

About This Manual

P/N: 4710.01118A01

Release Date: September, 2017

Product Model: EC-430, EC-430T, EC-430L, EC-430L/T

Copyright © 2017 SonoScape Medical Corp. All Rights Reserved.

Statement

SonoScape Medical Corp. (hereinafter called SonoScape) owns the intellectual property rights to this manual, and also maintains the contents of this manual as confidential information. This manual is a reference for the operation, maintenance and cleaning of this product and does not convey any license under the patent rights of SonoScape, nor the rights of others.

This manual contains the information protected by copyrights or patents. Reproduction, amendment or translation of this manual in any manner whatsoever without the written permission of SonoScape is strictly prohibited.

All information contained in this manual is believed to be correct. SonoScape shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance or use of this manual. SonoScape does not assume any liability arising out of any infringements of patents or other rights of third parties.

This manual is based on the maximum configuration and therefore some contents may not apply to your product.

This manual is subject to change without prior notice and legal obligation.




Manufacturer's Responsibility

SonoScape is responsible for the effects on safety, reliability and performance of this product, only if all the following requirements are met.

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

Documentation

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

Item	Meaning
	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
	Indicates a potentially hazardous situation which, if not avoided, may result in malfunction or damage of the system.
NOTE	Indicates precautions or recommendations that should be used in operating the system.
	Indicates a potentially biological hazardous situation which, if not avoided, may result in disease transmission.
Boldfaced Word	Indicates controls on the control panel, or on-screen objects such as menu items or keys.

Contact Information

Manufacturer: SonoScape Medical Corp.

Address: 4/F, 5/F, 8/F, 9/F & 10/F, Yizhe Building, Yuquan Road, Nanshan, Shenzhen, 518051, Guangdong, China

Tel: +86 755 2672 2890

Fax: +86 755 2672 2850

<http://www.sonoscape.com>

E-mail: sonoscape@sonoscape.net

EU Representative: SonoScape Europe S.r.l.

Address: Via Luigino Tandura, 74-00128 Rome, Italy

Tel: +39 06 508 2160

Fax: +39 06 508 4752

<http://www.sonoscapeeurope.com>

Contents

1 Safety	1
1.1 Intended Use.....	2
1.2 Contraindications.....	2
1.3 Product Compatibility	2
1.4 Safety Precautions	2
1.4.1 Electrical Safety.....	2
1.4.2 Accessory Safety.....	4
1.4.3 Biohazard Considerations	4
1.5 Safety Symbols.....	4
2 Overview	7
2.1 Packing	8
2.2 Endoscope Overview.....	8
2.2.1 Composition.....	8
2.2.2 Connector Section.....	8
2.2.3 Control and Insertion Section	10
2.2.4 Distal End	12
3 Preparations	13
3.1 Inspecting the Endoscope.....	14
3.1.1 Inspecting the Appearance and Flexibility.....	14
3.1.2 Inspecting the Angulation	14
3.2 Inspecting and Connecting the Accessories	16
3.2.1 Air/Water Valve.....	16
3.2.2 Suction Valve	17
3.2.3 Biopsy Valve	17
3.3 Connecting the Endoscopy System	18
3.3.1 Connecting the Light Source	19
3.3.2 Connecting the Water Bottle.....	19
3.3.3 Connecting the Endoscope Cable	20
3.3.4 Connecting the Image Processor.....	21
3.3.5 Connecting the Suction Pump.....	22

Contents

- 3.3.6 Connecting the Auxiliary Water-feeding Tube23
- 3.4 Inspecting the Endoscopy System23
 - 3.4.1 Inspecting the Image23
 - 3.4.2 Inspecting the remote buttons24
 - 3.4.3 Inspecting the Air Feeding Function.....24
 - 3.4.4 Inspecting the Water Feeding Function24
 - 3.4.5 Inspecting the Suction Function25
 - 3.4.6 Inspecting the Instrument Channel26
 - 3.4.7 Inspecting the Auxiliary Water-feeding Tube26
- 4 Operations.....29**
 - 4.1 General Operations.....31
 - 4.1.1 Inserting the Endoscope.....31
 - 4.1.2 Adjusting the Angle of Bending Section.....31
 - 4.1.3 Feeding Air/Water and Aspirating31
 - 4.1.4 Feeding Water Through the Auxiliary Water-feeding Port33
 - 4.2 Auxiliary Operations33
 - 4.2.1 Using the Biopsy Forceps34
 - 4.2.2 Using the Cytology Brush.....34
 - 4.2.3 Using the Syringe.....34
 - 4.3 Ending the Operation35
- 5 Cleaning, Disinfection and Sterilization.....37**
 - 5.1 Detergent, Disinfectant, and Flushing Fluid.....40
 - 5.1.1 Detergent.....41
 - 5.1.2 Disinfectant.....42
 - 5.1.3 Flushing Fluid42
 - 5.2 Cleaning and Disinfection Tools42
 - 5.3 Accessory Inspection and Connection.....43
 - 5.3.1 Waterproof Cap43
 - 5.3.2 Channel Plug.....44
 - 5.3.3 Injection Tube45
 - 5.3.4 Cleaning Brush47
 - 5.3.5 Channing-Opening Cleaning Brush.....47
 - 5.3.6 Leakage Detector48
 - 5.3.7 Auxiliary Water-feeding Tube.....49

5.4 Pre-cleaning.....	49
5.4.1 Insertion Section.....	50
5.4.2 Suction Channel.....	50
5.4.3 Air/Water Channel.....	50
5.4.4 Auxiliary Water-Feeding Channel.....	50
5.4.5 Reusable Parts.....	51
5.5 Leakage Test.....	51
5.6 Manual Cleaning.....	52
5.7 Rinsing.....	55
5.8 High-Level Disinfection.....	56
5.8.1 Automatic Disinfection.....	56
5.8.2 Manual Disinfection.....	56
5.9 Sterilization.....	59
5.10 Terminal Rinsing.....	61
5.10.1 Using Sterile Water.....	61
5.10.2 Using Filtered Water (or Tap Water) and Alcohol Flushing.....	61
5.11 Drying.....	62
5.12 Reusable Parts and Cleaning, Disinfection, or Sterilization Tools.....	63
5.12.1 Manual Cleaning.....	63
5.12.2 Rinsing.....	64
5.12.3 High-level Disinfection.....	65
5.12.4 Sterilization.....	65
5.12.5 Terminal Rinsing.....	66
5.12.6 Drying.....	67
6 Storage and Disposal.....	69
6.1 Storage.....	70
6.1.1 Storing the Endoscope.....	70
6.1.2 Storing the Accessories.....	70
6.2 Transportation.....	70
6.2.1 Indoor Transportation.....	70
6.2.2 Outdoor Transportation.....	71
6.3 Disposal.....	71
6.4 Customer Service.....	72

Contents

7 Troubleshooting..... 73

Appendix Specifications 77

1 Safety

This chapter describes important information for operating this endoscope. To ensure the safety of both operator and patient, 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 colonoscope (hereinafter called endoscope) is intended for use in examination and diagnosis of the lower digestive tract (including the anus, rectum, colon and ileocecal valve).

