About This Manual

P/N: 4710-01039A05

Release Date: February, 2023

Product Model: EG-550/EG-550L

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- 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.

Conventions

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

Item	Meaning
Click	Move the cursor to the controls on the display and press the **Set** key on the control panel.
>	Select a menu item or a key following the path.

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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 video gastroscope (hereinafter called endoscope) is intended to provide endoscopic images for the examination and diagnosis of the upper digestive tract (including the esophagus, stomach and duodenal bulb).

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.

1.1.1 Indications

The endoscope can be used for the following indications:

- Unexplained upper gastrointestinal hemorrhage
- Upper digestive tract symptoms requiring examination for diagnosis, aggravated digestive tract symptoms or pain pattern changes
- Upper gastrointestinal lesion that cannot be determined by the X-ray barium meal
- Suspected upper gastrointestinal tumor
- Lesions requiring follow-up, such as gastric ulcers, polyps and postoperative remnant stomach
- Lesions requiring endotherapy, such as foreign body taking, local hemostasis and stenting for upper gastrointestinal tract stenosis
- Unexplained anemia, especially persistent positive FOBT
- Healthy examination

1.1.2 Contraindications

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

■ **Relative contraindications**

- Common nervous but not organic mental disorders
- Mild cardiac arrhythmia, sinus tachycardia or atrial fibrillation
- Emphysema blood oxygen saturation less than normal
- Serious hypertension

■ **Absolute contraindications**

- Mental disorders and non-cooperated patient

- Severe cardiopulmonary insufficiency or organic disease, such as serious cardiac arrhythmias, severe heart failure and dyspnea
- Suspicious upper digestive tract perforation or perforation acute phase
- Severe acute throat disease, which cause the insertion failure
- Acute phase of gastric and esophageal chemical burns
- Severe spinal column deformity

1.2 Product Compatibility

The endoscope is used with HD-550 series image processor and VLS-50 series or VLS-55 series light source 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 stipulated 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 manufacturer can maintain the device. 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 standard for endoscopy and endoscopic treatment, follow the standard.
- Evaluate the property, purpose, benefit and risks (including medical risks, unknown risks and possibility) thoroughly before performing endoscopy. Perform endoscopy only when benefits outweigh risks.
- Make a detailed explanation to the patient about the benefits and risks of endoscopy and endoscopic diagnosis, as well as the methods to be applied.
- Only perform endoscopy with the patient's consent.
- Evaluate potential benefit 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 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 the 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.
- When the device is used with the electrosurgical accessories (such as high frequency electrotome), current leakage to the patient may be increased. Use the accessories with the safety protection type of at least Type BF.
- Ensure that no flammable gas exists in patient's body when using other accessories (such as high frequency surgical instruments). Otherwise, explosion may occur.

- When the device is used together with the endoscopically used accessories which are the applied parts of the high frequency surgical instruments, the isolation or insulation is provided by the endoscopically used accessories.
- Do not use the peak voltage higher than the rated one when using the high frequency surgical instruments. The maximum peak voltages in the following modes are:
  - Electrosurgical knife mode: 800 V
  - Mixed mode: 900 V
  - Coagulation electrode mode: 500 V

1.3.2 Accessory Safety

- 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.

1.3.3 Biohazard Considerations

- Patient's debris and chemicals for cleaning and disinfection 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, flush the eyes with water immediately 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 manufacturers or their local distributors.

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
	Type BF Applied Part
IPX7	Degree of protection against harmful liquid (Protection against short time immersion)
CE 0197	This product is provided with a CE marking in accordance with the regulations stated in Regulation (EU) 2017/745.
EC REP	Authorized representative in the European community

Symbol	Meaning
	Model number
	Country and date of manufacture, CHN is the country code of China.
	Medical device
	Unique device identifier
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	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

The endoscope is the hand-held, direct-viewing type.

To ensure the performance and availability of this endoscope, the operator should be 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.

- Video gastroscope
- Biopsy valve
- Injection tube
- Channel plug

Others: See the Packing List in the packaging box.

2.2 Component Introduction

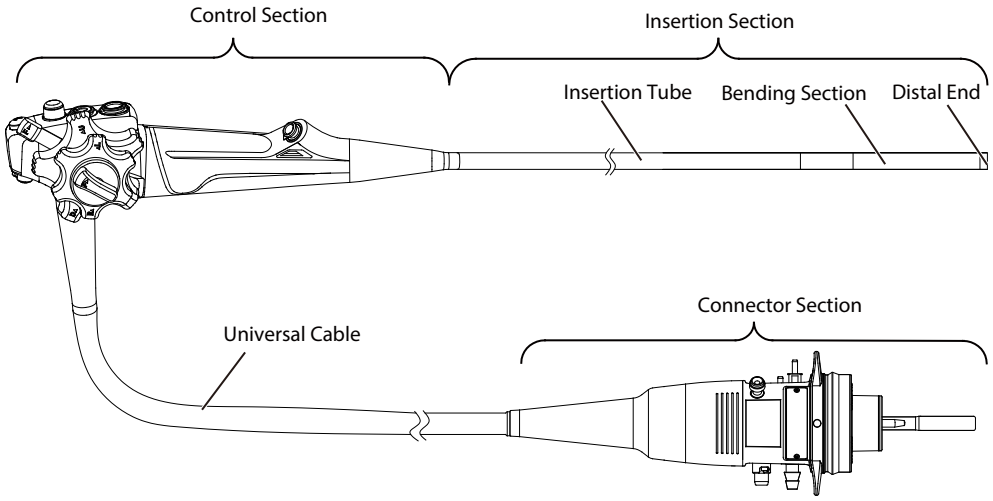


Figure 2-1 Endoscope

2.2.1 Connector Section

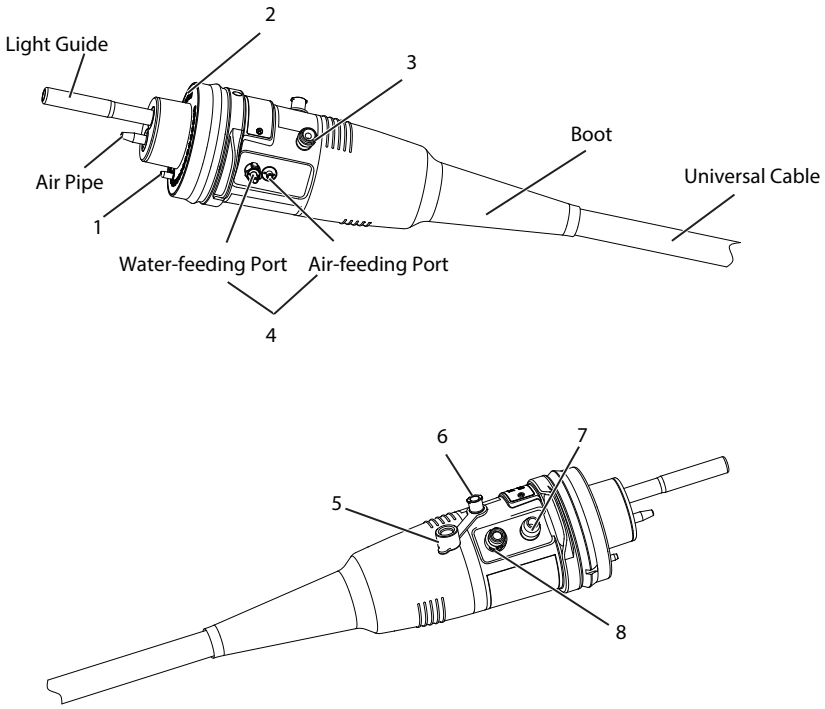


Figure 2-2 Connector Section

No.	Part Name	Description
1	Optical Fiber Connector	Used for transmitting image signals.
2	Electrical Contacts	Used for transmitting electrical signals.
3	Electrosurgical Equivalent Terminal	Used for connecting the electrosurgical equipment.
4	Air/Water-feeding Port	Used for connecting to the water bottle to feed water/air to the distal end.
5	Cap for Auxiliary Water-feeding Port	• Used for protecting the auxiliary water-feeding port. • Used for preventing the auxiliary water-feeding channel from being blocked by foreign objects. • Used for preventing gas or liquid in patient's body from blowing or flowing back during examination. Cover the cap when the auxiliary water-feeding tube is not in use.
6	Auxiliary Water-feeding Port	Used for connecting to the auxiliary water-feeding tube to feed water to the auxiliary water-feeding channel through the tube.
7	Suction Port	Used for connecting to the suction pump through the suction tube.
8	Leakage Detector Port	Used for connecting the leakage detector for leakage detection.

2.2.2 Control and Insertion Sections

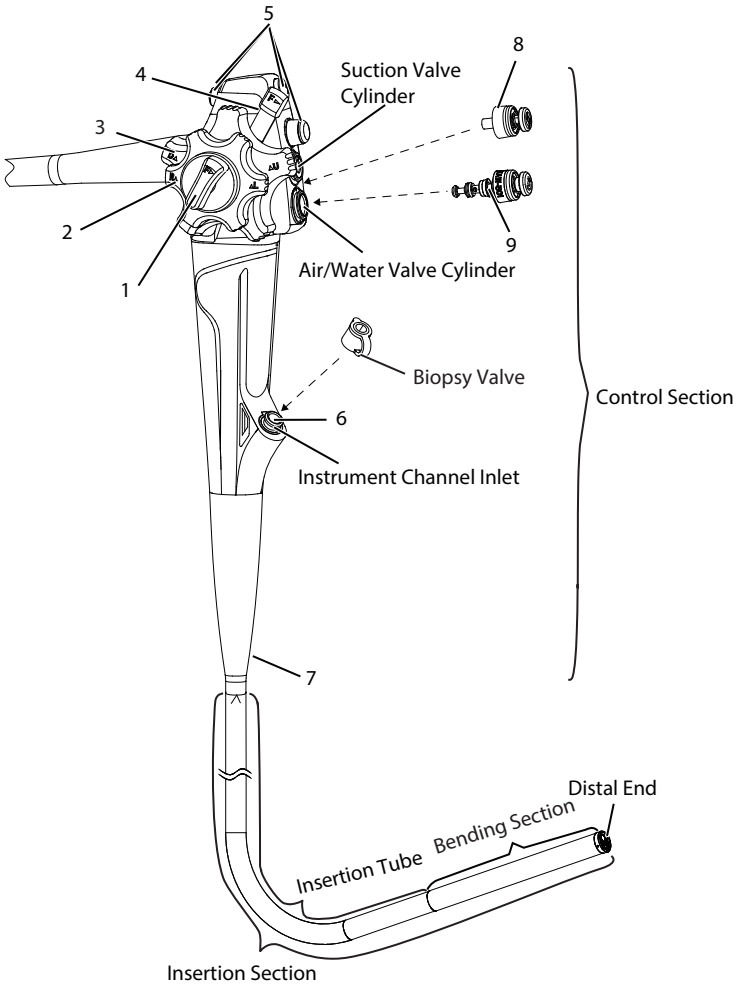


Figure 2-3 Control and Insertion Sections

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 any desired 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 any desired angle.
5	Remote Buttons (0-3)	Set the functions of the four buttons through the image processor connected with the endoscope.

No.	Part Name	Descriptions
6	Instrument Channel	This channel should be used with the biopsy valve and the functions are as follows. ● Used to feed the liquid to the distal end of the endoscope. ● Used for the endotherapy accessory. ● Used as a part of the suction channel.
7	Insertion Limit Mark	Indicates the maximum length of the insertion section that can be inserted into the patient's body.
8	Suction Valve	Press it to aspirate liquid, debris or gas from the patient's body.
9	Air/Water Valve	● Cover the hole on the valve with a finger to feed air. ● Press it 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.

