The operator should be capable of performing endoscopy and endoscopic diagnosis in accordance with the standards and principles developed by the endoscopic academic institutions. Therefore, endoscopic clinical technologies are not detailed in this manual.
- Do not operate the device in an atmosphere containing flammable gases such as anesthetic gases, hydrogen, and ethanol, because there is a danger of explosion.
- The device is not strictly cleaned and disinfected in the factory. Therefore, the operator should strictly perform cleaning and disinfection processes described in this manual before use.
- Prepare a spare endoscope to avoid an examination interruption caused by the device malfunction.
- The performance of the device and its accessories may be degraded over time. Perform periodic maintenance as described in this manual to ensure the safety of the device.

- Maintain and store the device as described in this manual after use. Improper maintenance and storage may cause cross infection, damage to the device or performance degradation.
- To ensure the device performance, maintain the device periodically (not more than a year), and ensure that the grounding of the device is correct and complies with the safety requirements.
- Do not use the endoscope in electrosurgeries.
- Do not use the endoscope on the body surface of a patient.
- Connect the earth connector only before powering on the system. Disconnect the grounding cable only after powering off the system. Otherwise, electrical shock may occur.
- Connect the equipotential grounding cable properly before plugging the power plugs of the image processor and the ultrasound system respectively into the socket.
- Within the environment that is 1.8 meters (6 feet) around a patient, connect peripherals to the auxiliary power outlet which is capable of isolation protection; or, power the peripherals by the auxiliary output cable or the isolation transformer complied with EN/IEC 60601-1, or the power input of the same safety level.
- Accessory equipment connected to the analog and digital interfaces should be certified according to the respective EN/IEC standards (for example, EN/IEC 62368-1 data processing equipment and EN/IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standards EN/IEC 60601-1.
- Parts of non-medical electrical equipment in the patient environment that, after the removal of covers, connectors, or other parts without use of a tool, may be contacted during routine maintenance, calibration, etc. You should not touch the referred parts and the patient simultaneously.
- Do not use the endoscope with other high-frequency accessories.
- The endoscope is MR (Magnetic Resonance) unsafe.
- Do not use the endoscope with WPT (wireless power transfer) and 5G equipment.
- Although the endoscope includes the endocavitary transducer, but the endoscope is not allowed to be used for vitro examination. If the transducer is activated outside the patient's body, it would not comply with electromagnetic compliance requirements and may cause harmful interference with other equipment in the environment.
- Connect the potential equalization lead wire to the system before connecting the compatible image processor and ultrasound system power plugs to the electrical outlets.

1.3.2 Accessory Safety

- Use the device carefully. If any part of the device is damaged, stop using the immediately.
- The balloon is not included in the endoscope. If necessary, use a legally marketed balloon in accordance with local laws and regulations. Contact with natural rubber latex may result in a severe anaphylactic reaction in persons sensitive to the natural latex protein. Read package labeling to determine latex content before use. For details, refer to the FDA's March 29, 1991 Medical Alert on latex products.
- Only the accessories provided or approved by the manufacturer can be used. Using other accessories may cause damage to the device and the expected performance described in this manual cannot be achieved.
- Do not reuse the single-use accessory.

Do not disconnect the ultrasound system connector from ultrasound system in real-time scan mode. Otherwise, it may result in damage to the endoscope.

1.3.3 Biohazard Considerations

- Patient debris and chemicals for cleaning, disinfection or sterilization are potentially dangerous. The operator should wear the medical protective clothing, goggle or gloves to minimize the risk of cross-contamination and disease infection. Take off the medical protective barriers before leaving the cleaning and disinfection room.
- The operator should take cautions to prevent the direct contact with the disinfectant or patient samples. If your skin is stained with them, thoroughly wash the area immediately with clean water. If the fluid comes into your eyes, immediately flush the eyes with water and seek the oculist for help.
- Dispose of the disinfectant, cleaner, and waste in accordance with local laws or regulations. For details, consult the relevant manufacturer or their local distributors.

1.3.4 Acoustic Power Principle

- Perform ultrasound procedures prudently under the guidance of the ALARA (as low as reasonably achievable) principle. Expose the patient to only the lowest practical transmit power levels in the shortest possible period to achieve a satisfactory diagnosis.
- Do not continuously scan the same part of a patient or expose the patient to prolonged scanning. Doing so may harm the patient.
- Although the output power is automatically controlled for the selected applications, high TI values should be kept to a minimum.
- You should be familiar with the performances and operations of the system, observe the ultrasound output parameters on the screen all the time.

1.3.5 Biological Safety

Diagnostic ultrasound is recognized as being safe, but the possibility of biological effects exists when using it in high exposure levels and long exposure times. Thus ultrasound should be used in a prudent manner to provide medical benefit to the patient.

1.3.6 ALARA

It is required to practice ALARA when using ultrasound energy. Practicing ALARA ensures that the total energy level is controlled below a low enough level at which bioeffects are not generated while diagnostic information is being accumulated. The total energy is controlled by output intensity and total radiation time. The output intensity necessary for examinations differs depending on the patient and the clinical case.

Not all examinations can be performed with an extremely low level of acoustic energy. Controlling the acoustic level at an extremely low level leads to low-quality images or insufficient Doppler signals, adversely affecting the reliability of the diagnosis. However, increasing the acoustic power more than necessary does not always contribute to an increase in quality of information required for diagnosis, rather increasing the risk of generating bioeffects.

The operator should take responsibility for the safety of the patient and utilize the ultrasound deliberately. Deliberate use of the ultrasound means that output power of the ultrasound should be selected based on ALARA. Additional information regarding the concept of ALARA and the possible bioeffects of Ultrasound are available in a document from the AIUM (American Institute of Ultrasound Medicine) title “Medical Ultrasound Safety”.

1.3.7 Mechanical and Thermal Indices

The display of the system consists of two parts: Thermal Index (TI) and Mechanical Index (MI).

■ **MI/TI Explanation**

In October 1987, the American Institute of Ultrasound in Medicine (AIUM) ratified a report prepared by its Bioeffects Committee (Bioeffects Considerations for the Safety of Diagnostic Ultrasound, J Ultrasound Med.,Sept. 1988: Vol. 7, No. 9 Supplement), sometimes referred to as the StoweReport, which reviewed available data on possible effects of ultrasound exposure. Another report “Bioeffects and Safety of Diagnostic Ultrasound” dated January28, 1993, provides more current information.

- **Mechanical Index (MI)**

  Mechanical bioeffects are threshold phenomena that occur when a certain level of output is exceeded. The threshold level varies, however, with different types of tissue. The potential mechanical bioeffects varies with peak pressure and ultrasound frequency. The MI accounts for these two factors. The higher the MI value, the greater the likelihood of mechanical bioeffects occurring. There is no specific MI value that means that a mechanical effect is actually occurring. The MI should be used as a guide for implementing the ALARA principle.

- **Thermal Index (TI)**

  The TI value informs the operator about the conditions that might lead to an increase in temperature on the surface of the body, within the body tissue, or at the point of focus of the ultrasound beam on bone. That is, the TI value informs the operator about the potential temperature rise in body tissue. It is an estimate of temperature increase in body tissue with specific properties. The actual amount of any temperature rise is influenced by factors such as tissue type, vascularity, mode of operation and others. The TI value should be used as a guide for implementing the ALARA principle.

  Depending on the examination and type of tissue involved, TI could be one of three types:

  – Soft Tissue Thermal Index (TIS) is used when imaging soft tissue only, it provides an estimate of potential temperature rise in soft tissue.
  – Bone Thermal Index (TIB) is used when bone is near the focus of the image as in the third trimester, it provides an estimate of potential temperature rise in the bone or adjacent soft tissue.
  – Cranial Bone Thermal Index (TIC) is used when bone is near the skin surface as in transcranial examination, it provides an estimate of potential temperature rise in the bone or adjacent soft tissue.

■ **MI/TI Display**

TI and MI values are displayed in real time on the screen. The operator should observe these index values during examinations and ensure that exposure time and output values are maintained at the minimum amounts needed for effective diagnosis.

The MI and TI precision is 0.1.

1.3.8 Transducer Surface Temperature Limits

For probes intended for internal applications, e.g. the endocavitary probe or transesophageal probe, the surface temperature of the probe may change by adjusting system parameters.

1.3.9 Ultrasound Acoustic Output Power

The ultrasound acoustic output power can be adjusted through changing the imaging mode, output power ratio, probe scan depth, focal position, sector width or sector angle, and frequency, etc. For more information, refer to the ultrasound system user manual.

1.4 Safety Symbols

The following table is provided for your identification of important symbols located in labels on the endoscope.

Symbol	Meaning
	Refer to instruction manual
	Caution
	Manufacturer
	Serial Number
IPX7	Degree of protection against harmful liquid (Protection against short time immersion)
	Lock
	Unlock
	Type BF applied part
	Medical device
	Model number
	Country and date of manufacture; CHN is the country code of China.
	Unique device identifier
	MR unsafe
	Non-sterile
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

Symbol	Meaning
	Stacking limit by number
	Fragile, handle with care
	Keep away from rain
	This way up
	This symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

2 Overview

To ensure the performance and availability of the endoscope, the operator should become thoroughly familiar with the operations of the endoscope and its accessories before use.

2.1 Packing

Make sure that all the following items are in the packaging box of the device. If the endoscope is damaged, any component is missing or a problem is found, do not use the endoscope and contact the local distributor of the manufacturer.

- Ultrasonic gastrovideoscope
- Biopsy valve
- Injection tube
- Channel plug

Others: See the Packing List in the packaging box.

2.2 Component Introduction

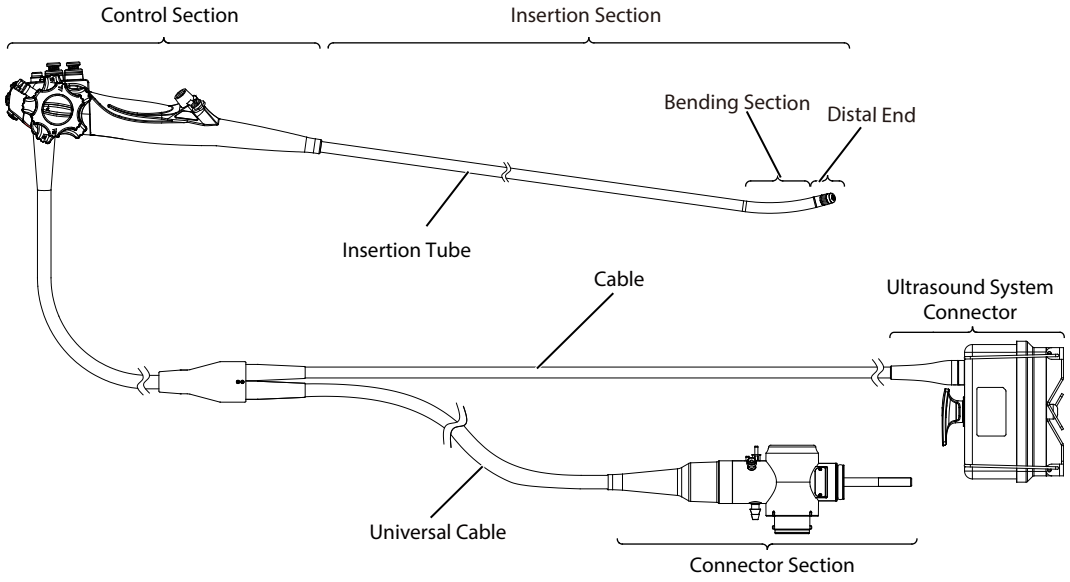


Figure 2-1 Endoscope

2.2.1 Connector Section and Ultrasound System Connector

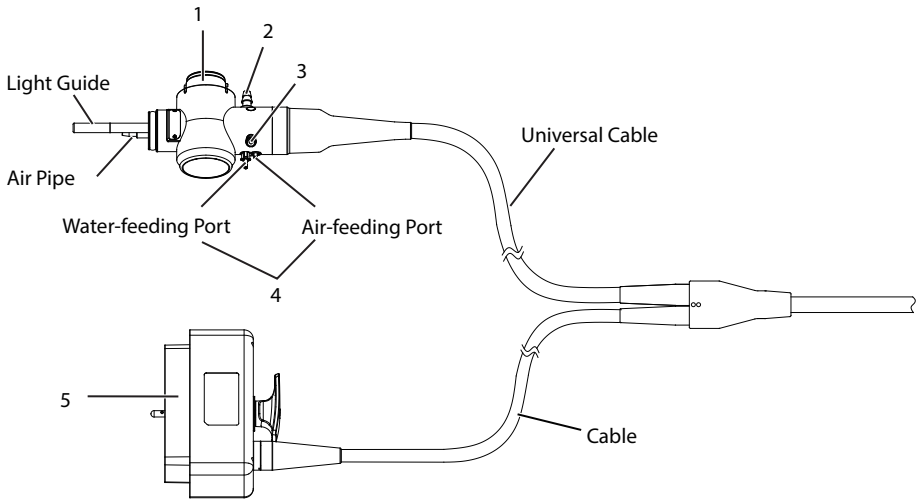


Figure 2-2 Connector Section and Ultrasound System Connector

No.	Part Name	Descriptions
1	Electrical Connector	Used for connecting the endoscope cable.
2	Suction Port	Used for connecting to the suction pump through the suction tube.
3	Reserved Terminal	/
4	Air/Water-feeding Port	Used for connecting to the water bottle to feed water/air to the distal end.
5	Ultrasound System Connector	Used for connecting to the ultrasound system.

2.2.2 Control and Insertion Sections

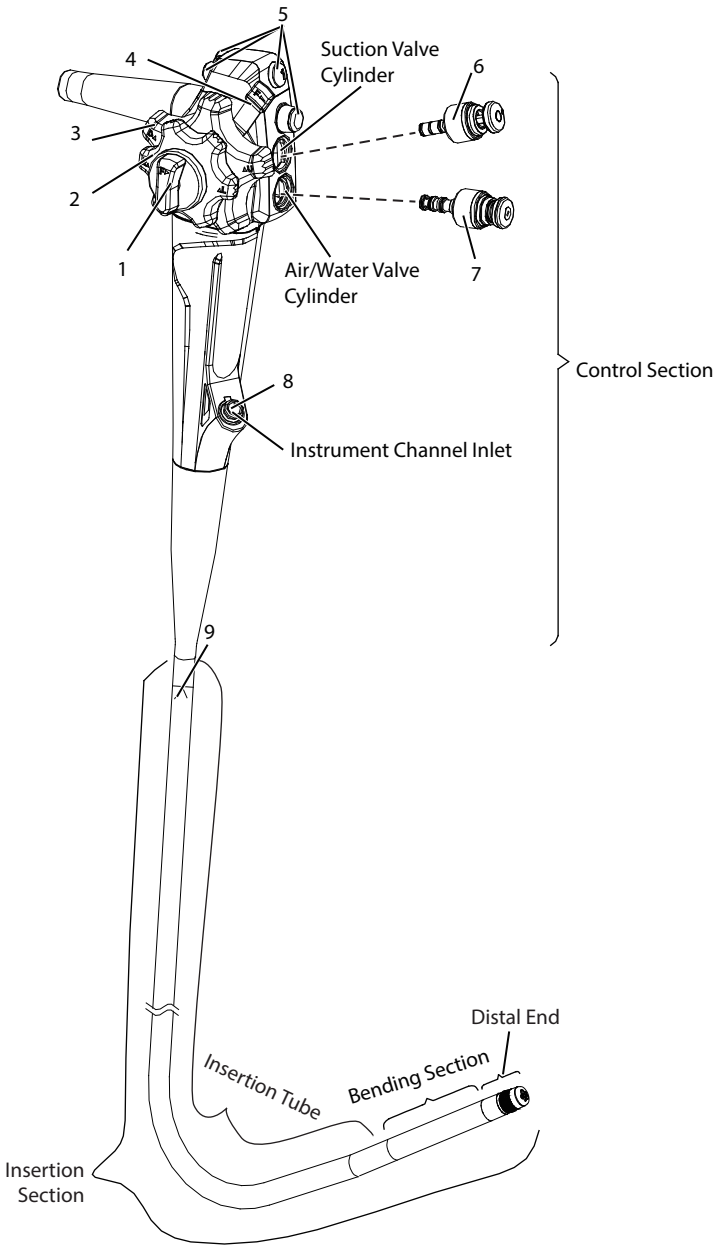


Figure 2-3 Control and Insertion Sections

No.	Part Name	Descriptions
1	Left/Right Angulation Lock (**F** ▶)	● Rotate it clockwise to free the bending section in the left or right direction. ● Rotate it anticlockwise to lock the bending section at the current angle.
2	Left (▲**L**)/Right (**R** ▲) Angulation Control Knob	● Rotate it clockwise to make the bending section move right. ● Rotate it anticlockwise to make the bending section move left.
3	Up (▲**U**)/Down (**D** ▲) Angulation Control Knob	● Rotate it clockwise to make the bending section move down. ● Rotate it anticlockwise to make the bending section move up.
4	Up/Down Angulation Lock (**F** ▶)	● Rotate it clockwise to free the bending section in the up or down direction. ● Rotate it anticlockwise to lock the bending section at the current angle.
5	Remote Buttons (0-3)	Set the functions of the four buttons through the image processor connected with the endoscope.
6	Suction Valve	● Press it slightly to aspirate liquid, debris or gas from the patient's body. ● Press it to the end to aspirate sterile water from the balloon.
7	Air/Water Valve	● Cover the hole on the valve with a finger to feed air. ● Press it slightly to feed water to clean the objective lens, and the air and water can remove the blood, debris or mucous membrane adhering to the objective lens. ● Press it to the end to inject sterile water into the balloon.
8	Instrument Channel	This channel should be used with the biopsy valve and the functions are as follows. ● Used to feed liquid to the distal end of the endoscope. ● Used for the endotherapy accessory. ● Used as a part of the suction channel.
9	Insertion Limit Mark	Indicates the maximum length of the insertion section that can be inserted into the patient's body.

2.2.3 Distal End

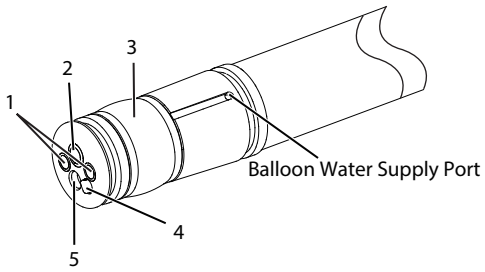


Figure 2-4 Distal End

No.	Part Name	Descriptions
1	Light Guide Lens	Light is transmitted through these lenses to assist endoscopic image observation.
2	Objective Lens	Used for transmitting the optical signals of the tissue image to be observed to the sensor.
3	Transducer	Used for transmitting and receiving ultrasonic waves.
4	Air/Water Nozzle	Used as an outlet for feeding air or water.
5	Instrument Channel Outlet	Used as an instrument (such as biopsy forceps) outlet, liquid feeding outlet or suction inlet.

3 Preparations

Preparations are necessary before use, which include inspecting and connecting the endoscope and accessories.

Strictly follow the descriptions below to inspect the endoscope and accessories before each use and inspect the peripherals used with the endoscope by following their own user manuals. In case of a problem, solve the problem by referring to Chapter 7 Troubleshooting. If the problem persists, please contact the local distributor of the manufacturer.

WARNING
- The endoscope is not cleaned and disinfected in the factory. Therefore, the operator should clean, disinfect or sterilize the endoscope according to Chapter 5 Cleaning, Disinfection and Sterilization.
- For the safety of the patient and operator, do not use the malfunctioning endoscope.

3.1 Inspecting the Endoscope

Before inspection, clean, disinfect or sterilize the endoscope as described in Chapter 5 Cleaning, Disinfection and Sterilization, and then remove the waterproof cap and protective cover from the electrical connector and ultrasound system connector respectively.

3.1.1 Inspecting the Appearance

CAUTION Exercise extreme caution while inspecting the transducer. Avoid damaging the transducer.