1.2 Contraindications

Do not use the endoscope in the following cases.

- Severe lower digestive obstruction and difficult exhaust or defecation.
- Organic mental disorders and non-cooperated patient.
- Severe disabled cardiopulmonary functions.
- Abdominal hernia or incision hernia.
- Suspicious colon perforation.
- Difficult insertion due to anus or rectal deformity or high-degree narrow.
- Severe spine deformity.

1.3 Product Compatibility

The device is used with HD-400/HD-350 series image processors and HDL-35E/HDL-40X light sources provided by the manufacturer.

1.4 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.

1.4.1 Electrical Safety



- If any qualifications for an operator are developed by the medical administration or other official institutions, the operator should meet the qualification requirements. Otherwise, only the medical staff approved by the hospital safety administrator or by the person who is in charge of the department can perform endoscopy.
- Only the personnel authorized or trained by the 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.
- Only the peripherals (such as image processors, light sources and so on) provided or recommended by the manufacturer can be used. Using other devices may increase the RF radiation and lower the device resistance to electromagnetic interference.
- 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.

1 Safety

- 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



- Do not use the device around a strong electric field, a strong electromagnetic field or mobile wireless communication devices. Using the device in an improper environment may cause malfunction or damage.
- 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 lowvoltage power supply network that supplies buildings used for domestic purposes.

1.4.2 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.

1.4.3 Biohazard Considerations










- Patients debris and chemicals for cleaning, disinfection and sterilization are potentially dangerous. The operator should wear the medical protective clothing, goggle or gloves to minimize the risk of cross-contamination and disease infection. 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.

1.5 Safety Symbols

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

Symbol	Meaning
	Follow instructions for use

Symbol	Meaning
	Caution
	Date of manufacture
	Manufacturer
	Serial Number
IPN₁N₂	Degree of IP protection
	Non-ionizing electromagnetic radiation.
CE ₀₁₉₇	This product is provided with a CE marking in accordance with the regulations stated in Council Directive 93/42/EEC.
	Type BF Applied Part
	Authorized representative in the European community

This page is intentionally left blank.

2 Overview

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

To ensure the performance of this endoscope, you should be thoroughly familiar with the operations of all components of the endoscope and its accessories before use.

2.1 Packing

Make sure all the following items are in the packing box of the device.

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

Others: See the Packing List in the packaging box.

2.2 Endoscope Overview

2.2.1 Composition

The endoscope consists of connector section, control section, insertion section and distal end.

2.2.2 Connector Section

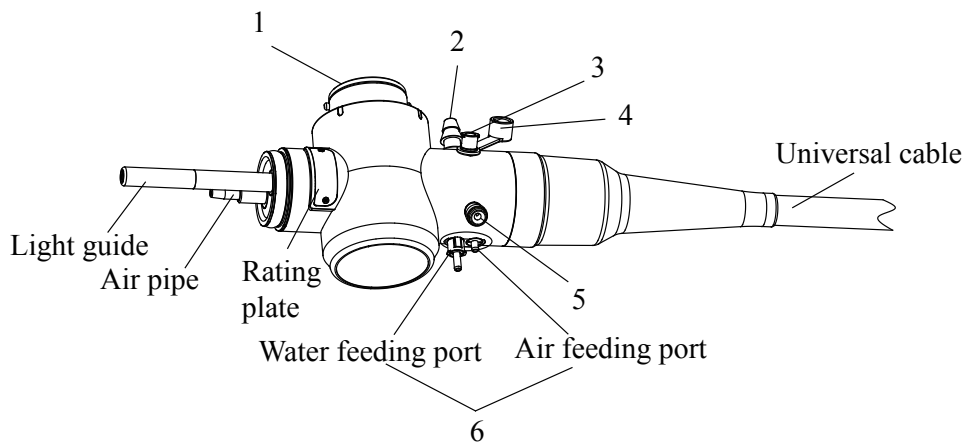


Figure 2-1 Connector Section

No.	Part Name	Description
1	Electrical connector	Used for connecting the endoscope cable to acquire video signal.
2	Suction port	Used for connecting to the suction pump.
3	Auxiliary water-feeding port	Used for connecting to the auxiliary water-feeding tube.

No.	Part Name	Description
4	Cap for auxiliary water-feeding port	<ul style="list-style-type: none">● Used for preventing the auxiliary water-feeding port.● Used for preventing the auxiliary water-feeding port from being blocked by foreign objects.● Used for preventing gas or liquid in patient's body from blowing or flowing back.
5	Electrosurgical equipment connector	Used for connecting the electrosurgical equipment.
6	Air/water feeding port	Used for connecting to the water bottle to feed air/water to the distal end.