2.2.3 Distal End

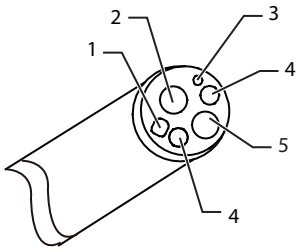


Figure 2-4 Distal End

No.	Part Name	Description
1	Air/Water Nozzle	Used as an outlet for feeding air or water.
2	Objective Lens	Used for transmitting the optical signals of the tissue image to be observed to the sensor.
3	Auxiliary Water-feeding Outlet	Water spurts out from the outlet.
4	Light Guide Lens	Light is transmitted through these lenses to assist endoscopic image observation.
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 this 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.

- The endoscope is not cleaned and disinfected in the factory. Therefore, the operator should clean and disinfect the endoscope as described in Chapter 5 Cleaning and Disinfection before use.
- For the safety of the patient and operator, do not use the malfunctioning endoscope.
- The operator should inspect the device periodically to ensure the performance of the device.
- Disinfect, terminally rinse and dry the device before the first use of the device everyday.

3.1 Inspecting the Endoscope

Before inspection, clean and disinfect the endoscope as described in Chapter 5 Cleaning and Disinfection.

3.1.1 Inspecting the Appearance and Flexibility

Perform the following inspections to inspect the appearance and flexibility of the endoscope.

- 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.
- Hold the insertion section with two hands and bend it to a semicircle to ensure that the entire insertion section is flexible and can be smoothly bent.
- Ensure that there is no scratchor breakage on the objective lens and light guide lenses 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.

3.1.2 Inspecting the Angulation

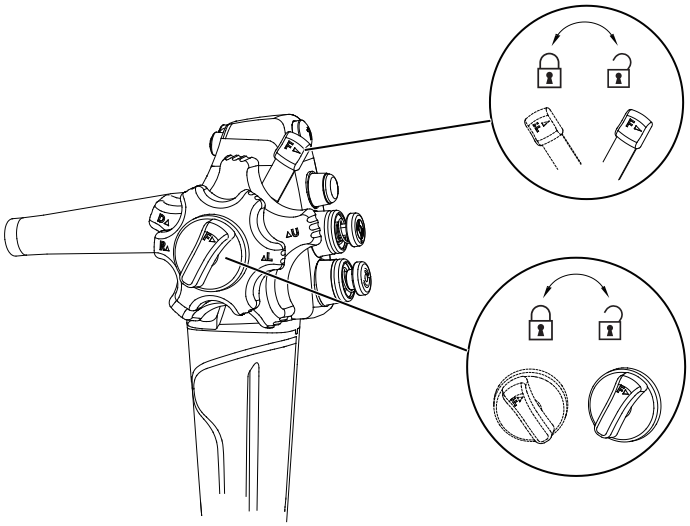
Do not use the endoscope if any angulation control knob is too loose or tight. Otherwise, it may result in injury, bleeding or perforation to the patient during the examination.

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

■ **To inspect the flexibility**

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.



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 can restore to almost 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 up and down 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 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

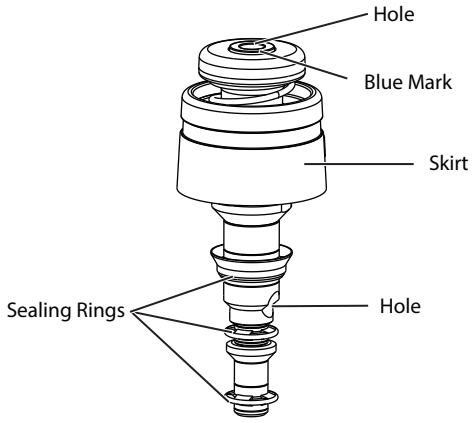
The accessories include the ones for clinical examination and the ones for cleaning and disinfection. This section only introduces the ones for clinical examination. For the information of other accessories, please refer to Section 5.2 Cleaning and Disinfection Tools.

3.2.1 Air/Water Valve

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

WARNING Ensure that the hole on the 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**



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**

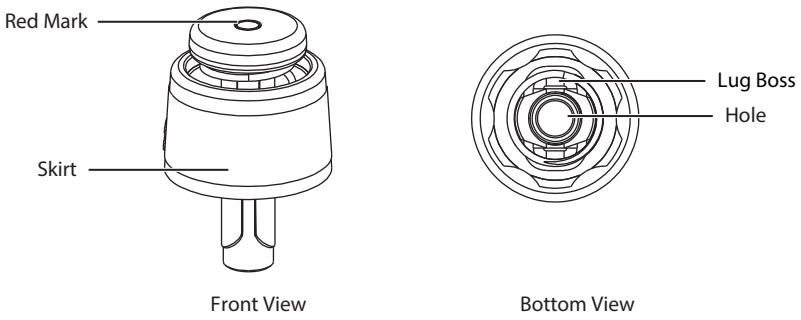
Install the air/water valve to the air/water valve cylinder of the endoscope properly.

NOTE:

- *Do not apply lubricant on the air/water valve. Otherwise, the sealing ring may bulge to cause the 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**



Perform the following inspections before using the suction valve.

- Ensure that the valve is not cracked, deformed or damaged.
- Ensure that the hole on the valve is not blocked.

■ **Installation**

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

NOTE:

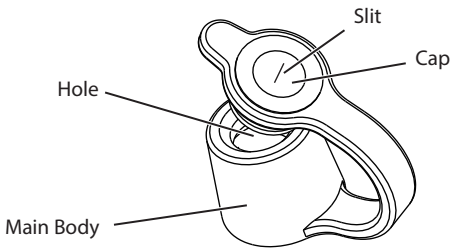
- *Noise may be heard during use if the suction valve is dry, which does not affect the valve function.*
- *Red mark is used to distinguish this valve from the air/water valve of the endoscope.*

3.2.3 Biopsy Valve

WARNING

- The 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 liquid and disease infection.

■ **Inspection**



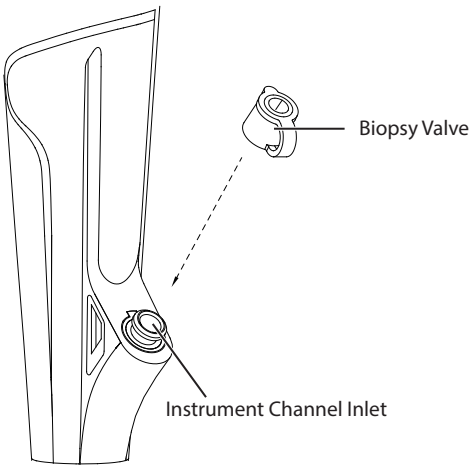
Perform the following inspections before using the biopsy valve .

- Ensure that the 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.



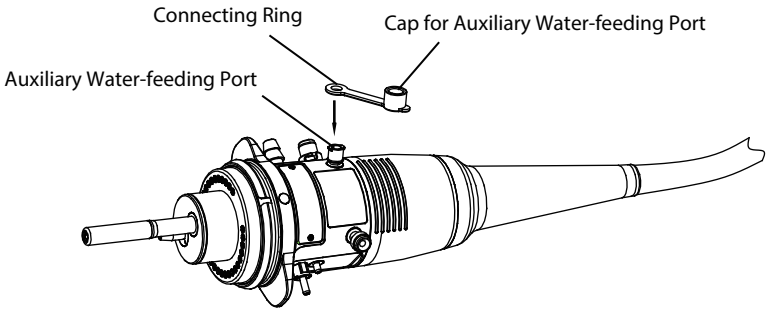
2. Install the biopsy valve to the instrument channel inlet of the endoscope properly.

3.2.4 Cap for Auxiliary Water-feeding Port

■ **Inspection**

Ensure that the cap for auxiliary water-feeding port is not deformed, cracked or damaged.

■ **Installation**



Install the connecting ring to the auxiliary water-feeding port of the connector section.

3.3 Connecting the Endoscopy System

NOTE:

- *Before connecting the endoscopy system, please power off all the 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.*

Connect the endoscopy system, as shown in Figure 3-1.

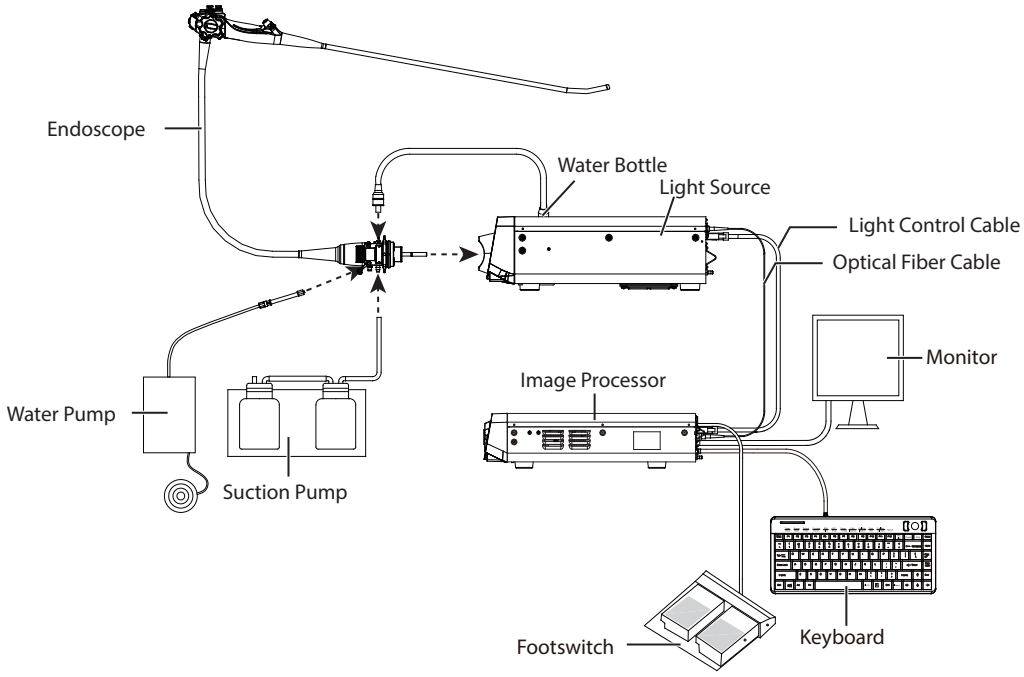
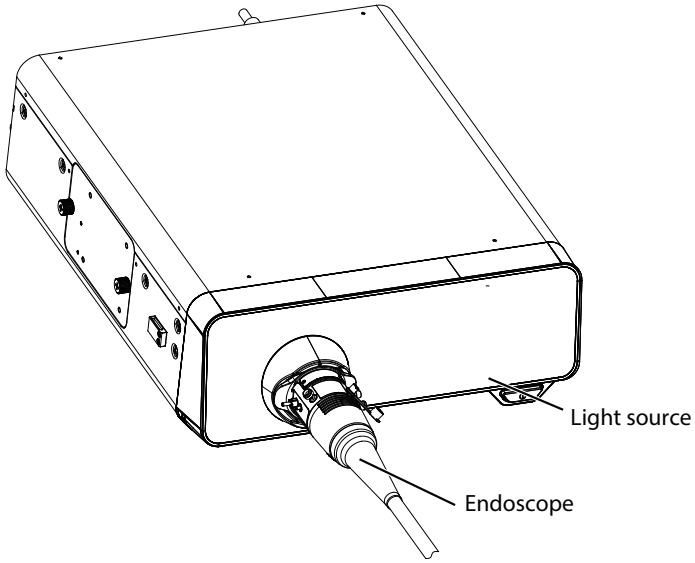


Figure 3-1 Connecting the Endoscopy System

3.3.1 Connecting the Light Source

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

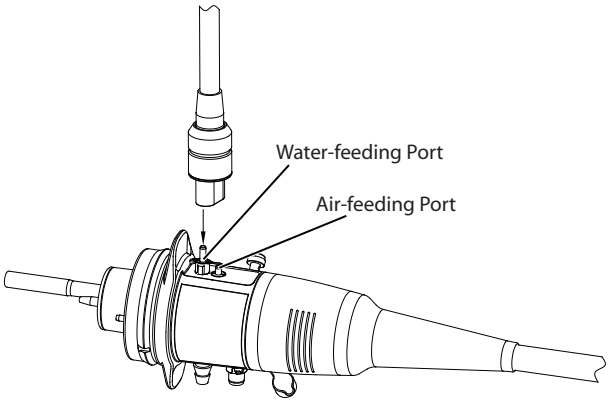


3.3.2 Connecting the Water Bottle

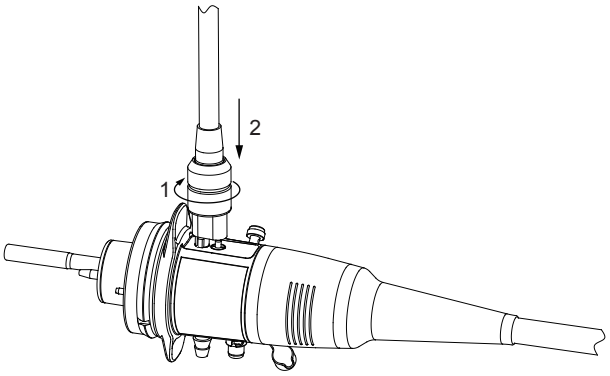
CAUTION The water bottle should be installed in the water bottle bracket at the right side of the light source. Do not place the water bottle casually. Otherwise, the water-feeding pipe would leak, causing malfunction.