Perform the following inspections to inspect the appearance of the endoscope:

- Ensure that there is no crack and dent on the ultrasound system connector and cable.
- Ensure that there is no deformed or broken pins inside the ultrasound system connector.
- Ensure that there is no dent, scratch, swelling or breakage on the transducer surface.
- Ensure that there is no excessive scratch, deformation or slack on the control section or the connector section.
- Ensure that there is no abnormal bending, twist or other abnormality on the boot or the insertion section near to the boot.
- Touch the entire insertion section (including the bending section and distal end) backwards and forwards gently to ensure that there is no dent, bulge, swelling, scratch, breakage, deformation, adhesion of foreign bodies, component missing or peeling.
- Ensure that there is no scratch or breakage on the objective lens, light guide lenses and transducer on the distal end, and no spot or crack on the edges of the objective lens.
- Ensure that there is no dent, protrusion or bulge on the air/water nozzle and the instrument channel outlet on the distal end.
- Hold the position 20 cm from the distal end and the midpoint of the bending section. Push and pull gently to ensure that junction between the bending section and the insertion section is not loose.

3.1.2 Inspecting the Flexibility

WARNING Do not use the endoscope if any angulation control knob is too loose or tight. Otherwise, it may result in injury, bleeding or perforation to the patient.

Perform the following inspections only when the bending section is free.

■ To inspect the bending angle

Hold the insertion section with your hands and bend it to a semicircle to ensure that the entire insertion section is flexible and can be smoothly bent.

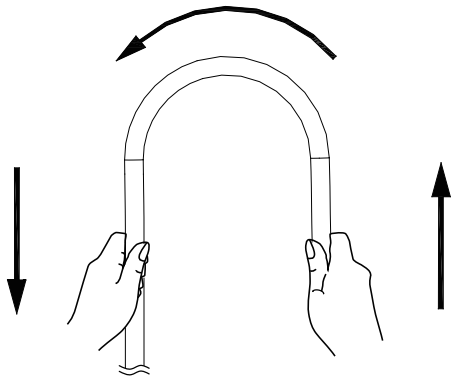


Figure 3-1 Inspecting the Bending Angle

■ To inspect the angulation lock

Perform the following steps.

1. Rotate the up/down and left/right angulation locks clockwise until they stop to ensure that the bending section is free.

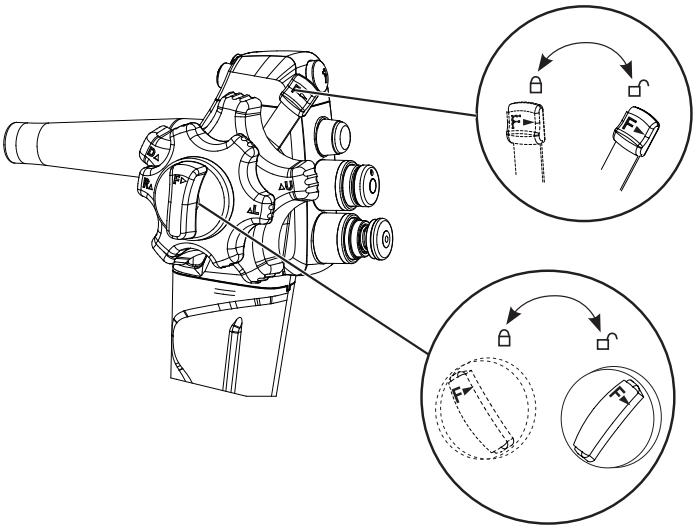


Figure 3-2 Inspecting the Angulation Lock

2. Rotate the up/down and left/right angulation control knobs respectively until they stop. Ensure that the bending section can be flexibly and properly bent, and slowly restore to almost a straight condition after the knobs are loosened.
3. When the up/down and left/right angulation control knobs are rotated to their original positions, ensure that the bending section restores to a straight condition.

■ **To inspect up/down angulation**

Perform the following steps.

1. Rotate the up/down angulation lock clockwise until it stops to free the up/down angulation control knob, and then rotate the up/down angulation control knob clockwise and anticlockwise respectively until it stops. Ensure that the bending section can move down and up and reach its maximum angle.
2. Rotate the up/down angulation lock anticlockwise until it stops to lock the up/down angulation control knob, and then loosen the knob. Ensure that the bending section can be fixed at the current angle.
3. When the bending section is fixed, rotate the up/down angulation lock clockwise until it stops to free the up/down angulation control knob, and then loosen the knob. Ensure that the bending section can restore to almost a straight condition.

■ **To inspect left/right angulation**

Perform the following steps.

1. Rotate the left/right angulation lock clockwise until it stops to free the left/right angulation control knob, and then rotate the left/right angulation control knob clockwise and anticlockwise respectively until it stops. Ensure that the bending section can move to the left and right and reach its maximum angle.
2. Rotate the left/right angulation lock anticlockwise until it stops to lock the left/right angulation control knob, and then loosen the knob. Ensure that the bending section can be fixed at the current angle.
3. When the bending section is fixed, rotate the left/right angulation lock clockwise until it stops free the left/right angulation control knob, and then loosen the knob. Ensure that the bending section can restore to almost a straight condition.

3.2 Inspecting and Connecting the Accessories

The accessories include the ones for clinical examination and the ones for cleaning, disinfection and sterilization. This section only introduces the ones for clinical examination. For the information of other accessories, please refer to Section 5.2 Cleaning, Disinfection and Sterilization Tools.

3.2.1 Air/Water Valve

Clean, disinfect or sterilize the air/water valve before inspection. For details, refer to Chapter 5 Cleaning, Disinfection and Sterilization.

Ensure that the hole on top of the air/water valve is not blocked. Otherwise, air will be continuously fed into the patient's body and it may result in personal injury.

■ **Inspection**

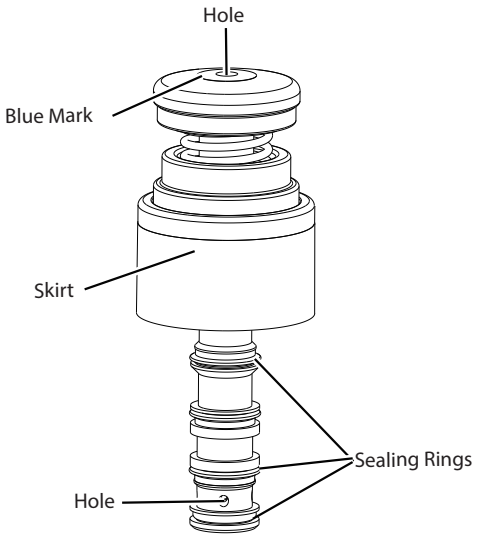


Figure 3-3 Air/Water Valve

Perform the following inspections before using the air/water valve.

- Ensure that the holes are not blocked.
- Ensure that the valve is not deformed or damaged.
- Ensure that the sealing rings are not cracked, scratched or damaged.

■ **Installation**

Install the air/water valve to the air/water valve cylinder of the endoscope properly.

NOTE:

- *Do not apply lubricant on the air/water valve. Otherwise, the sealing ring may bulge and cause valve malfunction.*
- *The air/water valve may be sticky for the initial use. After being pressed and released several times, it can be operated smoothly.*
- *Blue mark is used to distinguish this valve from the suction valve of the endoscope.*

3.2.2 Suction Valve

■ **Inspection**

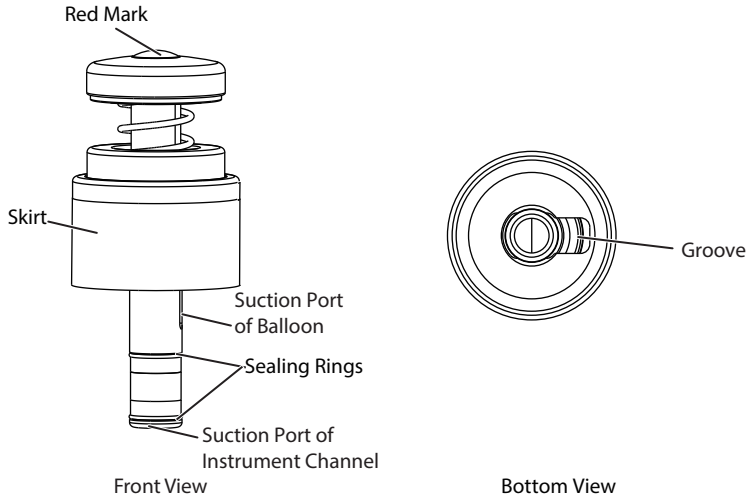


Figure 3-4 Suction Valve

Perform the following inspections before using the suction valve.

- Ensure that the suction port of instrument channel is not blocked.
- Ensure that the suction valve is not cracked, deformed or damaged.
- Ensure that the sealing rings are not cracked, scratched or damaged.

■ **Installation**

Align the groove on the skirt of the suction valve with the lug boss on the suction valve cylinder and press the suction valve until it stops. Ensure that the suction valve cannot be rotated.

NOTE:

- *Noise may be heard during use if the suction valve is dry, which does not affect the valve function.*
- *Red mark is used to distinguish this valve from the air/water valve of the endoscope.*

3.2.3 Biopsy Valve

WARNING

- The biopsy valve is replaceable. It can be used for at least 100 times with normal use. The operator should ensure that the cap of the biopsy valve is intact before each use. If any abnormality is found, replace the biopsy valve immediately.
- Using a damaged biopsy valve may degrade the suction performance of the endoscope, which may result in the spray or leakage of patient's debris or body fluid and disease infection.

■ **Inspection**

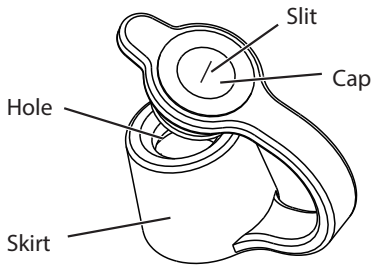


Figure 3-5 Biopsy Valve

Perform the following inspections before using the biopsy valve.

- Ensure that valve is not deformed, cracked and damaged.
- Cover the cap, and ensure that the main body and the cap are connected firmly.

■ **Installation**

Perform the following steps.

1. Cover the cap and ensure that the cap is firmly connected to the main body.

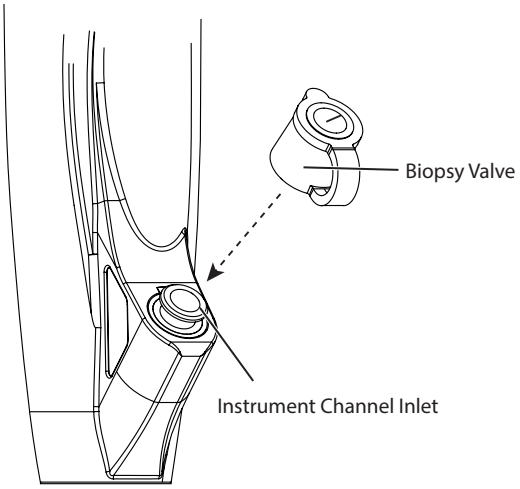


Figure 3-6 Installing the Biopsy Valve

2. Install the biopsy valve to the instrument channel inlet of the endoscope properly.

3.2.4 Balloon

■ Inspection

WARNING Only use the balloon provided or recommended by the manufacturer.

Ensure that there is no crack, deformation or other damage on the balloon.

The recommended balloon specifications are as follows.

- Total length: 21.0 mm
- Inner diameter: Φ 12.6 mm
- Wall thickness: 0.12 mm
- Maximum amount of fed water: 5 mL

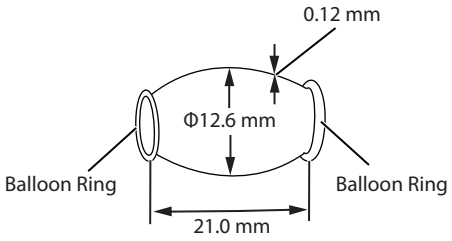


Figure 3-7 Balloon

■ Installation

CAUTION Inject sterile water into the balloon and ensure that the balloon diameter does not exceed 3 cm. Excessive sterile water may result in damage to the balloon.

Perform the following steps.

1. Dampen the balloon and the distal end of endoscope with sterile water.

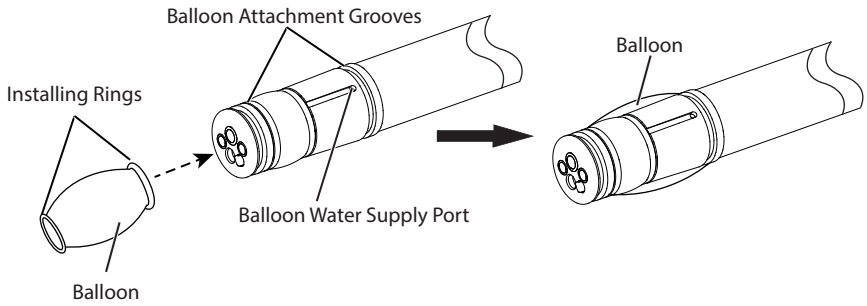


Figure 3-8 Installing the Balloon

2. Press the air/water valve to the end, until sterile water flows out from the balloon water supply port.
3. Install one installing ring of one balloon end to the distal end.
4. Slide the balloon carefully, until both the installing rings are installed into the balloon attachment grooves.

■ To drain the balloon

CAUTION If bubbles in the balloon cannot be removed, you can take down the balloon and install it again in the sterile water.

Perform the following steps.

1. Ensure that the balloon is installed to the distal end correctly.
2. Keep the distal end downward, and press the air/water valve to the end to inject sterile water into the balloon. Ensure that the balloon diameter does not exceed 3 cm.
3. Press the suction valve to the end to remove water in the balloon.
4. Repeat step 2 and step 3 to drain the balloon, until all bubbles in the balloon are removed.

3.3 Connecting the Endoscopy System

NOTE:

- *Before connecting the system, please power off all peripherals.*
- *Ensure that the peripherals are properly connected to the endoscope. For the detailed description about inspection and connection of the peripherals, refer to relevant user manuals.*
- *The compatible monitor (SonoScape Medical Corp Model: DSH-24W) is with the size of 24 inches, the resolution of 1920 × 1200, the contrast of 1000:1, and the input interfaces of DVI, VGA, SDI, S-VIDEO and VIDEO. The DVI, as the primary output, is used to transmit the video signal from the image processor to the monitor.*

Connect the endoscopy system, as shown in Figure 3-9.

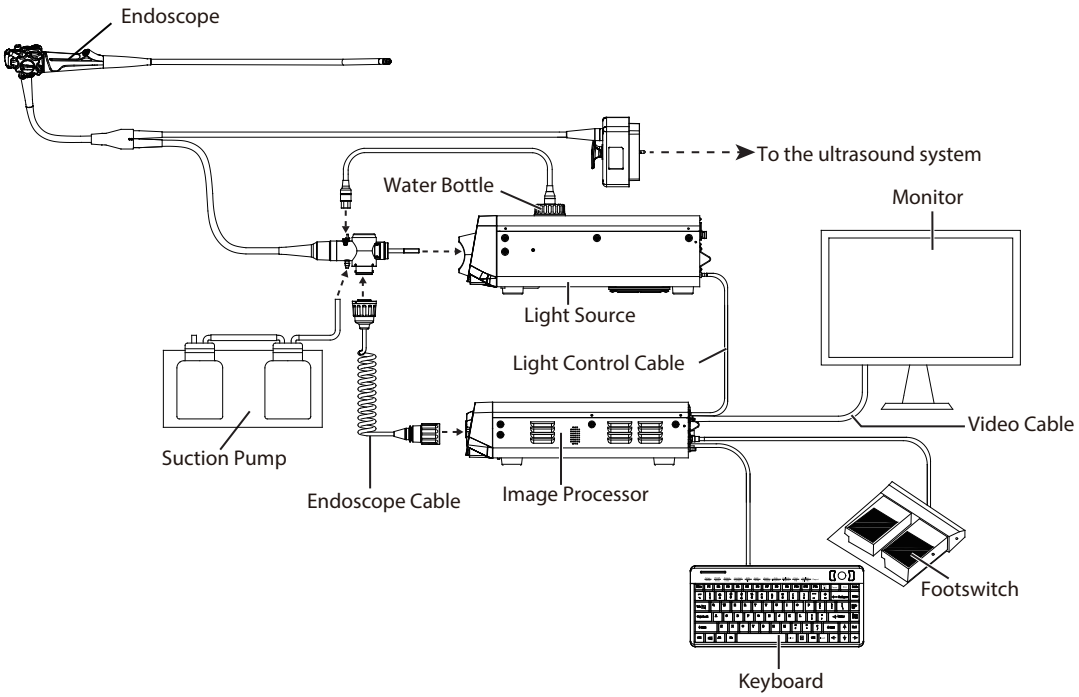


Figure 3-9 Connecting the Endoscopy System

3.3.1 Connecting the Ultrasound System

CAUTION Do not connect or disconnect the ultrasound system connector from the ultrasound system in real-time scan mode. Otherwise, it may result in damage to the endoscope.

Perform the following steps.

1. Rotate the locking lever on the ultrasound system connector anticlockwise to 🔓 position, and then insert the connector into the probe port on the ultrasound system firmly.

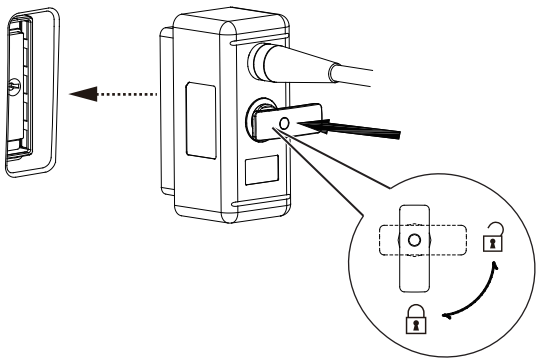


Figure 3-10 Connecting the Ultrasound System

2. Rotate the locking lever clockwise to 🔒 position, and lock the ultrasound system connector securely.

3.3.2 Connecting the Light Source

Insert the light guide and air pipe of the endoscope into the endoscope port of the light source firmly.

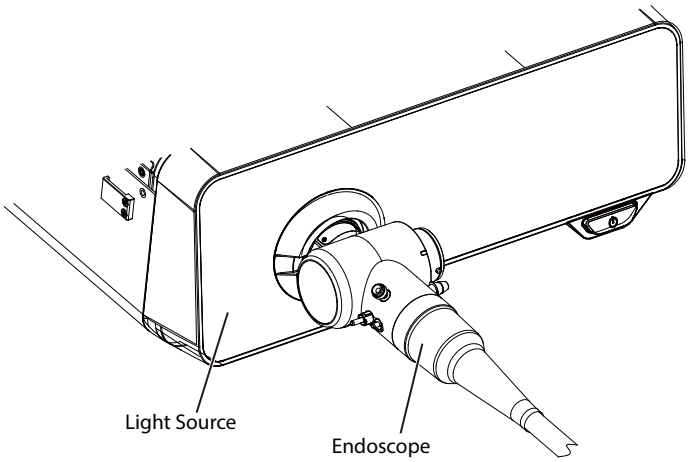


Figure 3-11 Connecting the Light Source

3.3.3 Connecting the Water Bottle

CAUTION The water bottle should be installed in the water bottle bracket at the right side of the light source. Do not place the water bottle casually. Otherwise, the water-feeding pipe would leakage, causing malfunction.

Perform the following steps.

1. Connect the water-feeding connector of the water bottle connector at the angle of 90° to the water-feeding port on the connector section firmly.

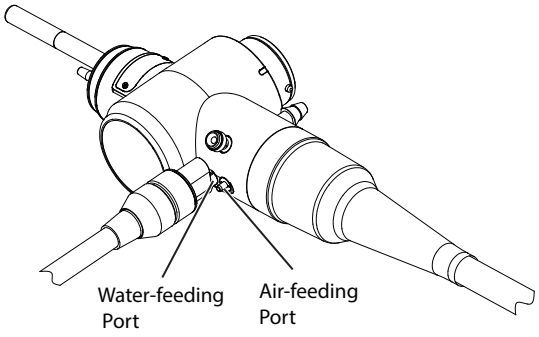


Figure 3-12 Connecting the Water-feeding Port

2. Rotate the water bottle connector 90° clockwise until the air-feeding connector of the water bottle connector is aligned with the air- feeding port on the connector section. Install the water bottle connector firmly.

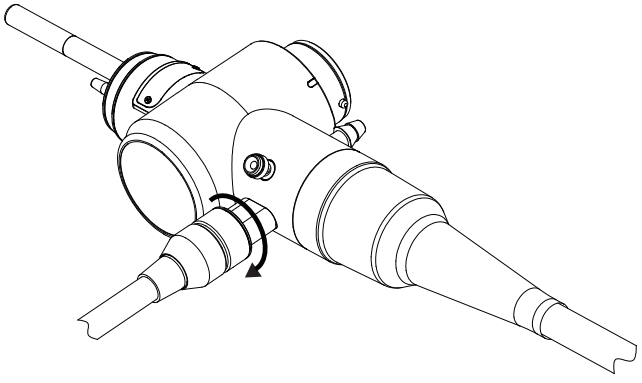


Figure 3-13 Connecting the Air-feeding Port

3. Ensure that water bottle connector is correctly connected and cannot be rotated.

3.3.4 Connecting the Endoscope Cable

The endoscope cable is shown in Figure 3-14.