2.2.3 Control and Insertion Section

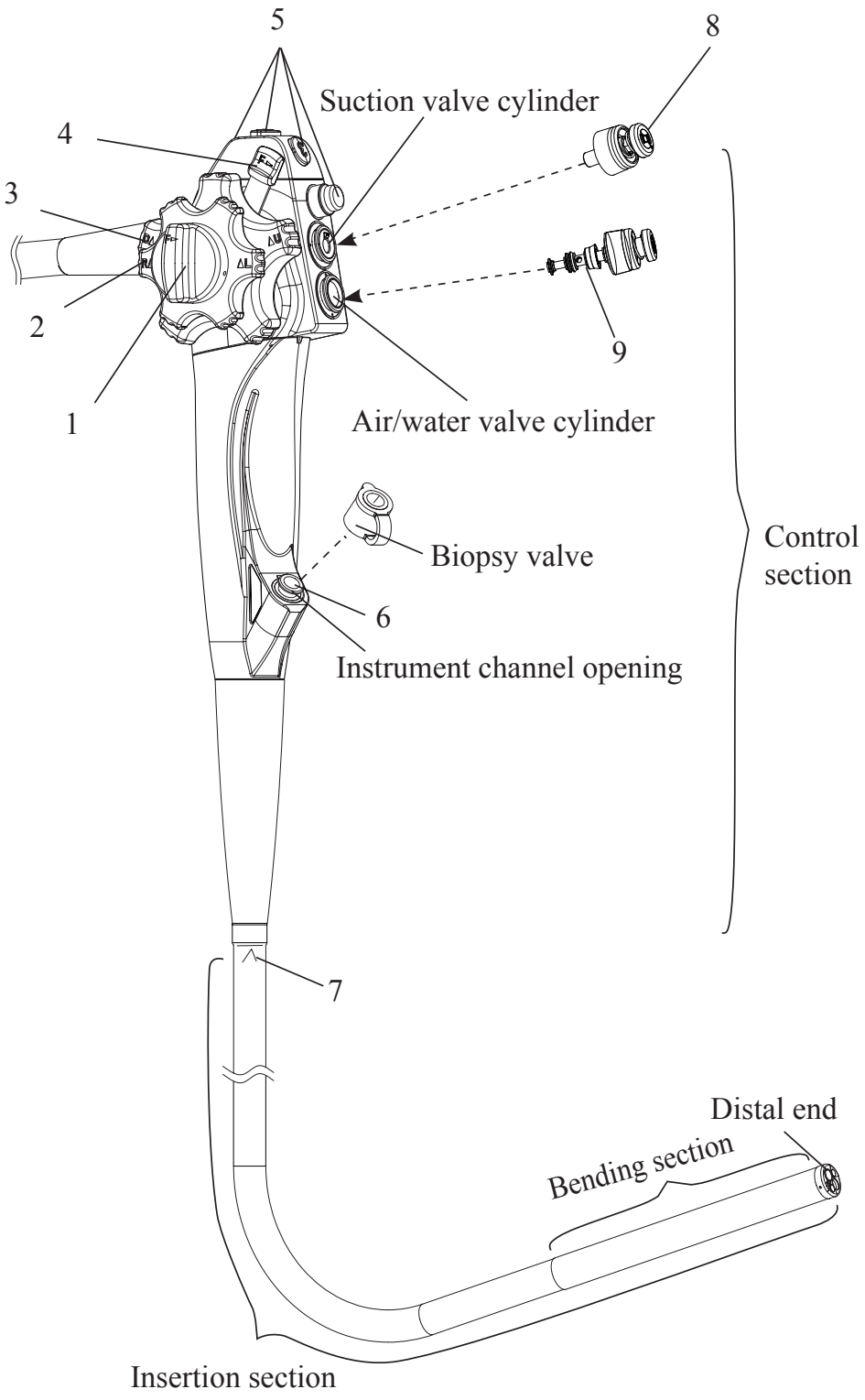


Figure 2-2 Control and Insertion Sections

No.	Part Name	Description
1	Left/right angulation lock	<ul style="list-style-type: none"> ● 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/right angulation control knob	<ul style="list-style-type: none"> ● Rotate it clockwise to make the bending section move right. ● Rotate it anticlockwise to make the bending section move left.
3	Up/down angulation lock	<ul style="list-style-type: none"> ● Rotate it clockwise to make the bending section move up. ● Rotate it anticlockwise to make the bending section move down.
4	Up/down angulation control knob	<ul style="list-style-type: none"> ● Rotate it clockwise to free the bending section in the up/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.
6	Instrument channel	<p>This channel should be used with the biopsy valve and the functions are as follows.</p> <ul style="list-style-type: none"> ● Used to feed the liquid to the distal end of the endoscope. ● Used for the endo-therapy accessory. ● Used as a suction channel.
7	Insertion limit mark	Indicates the maximum length of the insertion section that can be inserted into the body.
8	Suction valve	Press it to aspirate the liquid, debris or gas from the body.
9	Air/water valve	<ul style="list-style-type: none"> ● Cover the hole on the valve with finger to feed air. ● Press the valve to feed water. ● The fed air and water can remove the blood, debris or mucous membrane adhering to the objective lens.

2.2.4 Distal End

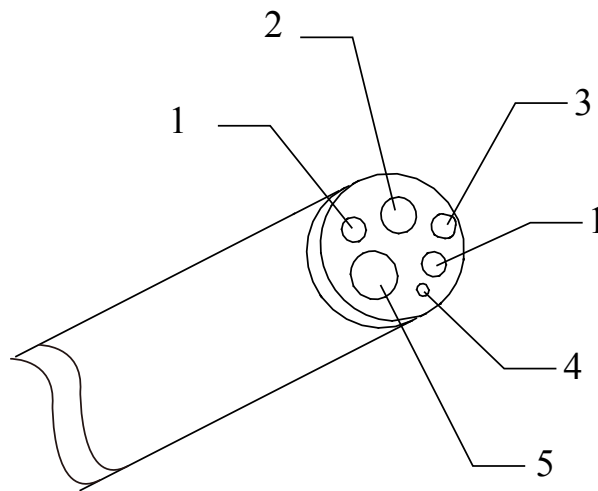


Figure 2-3 Distal End

No.	Part Name	Description
1	Light guide lens	Light is transmitted through these lenses for observing image.
2	Objective lens	Used to transmit the optical signal of the object to be observed inside human body to the CMOS sensor.
3	Air/water nozzle	The air or water will be fed to the distal end through this nozzle.
4	Auxiliary water-feeding outlet	Water or solution spurts out from this outlet.
5	Instrument channel outlet	Used as instrument outlet (such as biopsy forceps), liquid feeding outlet, or suction inlet.

3 Preparations

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

3 Preparations

Follow the descriptions in this chapter to inspect the endoscope and its accessories, and inspect the peripherals connected with the endoscope according to the relevant user manuals prior to each use. If any malfunction occurs, refer to Chapter 7 Troubleshooting. If the problem persists, please contact the local distributor.



- The endoscope is not disinfected in the factory. The operator should strictly perform cleaning and high-level disinfection for the endoscope before the initial use.
- For the safety of the patient and operator, do not use the damaged endoscope.
- To ensure the functionality of the endoscope, the operator should inspect the endoscope regularly.

3.1 Inspecting the Endoscope

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

3.1.1 Inspecting the Appearance and Flexibility

Perform the following inspections to inspect the appearance and flexibility.

- Ensure that there is no excessive scratch, deformation or slack on the control section or the connectors.
- Ensure that there is no abnormal bend or twist on the insertion section or the boot.
- Touch the entire insertion section (including the bending section and distal end) backwards and forwards gently to ensure that there is no dents, bulges, swelling, scratches, breakages, 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 scratches or breakages on the objective lens and light guide lenses, and no spots or cracks on the surface of the distal end.
- Ensure that there is no dents, protrusion or bulge on the air/water nozzle and the instrument channel outlet located on the distal end.

3.1.2 Inspecting the Angulation

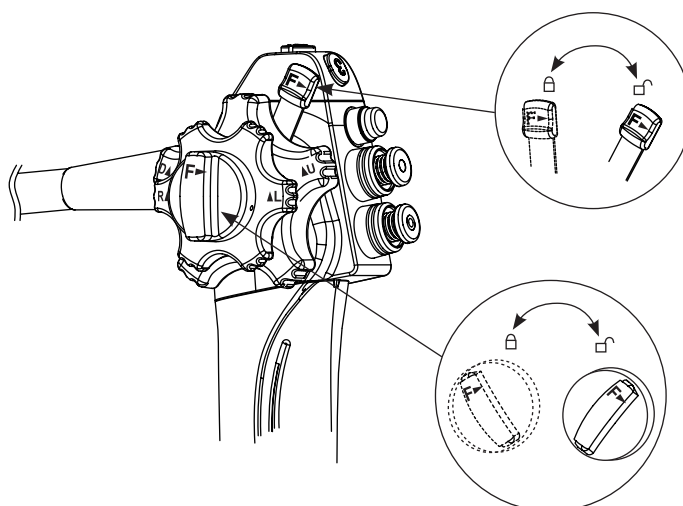


Do not use the endoscope if any angulation control knob is too loose or too tight. Otherwise, it may result in personal injury.