Perform the following steps.

1. Connect the water-feeding connector of water bottle connector to the water-feeding port on the connector section firmly.



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



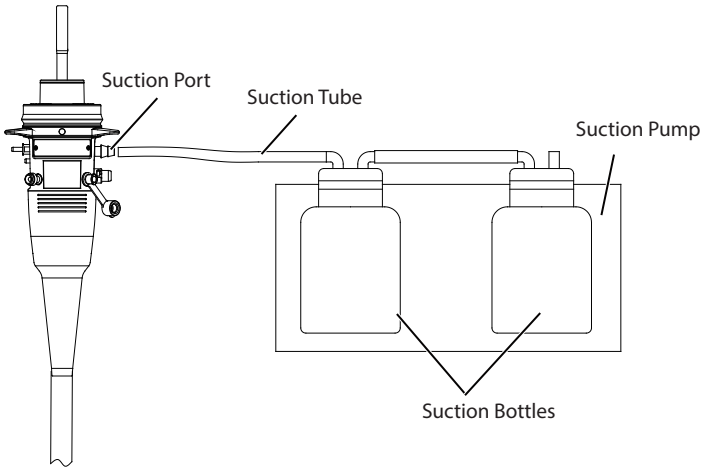
3. Ensure the water bottle connector is correctly connected and cannot be rotated.

3.3.3 Connecting the Suction Pump

WARNING

- If the suction tube is not connected firmly, patient's debris may leak from the tube during use and cause disease infection, suction degradation and damage to the device.
- 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.

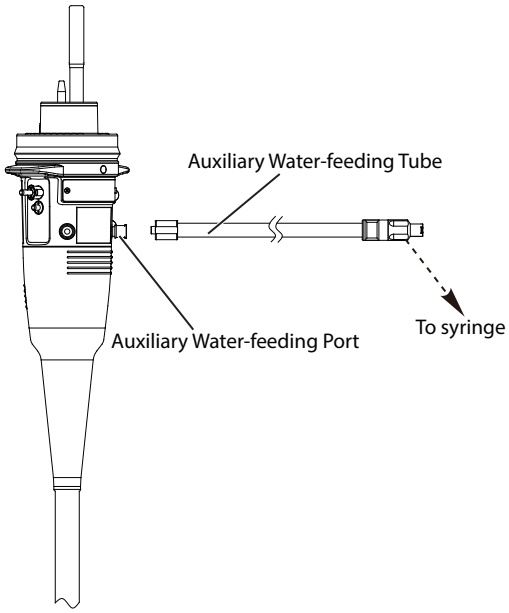


3.3.4 Connecting the Auxiliary Water-feeding Tube

NOTE:

Ensure that the auxiliary water-feeding tube is not scratched, cracked or damaged.

Remove the cap of auxiliary water-feeding port, connect one end of the auxiliary water-feeding tube to the auxiliary water-feeding port and rotate the tube clockwise until it is in position. Connect the other end to the syringe.



3.4 Inspecting the Endoscopy System

3.4.1 Inspecting the Image

WARNING Do not look straight 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. Press the **LAMP** button on the light source and ensure the 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 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.

3.4.3 Inspecting the Air-feeding Function

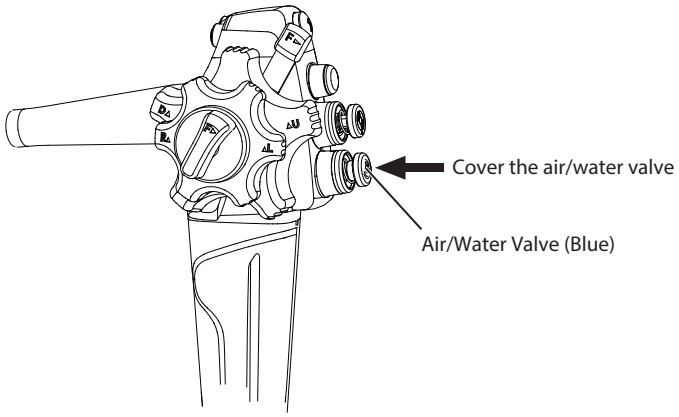
WARNING Use sterile water to inspect the air-feeding function to avoid disease infection.

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. Ensure that continuous bubbles are generated from the air/water nozzle.



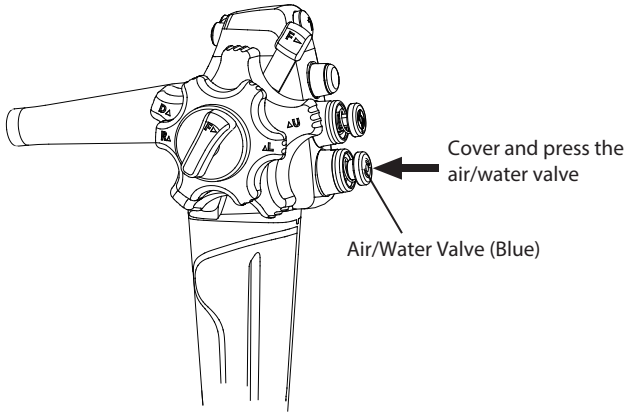
4. Release your finger and ensure that no bubble is generated from the air/water nozzle.

3.4.4 Inspecting the Water-feeding Function

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

Perform the following steps.

1. Cover the hole on the air/water valve with your finger, and press this valve to feed water. Observe the image on the monitor and ensure that water flows over the objective lens.



2. Release your finger and ensure that no water flows out, and the air/water valve restores to its original position smoothly.
3. Cover the hole with your finger and 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 image on the monitor is clear.

NOTE:

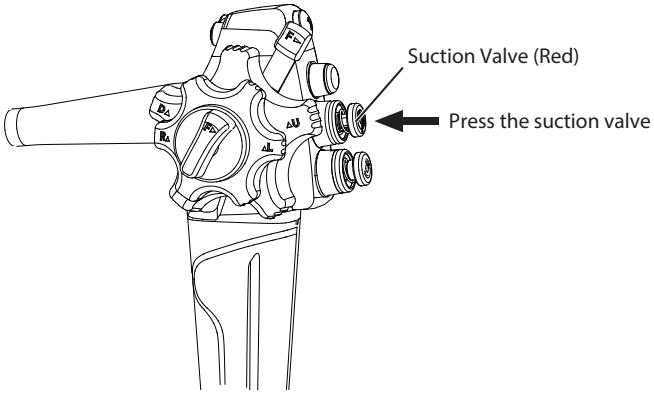
- *If the air/water valve is pressed for the first time, it may take a few seconds before water is fed.*
- *If the air/water valve restores to the original position very slowly after water-feeding, the operator should remove the air/water valve and moisten the sealing ring with sterile water.*

3.4.5 Inspecting the Suction Function

WARNING
- If the biopsy valve is leaky, patient's debris and body liquid could leak out and cause disease infection.
- If the suction valve cannot be 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.

Perform the following steps.

1. Adjust the suction pressure of the suction pump to the clinical examination standard.
2. Immerse the distal end in the 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. Press the suction valve and ensure that the water can be continuously aspirated to the suction bottle.



4. Release the suction valve and ensure that the suction stops, and the suction valve restores to its original position.
5. 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.
6. Take out the distal end from the container and press the suction valve to aspirate air for a few seconds to drain the water from the instrument channel and suction channel.

3.4.6 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 accessory can be smoothly withdrawn from the instrument channel.

3.4.7 Inspecting the Auxiliary Water-feeding Tube

WARNING
- Use sterile water to inspecting the auxiliary water-feeding tube avoid disease infection.
- The auxiliary water-feeding tube includes a back-flow preventer. Ensure that the tube is installed in position before use. Otherwise, back-flow liquid may result in damage to the device or personal injury.

Perform the following steps.

1. Connect one end of the auxiliary water-feeding tube to the auxiliary water-feeding port, and connect the other end to a syringe filled with sterile water.

2. Inject sterile water into the auxiliary water-feeding tube, and ensure that water flows from the distal end.
3. Observe both the connectors of the auxiliary water-feeding tube and ensure that there is no water leakage.
4. Remove the syringe from the auxiliary water-feeding tube, and ensure that no water flows from the tube connector connecting the syringe or the endoscope distal end.

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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's debris and chemicals for cleaning and disinfection 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 50°C due to intense illumination, which may cause mucosal burns. Always use the minimum 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.
- The patient should take off metallic accessories (watch, glasses, necklace and etc.) before the endoscopy when high frequency cauterization treatment is performed. Otherwise, it may result in skin burns around the accessories.
- 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 personal 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 variable intelligent staining technology (VIST) mode 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 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 false teeth to prevent it from accidentally falling off during the examination.

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 remote buttons with the index finger. Rotate the up/down and left/right angulation control knobs with the thumb. Operate the insertion section and the left/right and up/down angulation locks 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.

4.1.1 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.

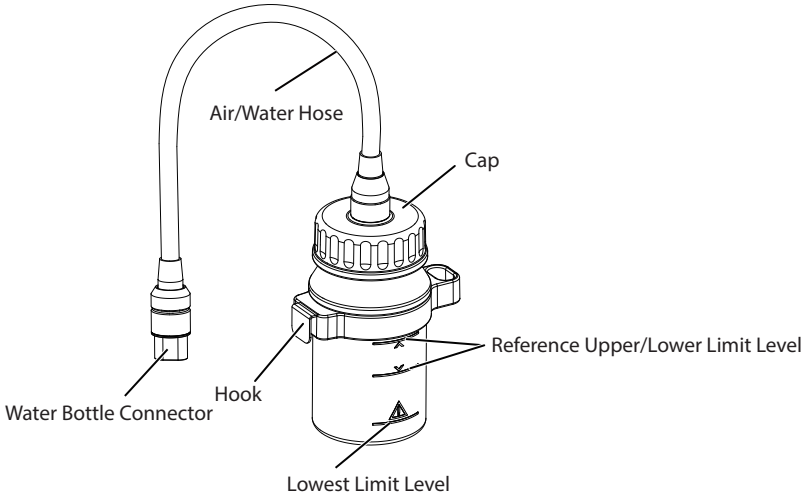
Perform the following steps.

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

4.1.2 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's 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 water bottle is shown in the following figure.



NOTE:

If the endoscope is used at a lower temperature, water vapor may condense on the surface of the objective lens, making the 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).

■ **To feed water/air**

Perform the following steps.

1. Cover the hole on the air/water valve to feed air through the air/water nozzle.
2. 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.

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.

4.1.3 Feeding Water through the Auxiliary Water-feeding Port

WARNING Use sterile water to avoid disease infection.