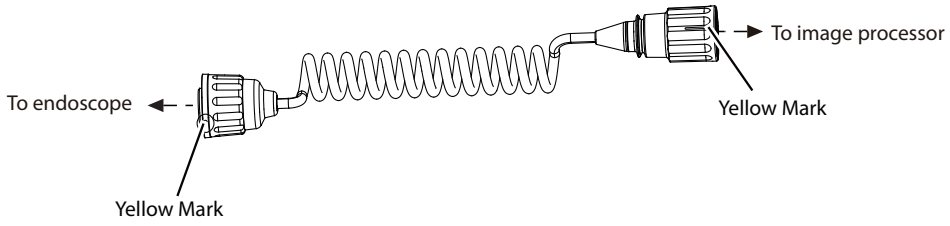


Figure 3-14 Endoscope Cable

Perform the following steps.

1. As shown in Figure 3-15, align the yellow mark on the endoscope cable connector with the yellow mark 1 on electrical connector of the endoscope, and insert the connector into the endoscope.

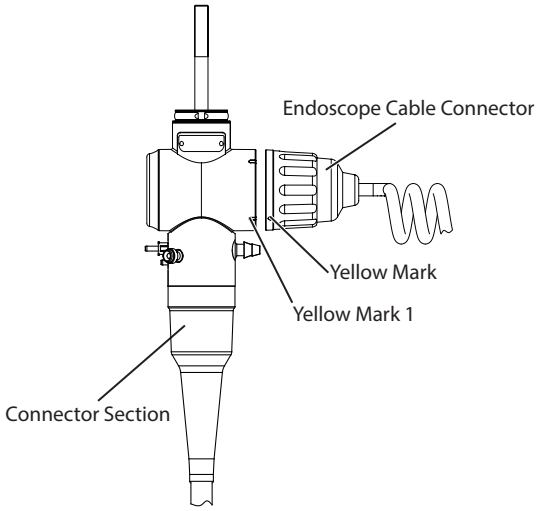


Figure 3-15 Connecting the Endoscope Cable 1

2. As shown Figure 3-16, rotate the endoscope cable connector clockwise, and align the yellow mark on the connector with the yellow mark 2 on the electrical connector of the endoscope until a click is heard.

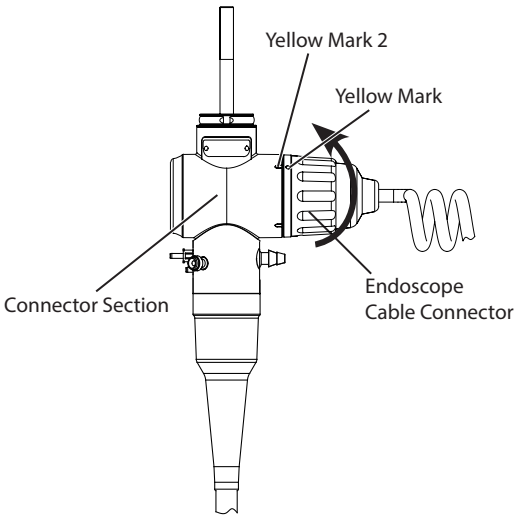


Figure 3-16 Connecting the Endoscope Cable 2

3.3.5 Connecting the Image Processor

NOTE:

- *Do not use the endoscope cable forcibly to avoid malfunctions.*
- *Do no touch the pins inside the connector of the endoscope cable to avoid damaging the image processor.*

Perform the following steps.

1. Align the yellow mark on the endoscope cable connector with the yellow mark 1 on the connector port of the image processor. Insert the connector into the connector port firmly.

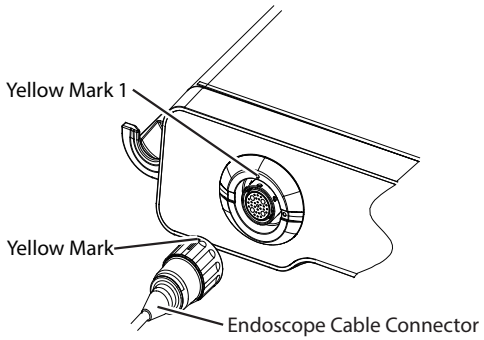


Figure 3-17 Aligning the Yellow Mark 1

2. Rotate the connector clockwise and align the yellow mark on the connector with the yellow mark 2 on the connector port until a click is heard.

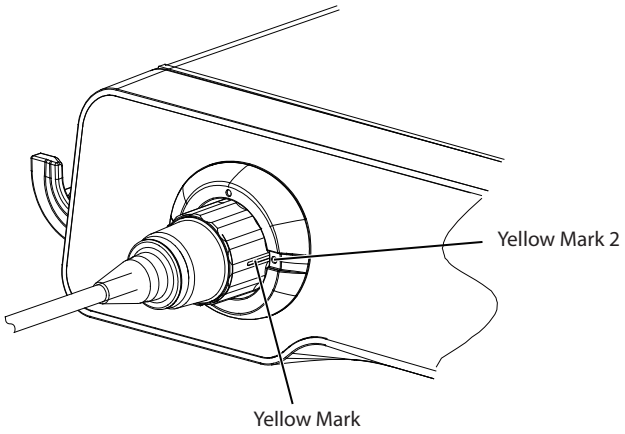


Figure 3-18 Installing the Endoscope Cable

3.3.6 Connecting the Suction Pump

- If the suction tube is not connected firmly, patient debris may leak from the tube during use and cause disease infection, suction degradation and damage to the endoscope.
- If any malfunction occurs during the examination, please turn off the suction pump immediately.

Connect the suction tube to the suction port of the endoscope firmly.

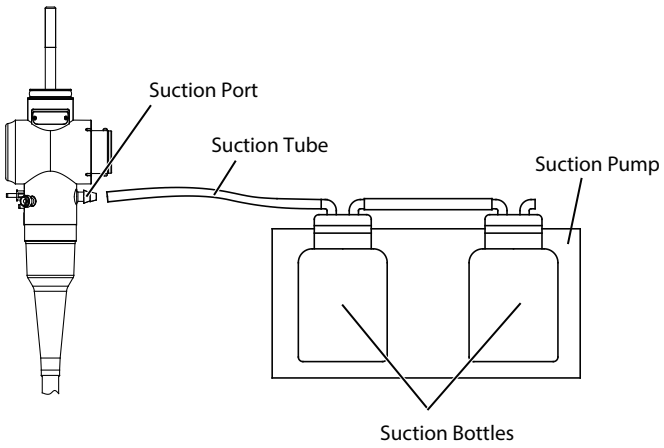


Figure 3-19 Connecting the Suction Pump

3.4 Inspecting the Endoscopy System

3.4.1 Inspecting the Endoscopic Image

WARNING Do not stare at the light emitted from the distal end. Otherwise, it may result in injury to eyes.

Perform the following steps.

1. Power on the light source, the image processor and the monitor.
2. Turn on the lamp of the light source and ensure that light emits from the distal end.
3. Place the distal end 10 mm away from your palm, and observe the image on the monitor while adjusting the brightness of the image by using relevant buttons on the image processor and the monitor.
4. Adjust the observation angle of the endoscope, and ensure that the image is normally displayed and does not disappear suddenly.

NOTE:

If the endoscopic image is unclear because the objective lens is dirty, use a soft lint-free cloth dampened with 75% ethyl alcohol to wipe the lens.

3.4.2 Inspecting the Ultrasonic Image

Perform the following steps.

1. Power on the ultrasound system.
2. Select the corresponding probe and the diagnosis mode.
3. Immerse the distal end into a container filled with water.
4. Observe the ultrasonic image on the monitor of the ultrasound system, and ensure that the image is clearly displayed.

3.4.3 Inspecting the Remote Buttons

WARNING Even if the remote buttons are not intended to be used, they also need to be inspected before performing an examination. Otherwise, an abnormal function may occur and result in injury, bleeding or perforation to the patient.

Press each remote button and check if the preset function can be normally achieved.

3.4.4 Inspecting the Air-feeding Function

WARNING Use sterile water to inspect the air-feeding function to avoid disease infection.

NOTE:

When the distal end is immersed to a depth less than 10 cm, a few bubbles may appear even if the air/water valve is not operated. This is a normal phenomenon.

Perform the following steps.

1. Press the **AIR** button on the light source to turn on the air pump and air is emitted.
2. Immerse the distal end of the endoscope in a container filled with sterile water to a depth of 10 cm. Do not operate the air/water valve and ensure that no bubble is generated from the air/water nozzle.
3. Cover the hole on the air/water valve with your finger to feed air, and ensure that continuous bubbles are generated from the air/water nozzle.

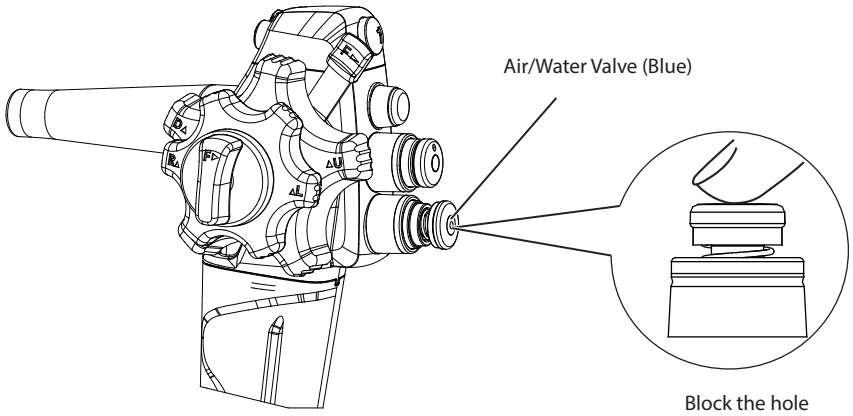


Figure 3-20 Inspecting the Air-feeding Function

4. Release your finger and ensure that no bubble is generated from the air/water nozzle.

3.4.5 Inspecting the Water-feeding Function

WARNING Use sterile water to inspect the water-feeding function to avoid disease infection.

The water-feeding function is achieved by using the air/water valve.

- Slightly press the valve to feed water for the distal end.
- Press the valve to the end to feed water for the balloon.

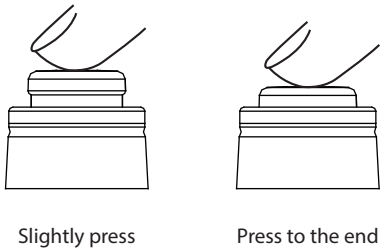


Figure 3-21 Inspecting the Water-feeding Function

Perform the following steps.

1. Slightly press the valve to feed water. Observe the endoscopic image on the monitor, and ensure that water flows over the objective lens.

2. Press the valve to the end to feed water to the balloon, and ensure that water flows from balloon water supply port.
3. Release your finger and ensure that no water flows out, and the air/water valve restores to its original position smoothly.
4. Slightly press the air/water valve again to feed water. Release the valve and cover the hole to feed air. Ensure that the residual water can be cleared away from the objective lens, and the endoscopic image on the monitor is clear.

NOTE:

- *If the air/water valve is pressed for the first time, it may take a few seconds before water is fed.*
- *If the air/water valve restores to the original position very slowly after water-feeding, the operator should remove the air/water valve and moisten the sealing rings with sterile water.*

3.4.6 Inspecting the Suction Function

WARNING

- If the biopsy valve is leaky, patient debris and body liquid could leak out and cause disease infection.
- If the suction valve is not operated smoothly, it may result in suction malfunction and personal injury. Please reinstall the suction valve or change a new one. If the problem still exists after the replacement, the endoscope may be malfunctioning. Please stop using the endoscope and contact the local distributor of the manufacturer.

The suction function is achieved by using the suction valve.

- Slightly press the valve to aspirate liquid, debris or gas from the patient's body.
- Press the valve to the end to aspirate water from the balloon.

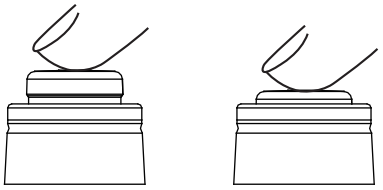


Figure 3-22 Inspecting the Suction Function

Perform the following steps.

1. Adjust the suction pressure of the suction pump to the clinical examination standard.
2. Immerse the distal end in sterile water, and keep the height of the instrument channel inlet as same as that of the water surface in the container filled with sterile water.
3. Slightly press the suction valve and ensure that water can be continuously aspirated to the suction bottle.
4. Press the suction valve to the end and ensure that the water in the balloon can be aspirated to the suction bottle.
5. Release the suction valve and ensure that the suction stops, and the suction valve restores to its original position.
6. Slightly press the suction valve to aspirate water for a few seconds, and release the valve and wait for a few seconds. Repeat the operation for several times, and ensure that no water leaks from the biopsy valve.
7. Take out the distal end from the container, and slightly press the suction valve to aspirate air for a few seconds to drain the water from the instrument channel and suction channel.

3.4.7 Inspecting the Instrument Channel

WARNING Keep your eyes away from the distal end when the biopsy forceps or other endotherapy accessories stretch out from the distal end. Otherwise, it may result in injury to eyes.

Perform the following steps.

1. Insert the endotherapy accessory into the instrument channel inlet through the slit on the biopsy valve. Ensure that the accessory can smoothly stretch out from the instrument channel outlet on the distal end without any foreign matter.
2. Ensure that the endotherapy accessory can be smoothly withdrawn from the instrument channel.

3.4.8 Inspecting the Balloon Tightness

Perform the following steps.

1. Ensure that the balloon is correctly installed on the distal end.
2. Drain the balloon. For details, refer to Section 3.2.4 Balloon.
3. Press the air/water valve to the end to feed sterile water into the balloon. Ensure that the diameter of the balloon does not exceed 3 cm.
4. Ensure that the balloon is not leaky.

4 Operations

The operator of this endoscope should be a physician or the medical personnel who operates under the supervision of the physician and should have received sufficient training in clinical endoscope technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures. It only describes basic operation and precautions related to the operation of this endoscope.

- Patient debris and chemicals for cleaning, disinfection and sterilization are potentially dangerous. The operator should wear the medical protective clothing, goggle or gloves to minimize the risk of cross-contamination and disease infection.
- Disconnect the endoscope from the light source after use to avoid accidents.
- The surface temperature of the distal end of the endoscope may exceed 41°C and reach 60°C due to intense illumination, which may cause mucosal burns. Always use the required level of illumination, minimum time and suitable distance necessary for adequate viewing. Whenever possible, avoid close stationary viewing and do not leave the distal end of the endoscope close to the mucous membrane for a long time.
- Do not insert or withdraw the endoscope in any of the following cases. Otherwise, it may result in injury, bleeding or perforation to the patient.
  - When the biopsy forceps stretches out from the distal end.
  - When the bending section of the endoscope is fixed.
  - When it is hard to insert or withdraw the endoscope, or the patient feels pain.
  - When the image is magnified.
- Before inserting the endoscope into the patient's body, the operator should ensure that the endoscope can be operated properly. If any abnormality is found on the distal end during the endoscopy, the operator should stop using the endoscope immediately and slowly withdraw it from the patient's body to avoid injury, bleeding or perforation.
- Do not operate the angulation control knob forcibly. Otherwise, the bending section could be inversely bent and it may result in injury, bleeding or perforation to the patient.
- If the image is unclear or frozen, the operator should not operate the bending section of the endoscope, feed air or insert/withdraw the insertion section. Otherwise, it may result in injury, bleeding or perforation to the patient.
- If the image or the function is abnormal, stop examining even if the abnormality disappears rapidly. Slowly withdraw the endoscope from the patient's body while observing the image. Otherwise, the abnormality may occur again and it may result in injury, bleeding or perforation to the patient.
- Before examining a patient with the endoscope, the physician shall fully explain the risks of the examination to the patient and ask the patient to sign an informed consent form.
- When switching among the special illumination modes and the common illumination mode, the image would be interfered. Therefore, do not operate the endoscope or perform a treatment while switching. Otherwise, it may result in personal injury.

4.1 General Operation

4.1.1 Inserting the Endoscope

CAUTION

- To prevent the patient from biting the insertion section of the endoscope during examination, it is suggested that the operator places a mouthpiece in the patient's mouth before inserting an endoscope.
- Remove the false teeth to prevent them from accidental falling off during the examination.
- Mouthpiece is a single-use accessory.

Perform the following steps.

1. Hold the control section of the endoscope with your left hand and operate the air/water valve, suction valve and up/down angulation control knob. Operate the insertion section and the left/right angulation lock with your right hand.
2. Turn on the lamp of the light source.
3. Place a mouthpiece between patient's teeth or gums, and slowly insert the distal end of the endoscope through the opening of the mouthpiece.
4. Observe the whole endoscope insertion process from the mouth to the esophagus and then to the stomach on the monitor carefully. Do not insert the insertion tube beyond its insertion limit mark.

4.1.2 Adjusting the Angle of Bending Section

WARNING

- Do not change the angle of the bending section rapidly during use. Otherwise, it may result in personal injury.
- Stop using the endoscope when the patient feels pain. Otherwise, it may result in personal injury.

CAUTION Do not adjust the angle of the bending section excessively. Otherwise, the steel wire may turn loose or be torn due to the excessive pulling and the bending section may be difficult to be adjusted.

Perform the following steps.

1. Rotate the up/down and left/right angulation control knobs to adjust the bending section to a desired observation angle.
2. Rotate the up/down and left/right angulation locks to fix the bending section.

4.1.3 Feeding Air/Water and Aspirating

WARNING

- If the surface of sterile water in the water bottle is under the lowest limit level during use, add sterile water into the bottle. Do not exceed the recommended upper limit level.
- Attach the cap of the biopsy valve firmly before suction operation. Otherwise, it may degrade the performance of the suction system and result in spilling and leakage of patient debris or body fluid and disease infection.
- During the process of aspiration, keep the suction pressure at the lowest level required to perform the endoscopy. Excessive suction pressure could cause aspiration of and /or injury to mucous membrane.
- Avoid aspirating solid or sticky matters. Otherwise, it may block instrument channel, suction channel or suction valve. If the suction valve is blocked, disconnect the suction tube, turn off the suction pump, and then remove and clean the suction valve to clear the solid matters.
- The balloon may result in severe anaphylactic reactions in some individuals. Before endoscopic ultrasonography, the physician should identify the latex-sensitive patients and prepare to treat anaphylactic reactions promptly.

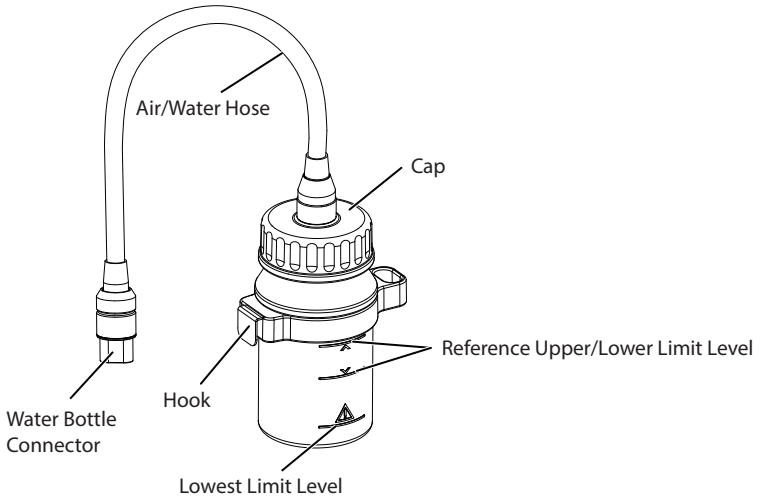
- Balloon is a single-use accessory. Dispose of the used balloon in accordance with the medical regulations of biohazard waste.

CAUTION Inject sterile water into the balloon and ensure that the balloon diameter does not exceed 3 cm. Excessive sterile water may result in damage to the balloon.

NOTE:

If the endoscope is used at a lower temperature, water vapor may condense on the surface of objective lens, making the endoscopic image cloudy. In this case, the operator should raise the temperature of sterile water in the water bottle to 40°C - 50°C (104°F - 122°F).

The water bottle is shown the following figure.



■ **To feed water/air**

Perform the following steps.