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

■ **To inspect the flexibility**

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 to ensure that the bending section can be bent flexibly and properly, and slowly restore to almost its original position after the knobs are loosened.
3. Rotate the up/down and left/right angulation control knobs to the original positions and ensure that the bending section return to a straight condition.

■ **To inspect up/down angulation**

1. Rotate the up/down angulation lock clockwise until it stops, 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 ensure that the bending section can be fixed at the desired angle.
3. When the bending section is fixed, rotate the up/down angulation lock clockwise until it stops to ensure that the bending section can restore to its original position.

■ **To inspect left/right angulation**

1. Rotate the left/right angulation lock clockwise until it stops, and then rotate the left/right angulation control knob clockwise and anticlockwise respectively until it stops. Ensure that the bending section can move to the left and right and reach its maximum angle.
2. Rotate the left/right angulation lock anticlockwise until it stops to ensure that the bending section can be fixed at the desired angle.
3. When the bending section is fixed, rotate the left/right angulation lock clockwise until it stops to ensure that the bending section can restore to its original position.

3.2 Inspecting and Connecting the Accessories

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

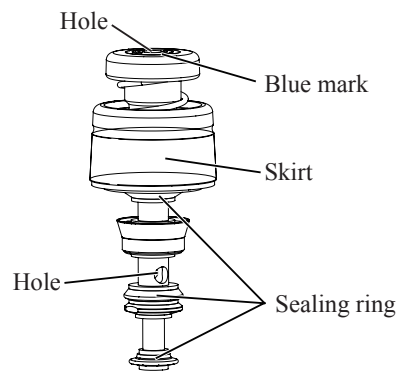
3.2.1 Air/Water Valve

The operator should clean and disinfect the air/water valve before inspection. For details, refer to 5 Cleaning, Disinfection and Sterilization.



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

■ Inspection



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

■ Installation

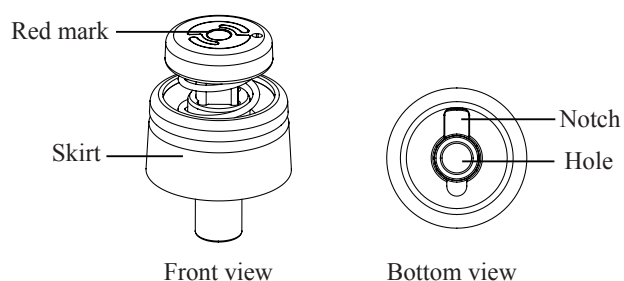
Install the air/water valve to the air/water valve cylinder of the endoscope properly.

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



- Ensure that hole are not blocked.
- Ensure that the valve is not deformed or damaged.

■ Installation

Align the notch at the bottom of the suction valve with the bulge on the suction valve cylinder and push 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. Therefore, it is recommended that the suction valve shaft be lubricated at regular intervals by using the lubricant provided by the manufacturer.
- Red mark is used to distinguish this valve from the air/water valve of the endoscope.

3.2.3 Biopsy Valve



- 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 debris or body liquid and disease infection.

■ To inspect the biopsy valve



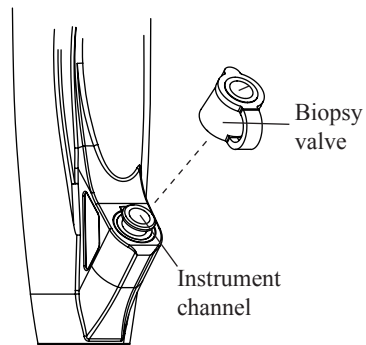
Perform the following inspections before using the biopsy valve.

3 Preparations

- Ensure that the valve is not deformed or damaged.
- Ensure that the main body and the cap are connected firmly.

■ To install the biopsy valve

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 of the endoscope properly.

3.3 Connecting the Endoscopy System

NOTE:

- Before connecting the endoscopy system, 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.

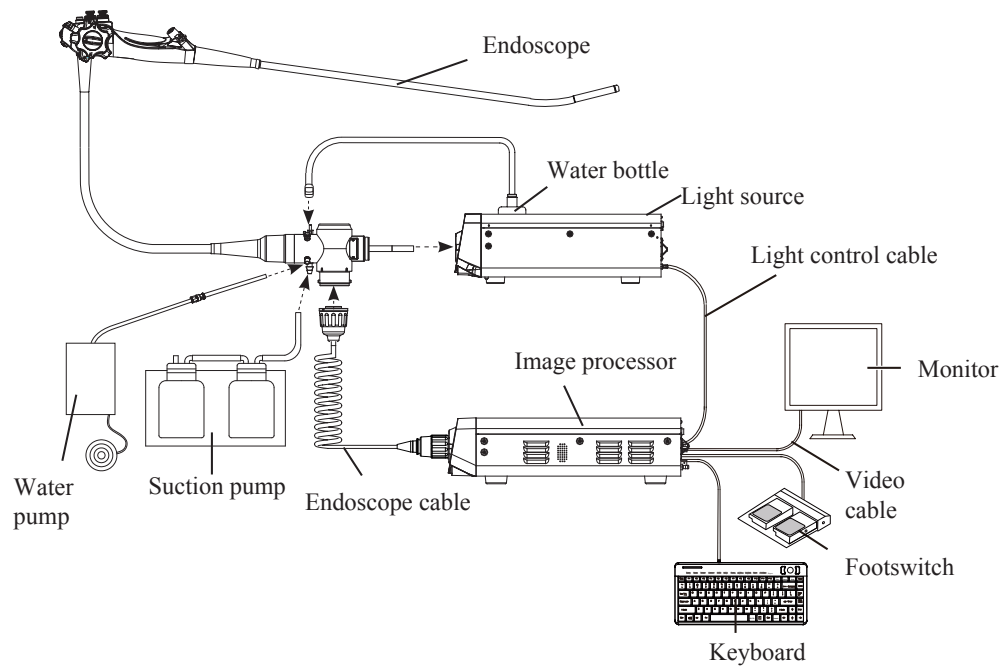
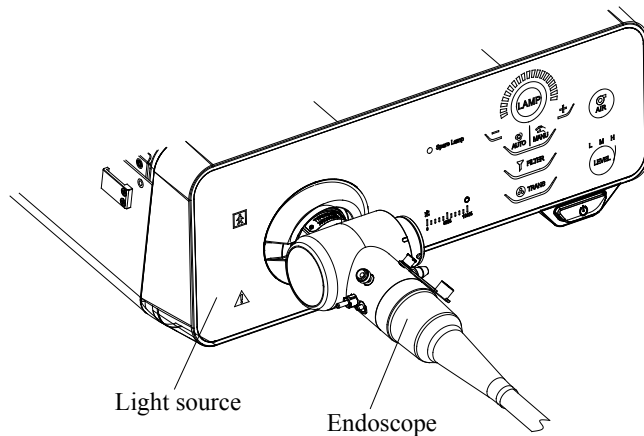