NOTE:

- *Do not remove the auxiliary water-feeding tube until the pre-cleaning is completed. Otherwise, the residual water in the tube may be splashed on the peripheral devices, causing damage to the peripheral devices.*
- *Cover the auxiliary water-feeding port with the cap when the port is not in use. Otherwise, debris or liquid in patient's body may flow back from the auxiliary water-feeding channel and spout from the auxiliary water-feeding port.*

Use a syringe to feed water to the endoscope through the auxiliary water-feeding tube and water will spurt out in stream from the distal end of the endoscope to flush the blood and debris adhering to the mucosa.

4.2 Observing the Endoscopic Image

Observe the endoscopic image on the monitor. For details, please refer to the light source user manual and image processor 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 image. Otherwise, it may result in serious personal injury or damage to the endoscope.
- 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.
- 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.

4.3.1 Using the Biopsy Forceps

WARNING

- Do not open the claws of the biopsy forceps if they are not visible on the endoscopic image. Otherwise, it may result in personal injury.
- When inserting or withdrawing the biopsy forceps, ensure that the claws are closed. Slowly and straightly insert or withdraw the endotherapy accessory into/from the instrument channel. Otherwise, the biopsy valve may be damaged and the biopsy tissues could fall off.
- Use the biopsy forceps before its expiration date of disinfection.
- The biopsy forceps are single-use accessories.

Perform the following steps.

1. Lock the up/down and left/right angulation control knobs and fix the bending section at the desired angle.
2. Ensure that the claws of the biopsy forceps are closed, and then slowly insert the biopsy forceps into the instrument channel.
3. Observe the image while slowly pushing the control handle of the biopsy forceps to ensure that the biopsy forceps move slowly in the instrument channel.
4. When the biopsy forceps are visible on the image, open the claws to nip the sample of tissue.
5. Slowly withdraw the biopsy forceps from the instrument channel. Ensure that the tissue is nipped securely during the withdrawal.

4.3.2 Using the Cytology Brush

Perform the following steps.

1. Lock the up/down and left/right angulation control knobs and fix the bending section at the desired angle.
2. Slowly insert the sheath in which the cytology brush is kept into the instrument channel while observing the image.
3. When the sheath is visible on the image, extend the cytology brush from the sheath and collect the sample by brushing the dropped cell gently.
4. Slowly retract the cytology brush back to the sheath and withdraw the sheath from the instrument channel.
5. Use the brush to make the smear sample.

4.3.3 Using the Syringe

Perform the following steps.

1. Fix the bending section at an appropriate angle.
2. Slowly insert the sheath in which the needle is kept into the instrument channel while observing the image.
3. When the sheath is visible on the image, gently extend the needle from the sheath and slowly inject the medicine or spray liquid.
4. Slowly retract the needle back to the sheath and withdraw the sheath from the instrument channel.

4.4 Withdrawing the Endoscope

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

Perform the following steps.

1. Ensure that the bending section of the endoscope is free.
2. Slowly withdraw the endoscope from the patient's body while observing the image.

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5 Cleaning and Disinfection

This chapter describes the methods for cleaning and disinfection of the series endoscopes mentioned in this manual and the basic information about how to safely and effectively clean and disinfect the series endoscopes.

Many medical science documents have recorded cross infection accidents caused by improper cleaning or high-level disinfection. 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 and disinfection standards
- Structures and usages of the endoscope and accessories
- Usage of relevant chemicals

For selecting the type and condition of cleaning and high-level disinfection, you can also refer to the cleaning and disinfection regulations of the local hospital for professional judgment.

- Patient's debris, cleaning solution and disinfectant are potentially dangerous. During cleaning or high-level disinfection, 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 and disinfection of the endoscope, all channels of the endoscope should be cleaned and disinfected, including the channel 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 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 45min.
- 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, the endoscope and its accessories should be destroyed by melting or burning when necessary because they cannot be completely disinfected.
- Dispose of single-use endotherapy accessories in accordance with local laws or regulations.
- Use the legally marketed automated endoscope reprocessor (AER) to reprocess the endoscope.
- If using an automated endoscope reprocessor (AER), ensure that it can thoroughly clean and disinfect the endoscope, including all channels. Otherwise, the next patient or the operator may be infected. For the operation, specifications and connector information of the AER, consult the AER manufacturer.
- The endoscope is not strictly cleaned and disinfected in the factory. Therefore, the operator should strictly perform the cleaning and high-level disinfection processes described in this manual before use.

- After use each time, the endoscope should be cleaned, disinfected 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 and disinfect the endoscope in accordance with the regulations of the local hospital based on the actual disinfection, and storage conditions of the endoscope.
- Before cleaning and disinfection, ensure that the insertion section of the endoscope is in natural state (unlocked). Otherwise, the endoscope may be damaged during the cleaning and disinfection process.
- Store the ethyl alcohol in a sealed container. Otherwise, a fire may be incurred. Besides, the alcohol may become invalid due to volatilization.
- The water quality for the cleaning and disinfection should meet the regulations in AAMI TIR34-2014.

5.1 Cleaning Solution, Disinfectant and Flush Fluid

- Use the cleaning solution and disinfectant that meet local laws and regulations.
- Use the cleaning solution and disinfectant recommended by the manufacturer, and ensure that their concentrations and the endoscope soak period meet the recommended conditions in this chapter. Otherwise, the endoscope may be damaged or the expected disinfection 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 and disinfectant in accordance with the instructions provided by the manufacturers.
- Do not use expired cleaning solution or disinfectant.
- The endoscope is not autoclavable or cannot be processed by low-temperature plasma.
- Do not dry any disinfectant on the surface of the endoscope in air.
- 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 dirt-removing power, facilitate cleaning, and improve the cleaning quality.

The following cleaning solutions are 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	Pre-cleaning and manual cleaning before manual disinfection
Dr. Weigert neodisher endo® CLEAN	5 -10 mL/L (0.5 - 1 %)	20°C - 40°C	5 - 10 min	Pre-cleaning and manual cleaning before automatic cleaning and disinfection
	5mL/L (0.5%)	35°C - 55°C	3 - 10 min	Automatic cleaning

NOTE:

- *Do not use the cleaning solution repeatedly.*

- *Excessive cleaning solution foaming could cause inadequate contact between the interior of the channels and the cleaning solution. Consequently, the endoscope cannot be cleaned completely.*

5.1.2 Disinfectant

The following disinfectants are recommended to disinfect the endoscope.

Table 5-2 Recommended Disinfectant and Method

Disinfectant	Concentration	Temperature	Contact Time	Using Method
MetriCide 28 Long-life Activated Dialdehyde Solution	2.5%	25°C	90 min	Manual disinfection
Dr. Weigert neodisher® Septo DN	10mL/L (1.0%)	55°C	5 min	Automatic 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 (with in 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 devices.*

5.1.3 Flush Fluid

The sterile water is recommended as the flush fluid. After high-level disinfection, completely rinse the endoscope, accessories and cleaning and disinfection tools with sterile water to remove the residual of disinfectant. 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 the flush fluid repeatedly.*

5.2 Cleaning and Disinfection Tools

Prepare the following items before cleaning and disinfection.

- Manual cleaning tank, rinse tank, disinfection tank and terminal rinse tank
- Manual cleaning basin, rinse basin, disinfection basin and terminal rinse basin
- Channel plug
- Injection tube
- Cleaning brush
- Channel-opening cleaning brush
- Leakage detector
- Suction pump
- Timer
- Transport container for endoscope
- Transport container for accessories

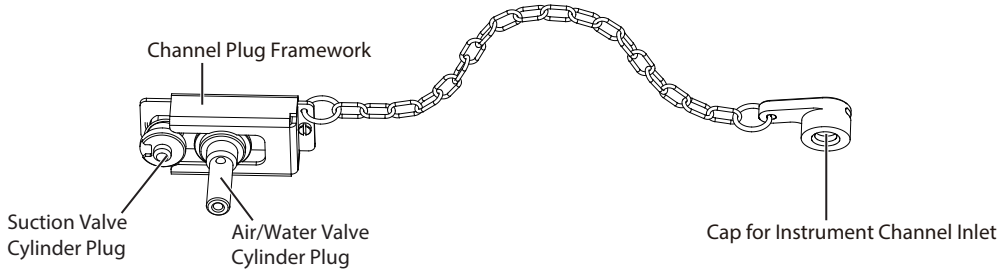
- Sterile mat
- Lint-free cloth (single-use)
- Sterile swab
- 30cm^3 (30 mL) syringe

5.3 Accessory Inspection and Connection

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

5.3.1 Channel Plug

The channel plug is used to plug the instrument channel inlet and the cylinders of air/water valve and suction valve during cleaning and disinfecting the endoscope. The following figure shows the channel plug.



NOTE:

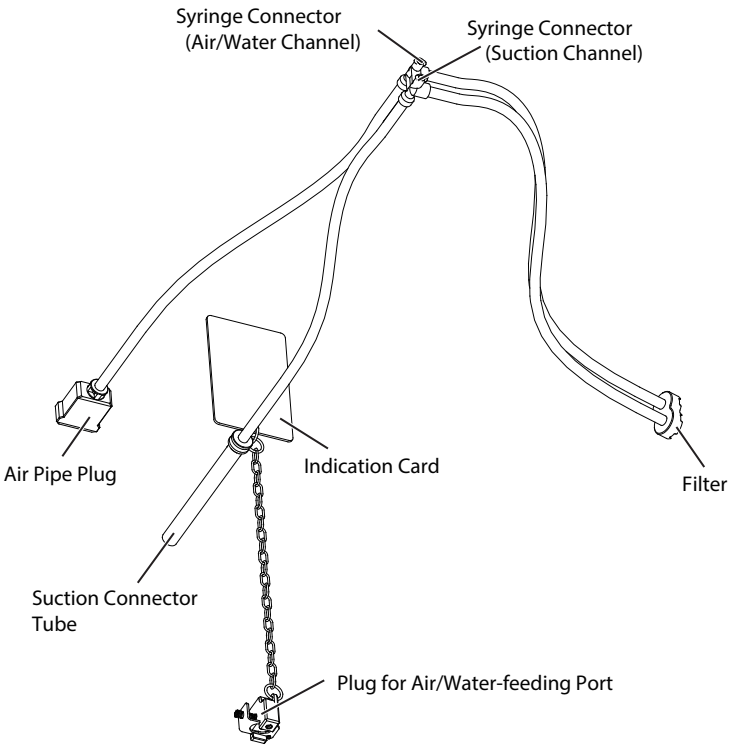
- *Before using a channel plug, ensure that there is no crack, scratch or debris on each plug and the cap.*
- *Ensure that the channel plug and the endoscope are firmly connected.*

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.
2. Press and push ahead the channel plug framework until the installation is firm.
3. Press the cap for instrument channel inlet into the instrument channel inlet, and ensure that the connection is firm.

5.3.2 Injection Tube

The injection tube is used to inject cleaning solution, disinfectant, 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.