1. Block the hole on the air/water valve to feed air through the air/water nozzle.
2. Block the hole and slightly press the air/water valve to feed water to the surface of objective lens.

■ **Aspiration**

CAUTION
- Empty the suction bottle before use. Otherwise, the overflow liquid may result in the suction pump malfunction.
- Discharge the waste in accordance with local laws and regulations. For details, please consult the local distributors.

  Slightly press the suction valve to aspirate excessive liquid and debris in the patient's body.

NOTE:

If air-feeding and suction are performed synchronously, the liquid drops on the objective lens can be removed easily.

4.2 Observing the Image

4.2.1 Observing the Endoscopic Image

For details on the observation of endoscopic images, refer to the relevant user manuals.

4.2.2 Observing the Ultrasonic Image

■ To use sterile deaerated water for observation

CAUTION If you observe the ultrasonic image through sterile deaerated water, do not press the suction valve to the end during the operation. Otherwise, the balloon channel may be blocked.

Perform the following steps.

1. Insert the distal end of the endoscope into the target position, and press the **Freeze** button on the ultrasound system to switch to the real-time image mode.
2. Disconnect the biopsy valve from the endoscope and connect the water injection equipment to the instrument channel inlet.
3. Follow the instructions of the water injection equipment to inject sterile deaerated water.
4. Observe the ultrasonic image. For detailed operation, refer to the relevant user manual.

■ To use the balloon for observation

CAUTION Inject sterile water into the balloon and ensure that the balloon diameter does not exceed 3 cm. Excessive sterile water may result in damage to the balloon.

Perform the following steps.

1. Insert the distal end into the target position and press the **Freeze** button on the ultrasound system to switch to the real-time image mode.
2. Press the air/water valve to the end to feed water to the balloon.
3. Observe the ultrasonic image and ensure that the balloon diameter does not exceed 3 cm.
4. Adjust the bending angle to make the balloon completely contact with body cavity, and insert the distal end to the target position.
5. Observe the ultrasonic image. For detailed operation, refer to the relevant user manual.

4.3 Using the Endotherapy Accessory

WARNING
- When using the endotherapy accessory, the distance between the distal end of the endoscope and the mucous membrane should be longer than the minimum visible distance to ensure that the accessory can be observed on the endoscopic image. Otherwise, it may result in serious personal injury or damage to the endoscope.
- When inserting and withdrawing the endotherapy accessory, ensure that the tip of the endotherapy accessory is closed or back to the tube sheath. Slowly insert or withdraw the accessory and get the accessory through the slit on the biopsy valve straightly. Otherwise, the biopsy valve may be damaged and tissue loss may be caused.
- If it is difficult to insert or withdraw the endotherapy accessory, you should straighten the bending section while observing the image. Inserting or withdrawing the endotherapy accessory forcibly may damage the biopsy valve or the endotherapy accessory.
- If the tip of the endotherapy accessory is invisible in the viewing area, do not stretch the tip out or open the tip. Otherwise, it may cause personal injury, bleeding or accessory damage.
- Do not forcibly or suddenly insert the endotherapy accessory. Otherwise, the endotherapy accessory extracted from the distal end may cause pain, injury, bleeding or perforation to the patient.
- Do not inject excessive air or any non-flammable gas into the patient's body during the endotherapy operation. It may result in air block.

- Do not hang the endotherapy accessory on the biopsy valve. Otherwise, the biopsy valve may be damaged.
- When using the fine needle, if the ultrasonic image disappears, stop the examination immediately and withdraw the fine needle from the tissue.

NOTE:

- *The ultrasound beam diffuses, thus the needle may not be inserted into the target tissue even if the needle overlaps the target tissue on the ultrasonic image.*
- *Be careful when opening the biopsy valve cap.*

Perform the following steps.

1. Select endotherapy accessories that are compatible with the device.
2. Lock the up/down and left/right angulation control knobs respectively.
3. Ensure that the tip of the endotherapy accessory is closed or in the tube sheath. Slowly insert the endotherapy accessory straightly into the slit on the biopsy valve cap.
4. Hold the endotherapy accessory at a position approximately 4 cm away from the instrument channel inlet, slowly insert the accessory into the instrument channel while observing the endoscope image.
5. Operate the endotherapy accessory. For details, refer to the relevant user manual.
6. Close the tip of the endotherapy accessory or retract it into the sheath, and slowly withdraw the endotherapy accessory.

4.4 Ending the Examination

If blood is found on the surface of the insertion section when the endoscope is withdrawn, the operator should take care to check the patient's body.

Perform the following steps.

1. If you used the balloon, contract the balloon completely.
2. Freeze the ultrasonic image.
3. Slightly press the suction valve to aspirate residual air, blood, mucus or other debris from the patient's body.
4. Ensure that the bending section of the endoscope is free.
5. Slowly withdraw the endoscope from the patient's body while observing the endoscopic image.
6. Take out the mouthpiece from patient's mouth.
7. Take down the balloon from the distal end.

5 Cleaning, Disinfection and Sterilization

This chapter describes the cleaning, disinfection and sterilization methods for the endoscope mentioned in this manual and the basic information about how to safely and effectively clean, disinfect and sterilize the endoscope.

Many medical science documents have recorded cross infection accidents caused by improper cleaning, disinfection or sterilization. Therefore, the operator should follow the descriptions in this manual and the manuals for the accessories of the endoscope. In addition, the operator should be familiar with the following items:

- Occupation health and the safety standards of your hospital
- Individual cleaning, disinfection and sterilization standards
- Structures and usages of the endoscope and accessories
- Usage of relevant chemicals

For selecting the types and conditions of cleaning, disinfection and sterilization, you can also refer to the cleaning, disinfection and sterilization regulations of the local hospital for professional judgment.

- Patient debris, cleaning solution, disinfectant and sterilant are potentially dangerous. During cleaning, disinfection and sterilization, the operator should follow the rules for safe operations in the disinfection room and wear medical protective clothing, goggle and gloves. Before leaving the disinfection room, the operator should take off these medical protective barriers.
- The disinfection room should be set separately and isolated from the procedure room. In addition, the room should have sufficient space and adequate ventilation to avoid accumulation of poisonous chemical gas.
- During cleaning, disinfection and sterilization of the endoscope, all channels of the endoscope should be cleaned, disinfected or sterilized, including the water balloon channel, even if the channel is not used during last examination. Otherwise, the next patient may be infected.
- Before manually cleaning the endoscope each time, perform a leakage test. When leakage is found, stop using the endoscope and return it to the local distributor for repair to avoid further damage. When a leaky endoscope is used, the endoscopic image may disappear and the bending function or other functions may become abnormal.
- Do not reuse the disposable accessories.
- After being used on a patient who is infected with mycobacterium tuberculosis or other mycobacterium, the endoscope should be immersed in 2.4% glutaraldehyde for at least 45 min.
- When finding that a patient is infected with unknown super bacteria after using the endoscope, please report the incident in accordance with local laws or regulations.
- After being contaminated by pathogenic bacterium that is hard to kill, such as cryptosporidium or prion virus, as they cannot be completely destroyed or inactivated, immediately dispose of the endoscope and accessories after use in an appropriate manner.
- Dispose of single-use endotherapy accessories in accordance with local laws or regulations.
- The endoscope is not strictly cleaned, disinfected and sterilized in the factory. Therefore, the operator should strictly perform the cleaning, disinfection or sterilization processes described in this manual before use.

- After each use, the endoscope should be cleaned, disinfected or sterilized, and stored as described in this user manual. Otherwise, it may result in disease infection of the patient or operator, damage to the endoscope or performance degradation.
- Before using the endoscope each time, you should clean, disinfect or sterilize the endoscope according to the regulations of the local hospital based on the actual disinfection and storage conditions of the endoscope.
- Before cleaning, disinfection and sterilization, ensure that the insertion section of the endoscope is free (unlocked). Otherwise, the endoscope may be damaged during the cleaning, disinfection and sterilization process.
- Store the ethyl alcohol in a sealed container. Otherwise, a fire may be incurred. Besides, the alcohol may become invalid due to volatilization.
- Immerse the endoscope into the liquid completely during cleaning, disinfection and sterilization. Ensure the endoscope contact the liquid completely.
- The water quality for the cleaning and disinfection should meet the regulations in AAMI TIR34-2014.

5.1 Cleaning Solution, Disinfectant, Sterilant and Flush Fluid

- Use the cleaning solution, disinfectant or sterilant that meet local laws and regulations.
- Use the cleaning solution, disinfectant and sterilant recommended by the manufacturer, and ensure that their concentrations and the endoscope soaking period meet the recommended conditions in this chapter. Otherwise, the endoscope may be damaged or the expected disinfection or sterilization effect cannot be achieved. If you have any special purpose or requirement, please consult the manufacturer.
- Prepare, use, store and dispose of the cleaning solution, disinfectant and sterilant according to the instructions provided by the manufacturers.
- Do not use expired cleaning solution, disinfectant and sterilant.
- The endoscope is not autoclavable or cannot be processed by low-temperature plasma.
- Do not dry any disinfectant and sterilant on the surface of the endoscope.
- Do not immerse the endoscope in the anhydrous ethanol or wipe the endoscope with the anhydrous ethanol.

5.1.1 Cleaning Solution

Cleaning solution can be used to dissolve and emulsify feculence and microbe, enhance the soil-removing power, facilitate cleaning, and improve the cleaning quality.

The Metrex EmPower medical cleaning solution is recommended to clean the endoscope.

Table 5-1 Recommended Cleaning Solution and Method

Cleaning Solution	Concentration	Temperature	Contact time	Using Method
Metrex EmPower	1:128	20°C - 40°C	≥1 min	Manual cleaning

NOTE:

- *For the detailed usage and precautions of the cleaning solution, refer to the instructions of the cleaning solution manufacturer.*
- *Do not use the cleaning solution repeatedly.*
- *Excessive cleaning solution foaming could cause inadequate contact between the interiors of the channels and the cleaning solution. Consequently, the endoscope cannot be cleaned completely.*

5.1.2 Disinfectant

The follow disinfectants are recommended to disinfect the endoscope.

Table 5-2 Recommended Disinfectant and Method

Disinfectant	Concentration	Temperature	Contact Time	Using Method
MetriCide Activated Glutaraldehyde Solution	2.6%	25°C	45 min	Manual disinfection

NOTE:

- *For the detailed usage and precautions of the disinfectant, refer to the instructions of the disinfectant manufacturer.*
- *The glutaraldehyde may incur stimulus or anaphylactic reaction of the endoscope cleaning and disinfection personnel, causing dermatitis, conjunctivitis, nasal inflammation or asthma. Therefore, the disinfectant should be used in an area with adequate ventilation and stored in a sealed container.*
- *The disinfectant used should have hygienic license (within the validation period) or the detect report, national health and safety assessment report and disinfectant production certificate published by the authority. The reference values are in the table above. If the value and using method of the disinfectant are not coincident with those in the approval document of sanitary license, the latter shall prevail.*
- *The glutaraldehyde is easy to condense on the surfaces of the endoscope and the cleaning and disinfection equipment.*

5.1.3 Sterilant

The follow sterilants are recommended to sterilize the endoscope.

Table 5-3 Recommended Sterilant and Method

Sterilant	Concentration	Temperature	Contact Time	Using Method
MetriCide Activated Glutaraldehyde Solution	2.6%	25°C	10 h	Manual sterilization

NOTE:

- *For the detailed usage and precautions of the sterilant, refer to the instructions of the sterilant manufacturer.*
- *The sterilant used should have hygienic license (within the validation period) or the detect report, national health and safety assessment report and sterilant production certificate published by the authority. The reference values are in the table above. If the value and using method of the sterilant are not coincident with those in the approval document of sanitary license, the latter shall prevail.*
- *The glutaraldehyde may incur stimulus or anaphylactic reaction of the endoscope cleaning and disinfection personnel, causing dermatitis, conjunctivitis, nasal inflammation or asthma. Therefore, the sterilant should be used in an area with adequate ventilation and stored in a sealed container.*
- *The glutaraldehyde is easy to condense on the surfaces of the endoscope and the cleaning and disinfection equipment.*

5.1.4 Flush Fluid

The sterile water is recommended as the flush fluid. After high-level disinfection or sterilization, completely rinse the endoscope, accessories, and cleaning, disinfection and sterilization tools with sterile water to remove the residual disinfectant or sterilant. If no sterile water is available, filtered water may be used only when the rinse is followed by 75% ethyl alcohol flushing and drying steps.

NOTE:

- *Do not use running water as flush fluid.*

- *Do not use flush fluid repeatedly.*

5.2 Cleaning, Disinfection and Sterilization Tools

Prepare the following items before cleaning, disinfection or sterilization.

- Manual cleaning tank, rinse tank, disinfection/sterilization tank and terminal rinse tank
- Manual cleaning basin, rinse basin, disinfection/sterilization basin and terminal rinse basin
- Waterproof cap
- Protective cover
- Channel plug
- Injection tube
- Cleaning brush (material: PA and SUS304 stainless steel; brush head diameter: φ5 mm)
- Channel-opening cleaning brush (material: PA and SUS304 stainless steel; thin brush head diameter: φ3 mm; thick brush head diameter: φ10 mm)
- Leakage detector
- Suction pump
- Timer
- Transport container for endoscope
- Transport container for accessories
- Clean lint-free cloth (single-use)
- Sterile lint-free cloth (single-use)
- Sterile mat
- Sterile swab
- Syringe (50 mL and 10 mL)

5.3 Accessory Inspection and Connection

For inspecting the accessories that are not mentioned below, refer to the relevant user manuals.

5.3.1 Waterproof Cap

Before cleaning, disinfection and sterilization, connect the waterproof cap to the endoscope electric connector to prevent water inflow. The following figure shows the waterproof cap.

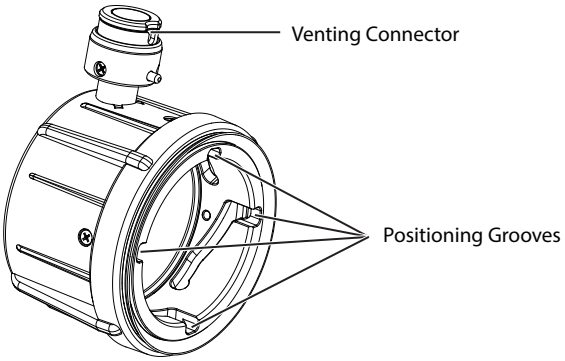


Figure 5-1 Waterproof Cap

Perform the following inspections before using the waterproof cap.

- Ensure that the inner wall of the waterproof cap is completely dry and there is no debris. If water drop or debris is found, wipe the inner wall with a dry and clean lint-free cloth.
- Ensure that there is no scratch, crack or debris on the sealing rings in the waterproof cap.
- Ensure that the venting connector is firm.

Perform the following steps to connect the waterproof cap.

1. Align the dowel pins of the electrical connector with the positioning grooves of the waterproof cap.

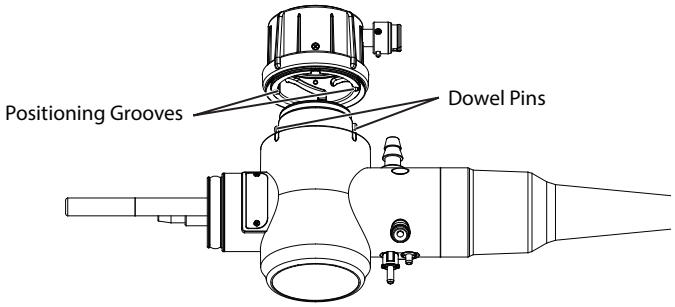


Figure 5-2 Aligning the Waterproof Cap

2. Press and rotate the waterproof cap clockwise according to direction of arrow in Figure 5-3. Ensure that the waterproof cap is firmly attached to the endoscope.

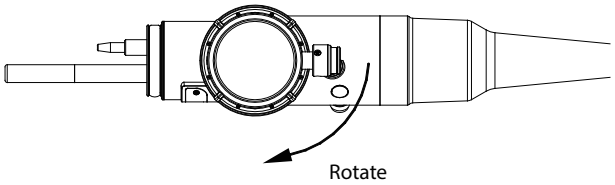


Figure 5-3 Installing the Waterproof Cap

NOTE:

Debris on the exterior of the electrical connector may scratch the sealing ring of the waterproof cap, and cause liquid leakage and damage to the endoscope.

5.3.2 Protective Cover

Before cleaning, disinfection and sterilization, connect the protective cover to the ultrasound system connector to prevent water inflow. The following figure shows the protective cover.

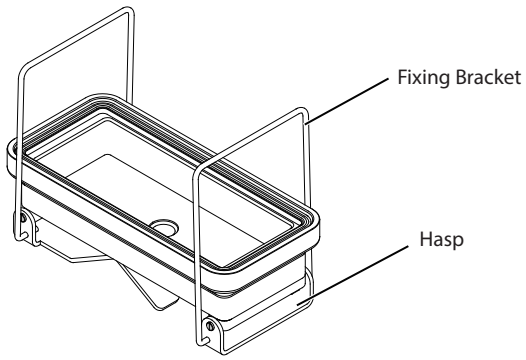


Figure 5-4 Protective Cover

Perform the following inspections before using the protective cover.

- Ensure that the inner wall of the protective cover is completely dry and there is no debris. If water drop or debris is found, wipe the inner wall with a clean and dry lint-free cloth.
- Ensure that there is no scratch, crack or debris on the protective cover.

Perform the following steps to connect the protective cover.

1. Align the protective connector with the ultrasound system connector, and fasten the two fixing brackets on the protective cover to the two grooves on the ultrasound system connector.

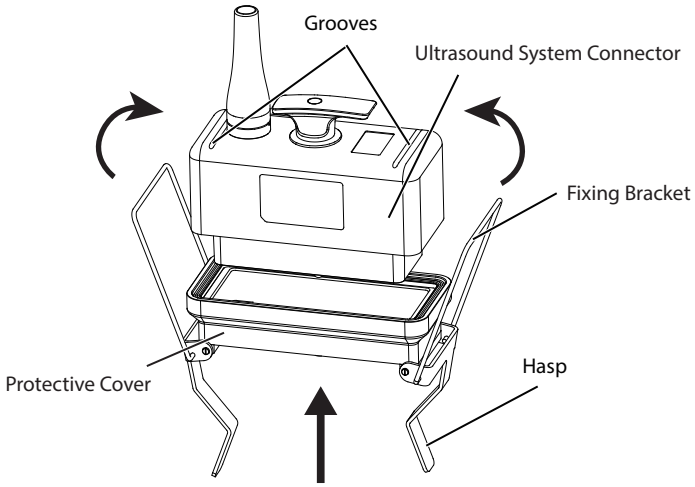


Figure 5-5 Installing the Protective Cover

2. Lock the hasps firmly.

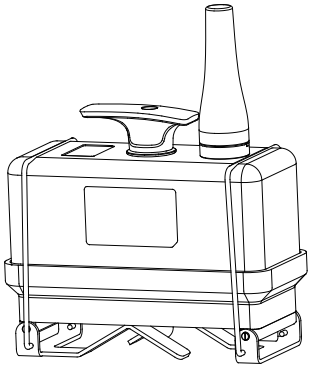


Figure 5-6 Locking the Protective Cover

5.3.3 Channel Plug

The channel plug is used to plug the instrument channel inlet, air/water valve cylinder and suction valve cylinder during cleaning, disinfecting or sterilizing the endoscope. The following figure shows the channel plug.

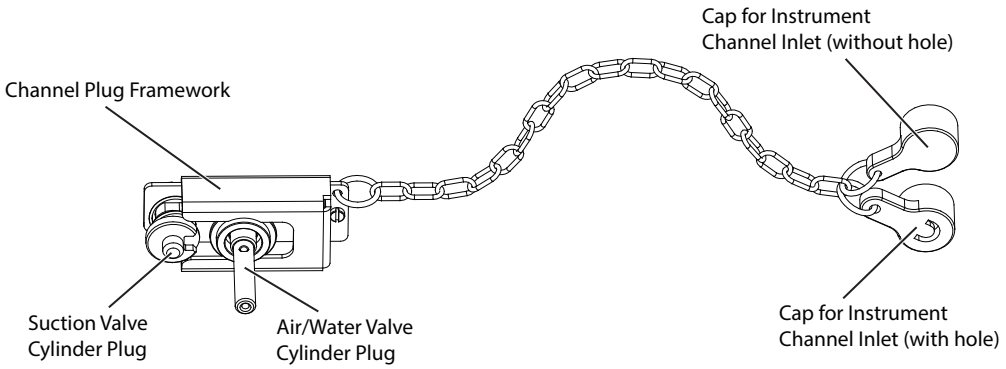


Figure 5-7 Channel Plug

NOTE:

- *Before using the channel plug, ensure that there is no crack, scratch or debris on each plug and cap.*
- *Ensure that the channel plug and the endoscope are firmly connected.*

Perform the following steps to connect the channel plug.