Figure 3-1 Connection of the Endoscopy System

3.3.1 Connecting the Light Source

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



3.3.2 Connecting the Water Bottle

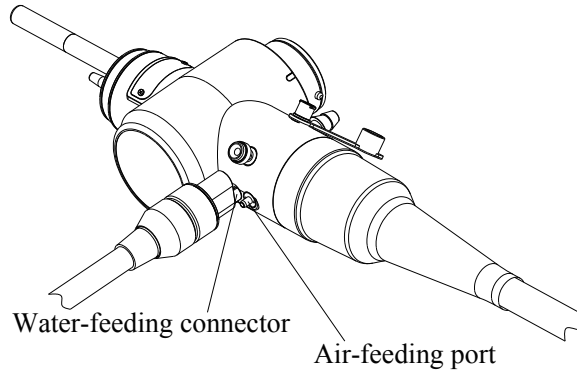


The water bottle should be installed in the water bottle bracket at the right side of the light source.

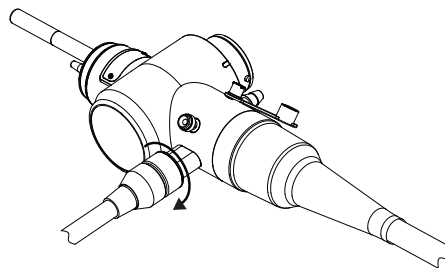
Perform the following steps to connect the water bottle to the endoscope.

3 Preparations

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



2. Rotate the water bottle connector 90 degrees clockwise until the air-feeding connector is aligned with the air-feeding port.



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

3.3.3 Connecting the Endoscope Cable

NOTE:

- Do not use the endoscope cable forcibly to avoid damage.
- Do not touch the pins inside the connector of the endoscope cable to avoid damage.

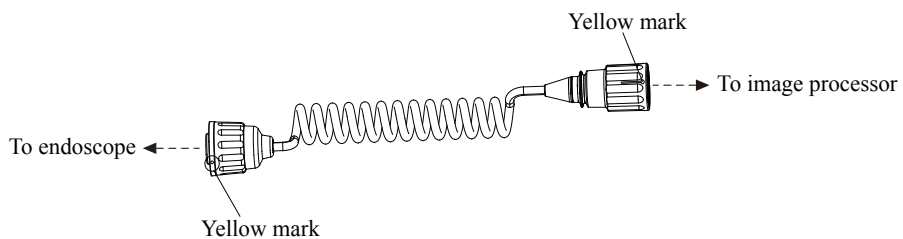


Figure 3-2 Endoscope Cable

Perform the following steps to connect the endoscope cable.

1. Align the two yellow mark on the endoscope cable connector with yellow mark 1 on the electrical connector of the endoscope, and insert the endoscope cable connector into the endoscope.

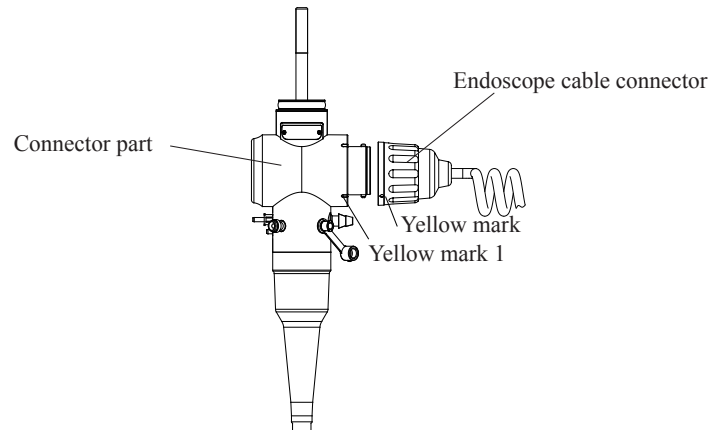


Figure 3-3 Endoscope Cable Connection 1

2. Rotate the connector clockwise and align the yellow mark on the connector with yellow mark 2 on the electrical connector of the endoscope until you hear a click.

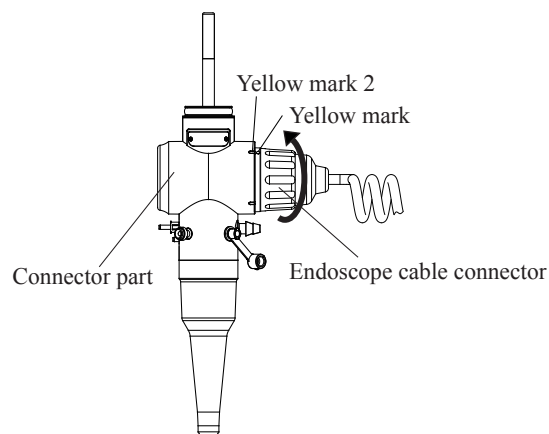
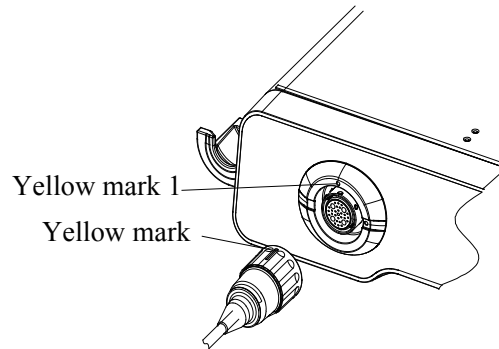


Figure 3-4 Endoscope Cable Connection 2

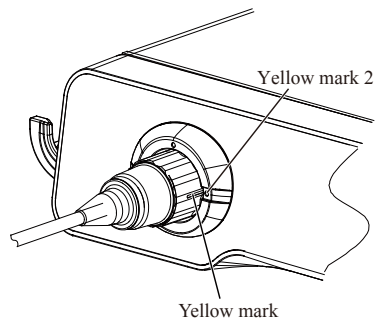
3.3.4 Connecting the Image Processor

Perform the following steps to connect the endoscope to the image processor.

1. Align the yellow mark on the endoscope cable connector with yellow mark 1 on the connector socket of the image processor. Connect the endoscope cable connector to the socket firmly.



2. Rotate the endoscope cable connector clockwise until the mark on the connector is aligned with yellow mark 2 on the socket.