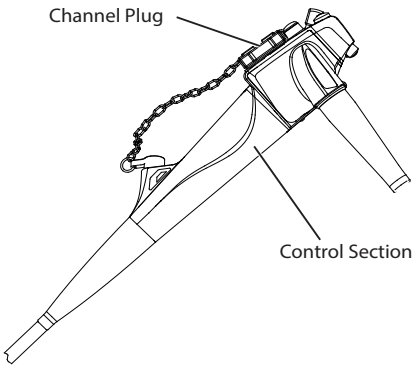


NOTE:

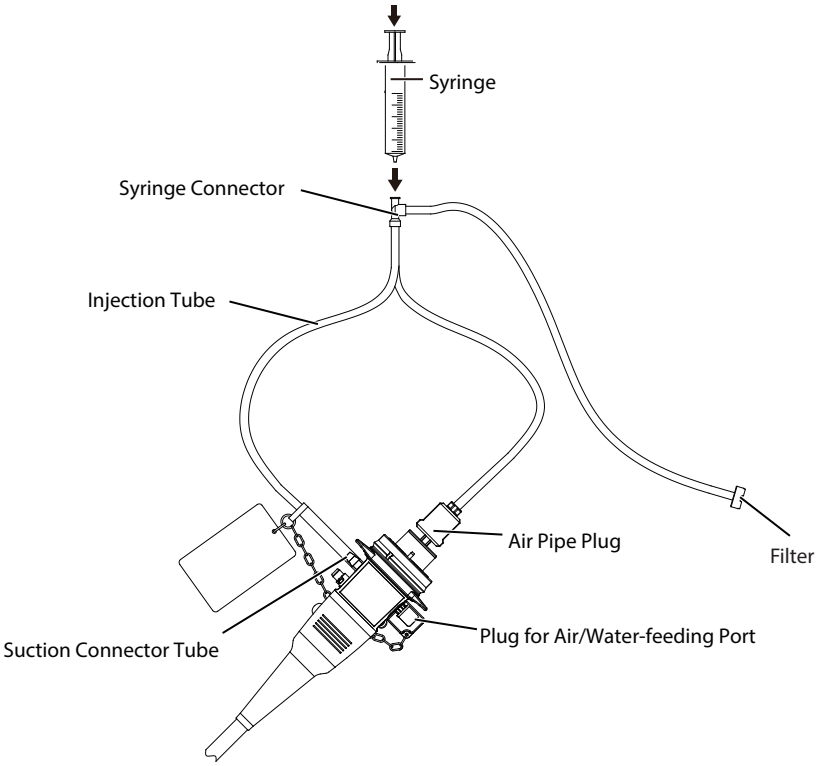
- *Before using the injection tube, ensure that there is no crack, scratch, flaw or debris on any component.*
- *Ensure that the filter mesh is intact.*
- *Connect a 30 cm^3 (30 mL) syringe to the syringe connector (air/water channel). Immerse the filter in the flush fluid, pull out the plunger of the syringe, and ensure that the flush fluid is aspirated into the syringe. Then, push the plunger, and ensure that flush fluid flows from the air pipe plug and no flush fluid flows from the filter.*
- *Connect a 30 cm^3 (30 mL) syringe to the syringe connector (suction channel). Immerse the filter in the flush fluid, pull out the plunger of the syringe, and ensure that the flush fluid is aspirated into the syringe. Then, push the plunger, and ensure that flush fluid flows from the suction connector tube and no flush fluid flows from the filter.*

Perform the following steps to connect the injection tube.

1. Connect the channel plug to the instrument channel inlet, suction valve cylinder and air/water valve cylinder respectively.

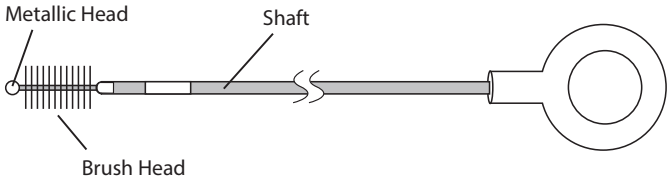


2. Connect the air pipe plug, suction connector tube, and plug for air/water-feeding port of the injection tube to the air pipe, suction port, and air/water-feeding port on the connector section of the endoscope respectively.



5.3.3 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.



Perform the following inspections before using the cleaning brush.

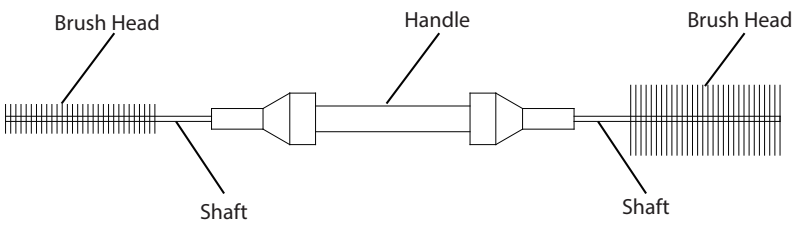
- Ensure that the brush head, metallic head, and bristle are firm.
- Ensure there is no bend, scratch or other damage on the brush shaft.
- Ensure that there is no debris on the brush shaft or bristle.

NOTE:

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

5.3.4 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 the instrument channel inlet. The following figure shows the channel-opening cleaning brush.

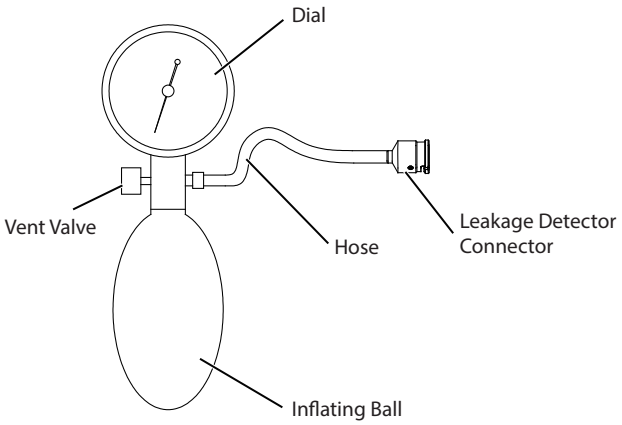


Perform the following inspections before using the channel-opening cleaning brush.

- 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.

5.3.5 Leakage Detector

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



NOTE:

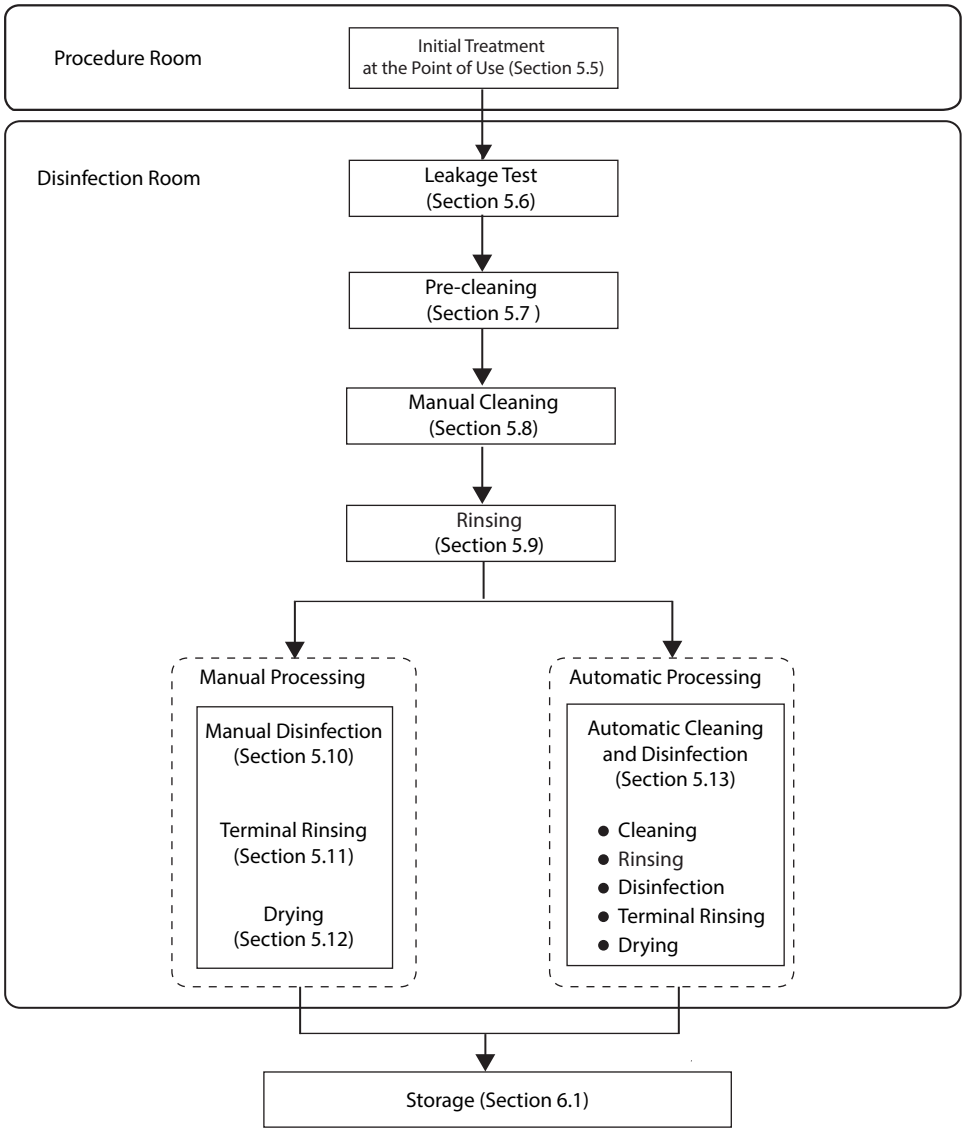
- *Before using the leakage detector, ensure that there is no crack, scratch, flaw or debris on any component of the leakage detector.*
- *Ensure that the hose of the leakage detector is firmly connected.*

Perform the following steps to connect the leakage detector.

1. Align the dowel pins on the inner hole of the leakage detector connector with the grooves on the leakage detector port of the connector section.
2. Rotate the leakage detector connector clockwise until it is locked.

5.4 Cleaning and Disinfection Process

Clean and disinfect the endoscope in accordance with the following diagram.



5.5 Initial Treatment at the Point of Use

WARNING

- After being withdrawn from the patient's body, the endoscope should be pre-cleaned at the bedside immediately.
- Pre-cleaning should be performed before the endoscope is disconnected from the image processor and light source.
- The endoscope should be pre-cleaned immediately after each examination. Otherwise, the residual debris may solidify. Consequently, cleaning and disinfection of the endoscope will be difficult.
- 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.

5.5.1 Wiping the Insertion Section

NOTE:

When wiping the endoscope, do not bend the insertion section excessively. Otherwise, the outer rubber of the insertion section may be damaged.

Perform the following steps.

1. 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.
2. Wipe the surface of the distal end carefully.

5.5.2 Flushing the Suction 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 correctly.
3. Immerse the distal end of the endoscope in the cleaning solution, and press the suction valve to aspirate cleaning solution into the suction channel for 30s.
4. Take out the distal end from the cleaning solution, and slightly press the suction valve to aspirate air for 10s.
5. Turn off the suction pump.

5.5.3 Flushing the Air/Water Channel

Perform the following steps.

1. Immerse the distal end in the cleaning solution.
2. Turn on the air pump of the light source, and adjust the air-feeding pressure to the maximum.
3. Press the air/water valve to feed water into the air/water channel for 10s.
4. Release the air/water valve and block the hole on the valve to feed air into the air/water channel for 10s.
5. Power off the light source.

5.5.4 Flushing the Auxiliary Water-feeding Channel

NOTE:

- *Do not remove the auxiliary water-feeding tube during pre-cleaning. Otherwise, the liquid may flow from the auxiliary water-feeding channel.*
- *Pre-clean the auxiliary water-feeding channel even if the channel is not used during the previous examination.*
- *You can directly use the water pump which is used in the examination to rinse the auxiliary water-feeding channel. Otherwise, use a syringe to rinse the auxiliary water-feeding channel.*

Perform the following steps.

1. Ensure that the auxiliary water-feeding tube is connected to the endoscope firmly.
2. Use a 30 mL syringe to inject at least 150 mL (5 times) filtered water into the auxiliary water-feeding channel through the auxiliary water-feeding tube.
3. Use a 30 mL syringe to inject at least 150 mL (5 times) air into the auxiliary water-feeding channel through the auxiliary water-feeding tube.

5.5.5 Disconnecting the Reusable Parts

Perform the following steps.

1. Disconnect the endoscope from the light source.
2. Remove the suction tube and water bottle connector from the endoscope.
3. Transport the endoscope to the disinfection room with the transport container for endoscope.
4. 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 When leakage is found on the endoscope, do not use the endoscope. Otherwise, the endoscope may be damaged and electric shock may occur. In case of leakage, please contact the local distributor.