1. Hold the channel plug, and install the suction valve cylinder plug and air/water valve cylinder plug to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.

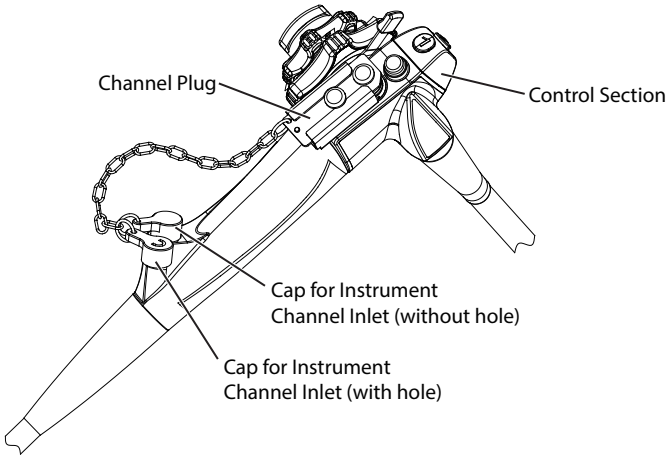


Figure 5-8 Installing the Channel Plug

2. Press and push ahead the channel plug framework until the installation is firm.
3. Press the cap for instrument channel inlet (with or without hole) to the instrument channel inlet, and ensure that the connection is firm.

5.3.4 Injection Tube

The injection tube is used to inject cleaning solution, disinfectant, sterilant, flush fluid or ethyl alcohol into the air/water channel and suction channel. It is also used to feed air into the channels to discharge residual liquid. The following figure shows the injection tube.

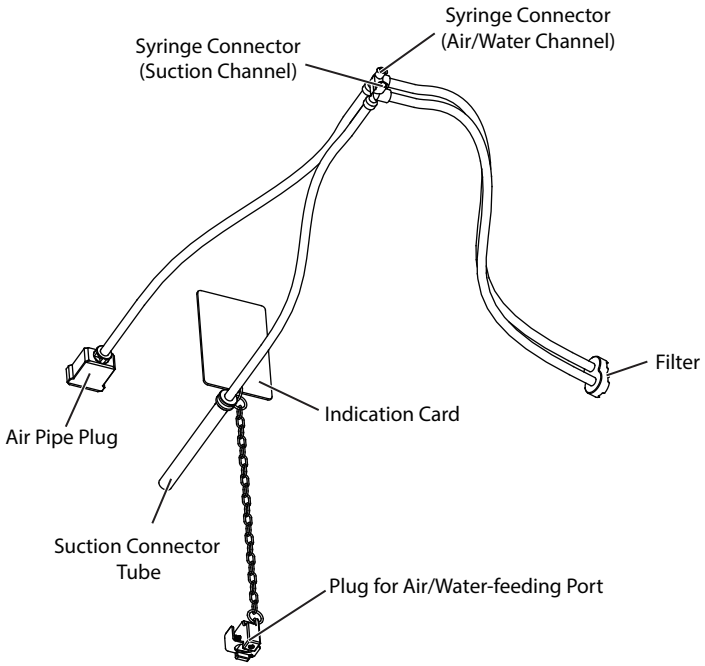


Figure 5-9 Injection Tube

NOTE:

- *Before using the injection tube, ensure that there is no crack, scratch, flaw or debris on any component.*

- *Ensure that the filter mesh is intact.*
- *Connect a 50 cm^3 (50 mL) syringe into the syringe connectors respectively. Immerse the filter in the flush fluid, pull out the plunger of the syringe, and ensure that flush fluid is aspirated into the syringe. Then, push the plunger, and ensure that flush fluid flows from the air pipe plug and suction connector tube and no filtered water flows from the filter.*

Connect the air pipe plug, suction connector tube and plug for air/water-feeding port of the injection tube to the air pipe, suction port and air/water-feeding port of the connector section of the endoscope respectively.

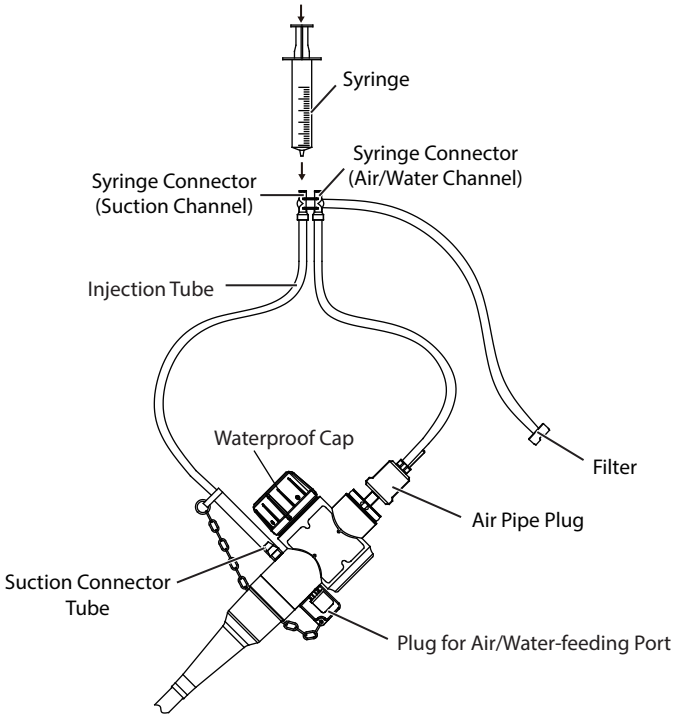


Figure 5-10 Installing the Injection Tube

5.3.5 Balloon Channel Cleaning Tube

The balloon channel cleaning tube is used to inject cleaning solution, disinfectant or sterilant, flush fluid and ethyl alcohol and to feed air to the balloon channel to drain the residual liquid.

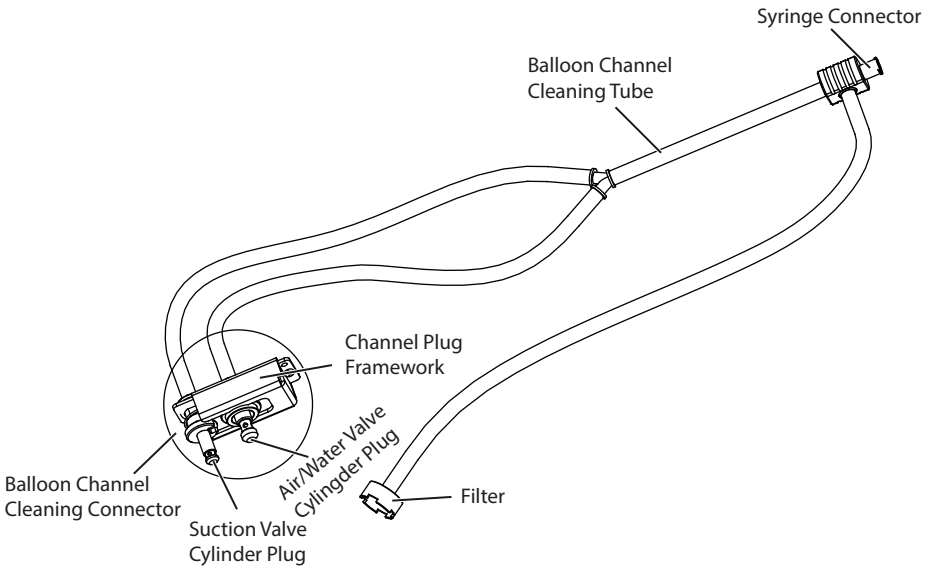


Figure 5-11 Balloon Channel Cleaning Tube

Perform the following inspections before using the balloon channel cleaning tube.

- Ensure that there is no crack, scratch or debris on any plug of the balloon channel cleaning connector.
- Ensure that the balloon channel cleaning connector connects to the endoscope firmly.

Perform the following steps to connect the balloon channel cleaning tube.

1. Connect the suction valve cylinder plug and air/water valve cylinder plug of the balloon channel cleaning connector into the suction valve cylinder and air/water valve cylinder on the endoscope respectively.

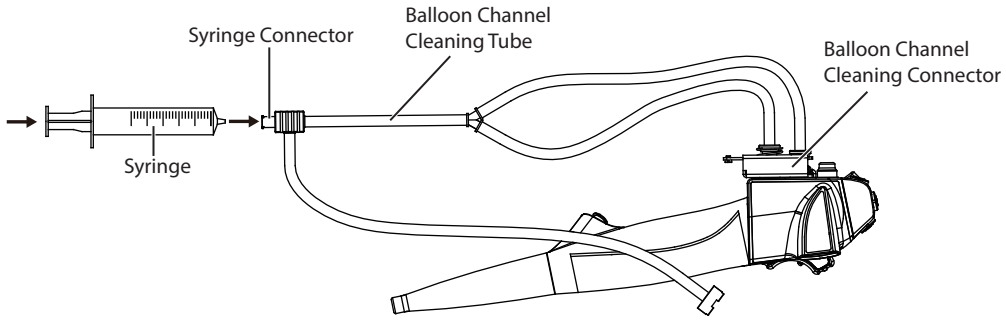


Figure 5-12 Installing the Balloon Channel Cleaning Tube

2. Press and push ahead the channel plug framework until the installation is firmly.

5.3.6 Cleaning Brush

The cleaning brush is used to brush the inner surfaces of the instrument channel and suction channel. The following figure shows the cleaning brush.

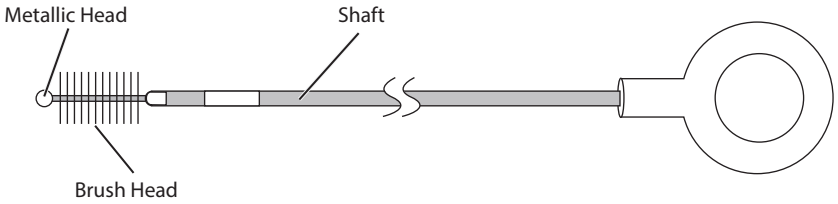


Figure 5-13 Cleaning Brush

Perform the following inspections before using the cleaning brush.

- Ensure that the brush head, metallic head and bristle are firm.
- Ensure there is no bend, scratch or other damage on the brush shaft.
- Ensure that there is no debris on the brush shaft or bristle.

NOTE:

- *Select an appropriate brush to brush the channels and accessories.*
- *Clean, disinfect and sterilize the reusable cleaning brush after each use.*

5.3.7 Channel-opening Cleaning Brush

The channel-opening cleaning brush is used to brush the air/water valve, suction valve, biopsy valve and interiors and openings of the air/water valve cylinder, suction valve cylinder and instrument channel inlet. The following figure shows the channel-opening cleaning brush.

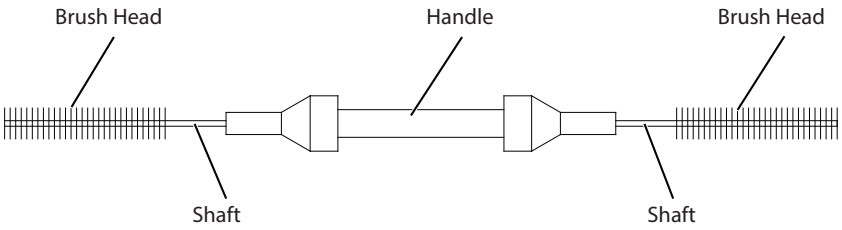


Figure 5-14 Channel-opening Cleaning Brush

Perform the following inspections before using the channel-opening cleaning brush.

- Ensure that the brush heads are firm.
- Ensure there is no bend, scratch or other damage on the brush shaft.
- Ensure that there is no debris on the brush shaft, bristle and handle.

5.3.8 Leakage Detector

The leakage detector is used to perform leakage test before cleaning, disinfecting and sterilizing the endoscope. The following figure shows leakage detector.

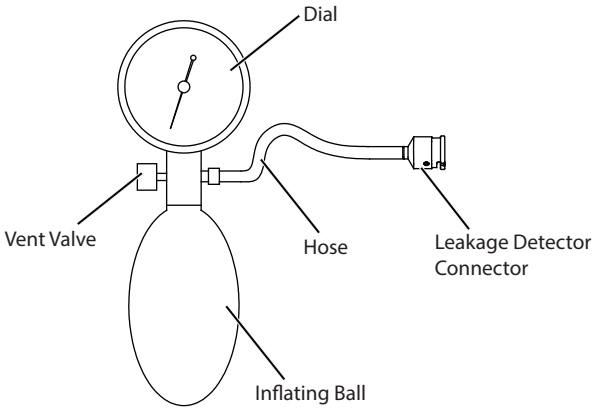


Figure 5-15 Leakage Detector

NOTE:

- *Before using the leakage detector, ensure that there is no crack, scratch, flaw or debris on any component of the leakage detector.*
- *Ensure that the hose of the leakage detector is firmly connected.*

Perform the following steps to connect the leakage detector.

1. Align the dowel pins on the venting connector of the waterproof cap with the grooves on the leakage detector connector.
2. Rotate the leakage detector connector clockwise until it is locked.

5.4 Cleaning, Disinfection and Sterilization Process

Clean, disinfect or sterilize the endoscope in accordance with the following diagram.

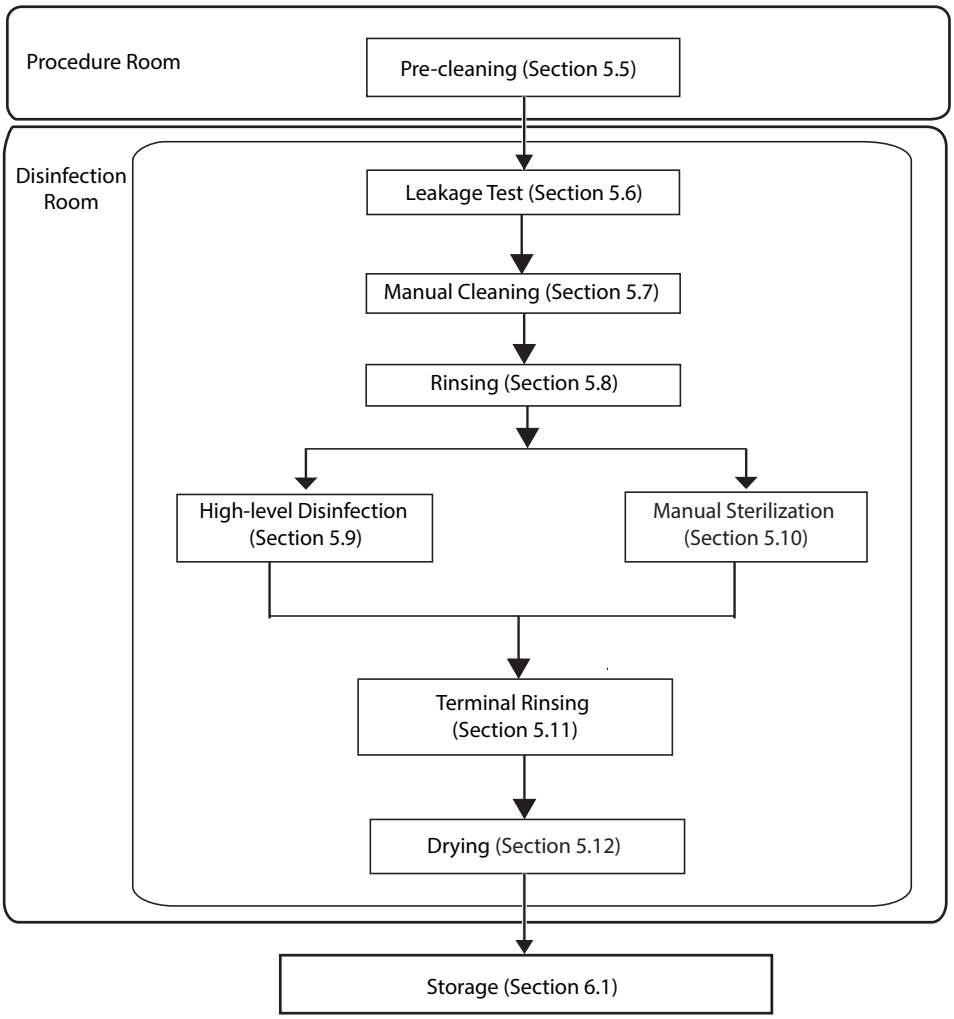


Figure 5-16 Cleaning, Disinfection and Sterilization Process

5.5 Pre-cleaning

WARNING

- Pre-cleaning should be performed before the endoscope is disconnected from the image processor, light source and ultrasound system.
- The endoscope should be pre-cleaned immediately after each examination. Otherwise, the residual debris may solidify. Consequently the cleaning, disinfection or sterilization of the endoscope will be difficult.

5.5.1 Wiping the Insertion Section

CAUTION

- When wiping the endoscope, do not bend the insertion section excessively. Otherwise, the outer rubber of the insertion section may be damaged.
- Take down the balloon carefully. Otherwise, it may result in damage to the endoscope.

Perform the following steps.

1. If you used the balloon, take down it from distal end.
2. After the endoscope is withdrawn from the patient's body, use a clean lint-free cloth dampened with cleaning solution to wipe the surface of the endoscope insertion section to remove all visible soil.
3. Wipe the surface of the ultrasound transducer carefully.

5.5.2 Flushing the Suction Channel and Balloon Channel

NOTE:

During aspiration, observe the liquid in the suction bottle carefully to avoid overflow, which might damage the suction pump.

Perform the following steps.

1. Turn on the suction pump.
2. Install the biopsy valve properly.
3. Immerse the distal end of the endoscope in the cleaning solution, and slightly press the suction valve to aspirate cleaning solution into the instrument channel for 30s.
4. Press the suction valve to the end to aspirate water into the balloon channel for 30s through the balloon water supply port.
5. Take out the distal end from the cleaning solution, and slightly press the suction valve to aspirate air for 10s.
6. Press the valve to the end to aspirate air into the balloon channel for 10s through the balloon water supply port.
7. Turn off the suction pump.

5.5.3 Flushing the Air/Water Channel

Perform the following steps.

1. Turn on the air pump of the light source, and adjust the air-feeding pressure to the maximum.
2. Slightly press the air/water valve to feed water into the air/water channel for at least 30s.
3. Press the valve to the end to feed water into the balloon for at least 30s.
4. Block and release the air/water valve to feed air into the air/water channel for at least 10s.
5. Power off the light source.

5.5.4 Disconnecting the Reusable Parts

Do not touch the light guide of endoscope and the endoscope port of light source when the endoscope is just disconnected from the light source. The extremely high temperature of the two parts may result in skin burns.

Perform the following steps.

1. Disconnect the endoscope from the image processor, and disconnect the endoscope cable, suction hose, and water bottle connector from the endoscope.
2. Disconnect the endoscope from the light source.
3. Disconnect the endoscope from the ultrasound system.
4. Connect the waterproof cap and protective cover to the endoscope, and transport the endoscope to the disinfection room with the transport container for endoscope.
5. Remove the air/water valve, suction valve and biopsy valve, and place these valves into the transport container for accessories filled with cleaning solution.

5.6 Leakage Test

A leakage test should be performed before manual cleaning.

CAUTION
- Connect the waterproof cap and protective cover to the electrical connector and the ultrasound system connector firmly. Otherwise, the endoscope may be damaged.
- When leakage is found on the endoscope, do not use the endoscope. Otherwise, the endoscope may be damaged and electrical shock may occur. In case of leakage, please contact the local distributor.

NOTE:

- *The endoscope should be pre-cleaned before leakage test, and the test should be conducted at least once a day if no condition allows.*
- *Before the leakage test, ensure that the waterproof cap and protective cover are firmly connected to the corresponding connectors. Otherwise, the pressure in the endoscope cannot be increased and the accurate leakage test cannot be conducted.*
- *It is normal that the rubber surface of the bending section starts swelling as the pressure in the endoscope increases after connected with the leakage detector.*
- *Do not place the leakage detector into the liquid during the test.*

Perform the following steps.