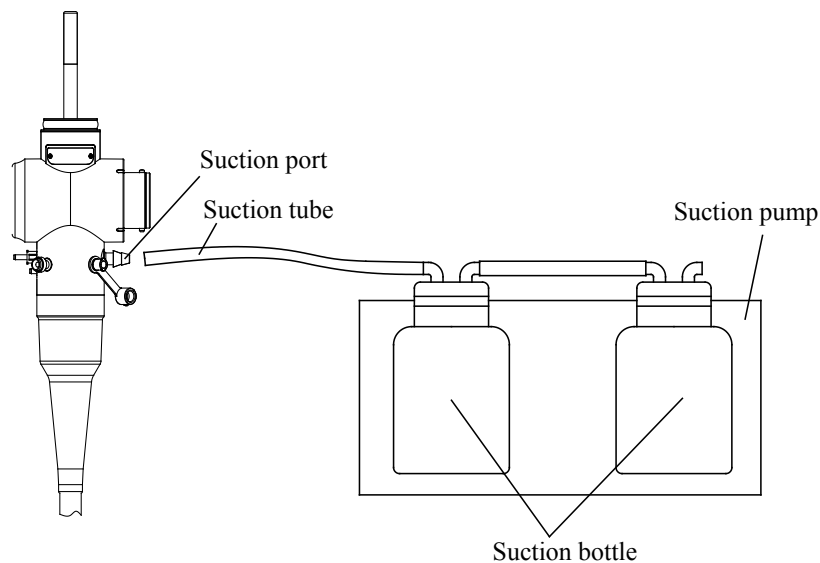


3.3.5 Connecting the Suction Pump



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

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

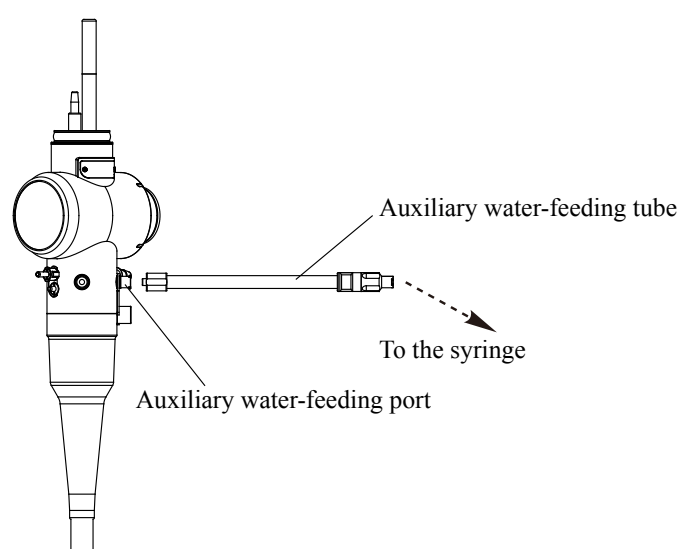


3.3.6 Connecting the Auxiliary Water-feeding Tube

NOTE:

- The longer auxiliary water-feeding tube is used in clinical examination, and the shorter auxiliary water-feeding tube is used in cleaning, disinfection or sterilization. The connection method of these two tubes are the same.
- Ensure that the tubes are not scratched, cracked or damaged.

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 to inspect the image.

1. Power on the light source, the image processor and the monitor.
2. Press the **LAMP** button on the light source and ensure that light is emitted 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 does not disappear suddenly and no exception occurs.

3 Preparations

NOTE:

If the endoscopic image is unclear because the lens is dirty, use a soft lint-free cloth dampened with 70% - 80% 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, you should inspect them before performing an exam. Otherwise, an abnormal function may occur and result in personal injury.

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

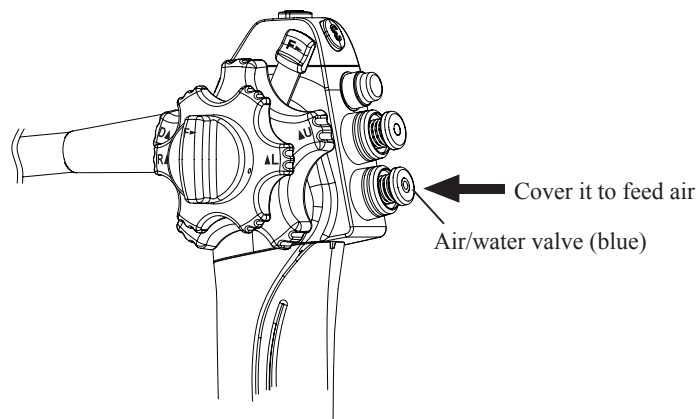
3.4.3 Inspecting the Air Feeding Function



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

Perform the following steps to inspect the air feeding function.

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



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

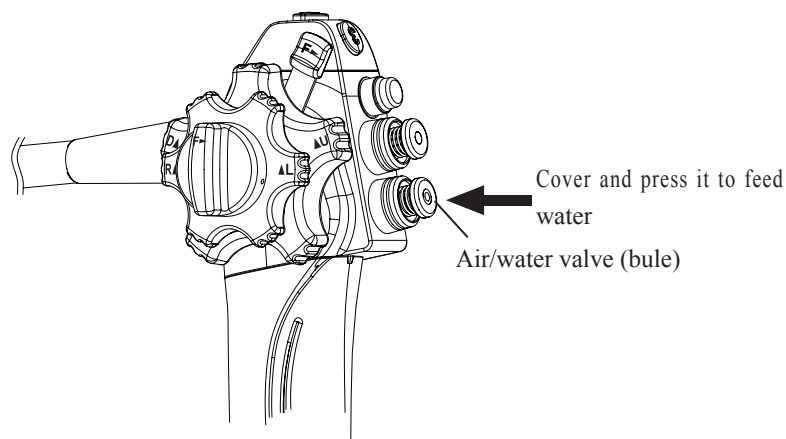
3.4.4 Inspecting the Water Feeding Function



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

Perform the following steps to inspect the water feeding function.

1. Cover the hole on the air/water valve with 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 the finger and ensure that no water is sprayed and the air/water valve restores to its original position smoothly.
3. Cover the hole 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.

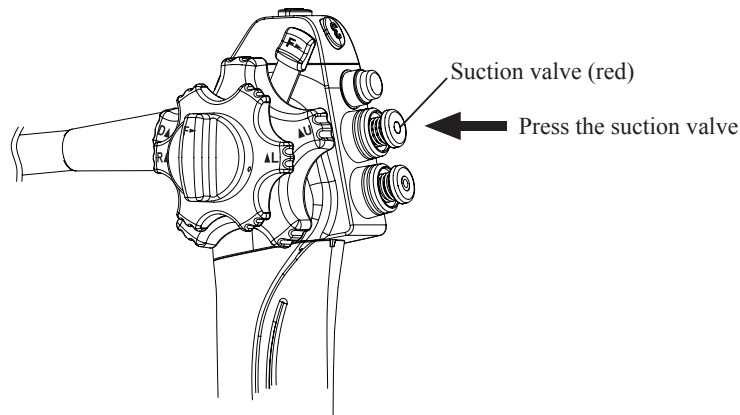
3.4.5 Inspecting the Suction Function



- If the biopsy valve is leaky, patient 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. Re-install the suction valve or replace it. If the problem still exists after the replacement, the endoscope may be malfunctioning. Stop using the endoscope and contact the local distributor.

Perform the following steps to inspect the suction function.

1. Adjust the suction pressure to the clinical standard.
2. Immerse the distal end in the sterile water and place the opening of instrument channel at the same height as the water level in the container filled with sterile water.
3. Press the suction valve and ensure that the water can be continuously extracted to the suction bottle.