NOTE:

- *The endoscope should be pre-cleaned before the leakage test, and the test should be conducted at least once a day if no condition allows.*
- *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 5.3.5 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 in flush fluid and inject running water into all channels with a syringe to remove 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 or the connector section. If bubbles generate continuously, the endoscope is leaky. The leaky endoscope cannot be cleaned and disinfected. Contact the local distributor.
4. Take out the endoscope and leakage detector from the flush fluid.
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 Pre-cleaning

WARNING

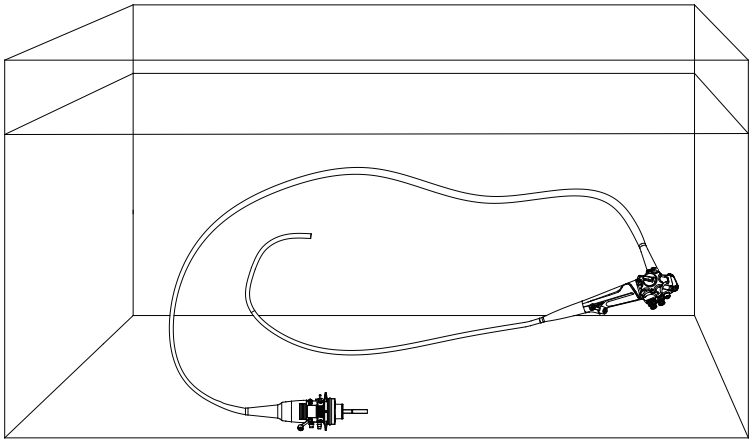
- To ensure the effectiveness of disinfection, clean the endoscope and accessories completely before disinfection to remove the microorganism or organism that may affect disinfection.
- Ensure the instrument channel and the suction channel are cleaned thoroughly. Insufficient cleaning and disinfection 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, clear it out 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:

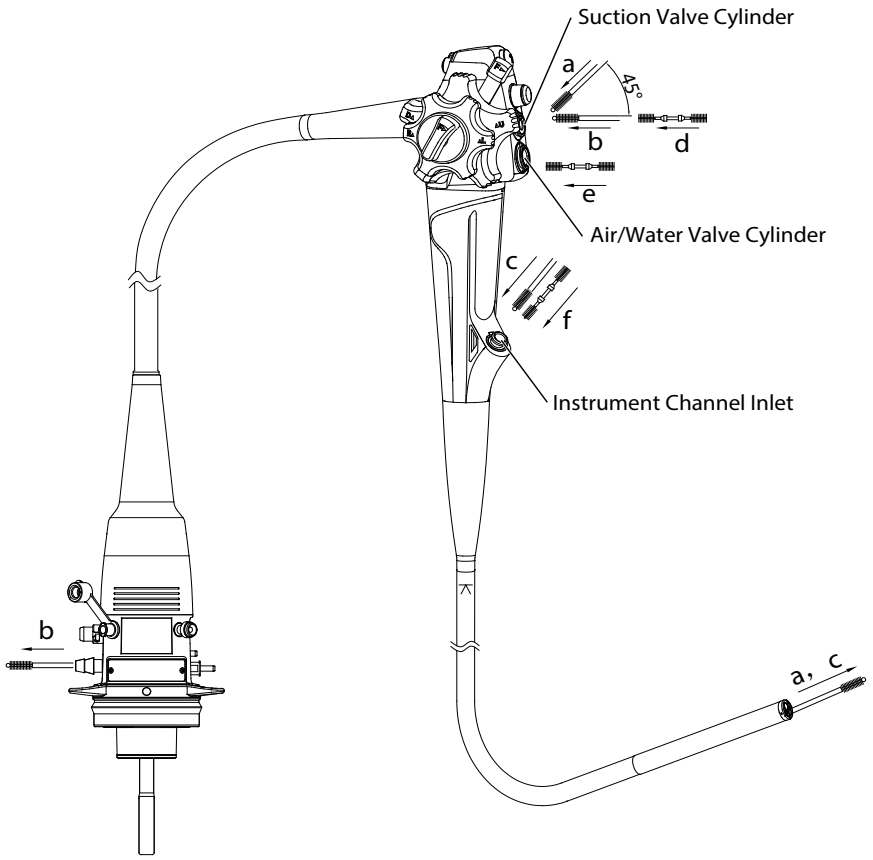
- *Gently pull out the cleaning brush from the instrument channel or suction channel to ensure that the brush shaft does not rub against the suction valve cylinder. Otherwise, the brush may be damaged and the suction valve cylinder may be scratched, causing suction performance degradation or leakage.*
- *Do not attempt to insert the cleaning brush from the distal end or the suction port. 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. Fill the manual cleaning tank with sufficient cleaning solution and ensure that the entire endoscope can be immersed in the cleaning solution. Prepare the cleaning solution in accordance the temperature and concentration recommended in Table 5-1.
2. Immerse the entire endoscope in the cleaning solution. Disconnect the auxiliary water-feeding tube and the cap of the auxiliary water-feeding port from 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. Brush channels in steps as shown in the following figure.



a. **To brush the suction channel from the control section to the distal end:** Straighten the bending section, insert the cleaning brush at a 45° angle down into 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 vertically 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:** 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 then pull out the brush from the channel 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.

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 handle touches the cylinder. Rotate the brush once, pull out the brush, 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 handle 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 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 handle touches the instrument channel inlet. Rotate the brush once, pull out the brush, 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.

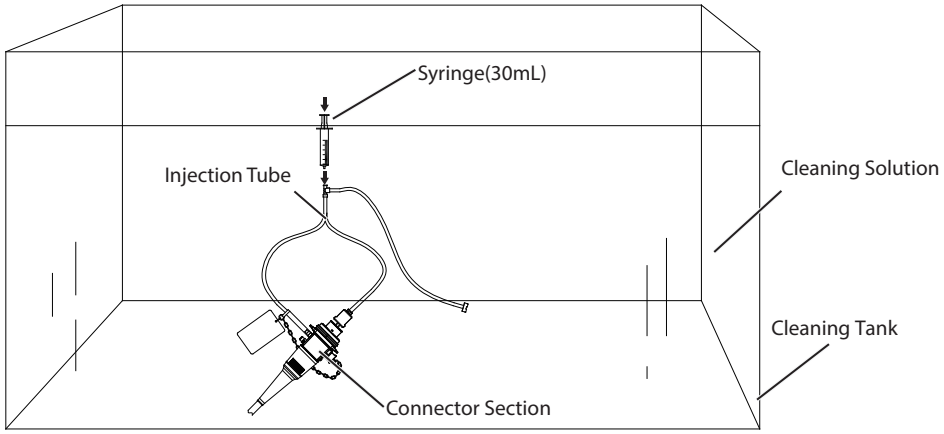
5.8 Manual Cleaning

NOTE:

- *Do not clean the endoscope with excessive force to avoid leakage.*
- *Do not immerse the endoscope together with its accessories to avoid damaging the endoscope.*

Perform the following steps.

1. Connect the channel plug and injection tube to the endoscope firmly.
2. Immerse the entire endoscope in the cleaning solution and ensure the filter of the injection tube is immersed in the cleaning solution.
3. Use a 30 mL syringe to inject at least 180 mL (6 times) cleaning solution into suction channel through the injection tube to fill the channel.
4. Use a 30 mL syringe to inject at least 180 mL (6 times) cleaning solution into air/water channel through the injection tube to fill the channel.
5. Use a 30 mL syringe to inject at least 90 mL (3 times) cleaning solution into the instrument channel through the instrument channel inlet.
6. Use a 30 mL syringe to inject at least 150 mL (5 times) cleaning solution into the auxiliary water-feeding channel through the auxiliary water-feeding port.
7. Disconnect the channel plug and injection tube from the endoscope, and immerse them in the cleaning solution.
8. During the immersing, use a clean lint-free cloth or a channel-opening cleaning brush to clean the outer surfaces and all connectors of the endoscope until no debris is left.
9. Cover the manual cleaning tank with a sealing cover to reduce cleaning solution volatilization.
10. Immerse the endoscope and all its accessories in accordance with the time, temperature and concentration recommended in Table 5-1.



5.9 Rinsing

NOTE:

Do not use immobile filtered water to rinse the endoscope.

Perform the following steps.

1. Place the cleaned endoscope into the rinse tank and wipe the endoscope outer surfaces with a clean lint-free cloth.
2. Connect the channel plug and injection tube to the endoscope firmly.

3. Immerse the entire endoscope, channel plug and injection tube in the filtered water and ensure the filter of the injection tube is immersed in the filtered water.
4. Use a 30 mL syringe to inject at least 180 mL (6 times) filtered water into the suction channel through the injection tube to fill the channel.
5. Use a 30 mL syringe to inject at least 180 mL (6 times) filtered water into the air/water channel through the injection tube to fill the channel.
6. Use a 30 mL syringe to inject at least 90 mL (3 times) filtered water into the instrument channel through the instrument channel inlet.
7. Use a 30 mL syringe to inject at least 150 mL (5 times) filtered water into the auxiliary water-feeding channel through the auxiliary water-feeding port.
8. Disconnect the channel plug and injection tube from the endoscope.
9. Flush the outer surfaces of the endoscope and all its accessories with running filtered water.
10. Take out the endoscope and its accessories from the running filtered water.
11. Cover the distal end and control section with a clean lint-free cloth.
12. Connect the channel plug and injection tube to the endoscope firmly.
13. Use a 30 mL syringe to inject at least 180 mL (6 times) air into the suction channel through the injection tube to remove water in the channel.
14. Use a 30 mL syringe to inject at least 180 mL (6 times) air into the air/water channel through the injection tube to remove water in the channel.
15. Use a 30 mL syringe to inject at least 90 mL (3 times) air into the instrument channel through the instrument channel inlet.
16. Use a 30 mL syringe to inject at least 150 mL (5 times) air into the auxiliary water-feeding channel through the auxiliary water-feeding port.
17. Remove the clean lint-free cloth from the distal end and control section.
18. Disconnect the channel plug and injection tube from the endoscope.
19. Wipe the outer surfaces of the endoscope and all its accessories with a clean lint-free cloth.
20. Ensure that no debris is left on the endoscope or any of its accessories. Otherwise, repeat the procedures in Section 5.7 Pre-cleaning, Section 5.8 Manual Cleaning and Section 5.9 Rinsing.

5.10 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 the endoscope and its accessories, you should use a lint-free cloth to wipe them off.
- The endoscope and its accessories should be completely immersed in the disinfectant for high-level disinfection.

Perform the following steps.

1. Place the endoscope, channel plug and injection tube into the disinfection tank.
2. Fill the tank with sufficient disinfectant, and ensure that the entire endoscope and all its accessories can be immersed in the disinfectant. Prepare the disinfectant in accordance with the time, temperature and concentration recommended in Table 5-2.

3. Connect the channel plug and injection tube to the endoscope firmly.
4. Immerse the entire endoscope in the disinfectant, and ensure the filter of the injection tube is in the disinfectant.
5. Use a 30 mL syringe to inject at least 180 mL (6 times) disinfectant into the suction channel through the injection tube to fill the channel, and ensure that no bubble generates from the distal end.
6. Use a 30 mL syringe to inject at least 180 mL (6 times) disinfectant into the air/water channel through the injection tube to fill the channel, and ensure that no bubble generates from the distal end.
7. Use a 30 mL syringe to inject at least 90 mL (3 times) disinfectant into the instrument channel through the instrument channel inlet.
8. Use a 30 mL syringe to inject at least 150 mL (5 times) disinfectant into the auxiliary water-feeding channel through the auxiliary water-feeding port.

   NOTE:

   - *Ensure that the syringe connectors of the injection tube are completely immersed in the disinfectant.*
   - *Ensure that all channels of the endoscope are filled with disinfectant.*
9. Disconnect the channel plug and injection tube from the endoscope, and immerse the channel plug, injection tube and endoscope in the disinfectant.
10. If bubbles adhere to the endoscope surface or the tools, wipe the bubbles with a clean lint-free cloth.
11. Cover the disinfection tank with a sealing cover to reduce disinfectant volatilization.
12. Immerse the endoscope and all its accessories in the disinfectant in accordance with the time, temperature and concentration recommended in Table 5-2 for high-level disinfection.
13. Before taking out the endoscope and all its accessories from the disinfectant, connect the channel plug and injection tube to the endoscope.
14. Take out the filter of the injection tube from the disinfectant.
15. Use a 30 mL syringe to inject at least 180 mL (6 times) air into the suction channel through the injection tube.
16. Use a 30 mL syringe to inject at least 180 mL (6 times) air into the air/water channel through the injection tube.
17. Use a 30 mL syringe to inject at least 90 mL (3 times) air into the instrument channel through the instrument channel inlet.
18. Use a 30 mL syringe to inject at least 150 mL (5 times) air into the auxiliary water-feeding channel through the auxiliary water-feeding port.
19. Take out the endoscope and all its accessories from the disinfectant.
20. Disconnect the channel plug 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 the residual of high-level disinfectant.