1. Connect the leakage detector. For details, refer to section 5.3.8 Leakage Detector.
2. Rotate the vent valve of the leakage detector clockwise to fasten it, use the inflating ball to increase the pressure to 22 kPa, and wait for 3 minutes. If the reading on the dial decreases continuously, the endoscope is leaky. In this case, stop testing and contact the local distributor.
3. Immerse the entire endoscope that the pressure has been increased into clean water, and inject water into all the channels with the syringe to remove the air. Use the up/down and left/right angulation control knobs to adjust the angle of the bending section, and wait for 3 minutes. Check if there are bubbles generating from the insertion section, the control section and the connector section. If bubbles generate continuously, the endoscope is leaky. The leaky endoscope cannot be cleaned, disinfected and sterilized. Contact the local distributor.
4. Take out the endoscope from the water.
5. Rotate the vent valve anticlockwise until the pointer on the dial returns to the zero position again.
6. Disconnect the leakage detector.

5.7 Manual Cleaning

WARNING
- To ensure the effectiveness of disinfection or sterilization, clean the endoscope and accessories completely before high-level disinfection or sterilization to remove the microorganism or organism that may affect high-level disinfection or sterilization.
- Ensure that the instrument channel and the suction channel are cleaned thoroughly. Insufficient cleaning, disinfection or sterilization of the endoscope may pose a disease infection risk to the next patient who uses this endoscope.
- To prevent cleaning solution spatter, pull out the cleaning brush in the water.
- The brush may bend or knot and the brush head may even fall off due to repeated use. The operator should ensure that there is no damage or other abnormalities on the brush before and after each use.
- If the brush head falls off in the channel, remove it immediately, and insert a new cleaning brush or other endotherapy accessory into the channel to ensure that no part is left inside the instrument channel or suction channel.

NOTE:

- *Gently pull out the cleaning brush from the instrument channel or suction channel to ensure that the shaft of the brush does not rub against the suction valve cylinder. Otherwise, the brush may be damaged and the suction valve cylinder may be scratched, causing suction performance degradation or leakage .*

- *Do not attempt to insert the cleaning brush from the distal end of the insertion section or the suction connector. Otherwise, the cleaning brush could get stuck and cannot be pulled out.*
- *Do not immerse the endoscope together with its accessories to avoid damaging the endoscope.*
- *To avoid endoscope leakage, please clean the endoscope gently.*

After the endoscope passes the leakage test, perform the following steps to clean the endoscope manually.

1. Prepare the cleaning solution in accordance with the temperature and concentration recommended in Table 5-1. Fill the manual cleaning tank with sufficient cleaning solution and ensure that the entire endoscope can be immersed in the cleaning solution.
2. Immerse the entire endoscope into the cleaning solution.

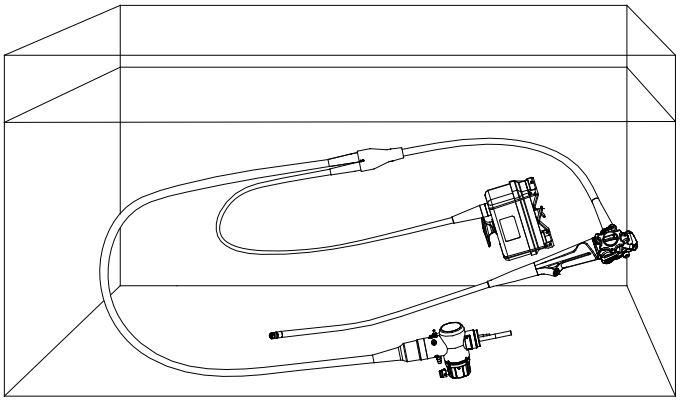


Figure 5-17 Immersing the Endoscope

3. Wipe the outer surface of the entire endoscope in the cleaning solution with a clean lint-free cloth, especially the air/water nozzle. Ensure that the outer surface of the endoscope is cleaned completely.
4. Use a channel-opening cleaning brush to thoroughly clean the balloon attachment grooves and the balloon water supply port. If necessary, clean the distal end with the channel-opening cleaning brush.
5. Brush channels and connectors as shown in the following figure.

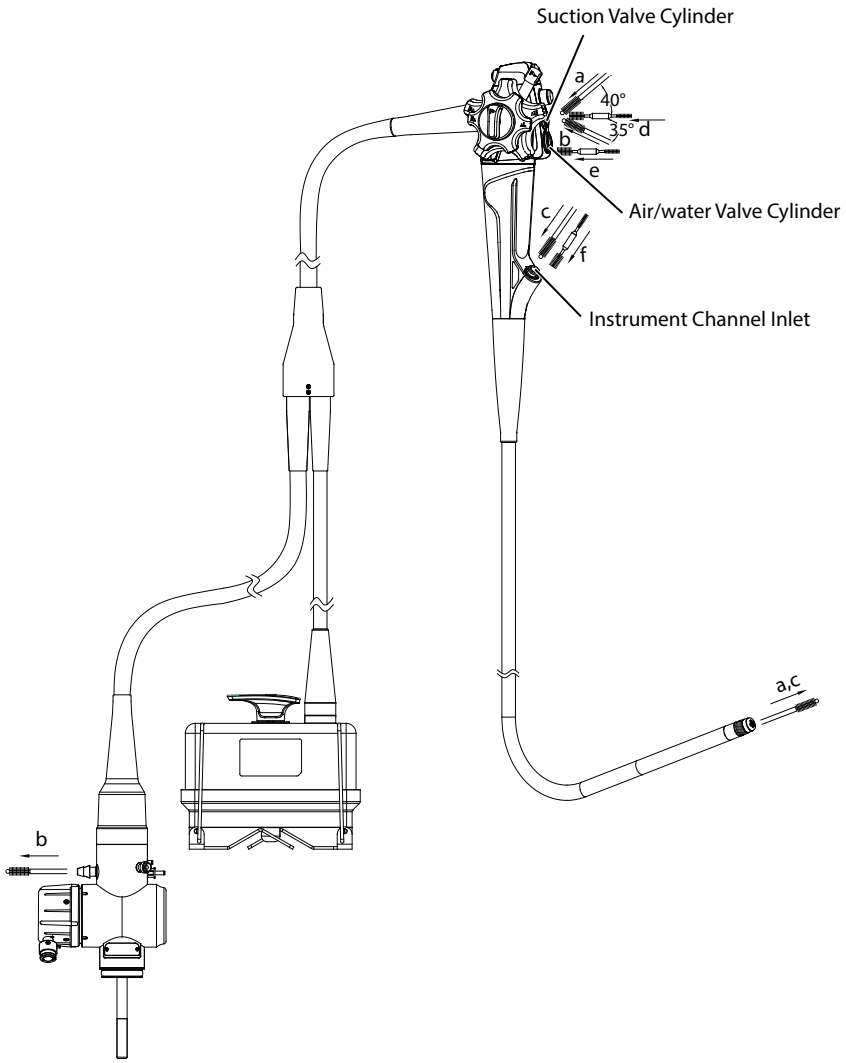


Figure 5-18 Brushing the Endoscope

a. **To brush the suction channel from the control section to the distal end:** Straighten the bending section, insert the cleaning brush at a 40° angle down into the side opening of the suction valve cylinder, and slowly advance the brush until the brush head emerges from the distal end. Clean the bristles with your fingertips in the cleaning solution, and then pull out the brush from the suction valve cylinder carefully. Clean the bristles with your fingertips in the cleaning solution again. Repeat the procedure at least 3 times to ensure that no debris is left.

b. **To brush the suction channel from the control section to the connector section:** Insert the cleaning brush at a 35° angle up into the suction valve cylinder, and slowly advance the brush until the brush head emerges from the suction port. Clean the bristles with your fingertips in the cleaning solution, and then pull out the brush from the suction valve cylinder carefully. Clean the bristles with your fingertips in the cleaning solution again. Repeat the procedure at least 3 times to ensure that no debris is left.

c. **To brush the instrument channel from the instrument channel inlet to the distal end:** Straighten the bending section, insert the cleaning brush into the instrument channel inlet, and slowly advance the brush until the brush head emerges from the distal end. Clean the bristles with your fingertips in the cleaning solution, and pull out the brush from the instrument channel inlet carefully. Repeat the procedure at least 3 times to ensure that no debris is left.

d. **To brush the suction valve cylinder:** Insert the channel-opening cleaning brush into the suction valve cylinder and slowly advance the brush until the brush head touches the cylinder. Rotate the brush once, pull out the brush carefully and clean the bristles with your fingertips in the cleaning solution. Repeat the procedure at least 3 times to ensure that no debris is left.

e. **To brush the air/water valve cylinder:** Insert the channel-opening cleaning brush into the air/water valve cylinder and slowly advance the brush until the brush head touches the cylinder. Rotate the brush once, pull out the brush carefully and clean the bristles with your fingertips in the cleaning solution. Repeat the procedure at least 3 times to ensure that no debris is left.

f. **To brush the instrument channel inlet**: Insert the channel-opening cleaning brush into the instrument channel inlet and slowly advance the brush until the brush head touches the instrument channel inlet. Rotate the brush once, pull out the brush carefully and clean the bristles with your fingertips in the cleaning solution. Repeat the procedure at least 3 times to ensure that no debris is left.

6. Connect the injection tube and channel plug to the endoscope firmly. Connect the cap for instrument channel inlet without hole of the channel plug to the instrument channel inlet, and ensure that the filter of the injection tube is immersed in the cleaning solution.
7. Use a 50 mL syringe to inject at least 200 mL (4 times) cleaning solution into the suction channel through the injection tube to fill the channel.
8. Disconnect the cap for instrument channel inlet without hole, and connect the one with hole.
9. Use a 50 mL syringe to inject at least 200 mL (4 times) cleaning solution into the suction channel through the injection tube to fill the instrument channel inlet.
10. Use a 50 mL syringe to inject at least 400 mL (8 times) cleaning solution into air/water channel and balloon channel through the injection tube to fill the channels.

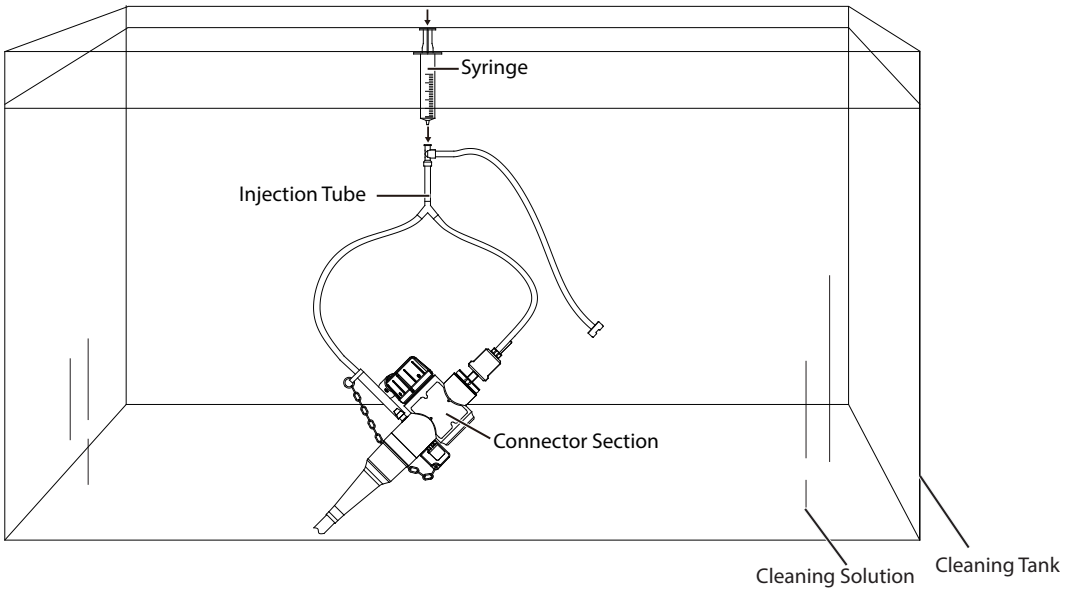


Figure 5-19 Injecting Cleaning Solution

11. Disconnect the channel plug, and connect the balloon channel cleaning tube connector to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.

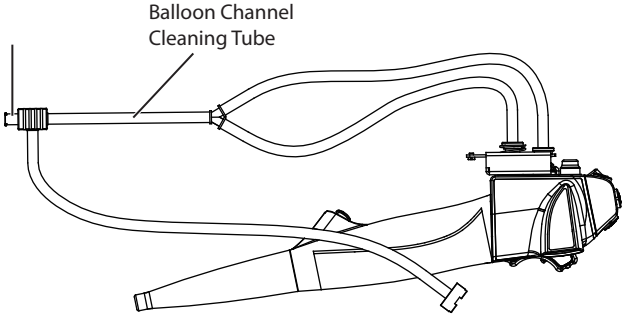


Figure 5-20 Installing the Balloon Channel Cleaning Tube

12. Use a 10 mL syringe to inject at least 180 mL (18 times) cleaning solution into the balloon channel through the balloon channel cleaning tube to fill the channel.
13. Disconnect the balloon channel cleaning tube and injection tube from the endoscope, and immerse all accessories.
14. During the immersion, use a clean lint-free cloth or a channel-opening cleaning brush to clean the outer surface of and all connectors on the endoscope, until no debris is left.
15. Cover the manual cleaning tank with a sealing cover to reduce cleaning solution volatilization.
16. Immerse the endoscope and all its accessories in accordance with the time, temperature and concentration recommended in Table 5-1.

5.8 Rinsing

Perform the following steps.

1. Place the cleaned endoscope into the rinse tank, and thoroughly wipe the outer surface of the entire endoscope with a clean lint-free cloth.
2. Connect the channel plug and injection tube to the endoscope firmly. Connect the cap for instrument channel inlet without hole of the channel plug to the instrument channel inlet.
3. Use a 50 mL syringe to inject at least 200 mL (4 times) running water into the suction channel through the injection tube to fill the channel.
4. Disconnect the cap for instrument channel inlet without hole, and connect the one with hole.
5. Use a 50 mL syringe to inject at least 200 mL (4 times) running water into the suction channel through the injection tube to fill the instrument channel inlet.
6. Use a 50 mL syringe to inject at least 400 mL (8 times) running water into the air/water channel and balloon channel through the injection tube to fill the channels.
7. Disconnect the channel plug, and connect the balloon channel cleaning tube connector to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.
8. Use a 10 mL syringe to inject at least 180 mL (18 times) running water into the balloon channel through the balloon channel cleaning tube to fill the channel.
9. Disconnect the balloon channel cleaning tube from the endoscope.
10. Flush the outer surfaces of the endoscope and all its accessories with running water.
11. Take out the endoscope and all its accessories from the running water.
12. Connect the channel plug and injection tube to the endoscope firmly. Connect the cap for instrument channel inlet without hole of the injection tube to the instrument channel inlet.
13. Cover the distal end and control section with a clean lint-free cloth.
14. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the suction channel through the injection tube.
15. Disconnect the cap for instrument channel inlet without hole, and connect the one with hole.
16. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the suction channel through the injection tube to remove water in the instrument channel inlet.
17. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the air/water channel and balloon channel through the injection tube.
18. Disconnect the channel plug, and connect the balloon channel cleaning tube connector to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.

19. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the balloon channel through the balloon channel cleaning tube.
20. Remove the clean lint-free cloth from the distal end and control section.
21. Disconnect the balloon channel cleaning tube and injection tube from the endoscope.
22. Wipe the outer surfaces of endoscope and all its accessories with a clean lint-free.
23. Ensure that no debris is left on the outer surfaces of the endoscope or all its accessories. Otherwise, repeat the procedures in Section 5.7 Manual Cleaning and Section 5.8 Rinsing.

5.9 Manual Disinfection

- For sufficient high-level disinfection, ensure that the outer surfaces of the endoscope and all its accessories are in full contact with the disinfectant.
- Bubbles adhering to the channels may degrade the disinfection effect. The operator can forcibly inject disinfectant into the endoscope channels to ensure that no bubble exists. If any bubbles adhere to the outer surface of endoscope and its accessories, you should use a clean lint-free cloth to wipe them off.
- The endoscope and all its accessories should be completely immersed in the disinfectant for high-level disinfection.

Perform the following steps.

1. Place the endoscope and all its accessories into the disinfection tank.
2. Prepare the disinfectant in accordance with the temperature and concentration recommended in Table 5-2. Fill the tank with sufficient disinfectant, and ensure that the endoscope and all its accessories can be immersed in the disinfectant.
3. Connect the channel plug and injection tube into the endoscope firmly. Connect the cap for instrument channel inlet without hole of the channel plug to the instrument channel inlet.
4. Use a 50mL syringe to inject at least 200mL (4 times) disinfectant into the suction channel through the injection tube to fill the channel.
5. Disconnect the cap for instrument channel inlet without hole, and connect the one with hole.
6. Use a 50mL syringe to inject at least 200 mL (4 times) disinfectant into the suction channel through the injection tube to fill the instrument channel inlet.

   NOTE:

   - *Ensure that the syringe connector of the injection tube is completely immersed in the disinfectant.*
   - *Ensure that all channels of the endoscope are filled with disinfectant.*
7. Use a 50 mL syringe to inject at least 400 mL (8 times) disinfectant into the air/water channel and balloon channel through the injection tube to fill the channels.
8. Disconnect the channel plug, and connect the balloon channel cleaning tube connector to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.
9. Use a 10 mL syringe to inject at least 180 mL (18 times) disinfectant into the balloon channel through balloon channel cleaning tube to fill the channel.
10. Disconnect the balloon channel cleaning tube and injection tube from the endoscope, and immerse all accessories in the disinfectant.
11. If bubbles adhere to the endoscope surface or the tools, wipe the bubbles with a clean lint-free cloth.
12. Cover the disinfection tank with a sealing cover to reduce disinfectant volatilization.

13. Immerse the endoscope and all its accessories in accordance with the time, temperature and concentration recommended in Table 5-2 for high-level disinfection.
14. Before taking out the endoscope and all its accessories from the disinfectant, connect the channel plug and injection tube to the endoscope firmly. Connect the cap for instrument channel inlet without hole of the channel plug to the instrument channel inlet.
15. Take out the filter of the injection tube from the disinfectant.
16. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the suction channel through the injection tube.
17. Disconnect the cap for instrument channel inlet without hole, and connect the one with hole.
18. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the suction channel through the injection tube to remove disinfectant in the instrument channel inlet.
19. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the air/water channel and balloon channel.
20. Disconnect the channel plug, and connect the balloon channel cleaning tube connector to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.
21. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the balloon channel through the balloon channel cleaning tube.
22. Take out the endoscope and all its accessories from the disinfectant.
23. Disconnect the channel plug and injection tube from the endoscope.

5.10 Sterilization

NOTE:

- *During the sterilization process, the endoscope and all accessories should be immersed in the sterilant completely.*
- *The sterile regulations should be followed during the sterilization. After sterilization, use sterile water to flush the endoscope, and transport the endoscope with sterile package.*
- *Ensure that all channels of the endoscope are filled with sterilant.*

After the endoscope enters the sterile human tissue and organ or contacts damaged tissue, damaged mucous membrane, and blood (for example, in a surgery), it should be sterilized after conducting the procedures of Section 5.5 Pre-cleaning, Section 5.6 Leakage Test, Section 5.7 Manual Cleaning and Section 5.8 Rinsing.

Perform the follow steps.

1. Place the endoscope and all its accessories into the sterilization tank.
2. Prepare the sterilant in accordance with the temperature and concentration recommended in Table 5-3. Fill the tank with sufficient sterilant, and immerse the entire endoscope and all its accessories in the sterilant.
3. Connect the channel plug and injection tube to the endoscope firmly. Connect the cap for instrument channel inlet without hole of the channel plug to the instrument channel inlet.
4. Use a 50 mL syringe to inject at least 200 mL (4 times) sterilant into the suction channel through the injection tube to fill the channel.
5. Disconnect the cap for instrument channel inlet without hole, and connect the one with hole.
6. Use a 50 mL syringe to inject at least 200 mL (4 times) sterilant into the suction channel through the injection tube to fill the instrument channel inlet.