4. Release the suction valve and ensure that the suction is stopped and the suction valve restores to the original position.
5. Press and hold the suction valve for a few seconds, and then release the valve. Repeat the operations 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 internal endo-therapy accessories are extracted from the distal end. Otherwise, it may result in injuries to eyes.

Perform the following steps to inspect the instrument channel.

1. Insert the endo-therapy accessory into the opening of instrument channel. Ensure that the instrument can be successfully extracted from the distal end without foreign object.
2. Ensure that the instrument can be successfully withdrawn from the opening of instrument channel.

3.4.7 Inspecting the Auxiliary Water-feeding Tube



- Use sterile water to inspect the auxiliary water-feeding function to 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 system and personal injury.

Perform the following steps to inspect the longer auxiliary water-feeding tube.

1. Connect one end of the longer auxiliary water-feeding tube to the auxiliary water-feeding port firmly, and connect the other end to a syringe filled with sterile water.
2. Feed sterile water and ensure that the water flows from the distal end.

3. Observe the both connectors of the longer auxiliary water-feeding tube and ensure that there is no leakage.
4. Remove the syringe and ensure that no water flows from the longer auxiliary water-feeding outlet or the distal end.

This page is intentionally left blank.

4 Operations

The operator of this endoscope must be a physician or the medical personnel who operates under the supervision of the physician and must 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.



- Patients 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 accident.
- 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 required level of illumination, time and distance to examine the patient.
- Do not insert or withdraw the endoscope in any of the following cases. Otherwise, it may result in personal injury.
 - When the biopsy forceps are extracted 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 using the endoscope, 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 personal injury.
- Do not operate the angulation control knob forcibly. Otherwise, the bending section could be inversely bent and it may result in personal injury.
- 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.
- If the image or the function is abnormal, stop examining even if the abnormality disappears rapidly. Slowly withdraw the endoscope from the patient body while observing the image. Otherwise, the abnormality may occur again and it may result in personal injury.
- Before examining a patient with the endoscope, the doctor shall fully explain the risks of the examination to the patient and ask the patient to sign an informed consent form.
- Do not operate the endoscope when changing the observation modes between variable intelligent staining technology mode (VIST) and common mode as the endoscopic image may be disturbed. Otherwise, it may result in personal injury.

4.1 General Operations

4.1.1 Inserting the Endoscope

Perform the following steps to insert the endoscope.

1. Hold the control section of the endoscope with your left hand and operate the air/water valve, the suction valve and the 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. If necessary, use the medical-grade water-soluble lubricant on the insertion section.
3. Turn on the lamp of the light source.
4. Observe the whole endoscope insertion process from the anus to colon on the monitor carefully. Do not insert the insertion tube beyond its limit mark.

4.1.2 Adjusting the Angle of Bending Section



- Do not rapidly change the angle of the bending section 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.



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 to adjust the angle of the bending section.

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.

4.1.3 Feeding Air/Water and Aspirating



- If the sterile water level 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.
- Cover the cap of the biopsy valve firmly before aspiration. Otherwise, the efficacy of the suction system is degraded and the patient debris and body fluid may be leaked, causing 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 mucous membrane injury.

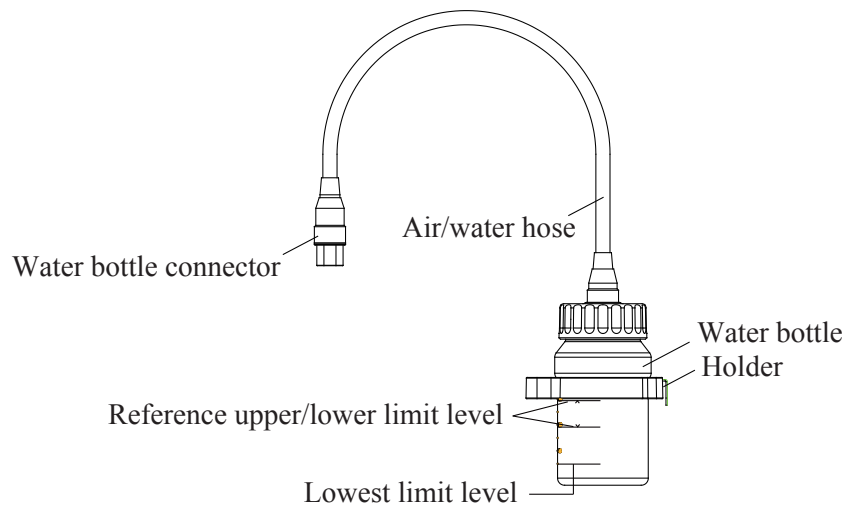
4 Operations

- Avoid aspirating solid or sticky matters. Otherwise, it may block instrument channel or suction valve. If the suction valve is blocked, disconnect the suction tube and turn off the suction pump, then remove and clean the suction valve to clear the solid matters.

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).

The water bottle is shown in the following figure.



■ To feed water/air

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 onto the surface of objective lens.

■ To aspirate



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

Press the suction valve to aspirate excess liquid and debris in the patient body.

NOTE:

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

4.1.4 Feeding Water Through the Auxiliary Water-feeding Port



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

NOTE:

- Feed water by using the longer auxiliary water-feeding tube.
- Do not remove the longer auxiliary water-feeding tube until the pre-cleaning is completed. Otherwise, the residual water in the tube may be spilled on the equipment, causing damage of the equipment.
- Cover the auxiliary water-feeding port with the cap when the port is not in use. Otherwise, debris or liquid in patient body may flow back from the tube and spout from the auxiliary water-feeding port.

Use a syringe to feed water to the endoscope through the auxiliary water-feeding port, and water will spurt out from the distal end of the endoscope to flush the blood and debris attached to the mucosa.

4.2 Auxiliary Operations



- **WARNING** When using the endo-therapy 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 in the image. Otherwise, it may result in serious injury or endoscope damage.
- If it is difficult to insert or withdraw the endo-therapy accessory, you should straighten the bending section while observing the image. Inserting or withdrawing endo-therapy accessory forcibly may damage the instrument channel or the endo-therapy accessory.
- Do not forcibly or suddenly insert the endo-therapy accessory. Otherwise, the endo-therapy accessory extracted from the distal end may injure the patient.
- Do not inject excessive air or any non-flammable gas into the patient body during the endo-therapy operation. It may result in air block.
- Do not hang the endo-therapy accessory on the biopsy valve to avoid damage.

4.2.1 Using the Biopsy Forceps



- 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 endo-therapy 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 the expiration date.
- The biopsy forceps is a single-use accessory.

Perform the following steps to use the biopsy forceps.

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 insert the biopsy forceps into the slot of the biopsy valve slowly.
3. Observe the endoscopic image while inserting the biopsy forceps into the instrument channel slowly.
4. When the biopsy forceps are visible on the image, open the claws to nip the sample of tissue, and then draw in the claws and retract the biopsy forceps gently.
5. Slowly withdraw the biopsy forceps from the instrument channel. Ensure that the tissue is nipped securely during the withdrawal.