■ To use sterile water

Perform the following steps.

1. Place the endoscope, channel plug and injection tube into the terminal rinse tank.

2. Fill the tank with sufficient sterile water, and ensure that the endoscope and accessories 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 to the endoscope firmly.
5. Immerse the entire endoscope in the sterile water and ensure the filter of the injection tube is in the sterile water.
6. Use a 30 mL syringe to inject at least 180 mL (6 times) sterile water into the suction channel through the injection tube to fill the channel. Ensure that no disinfectant is left in the channel.
7. Use a 30 mL syringe to inject at least 180 mL (6 times) sterile water into the air/water channel through the injection tube to fill the channel. Ensure that no disinfectant is left in the channel.
8. Use a 30 mL syringe to inject at least 90 mL (3 times) sterile water into the instrument channel through the instrument channel inlet. Ensure that no disinfectant is left in the channel.
9. Use a 30 mL syringe to inject at least 150 mL (5 times) sterile water into the auxiliary water-feeding channel through the auxiliary water-feeding port. Ensure that no disinfectant is left in the channel.
10. Disconnect the channel plug and injection tube from the endoscope.
11. Flush the outer surfaces the endoscope and accessories with sterile water.
12. Take out the endoscope and accessories from the sterile water.
13. Cover the distal end and control section with a sterile lint-free cloth.
14. Connect the channel plug and injection tube to the endoscope firmly.
15. Use a 30 mL syringe to inject at least 180 mL (6 times) air into the suction channel through the injection tube to remove the sterile water in the suction channel.
16. Use a 30 mL syringe to inject at least 180 mL (6 times) air into the air/water channel through the injection tube to remove the sterile water in the air/water channel.
17. Use a 30 mL syringe to inject at least 90 mL (3 times) air into the instrument channel through the instrument channel inlet.
18. Use a 30 mL syringe to inject at least 150 mL (5 times) air into the auxiliary water-feeding channel through the auxiliary water-feeding port.
19. Remove the sterile lint-free cloth from the distal end and control section.
20. Disconnect the channel plug and injection tube from the endoscope.
21. 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**

Perform the following steps.

1. Place the endoscope, channel plug and injection tube into the terminal rinse tank.
2. Fill the tank with sufficient filtered water, and ensure that the entire endoscope and all its accessories can 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.
5. Immerse the entire endoscope in the filtered water and ensure the filter of the injection tube is in the filtered water.
6. Use a 30 mL syringe to inject at least 180 mL (6 times) filtered water into the suction channel through the injection tube to fill the channel.

7. Use a 30 mL syringe to inject at least 180 mL (6 times) filtered water into the air/water channel through the injection tube to fill the channel.
8. Use a 30 mL syringe to inject at least 90 mL (3 times) filtered water into the instrument channel through the instrument channel inlet.
9. Use a 30 mL syringe to inject at least 150 mL (5 times) filtered water into the auxiliary water-feeding channel through the auxiliary water-feeding port.
10. Disconnect the channel plug and injection tube from the endoscope.
11. Flush the outer surfaces of the endoscope and all its accessories with filtered water.
12. Take out the endoscope and all its accessories from the filtered water.
13. Cover the distal end and control section with a clean lint-free cloth.
14. Connect the channel plug and injection tube to the endoscope firmly.
15. Use a 30 mL syringe to inject at least 180 mL (6 times) air into the suction channel through the injection tube to remove the filtered water in the channel.
16. Use a 30 mL syringe to inject at least 180 mL (6 times) air into the air/water channel through the injection tube to remove the filtered water in the channel.
17. Use a 30 mL syringe to inject at least 90 mL (3 times) air into the instrument channel through the instrument channel inlet.
18. Use a 30 mL syringe to inject at least 150 mL (5 times) air into the auxiliary water-feeding channel through the auxiliary water-feeding port.
19. Remove the clean lint-free cloth from distal end and control section.
20. Disconnect the channel plug and injection tube from the endoscope.
21. Wipe the outer surfaces of the endoscope and all its accessories with a clean lint-free cloth.
22. Place the endoscope and all its accessories on a sterile mat which is placed on the medical drying table.
23. Fill a container with sufficient 75% ethyl alcohol.
24. Connect the channel plug and injection tube to the endoscope, and immerse the filter of the injection tube in the ethyl alcohol.
25. Cover the distal end and control section with a clean lint-free cloth.
26. Use a 30 mL syringe to inject at least 60 mL (2 times) ethyl alcohol into the suction channel through the injection tube.
27. Use a 30 mL syringe to inject at least 60 mL (2 times) ethyl alcohol into the air/water channel through the injection tube.
28. Use a 30 mL syringe to inject at least 60 mL (2 times) ethyl alcohol into the instrument channel through the instrument channel inlet.
29. Use a 30 mL syringe to inject at least 60 mL (2 times) ethyl alcohol into the auxiliary water-feeding channel through the auxiliary water-feeding port.
30. Take out the filter from the ethyl alcohol.
31. Use a 30 mL syringe to inject at least 180 mL (6 times) air into the suction channel through the injection tube to remove the ethyl alcohol in the channel.
32. Use a 30 mL syringe to inject at least 180 mL (6 times) air into the air/water channel through the injection tube to remove the ethyl alcohol in the channel.

33. Use a 30 mL syringe to inject at least 90 mL (3 times) air into the instrument channel through the instrument channel inlet.
34. Use a 30 mL syringe to inject at least 150 mL (5 times) air into the auxiliary water-feeding channel through the auxiliary water-feeding port.
35. Remove the clean lint-free cloth from distal end and control section.
36. Disconnect all the accessories from the endoscope.
37. Wipe the outer surface of the endoscope and all its accessories with a sterile lint-free cloth dampened with ethyl alcohol.
38. Wipe the air/water valve cylinder, suction valve cylinder and inner side of the instrument channel inlet with sterile swabs.

5.12 Drying

WARNING

- After cleaning and high-level disinfection, 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 a container with sufficient 75% ethyl alcohol.
3. Connect the channel plug and injection tube to the endoscope firmly, and immerse the filter of the injection tube in the ethyl alcohol.
4. Cover the distal end and control section with a clean or sterile lint-free cloth.
5. Use a 30 mL syringe to inject at least 30 mL (1 time) ethyl alcohol into the suction channel through the injection tube.
6. Use a 30 mL syringe to inject at least 30 mL (1 time) ethyl alcohol into the air/water channel through the injection tube.
7. Use a 30 mL syringe to inject at least 30 mL (1 time) ethyl alcohol into the instrument channel through the instrument channel inlet.
8. Use a 30 mL syringe to inject at least 30 mL (1 time) ethyl alcohol into the auxiliary water-feeding channel through the auxiliary water-feeding port.
9. Take out the filter from the ethyl alcohol.
10. Use a 30 mL syringe to inject at least 180 mL (6 times) air into the suction channel through the injection tube to remove ethyl alcohol in the channel.
11. Use a 30 mL syringe to inject at least 180 mL (6 times) air into the air/water channel through the injection tube to remove ethyl alcohol in the channel.
12. Use a 30 mL syringe to inject at least 90 mL (3 times) air into the instrument channel through the instrument channel inlet.
13. Use a 30 mL syringe to inject at least 150 mL (5 times) air into the auxiliary water-feeding channel through the auxiliary water-feeding port.
14. Remove the clean lint-free cloth from the distal end and control section.
15. Disconnect all the accessories from the endoscope.
16. Wipe the outer surfaces of endoscope and all its accessories with a sterile or clean lint-free cloth dampened with ethyl alcohol.

17. Wipe the inner surface of the air/water valve cylinder, suction valve cylinder, distal end and the inner side of the instrument channel inlet with sterile swabs.
18. Dry the endoscope and all its accessories.

5.13 Automatic Cleaning and Disinfection

Before automatic cleaning and disinfection, the endoscope should be initially treated at the point of use, pre-cleaned, manually cleaned and rinsed, and the leakage should be detected.

The AER can be used for cleaning and disinfecting the air/water valve, suction valve and biopsy valve. Before placing the valves into the AER, these valves should be pre-cleaned, manually cleaned and rinsed. For details, refer to Section 5.14.1 Pre-cleaning, Section 5.14.2 Manual Cleaning and Section 5.14.3 Rinsing.

For the cleaning and disinfection of other accessories, refer to Section 5.14 Reusable Parts and Cleaning and Disinfection Tools.

■ Recommended Automated Endoscope Reprocessor

The Endoscope WD BHT INNOVA® E3 CMS DC that meets EN ISO 15883-4 is recommended by the manufacturer in Table 5-3.

Table 5-3 Automated Endoscope Reprocessor

Equipment Name	Model	Manufacturer
Endoscope WD BHT INNOVA® E3 CMS DC	Innova E3-CMS DC-1000	BHT Disinfection Technology

■ Reprocessing Procedure

NOTE:

If the AER does not support the drying function, the endoscope and all accessories should be dried after automatic cleaning and disinfection. For details, refer to Section 5.12 Drying.

Perform the following steps to clean and disinfect the endoscope and valves.

1. Prepare the cleaning solution and disinfectant for automatic cleaning and disinfection in accordance with the temperature and concentration recommended in Table 5-1 and Table 5-2 respectively.
2. Place the endoscope, air/water valve, suction valve and biopsy valve into the AER.
3. Connect the channel plug to the air/water valve cylinder and suction valve cylinder.
4. Connect the plug for air/water-feeding port to the air/water-feeding port.
5. Connect one end of air pipe plug to the air pipe, and connect the other end to the AER.
6. Connect the suction port, auxiliary water-feeding port and instrument channel inlet to the AER.
7. Select the Normal GA Sonoscape (P052) program, and set the processing parameters and check the values on the screen.

   The recommended reprocessing parameters are as follows.

Table 5-4 Automatic Reprocessing

Stage	Procedure	Temperature	Contact Time	Solution	Note
1	Pre-cleaning	/	4 min	Cold tap water	/
2	Cleaning	35°C	3 min	Cleaner	5mL/L in cold tap water

Stage	Procedure	Temperature	Contact Time	Solution	Note
3	Rinsing	/	2 min	Demineralized water	/
4	Disinfection	55°C	5 min	Disinfectant	10mL/L in demineralized water
5	Terminal rinsing	20°C	4 min	Demineralized water	/

8. Start the automatic cleaning and disinfection procedures.
9. Take out the endoscope and accessories after the reprocessing finishes.

5.14 Reusable Parts and Cleaning and Disinfection Tools

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

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

- Air/water valve
- Suction valve
- Biopsy valve
- Auxiliary water-feeding tube
- Injection tube
- Cleaning brush
- Channel-opening cleaning brush

5.14.1 Pre-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.*

Perform the following steps.

1. Place all parts and tools into the manual cleaning basin.
2. Fill the basin with sufficient cleaning solution, and ensure that all parts and tools can be immersed in the cleaning solution. Prepare the cleaning solution in accordance with the temperature and concentration recommended in Table 5-1.
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 suction valve to remove all debris.
5. Use the channel-opening cleaning brush to thoroughly clean the interiors and openings of the biopsy valve and the cap for auxiliary water-feeding channel to remove all debris.

5.14.2 Manual Cleaning

Perform the following steps.