7. Disconnect the cap for instrument channel inlet with hole, and connect the one without hole.
8. Use a 50 mL syringe to inject at least 400 mL (8 times) sterilant into the air/water channel and balloon channel through the injection tube to fill the channels.
9. Disconnect the channel plug, and connect the balloon channel cleaning tube connector to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.
10. Use a 10 mL syringe to inject at least 180 mL (18 times) sterilant into the balloon channel through balloon channel cleaning tube to fill the channel.
11. Disconnect the balloon channel cleaning tube and injection tube from the endoscope, and immerse them in the sterilant.
12. If bubbles adhere to the endoscope surface or the tools, wipe the bubbles with a sterile lint-free cloth.
13. Cover the sterilization tank with a sealing cover to reduce sterilant volatilization.
14. Immerse the endoscope and all its accessories in accordance with the time, temperature and concentration recommended in Table 5-3 for sterilization.
15. Before taking out the endoscope and all its accessories from the sterilant, connect the channel plug and injection tube to the endoscope firmly. Connect the cap for instrument channel inlet without hole of the channel plug to the instrument channel inlet.
16. Take out the filter of the injection tube from the sterilant.
17. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the suction channel.
18. Disconnect the cap for instrument channel inlet without hole, and connect the one with hole.
19. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the suction channel to remove the sterilant in the instrument channel inlet.
20. Disconnect the cap for instrument channel inlet with hole, and connect the one without hole.
21. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the air/water channel and balloon channel.
22. Disconnect the channel plug, and connect the balloon channel cleaning tube connector to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.
23. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the balloon channel.
24. Take out the endoscope and all its accessories from the sterilant.
25. Disconnect the balloon channel cleaning tube and injection tube from the endoscope.

5.11 Terminal Rinsing

- After high-level disinfection, the operator should use filtered water and 75% ethyl alcohol or sterile water to completely rinse the outer surfaces and all channels of the endoscope to remove residual of high-level disinfectant.
- After manual sterilization, rinse the outer surface and all channels of the endoscope thoroughly with sterile water to remove the residue of sterilant.

■ To use sterile water for terminal rinsing

Perform the follow steps.

1. Place the endoscope and all its accessories into the terminal rinse tank.
2. Fill the tank with sufficient sterile water, and ensure that the entire endoscope can be immersed in the sterile water.

3. Thoroughly wipe the outer surface of the entire endoscope with a sterile lint-free cloth.
4. Connect the channel plug and injection tube into the endoscope firmly. Connect the cap for instrument channel inlet without hole of the channel plug to the instrument channel inlet.
5. Use a 50 mL syringe to inject at least 200 mL (4 times) sterile water into the suction channel through the injection tube to fill the channel.
6. Disconnect the cap for instrument channel inlet without hole, and connect the one with hole.
7. Use a 50 mL syringe to inject at least 200 mL (4 times) sterile water into the suction channel through the injection tube to fill the instrument channel inlet.
8. Disconnect the cap for instrument channel inlet with hole, and connect the one without hole.
9. Use a 50mL syringe to inject at least 400 mL (8 times) sterile water into the air/water channel and balloon channel through the injection tube to fill the channels.
10. Disconnect the channel plug, and connect the balloon channel cleaning tube connector to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.
11. Use a 10 mL syringe to inject at least 180 mL (18 times) sterile water into the balloon channel through the balloon channel cleaning tube to fill the channel.
12. Disconnect the balloon channel cleaning tube from the endoscope.
13. Flush the outer surfaces of the endoscope and all its accessories with sterile water.
14. Take out the endoscope and all its accessories from the sterile water.
15. Cover the distal end and control section with a sterile lint-free cloth.
16. Connect the channel plug. Connect the cap for instrument channel inlet without hole of the channel plug to the instrument channel inlet.
17. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the suction channel through the injection tube.
18. Disconnect the cap for instrument channel inlet without hole, and connect the one with hole.
19. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the suction channel through the injection tube to remove water in the instrument channel inlet.
20. Disconnect the cap for instrument channel inlet with hole, and install the one without hole.
21. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the air/water channel and balloon channel through the injection tube.
22. Disconnect the channel plug, and connect the balloon channel cleaning tube connector to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.
23. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the balloon channel through the balloon channel cleaning tube.
24. Remove the sterile lint-free cloth from the distal end and control section.
25. Disconnect the balloon channel cleaning tube and injection tube from the endoscope, and wipe the outer surface of the endoscope and all its accessories with a sterile lint-free cloth.

■ **To use filtered water and 75% ethyl alcohol for terminal rinsing**

Perform the following steps.

1. Place the endoscope and all its accessories into the terminal rinse tank.
2. Fill the tank with sufficient filtered water, and ensure that the entire endoscope can be immersed in the filtered water.

3. Thoroughly wipe the outer surface of the entire endoscope with a clean lint-free cloth.
4. Connect the channel plug and injection tube to the endoscope firmly. Connect the cap for instrument channel inlet without hole to the instrument channel inlet.
5. Use a 50 mL syringe to inject at least 200 mL (4 times) filtered water into the suction channel through the injection tube to fill the channel.
6. Disconnect the cap for instrument channel inlet without hole, and connect the one with hole.
7. Use a 50 mL syringe to inject at least 200 mL (4 times) filtered water into the suction channel through the injection tube to fill the instrument channel inlet.
8. Use a 50 mL syringe to inject at least 400 mL (8 times) filtered water into the air/water and balloon channel through the injection tube to fill the channels.
9. Disconnect the channel plug, and connect the balloon channel cleaning tube connector to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.
10. Use a 10 mL syringe to inject at least 180 mL (18 times) filtered water into the balloon channel through the balloon channel cleaning tube to fill the channel.
11. Disconnect the balloon channel cleaning tube from the endoscope.
12. Flush the outer surfaces of the endoscope and all its accessories with filtered water.
13. Take out the endoscope and all its accessories from the filtered water.
14. Cover the distal end and the control section with a clean lint-free cloth.
15. Connect the channel plug and injection tube into the endoscope firmly. Connect the cap for instrument channel inlet without hole of the channel plug to the instrument channel inlet.
16. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the suction channel through the injection tube.
17. Disconnect the cap for instrument channel inlet without hole, and connect the one with hole.
18. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the suction channel through the injection tube to remove water in the instrument channel inlet.
19. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the air/water channel and balloon channel through the injection tube.
20. Disconnect the channel plug, and connect the balloon channel cleaning tube connector to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.
21. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the balloon channel through the balloon channel cleaning tube.
22. Disconnect the balloon channel cleaning tube. Connect the channel plug, and connect the cap for instrument channel inlet without hole of the channel plug to the instrument channel inlet.
23. Use a 50 mL syringe to inject at least 100 mL (twice) ethyl alcohol into the suction channel through the injection tube to remove water in the channel.
24. Disconnect the cap for instrument channel inlet without hole, and connect the one with hole.
25. Use a 50 mL syringe to inject at least 50 mL (once) ethyl alcohol into the suction channel through the injection tube to remove water in the instrument channel inlet.
26. Use a 50 mL syringe to inject at least 100 mL (twice) ethyl alcohol into the air/water channel and balloon channel through the injection tube to remove water in the channel.
27. Disconnect the channel plug, and connect the balloon channel cleaning tube connector to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.

28. Use a 10 mL syringe to inject at least 50 mL (5 times) ethyl alcohol into the balloon channel through balloon channel cleaning tube to remove water in the channel.
29. Disconnect the balloon channel cleaning tube. Connect the channel plug, and connect the cap for instrument channel inlet without hole of the channel plug to the instrument channel inlet.
30. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the suction channel through the injection tube.
31. Disconnect the cap for instrument channel inlet without hole, and install the one with hole.
32. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the suction channel through the injection tube.
33. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the air/water channel and balloon channel through the injection tube.
34. Disconnect the channel plug, and connect the balloon channel cleaning tube connector to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.
35. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the balloon channel through the balloon channel cleaning tube.
36. Remove the clean int-free cloth from the distal end and control section.
37. Disconnect the balloon channel cleaning tube and injection tube from the endoscope, and wipe the outer surface of the endoscope and all its accessories with a clean lint-free cloth.

5.12 Drying

- After cleaning, high-level disinfection or manual sterilization, the operator should dry all channels of the endoscope completely to avoid breeding of bacteria that might cause disease infection of the next patient or operator.
- The sterile mat should be replaced every 4 hours.

Perform the following steps.

1. Place the endoscope and all its accessories on a sterile mat which is placed on the medical drying table.
2. Fill the container with sufficient 75% ethyl alcohol.
3. Connect the channel plug and injection tube to the endoscope firmly. Connect the cap for instrument channel inlet without hole of the channel plug to the instrument channel inlet, and immerse the filter of the injection tube in the ethyl alcohol.
4. Cover the distal end and control section with a sterile lint-free cloth.
5. Use a 50 mL syringe to inject at least 50 mL (once) ethyl alcohol into the suction channel through the injection tube.
6. Disconnect the cap for instrument channel inlet without hole, and connect the one with hole.
7. Use a 50 mL syringe to inject at least 50 mL (once) ethyl alcohol into the suction channel through the injection tube to dry the instrument channel inlet.
8. Use a 50 mL syringe to inject at least 50 mL (once) ethyl alcohol into the air/water channel and balloon channel through the injection tube.
9. Disconnect the channel plug, and connect the balloon channel cleaning tube connector to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.

10. Use a 10 mL syringe to inject at least 30 mL (3 times) ethyl alcohol into the balloon channel through the balloon channel cleaning tube.
11. Take out the filter from the ethyl alcohol.
12. Disconnect the balloon channel cleaning tube. Connect the channel plug, and connect the cap for instrument channel inlet without hole of the channel plug to the instrument channel inlet.
13. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the suction channel through the injection tube.
14. Disconnect the instrument channel cap without hole, and connect the one with hole.
15. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the suction channel through the injection tube to remove ethyl alcohol in the instrument channel inlet.
16. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the air/water channel and balloon channel through the injection tube.
17. Disconnect the channel plug, and connect the balloon channel cleaning tube connector to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.
18. Use a 50 mL syringe to inject at least 400 mL (8 times) air into the balloon channel through the balloon channel cleaning tube.
19. Remove the sterile lint-free cloth from the distal end and control section.
20. Disconnect the balloon channel cleaning tube and injection tube from the endoscope.
21. Wipe the outer surface of the entire endoscope and all its accessories thoroughly with a sterile or clean lint-free cloth dampened with ethyl alcohol.
22. Wipe the inner surfaces of the air/water valve cylinder, suction valve cylinder and instrument channel inlet with sterile swabs.
23. Dry the endoscope and all its accessories.

5.13 Reusable Parts and Cleaning, Disinfection and Sterilization Tools

After being used each time, the reusable parts and cleaning, disinfection and sterilization tools should be cleaned, disinfected and sterilized. Otherwise, the patient or operator may be infected.

The following reusable parts and cleaning, disinfection and sterilization tools can be cleaned, disinfected and sterilized.

- Air/water valve
- Suction valve
- Biopsy valve
- Cleaning brush
- Channel-opening cleaning brush

5.13.1 Manual Cleaning

NOTE:

- *Ensure that the parts and tools immersed in the cleaning solution are not in contact with each other.*
- *Ensure that the sealing rings on the air/water valve are not scratched.*
- *Remove the cap from the main body of biopsy valve. Otherwise, the biopsy valve cannot be completely cleaned and disinfected or sterilized.*

Perform the following steps.

1. Place all parts and tools into the manual cleaning basin.

2. Prepare the cleaning solution in accordance with the temperature and concentration recommended in Table 5-1. Fill the basin with sufficient cleaning solution, and ensure that all parts and tools can be immersed in the cleaning solution.
3. Wipe the outer surfaces of the parts and tools in the cleaning solution with a clean lint-free cloth.
4. Use the channel-opening cleaning brush to thoroughly clean the openings of the air/water valve and the suction valve thoroughly to remove all debris.
5. Use the channel-opening cleaning brush to thoroughly clean the openings and interiors of the biopsy valve to remove all debris.
6. Use a 50 mL syringe to inject cleaning solution to thoroughly flush the interiors and openings of all the parts and tools to remove all bubbles.
7. During the immersion, press the pistons of the air/water valve and suction valve to the end and release them for at least 3 times to remove all bubbles.
8. Clean bristles of the cleaning brush and channel-opening cleaning brush in the cleaning solution to remove all bubbles.
9. Cover the basin with a sealing cover to reduce cleaning solution volatilization.
10. Immerse the parts and tools in accordance with the time, temperature and concentration recommended in Table 5-1.
11. Take out all parts and tools from the basin and ensure that no debris left on all parts and tools.

5.13.2 Rinsing

Perform the following steps.

1. Place all cleaned parts and tools into the rinse basin.
2. Wipe the outer surfaces of the parts and tools in the running filtered water with a clean lint-free cloth.
3. Use a 50 mL syringe to thoroughly flush the interiors and openings of all parts and tools in the filtered water, until no bubble generates.
4. During the immersion, press the pistons of the air/water valve and suction valve to the end and release them for at least 3 times to remove all bubbles.
5. Clean the bristles of cleaning brush and channel-opening cleaning brush in the filtered water to remove all bubbles.
6. Take out all parts and tools and wipe the outer surfaces of all parts and tools with a lint-free cloth.
7. Ensure that no debris is left on any part and tool. Otherwise, repeat procedures in Section 5.13.1 Manual Cleaning and Section 5.13.2 Rinsing.

5.13.3 Disinfection

- Ensure all bubbles adhering to the parts and tools are removed. Otherwise, it may degrade the high-level disinfection effect.
- Perform the high-level disinfection when all parts and tools are immersed in the disinfectant. For sufficient high-level disinfection, ensure that all parts and tools are in full contact with the disinfectant.

Perform the following steps.

1. Prepare the disinfectant in accordance with the temperature and concentration recommended in Table 5-2. Fill the basin with sufficient disinfectant and ensure that all the parts and tools can be immersed in the disinfectant.
2. Place all parts and tools in the basin and immerse them in the disinfectant.

3. Wipe the outer surface of all parts and tools in the disinfectant with a clean lint-free cloth to remove all bubbles.
4. Use a 50 mL syringe to thoroughly flush the interiors, external grooves and openings of all parts and tools in the disinfectant to remove all bubbles.
5. During the immersion, press the pistons of air/water valve and suction valve to the end and release them for at least 3 times to remove all bubbles.
6. Clean the bristles of the cleaning brush and channel-opening cleaning brush in the disinfectant to remove all bubbles.
7. Cover the disinfection basin with a sealing cover to reduce disinfectant volatilization.
8. Immerse all parts and tools in accordance with the time, temperature and concentration recommended in Table 5-2 for high-level disinfection.
9. Take out all the parts and tools.

5.13.4 Sterilization

Perform the following steps.

1. Prepare the sterilant in accordance with the temperature and concentration recommended in Table 5-3. Fill the basin with sufficient sterilant, and ensure that all parts and tools can be immersed in the sterilant.
2. Place all parts and tools in the sterilization basin and immerse them in the sterilant.
3. Wipe the outer surfaces of all parts and tools in the sterilant with a sterile lint-free cloth.
4. Use a 50 mL syringe to flush the interiors and openings of all part and tools thoroughly in the sterilant to remove all bubbles.
5. During the immersion, press the pistons of air/water valve and suction valve to the end and release them for at least 3 times to remove all bubbles.
6. Clean the bristles of the cleaning brush and channel-opening cleaning brush in the sterilant to remove all bubbles.
7. Cover the sterilization basin with a sealing cover to reduce sterilant volatilization.
8. Immerse all parts and tools in accordance with the time, temperature and concentration recommended in Table 5-3 for sterilization.
9. Take out all parts and tools.

5.13.5 Terminal Rinsing

- After high-level disinfection, completely rinse the endoscope accessories, and the cleaning, disinfection and sterilization tools with sterile water or filtered water.
- After manual sterilization, completely rinse the endoscope accessories, and cleaning, disinfection and sterilization tools with sterile water.

■ To use sterile water for terminal rinsing

Perform the following steps.

1. Fill the terminal rinse basin with sufficient sterile water, and ensure that all parts and tools can be immersed in the sterile water.
2. Place all parts and tools into the basin, and immerse them in the sterile water.
3. Wipe the outer surfaces of all parts and tools in the sterile water with a sterile lint-free cloth.

4. Use a 50 mL syringe to flush the interiors and openings of all parts and tools in the sterile water to remove all bubbles.
5. During the immersion, press the pistons of air/water valve and suction valve to the end and release them for at least 3 times to remove all bubbles.
6. Clean the bristles of the cleaning brush and channel-opening cleaning brush in the sterile water to remove all bubbles.
7. Take out all parts and tools and wipe the outer surfaces of the parts and tools with a sterile lint-free cloth.

■ **To use filtered water and 75% ethyl alcohol for terminal rinsing**

Perform the following steps.

1. Fill the terminal rinse basin with sufficient filtered water, and ensure that all parts and tools can be immersed in the filtered water.
2. Place all parts and tools into the basin and immerse them in the filtered water.
3. Wipe the outer surfaces of all parts and tools in the filtered water with a clean lint-free cloth.
4. Use a 50 mL syringe to flush the interiors and openings of all parts and tools with filtered water to remove all bubbles.
5. During the immersion, press the pistons of air/water valve and suction valve to the end and release them for at least 3 times to remove all bubbles.
6. Clean the bristles of the cleaning brush and channel-opening cleaning brush in the filtered water to remove all bubbles.
7. Take out all parts and tools.

5.13.6 Drying

Perform the following steps.

1. Fill a basin with sufficient 75% ethyl alcohol.
2. Immerse all parts and tools into the ethyl alcohol and gently stir them.
3. Use a 50 mL syringe to inject the ethyl alcohol into the interiors and openings of all parts and tools to remove all bubbles.
4. Clean the bristles of the cleaning brush and channel-opening cleaning brush in the ethyl alcohol to remove all bubbles.
5. During the immersion, press the pistons of air/water valve and suction valve to the end and release them for at least 3 times to remove all bubbles.
6. Take out all parts and tools from the ethyl alcohol.
7. Place the parts and tools on a sterile mat which is placed on a medical drying table.
8. Thoroughly wipe the outer surfaces of all parts and tools with a sterile lint-free cloth.
9. Use a syringe to inject air to the interiors and openings of all parts and tools to dry them.

6 Storage and Disposal

Please store and dispose of the endoscope and its accessories as described in this chapter.

WARNING

- Before storage, the endoscope should be cleaned, disinfected or sterilized completely.
- After being dried, the endoscope should be stored in the clean endoscope cabinet with sound ventilation.
- Do not store the endoscope in a carrying case.
- The cabinet wall should be wiped with 0.05% chlorine solution twice a week. The cabinet should be handled immediately once it is contaminated.
- If the endoscope has been stored for more than 24 hours, it should be cleaned and disinfected again.

6.1 Storage

6.1.1 Storing the Endoscope

NOTE:

Before storing the endoscope, ensure that the surface of endoscope and the interiors of all channels are dry.

Perform the following steps.

1. Disconnect all accessories from the endoscope, including the air/water valve, suction valve, biopsy valve, waterproof cap and protective cover.
2. Ensure that the outer surface of the entire endoscope is dry.
3. Rotate the up/down and left/right angulation locks to free the bending section of the endoscope completely.
4. Hang the endoscope in the endoscope cabinet and ensure that the insertion section is vertically hung and completely stretched.

6.1.2 Storing the Accessories

NOTE:

Before storing the accessories, ensure that the air/water valve, suction valve, biopsy valve, waterproof cap and protective cover that have been cleaned, disinfected or sterilized are dry.

Perform the following steps.

1. Keep all accessories dry.
2. Store the reusable accessories in the endoscope cabinet and ensure that they are not in contact with each other.
3. Place the reusable cleaning, disinfection and sterilization tools in a container and put the container in the endoscope cabinet.

6.2 Transportation

■ Indoor Transportation

When transporting the endoscope from the disinfection room to the procedure room, the transport container for endoscope should be used.

■ Outdoor Transportation

WARNING

- The endoscope should be cleaned, disinfected or sterilized before being placed into the carrying case. Otherwise, the carrying case may be contaminated or cross contamination may be incurred.
- The waterproof cap and protective cover should be disconnected before transportation. Otherwise, the endoscope may be damaged by air pressure.

Perform the following steps.

1. Disconnect the waterproof cap and protective cover from the endoscope.
2. Rotate the up/down and left/right angulation locks of the endoscope to free the bending section completely.
3. Place the endoscope into the carrying case provided by the manufacturer.
4. Lock the carrying case for transportation.

6.3 Disposal

The manufacture date of the device is on the nameplate as shown in Figure 6-1. The expected service life of the device is five years with normal use, and its service life can be prolonged according to its using frequency and maintenance. When the device expired, you should dispose of the device according to local laws and regulations, or contact the manufacturer for maintenance.

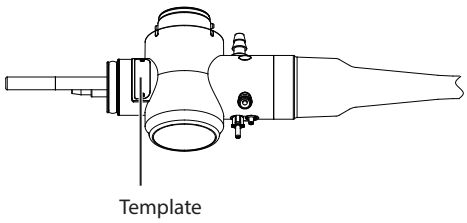


Figure 6-1 Date of Manufacture

6.4 Customer Service

Only the service personnel of or authorized by the manufacturer can service the device. Any feedback or inquiries concerning our product or services should be directed to the manufacturer.

Contact address: 2F, 12th Building, Shenzhen Software Park Phase II, Keji Middle 2nd Road, Nanshan District, Shenzhen, 518057, Guangdong, China

Tel: +86-755-26722890

E-mail: service@sonoscape.net

7 Troubleshooting

This endoscope should be maintained by the qualified technical personnel. If the problem still exists after resolving as described in this chapter, stop using the endoscope immediately and return it to the manufacturer for repair.

The manufacturer is not responsible for repairing the accessories of this endoscope. If any accessory is damaged, please contact the local distributor of the manufacturer for replacement. During use, any serious incident that has occurred in relation to the device should be reported to the local distributor and the competent authority of the Member State.

Item	Descriptions	Level	Cause	Solutions
Leakage	The leakage detector does not function or continuous bubbles appear.	B	The rubber wrapping the bending section of the endoscope is damaged.	Stop using the endoscope.
		B	The sealing ring is aging.	Stop using the endoscope.
		B	The channel is broken.	Stop using the endoscope.
Endoscopic image	No image.	C	The power cable of the image processor is not connected.	Connect the image processor and power on the processor.
		C	The endoscope cable is not connected.	Connect the endoscope cable.
		C	The image processor is not powered on.	Power on the image processor.
		B/A	Others	Stop using the endoscope.
	Image is dimmer.	C	The intensity of the light source is too low.	Adjust the intensity of the light source.
	Image is too bright.	C	The intensity of the light source is too high.	Adjust the intensity of the light source.
	Image is blurry.	C	The objective lens is dirty.	Clean the objective lens.
		B	Water drops or color bar appear in the field of view.	Stop using the endoscope.

Item	Descriptions	Level	Cause	Solutions
Ultrasonic image	No image.	C	The ultrasound system is disconnected.	Connect and power on the ultrasound system.
		C	The ultrasound system is powered off.	Power on the ultrasound system.
		C	The transducer is far away from the upper digestive tract wall.	Inject sterile water and adjust the distal end.
		C	The ultrasound system connector is disconnected.	Connect the ultrasound system connector to the ultrasound system.
	Image is blurred.	C	The image gain level of the ultrasound system is too low.	Adjust the image gain level of the ultrasound system.
	Image is too bright.	C	The image gain level of the ultrasound system is too high.	Adjust the image gain level of the ultrasound system
	Image is interfered.	B	The image is interfered by high frequency noise.	Power off the high frequency endotherapy accessory.
Feed air	The air is insufficient.	C	The water bottle cap is loose.	Fasten the cap of the water bottle.
		C	The air/water nozzle is blocked.	Immerse the distal end in the soapy water at the appropriate temperature and feed air to remove objects from the air/water nozzle.
	Cannot feed air.	C	The air/water valve is damaged.	Replace the air/water valve.
		C	The air pump is not turned on.	Turn on the air pump of the light source as described in the user manual.

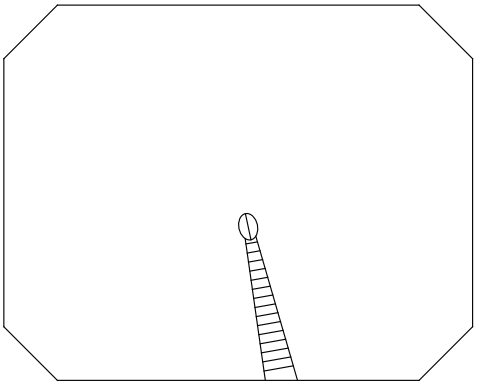
Item	Descriptions	Level	Cause	Solutions
Feed water	The water is insufficient.	C	The air/water nozzle is blocked.	Immerse the distal end in the soapy water at the appropriate temperature and feed air to remove the objects from the air/water nozzle.
		C	The water bottle cap is loose.	Fasten the cap of the water bottle.
	Cannot feed water.	C	There is no water in the bottle.	Pour an appropriate amount of sterile water into the bottle.
		C	The air/water valve is damaged.	Replace the air/water valve.
		C	The air pump is not turned on.	Turn on the air pump of the light source as described in the user manual.
Suction	Cannot aspirate or the aspirated amount decreases.	C	The suction valve is blocked.	Remove the suction valve and clean the hole with a swab.
		C	The suction valve is damaged.	Replace the suction valve.
		C	The channel is blocked.	Stop using the endoscope.
		C	The biopsy valve is damaged.	Replace the spare biopsy valve.
	The suction valve is sticky.	C	The suction valve is dirty.	Remove and flush the suction valve and clean the opening of the valve with the a swab dampened with ethyl alcohol.
	The instrument channel leaks.	B	The instrument channel is damaged by improperly using of the accessories such as biopsy forceps.	Stop using the endoscope.
	Liquid or air leaks from the biopsy valve.	C	The biopsy valve is aging or damaged.	Replace the spare biopsy valve.

Item	Descriptions	Level	Cause	Solutions
Bending section	It is hard to rotate the angulation control knob.	C	The angulation control knob is locked.	Unlock the angulation control knob.
		B	Others	Stop using the endoscope.
	The bending section is not sensitive.	B	The elasticity of steel wires inside the endoscope degrades after being used for a long period.	Stop using the endoscope.
	The bending section cannot reach the maximum angle.	B	The elasticity of steel wires inside the endoscope degrades after being used for a long period.	Stop using the endoscope.
	The bending section does not function.	A	The steel wires inside the endoscope are damaged.	Stop using the endoscope.
Accessories	The endoscope cable malfunctions.	B	The endoscope cable is damaged.	Stop using the endoscope.
	The endotherapy accessory cannot get through the instrument channel smoothly.	C	The endotherapy accessory and the endoscope are not compatible.	Select a compatible endotherapy accessory.
		C	The tip of endotherapy accessory is open.	Close the endotherapy accessory tip.
		C	The bending section of the endoscope is bent.	Adjust the distal end and reinsert the endotherapy accessory.

NOTE:

- *Level C means that you can solve the problem by yourself.*
- *Level B means that you should contact the local distributor.*
- *Level A means that you should return the endoscope to the local distributor for repair.*

Appendix A Specifications

Dimensions	Total length	1600 mm, allowance: ± 10%
	Working length	1250 mm, allowance: ± 10%
	Minimum inner diameter of the instrument channel	≥ Φ2.2 mm
	Outer diameter of the insertion tube	Φ11.5 mm, allowance: +10%, not considering lower limit.
	Outer diameter of the distal end	Φ11.3 mm, allowance: +5%, not considering lower limit.
Ultrasound imaging	Display mode	B, M, CFM, PW, PDI and THI
	Scanning method	Ring array scanning
	Scanning direction	Perpendicular to the insertion direction
	Frequency	4.5 MHz - 12.5 MHz
	Scanning angle	360°
	Contact method	Using balloon or sterile deaerated water
Imaging system	Field of view	140°, allowance: ± 10%
	Depth of view	3 - 100 mm
	Biopsy entrance position	
Water/air-feeding & Suction System	Amount of fed water	≥ 40 mL/min
	Amount of fed air	≥ 800 mL/min
	Aspirated amount	≥ 200 mL/min
Bending Section	Range	Up 180°, down 90°, left 100°, right 100° Allowance: -10%, not considering upper limit.

Environment requirements	Operation	Temperature	5°C - 40°C
		Relative humidity	30% - 80%
		Atmospheric pressure	700hPa - 1060hPa
	Storage	Temperature	-5°C - +40°C
		Relative humidity	30% - 80%
		Atmospheric pressure	700hPa - 1060hPa
	Transportation	Temperature	-20°C - +55°C
		Relative humidity	20% - 90%
		Atmospheric pressure	700hPa - 1060hPa
Safety types	Degree of protection against electric shock	Type BF applied part (Applied part: the ultrasonic gastrovideoscope)	
	Degree of protection against harmful liquid	IPX7	

Appendix B EMC Guidance and Manufacturer's Declaration

CAUTION

- The device is suitable for use in professional healthcare facility environment. Do not use it in domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
- Do not use this device around strong electric field, electromagnetic field (e.g. MRI scan room) and mobile wireless communication devices. Using the device in an improper environment may cause malfunction or damage.
- Only the peripherals (such as ultrasound system, image processor, light source, etc.) provided or recommended by the manufacturer can be used. Using other devices may increase RF radiation and degrade the device performance of anti-electromagnetic interference.
- Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.
- Use of accessories and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- 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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.

The following cables should be used with the device to comply with the requirements of electromagnetic emissions and electromagnetic immunity.

No.	Name	Length (m)	Shielded or Not
1	AC Power Cable	2.5	No
2	Endoscope Cable	0.387 (natural state)	Yes
3	DVI Cable	2.9	Yes
4	Light Control Cable	1.0	Yes
5	DC Power Cable	1.05	No
6	Keyboard Cable	1.8	No
7	Footswitch Cable	2.9	No

The essential performance of the device is as follows:

- The device can continuously output normal real-time images without affecting basic observation effects (free from image flip, black screen, blurred screen, severe screen interference, or screen flickering).
- The device can output expected real-time ultrasound images (free from noise on a waveform or artefacts or distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis).
- The working status of the transducer is within the expected range.
- The temperature rise of the transducer is within the standard requirements.

B.1 Electromagnetic Emissions

Emissions Test	Compliance
Conducted and Radiated RF Emissions CISPR 11	Group 1 Class A
Harmonic Distortion IEC 61000-3-2	Not Applicable
Voltage Fluctuations and Flicker IEC 61000-3-3	Not Applicable

B.2 Electromagnetic Immunity

Immunity Test	Compliance Level
Electrostatic Discharge (ESD) IEC 61000-4-2	±8kV Contact, ±2kV, ±4kV, ±8kV, ±15kV Air
Radiated RF EM fields IEC 61000-4-3	3V/m
Electrical Fast Transient and bursts IEC 61000-4-4	±2kV for power supply lines, ±1kV for SIP/SOP ports
Surges IEC 61000-4-5	±1kV differential mode ±2kV common mode
Conducted Disturbances IEC 61000-4-6	3V 6V at ISM bands
Voltage dips and interruptions IEC 61000-4-11	0% U_T for 0.5 cycle at 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º
	0% U_T for 1 cycle Single phase: at 0º
	70% U_T for 25 cycle Single phase: at 0º
	0% U_T for 250 cycle
Power frequency Magnetic field IEC 61000-4-8	30A/m

Appendix C Acoustic Output Data

Refer to the next page.

Acoustic Output of P60 Series Ultrasound System

Operating Mode: B

Index label		*MI*	*TIS*		*TIB*		*TIC*
			At Surface	**Below Surface**	**At Surface**	**Below Surface**	
Maximum index value		0.608	0.217		2.818		n/a
Index component value			0.217	0.217	2.818	0.217	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.056					
	P (mW)		86		86		n/a
	P_{1x1} (mW)		18.7		18.7		
	Z_s (cm)			n/a			
	Z_b (cm)					n/a	
	Z_{MI} (cm)	2.9					
	$Z_{pii,\alpha}$ (cm)	2.9					
	f_{awf} (MHz)	6.552	6.552		6.552		n/a
Other Informantion	prr (Hz)	32000					
	Srr (Hz)	70					
	n_{pps}	11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm²)	17.30					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm²)	30.48					
	I_{spta} at z_{pii} or z_{sii} (mW/cm²)	49.12					
	p_r at z_{pii} (MPa)	1.043					
Operating control conditions	Control 1						
	Control 2						
	Control 3						
	Control 4						
	……						
	Control x						

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface”and “below surface”both in the columns related to *TIS* or *TIB.*

NOTE 3 Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS, TIB* or *TIC.*

NOTE 5 If the requirement of 201.12.4.2b) are met, it is not required to enter any data in the columns related to *MI*.

NOTE 6 “√”indicates cells where a numerical value should be entered.The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON—SCANNING MODES,while the depths z_{pii} and $z_{pii,\alpha}$ apply to SCANNING MODES.

Operating Mode: THI

Index label		*MI*	*TIS*		*TIB*		*TIC*
			At Surface	**Below Surface**	**At Surface**	**Below Surface**	
Maximum index value		0.307	0.967		5.22		n/a
Index component value			0.967	0.967	5.22	0.852	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.508					
	P (mW)		160.5		160.5		n/a
	P_{1x1} (mW)		34.4		34.4		
	Z_s (cm)			n/a			
	Z_b (cm)					n/a	
	Z_{MI} (cm)	4					
	$Z_{pii,\alpha}$ (cm)	4					
	f_{awf} (MHz)	6.75	6.75		6.75		n/a
Other Informantion	prr (Hz)	28000					
	Srr (Hz)	25					
	n_{pps}	11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	1.95					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	1.467					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	3.38					
	p_r at z_{pii} (MPa)	0.533					
Operating control conditions	Control 1						
	Control 2						
	Control 3						
	Control 4						
	……						
	Control x						

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface”and “below surface”both in the columns related to *TIS* or *TIB.*

NOTE 3 Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS, TIB* or *TIC.*

NOTE 5 If the requirement of 201.12.4.2b) are met, it is not required to enter any data in the columns related to *MI*.

NOTE 6 “√”indicates cells where a numerical value should be entered.The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON—SCANNING MODES,while the depths z_{pii} and $z_{pii,\alpha}$ apply to SCANNING MODES.

Operating Mode: B+CFM

Index label		*MI*	*TIS*		*TIB*		*TIC*
			At Surface	**Below Surface**	**At Surface**	**Below Surface**	
Maximum index value		0.832	0.218		1.042		n/a
Index component value			0.218	0.218	4.94	1.042	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.286					
	P (mW)		271.9		544		n/a
	P_{1x1} (mW)		52.21		104.4		
	Z_s (cm)			n/a			
	Z_b (cm)					n/a	
	Z_{MI} (cm)	4.2					
	$Z_{pii,\alpha}$ (cm)	4.2					
	f_{awf} (MHz)	6.55	6.74		6.74		n/a
Other Informantion	prr (Hz)	5000					
	Srr (Hz)	17					
	n_{pps}	11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	99					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	10.9					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	21.93					
	p_r at z_{pii} (MPa)	1.676					
Operating control conditions	Control 1						
	Control 2						
	Control 3						
	Control 4						
	……						
	Control x						

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface”and “below surface”both in the columns related to *TIS* or *TIB.*

NOTE 3 Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS, TIB* or *TIC.*

NOTE 5 If the requirement of 201.12.4.2b) are met, it is not required to enter any data in the columns related to *MI*.

NOTE 6 “√”indicates cells where a numerical value should be entered.The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON—SCANNING MODES,while the depths z_{pii} and $z_{pii,\alpha}$ apply to SCANNING MODES.

Operating Mode: B+PDI

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		0.891	0.236		0.785		n/a
Index component value			0.236	0.236	3.56	0.785	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.47					
	P (mW)		233.3		465		n/a
	P_{1x1} (mW)		46.2		92.4		
	Z_s (cm)			n/a			
	Z_b (cm)					n/a	
	Z_{MI} (cm)	4.2					
	$Z_{pii,\alpha}$ (cm)	4.2					
	f_{awf} (MHz)	6.8	6.987		6.987		n/a
Other Informantion	prr (Hz)	1000					
	Srr (Hz)	18					
	n_{pps}	11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	130.5					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	7.47					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	17.16					
	p_r at z_{pii} (MPa)	2.031					
Operating control conditions	Control 1						
	Control 2						
	Control 3						
	Control 4						
	……						
	Control x						

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface”and “below surface”both in the columns related to *TIS* or *TIB.*

NOTE 3 Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS, TIB* or *TIC.*

NOTE 5 If the requirement of 201.12.4.2b) are met, it is not required to enter any data in the columns related to *MI*.

NOTE 6 “√”indicates cells where a numerical value should be entered.The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON—SCANNING MODES,while the depths z_{pii} and $z_{pii,\alpha}$ apply to SCANNING MODES.

Operating Mode: B+PW

Index label		*MI*	*TIS*		*TIB*		*TIC*
			At Surface	**Below Surface**	**At Surface**	**Below Surface**	
Maximum index value		0.605	1.234		2.825		n/a
Index component value			1.234	1.101	5.331	2.825	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.97					
	P (mW)		192.8		385		n/a
	P_{1x1} (mW)		106.2		213.8		
	Z_s (cm)			2			
	Z_b (cm)					2	
	Z_{MI} (cm)	2.9					
	$Z_{pii,\alpha}$ (cm)	2.9					
	f_{awf} (MHz)	6.55	6.55	6.745	6.55	6.745	n/a
Other Informantion	prr (Hz)	32000					
	Srr (Hz)	70					
	n_{pps}	11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	17.35					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	30.47					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	49.11					
	p_r at z_{pii} (MPa)	1.035					
Operating control conditions	Control 1						
	Control 2						
	Control 3						
	Control 4						
	……						
	Control x						

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface”and “below surface”both in the columns related to *TIS* or *TIB.*

NOTE 3 Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS, TIB* or *TIC.*

NOTE 5 If the requirement of 201.12.4.2b) are met, it is not required to enter any data in the columns related to *MI*.

NOTE 6 “√”indicates cells where a numerical value should be entered.The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON—SCANNING MODES, while the depths z_{pii} and $z_{pii,\alpha}$ apply to SCANNING MODES.

Operating Mode: B+CFM+PW

Index label		*MI*	*TIS*		*TIB*		*TIC*
			At Surface	**Below Surface**	**At Surface**	**Below Surface**	
Maximum index value		0.823	1.215		3.45		n/a
Index component value			1.215	1.101	5.44	3.45	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.287					
	P (mW)		378.0		752.0		n/a
	P_{1x1} (mW)		140.6		280.4		
	Z_s (cm)			2			
	Z_b (cm)					2	
	Z_{MI} (cm)	4.2					
	$Z_{pii,\alpha}$ (cm)	4.2					
	f_{awf} (MHz)	6.75	6.984	6.421	6.984	6.5	n/a
Other Informantion	prr (Hz)	5000					
	Srr (Hz)	17					
	n_{pps}	11					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	99					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	10.82					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	21.91					
	p_r at z_{pii} (MPa)	1.674					
Operating control conditions	Control 1						
	Control 2						
	Control 3						
	Control 4						
	……						
	Control x						

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface”and “below surface”both in the columns related to *TIS* or *TIB.*

NOTE 3 Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS, TIB* or *TIC.*

NOTE 5 If the requirement of 201.12.4.2b) are met, it is not required to enter any data in the columns related to *MI*.

NOTE 6 “√”indicates cells where a numerical value should be entered.The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON—SCANNING MODES,while the depths z_{pii} and $z_{pii,\alpha}$ apply to SCANNING MODES.

Operating Mode: B+M

Index label		MI	TIS		TIB		TIC
			At Surface	Below Surface	At Surface	Below Surface	
Maximum index value		0.774	0.246		2.224		n/a
Index component value			0.246	0.246	1.972	2.224	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.204					
	P (mW)		176.2		352.6		n/a
	P_{1x1} (mW)		102.7		205.6		
	Z_s (cm)			4.2			
	Z_b (cm)					5	
	Z_{MI} (cm)	5					
	$Z_{pii,\alpha}$ (cm)	5					
	f_{awf} (MHz)	6.4	6.63	6.4	6.63	6.4	n/a
Other Informantion	prr (Hz)	2000					
	Srr (Hz)	n/a					
	n_{pps}	n/a					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	67.3					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	69.7					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	165.3					
	p_r at z_{pii} (MPa)	1.774					
Operating control conditions	Control 1						
	Control 2						
	Control 3						
	Control 4						
	……						
	Control x						

NOTE 1 Only one operating condition per index.

NOTE 2 Data should be entered for “at surface”and “below surface”both in the columns related to *TIS* or *TIB.*

NOTE 3 Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to *TIS, TIB* or *TIC.*

NOTE 5 If the requirement of 201.12.4.2b) are met, it is not required to enter any data in the columns related to *MI*.

NOTE 6 “√”indicates cells where a numerical value should be entered.The equipment setting related to the index has to be entered in the operating control section.

NOTE 7 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON—SCANNING MODES, while the depths z_{pii} and $z_{pii,\alpha}$ apply to SCANNING MODES.