1. Use a 30 mL syringe to inject at least 90 mL (3 times) cleaning solution into the auxiliary water-feeding tube.
2. Use a 30 mL syringe inject cleaning solution to thoroughly flush the interiors and openings of all the parts and tools to remove all air bubbles.

3. 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.
4. Clean the bristles of cleaning brush and channel-opening cleaning brush in the cleaning solution to remove all bubbles.
5. Cover the basin with a sealing cover to reduce cleaning solution volatilization.
6. Immerse the parts and tools in accordance with the period, temperature, and concentration recommended in Table 5-1.
7. Take out all parts and tools from the basin and ensure that no debris is left on the parts and tools.

5.14.3 Rinsing

Perform the following steps.

1. Place all cleaned parts and tools into the rinse basin.
2. Wipe the outer surfaces of parts and tools in the running filtered water with a clean lint-free cloth.
3. Use a 30 mL syringe to inject at least 90 mL (3 times) filtered water into the auxiliary water-feeding tube.
4. Take out the auxiliary water-feeding tube, and use a 30 mL syringe to inject at least 90 mL (3 times) air into the auxiliary water-feeding tube.
5. Use a 30 mL syringe to thoroughly flush the interiors and openings of all the parts and tools to remove all bubbles.
6. 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.
7. Clean the bristles of cleaning brush and channel-opening cleaning brush in the filtered water to remove all bubbles.
8. Take out all parts and tools and wipe the outer surfaces of the parts and tools with a a clean lint-free cloth.
9. Ensure that no debris is left on any part and tool. Otherwise, repeat the procedures in Section 5.14.1 Pre-cleaning, Section 5.14.2 Manual Cleaning and Section 5.14.3 Rinsing.

5.14.4 Manual Disinfection

- Ensure all the 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. Place all cleaned parts and tools into the disinfection basin.
2. Fill the basin with sufficient disinfectant and ensure that all the parts and tools can be immersed in the disinfectant. Prepare the disinfectant in accordance with the time, temperature and concentration recommended in Table 5-2.
3. Immerse all parts and tools into the disinfectant.
4. Wipe the outer surfaces of the parts and tools in the disinfectant with a clean lint-free cloth to remove all bubbles.
5. Use a 30 mL syringe to inject at least 90 mL (3 times) disinfectant into the auxiliary water-feeding tube.
6. Use a 30 mL syringe to thoroughly flush the interiors and openings of all parts and tools in the disinfectant 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 at least 3 times to remove all bubbles.
8. Clean the bristles of the cleaning brush and channel-opening cleaning brush completely to remove all bubbles.
9. Cover the high-level disinfection basin with a sealing cover to reduce disinfectant volatilization.
10. Immerse all parts and tools in accordance with the time, temperature and concentration recommended in Table 5-2 for high-level disinfection.
11. Take out all the parts and tools.

5.14.5 Terminal Rinsing

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

■ **To use sterile water**

Perform the following steps.

1. Place all parts and tools into the terminal rinse basin.
2. Fill the basin with sufficient sterile water, and ensure that all parts and tools can be immersed in the sterile water.
3. Gently stir the sterile water to thoroughly clean all parts and tools.
4. Clean the outer surfaces of the parts and tools in the water with a sterile lint-free cloth.
5. Use a 30 mL syringe to inject at least 90 mL (3 times) sterile water into the auxiliary water-feeding tube.
6. Use a 30 mL syringe to thoroughly flush the interiors and openings of 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 the bristles of the cleaning brush and channel-opening cleaning brush in the sterile water to remove all bubbles.
9. Take out all the parts and tools.

■ **To use filtered water and 75% ethyl alcohol**

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 terminal rinse 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 30 mL syringe to inject at least 90 mL (3 times) filtered water into the auxiliary water-feeding tube.
5. Use a 30 mL syringe to flush the interiors and openings of all parts and tools with filtered water to remove all bubbles.
6. 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.
7. Clean the bristles of the cleaning brush and channel-opening cleaning brush in the filtered water to remove all bubbles.

8. Take out all the parts and tools, fill the basin with sufficient 75% ethyl alcohol, and immerse the parts and tools in ethyl alcohol.
9. Place all parts and tools in the ethyl alcohol and gently stir them.
10. Use a 30 mL syringe to inject at least 60 mL (2 times) ethyl alcohol into the auxiliary water-feeding tube.
11. Use a 30 mL syringe to thoroughly clean the interiors and openings of the parts and the tools with ethyl alcohol to remove all bubbles.
12. Clean the bristles of the cleaning brush and channel-opening cleaning brush to remove all bubbles.
13. 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.
14. Take out all parts and tools.
15. Place the parts and tools on a drying table with sterile mat.
16. Wipe the outer surfaces of all parts and tools with a clean lint-free cloth.
17. Use a 30 mL syringe to flush the interiors and openings of the parts and tools to dry them.

5.14.6 Drying

Perform the following steps .

1. Fill a basin with 75% ethyl alcohol.
2. Place all parts and tools in the ethyl alcohol and gently stir them.
3. Use a 30 mL syringe to inject at least 30 mL (1 time) ethyl alcohol into the auxiliary water-feeding tube.
4. Use a 30 mL syringe to inject ethyl alcohol to interiors and openings of all parts and tools to remove bubbles.
5. Clean the bristles of the cleaning brush and channel-opening cleaning brush in ethyl alcohol to remove all bubbles.
6. 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.
7. Take out all parts and tools.
8. Place the parts and tools on a sterile mat which is placed on a medical drying table.
9. Use a 30 mL syringe to inject at least 90 mL (3 times) air into the auxiliary water-feeding tube.
10. Use a 30 mL syringe to flush the interiors and openings of the parts and tools to dry them.
11. Thoroughly wipe the outer surfaces of all parts and tools with a sterile lint-free cloth.
12. Thoroughly wipe the outer surfaces of parts and tools with a clean lint-free cloth dampened with ethyl alcohol.
13. Thoroughly wipe the outer surfaces of all parts and tools with sterile swabs.

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6 Storage and Disposal

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

- Before storage, the endoscope should be cleaned and disinfected completely.
- After being dried, the endoscope should be hung in the endoscope cabinet.
- Do not store the endoscope in a carrying case.
- The cabinet wall should be wiped with the 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 the endoscope and the interior of all channels are dry.

Perform the following steps.

1. Disconnect all accessories from the endoscope, including the air/water valve, suction valve and biopsy valve.
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 cleaned and disinfected air/water valve, suction valve and biopsy valve are dry.

Store the accessories in the endoscope cabinet, and ensure that they are not in contact with each other.

6.2 Transportation

6.2.1 Indoor Transportation

Perform the following steps.

1. Rotate the up/down and left/right angulation locks of the endoscope to free the bending section completely.
2. Hold the connector section and control section of the endoscope with one hand. Hold the insertion section of the endoscope with the other hand gently, and ensure that the distal end is upwards.

6.2.2 Outdoor Transportation

WARNING The endoscope should be cleaned and disinfected before being placed into the carrying case. Otherwise, the carrying case may be contaminated or cross contamination may be incurred.

Perform the following steps.

1. Rotate the up/down and left/right angulation locks of the endoscope to free the bending section completely.
2. Place the endoscope into the carrying case provided by the manufacturer.
3. 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 in accordance with its using frequency and maintenance. When the device expired, you should dispose of the device in accordance with local laws or regulations, or contact the manufacturer for maintenance.

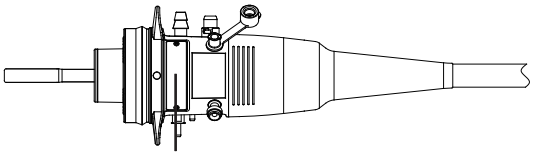


Figure 6-1 Date of Manufacture

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 repaired 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 an 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	Solution
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.
Image	No image	C	The image processor is not powered on.	Check the connections. For details, refer to Chapter 3 Preparations.
		B/A	Others	Stop using the endoscope.
	Image is dimmer.	C	The intensity of the light source is too low.	Adjust the intensitye as described in the light source user manual.
	Image is blurry.	C	The objective lens is dirty.	Feed water to flush the mucus on the objective lens.
		B	Water drops or color bar appears in the field of view.	Stop using the endoscope.
Feed air	The air is insufficient.	C	The water bottle cap is loosen.	Fasten the cap of 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 the objects from the air/water nozzle.
		B	Others	Stop using the endoscope.

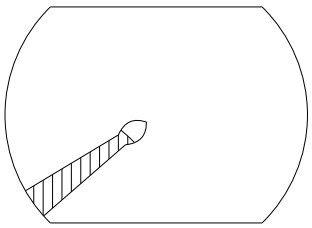
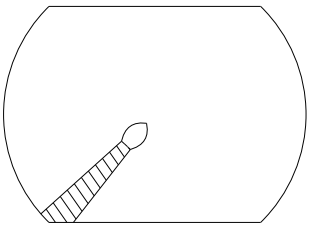
Item	Descriptions	Level	Cause	Solution
Feed air	Cannot feed air.	C	The air/water valve is damaged.	Replace the air/water valve.
		C	The air pump does not function.	Turn on the air pump on light source as described in the user manual.
Feed water	The water is insufficient.	C	The air/water nozzle is blocked.	Immerse the distal end in the soapy water at the appropriate temperature and feed air to remove the objects by 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 does not function.	Turn on the air pump on 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. Brush the suction channel as described in Section 5.7 Pre-cleaning.
		C	The biopsy valve is damaged.	Replace the spare biopsy valve.
	The suction valve is sticky.	C	The suction valve is dirty.	Remove and rinse the suction valve, and clean the valve opening with a swab dampened with ethyl alcohol.
	The instrument channel leaks.	B	The instrument channel is damaged by improper using of the accessories such as biopsy forceps.	Stop using the endoscope.
	Liquid or air is leaks from the biopsy valve.	C	The biopsy valve is aging or damaged.	Replace the spare biopsy valve.

Item	Descriptions	Level	Cause	Solution
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 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	Other problems	B	----	Stop using the endoscope.

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 authorized local distributor for repair.*

Appendix A Specifications

Technical Parameters		Product Model	
		EG-550	EG-550L
Dimensions	Total length	1350 mm, allowance: ± 10%	
	Working length	1050 mm, allowance: ± 10%	
	Min. inner diameter of the instrument channel	≥ Φ2.8 mm	≥ Φ3.2 mm
	Outer diameter of the insertion tube	Φ9.3 mm, allowance: + 10%, not considering lower limit	Φ9.8 mm, allowance: + 10%, not considering lower limit
	Outer diameter of the distal end	Φ9.3 mm, allowance: + 5%,not considering lower limit	Φ9.8 mm, allowance: + 5%, not considering lower limit
Imaging System	Field of view	140°, allowance: ± 10%	
	Depth of field	3 mm -100mm	
	Resolution	≥ 11.1 lp/mm (working distance: 10mm)	
	Biopsy entrance position		
Water/air-feeding & Suction System	Amount of fed water	≥ 40 mL/min	
	Amount of fed air	≥ 800 mL/min	
	Aspirated amount	≥ 400 mL/min	
Bending Section	Angle	Up 210°, down 90°, left 100°, right 100° Allowance: -10%, not considering upper limit	
Operation Environment	Temperature	5°C - 40°C	
	Relative humidity	30% - 80%	
	Atmospheric pressure	700 hPa - 1060 hPa	
Storage Environment	Temperature	-5°C - +40°C	
	Relative humidity	30% - 80%	
	Atmospheric pressure	700 hPa - 1060 hPa	

Technical Parameters		Product Model	
		EG-550	EG-550L
Transportation Environment	Temperature	-20℃ - +55℃	
	Relative humidity	20% - 90%	
	Atmospheric pressure	700 hPa - 1060 hPa	
Safety Types	Degree of protection against electric shock	Type BF applied part	
	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 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.

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

Immunity Test	Compliance Level
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 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
	0% U_T for 1 cycle Single phase: at 0°
	70% U_T for 25 cycle Single phase: at 0°
	0% U_T for 250 cycle
Power frequency Magnetic field IEC 61000-4-8	30A/m

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