4.2.2 Using the Cytology Brush

Perform the following steps to use the cytology brush.

1. Lock the up/down and left/right angulation control knobs and fix the bending section at the desired angle.
2. Insert the sheath into the instrument channel slowly, and keep the cytology brush in the sheath simultaneously. Observe the image.
3. When the cytology brush is visible on the image, extend the cytology brush from the sheath and collect the sample by brushing the dropped cell gently.
4. Retract the brush back to the sheath slowly, and withdraw the sheath from the instrument channel.
5. Use the brush to make the smear sample.

4.2.3 Using the Syringe

Perform the following steps to use the syringe.

1. Insert the syringe sheath into the instrument channel straightly, and keep the syringe in the sheath simultaneously. Observe the image.
2. When the syringe sheath is visible on the image, extend the needle from the sheath gently and inject the medicine or spray liquid slowly.
3. Retract the needle back to the sheath slowly, and keep the syringe in the sheath simultaneously. Withdraw the sheath from the instrument channel.

4.3 Ending the Operation



WARNING 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 body.

Perform the following steps to withdraw the endoscope.

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

This page is intentionally left blank.

5 Cleaning, Disinfection and Sterilization

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

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

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

For selecting the type and condition of cleaning, disinfecting, and sterilizing the endoscope and its accessories, you can also refer to the cleaning, disinfection, and sterilization regulations of the local hospital for professional judgment.

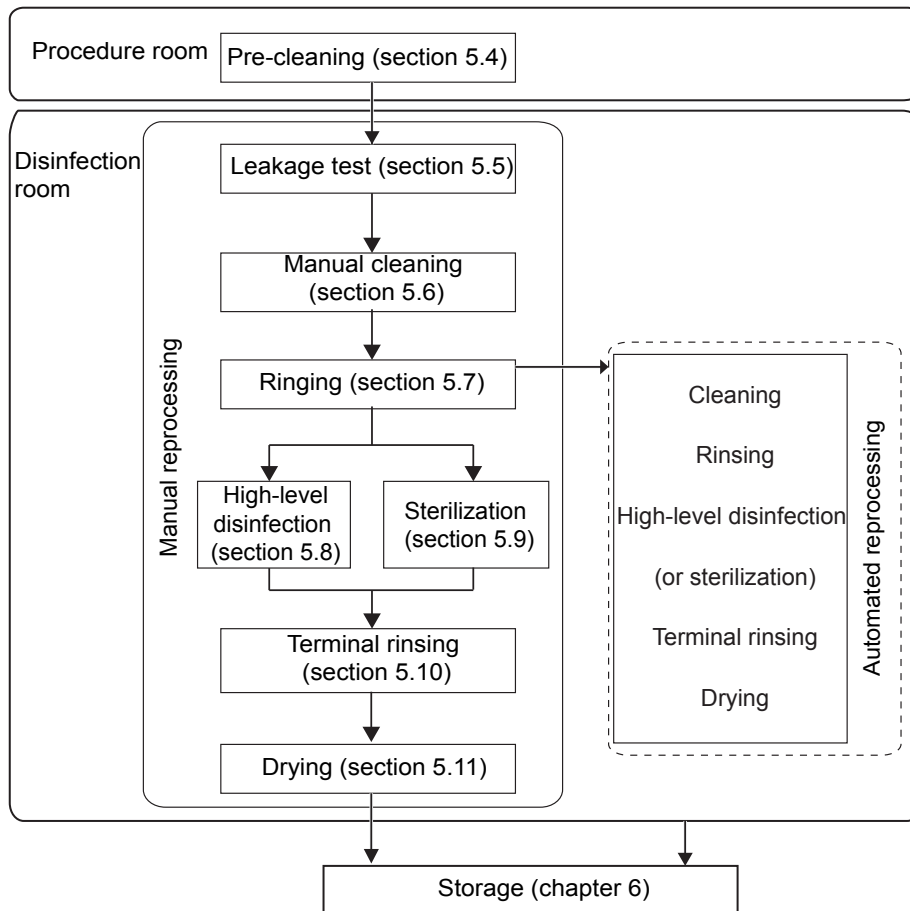
5 Cleaning, Disinfection and Sterilization



- Patient debris and chemicals for cleaning and disinfection or sterilization are potentially dangerous. The operator should wear 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 disinfection room.
- The disinfection room should be set separately and isolated from the procedure room. In addition, the disinfection room must have sufficient space and adequate ventilation.
- During cleaning, disinfection, or sterilization of the endoscope, all channels of the endoscope must be cleaned, disinfected, or sterilized, including the channel not used during last examination. Otherwise, the next patient may be infected.
- Before manual cleaning of 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 single-use accessories.
- After being used on a patient who is infected with mycobacterium tuberculosis or other mycobacterium, the endoscope should be immersed in 2.4% glutaraldehyde for at least 45 min. The sensitivity of some pathogenic microorganisms to the disinfectant is very low. Therefore, sterilization should be performed as required and the endoscope should even be destroyed by melting or burning when necessary.
- 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/sterilized.
- When finding that a patient is infected with unknown super bacteria after use of endoscope, report the incident in accordance with local laws or regulations.
- Dispose of endo-therapy accessories in accordance with local laws or regulations.
- Use the legally marketed automatic disinfection machine to reprocess the endoscope.
- The automatic disinfection machine is only applicable to the high-level disinfection of the endoscope. If using an automatic disinfection machine, ensure that it is capable of thoroughly reprocessing the endoscope including all channels. Otherwise, insufficient cleaning and disinfection of the endoscope may result in infection of the patient and/or the operator. Please contact the machine supplier for information of operation, specification and connectors.
- The endoscope 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.

- After being used each time, the endoscope must be cleaned, disinfected, or sterilized, and stored according to the descriptions in this chapter. If the endoscope is not completely cleaned, disinfected, or sterilized or it is improperly stored, the patient or operator may be infected and the device may be damaged or the device performance may be degraded.
- Before using the endoscope each time, you should clean, disinfect, or sterilize the endoscope according to the regulations of the local hospital based on the actual disinfection, sterilization, and storage conditions of the endoscope.
- Before cleaning, disinfecting, or sterilizing the endoscope, ensure that the insertion section of the endoscope is in natural state (unlocked). Otherwise, the endoscope may be damaged during the cleaning, disinfection, or sterilization process.
- Store alcohol in a sealed container. Otherwise, a fire may be incurred. Besides, the alcohol may become invalid due to volatilization.
- Although the instrument channel dimensions of this series endoscopes are different, the cleaning and high-level disinfection methods are exactly the same. The difference of instrument channel dimension has been considered in the development of the cleaning and high-level disinfection methods described in this user manual.
- The quality of water used for cleaning and high-level disinfection should accord with AAMI TIR34: 2014 standards.

Perform the following steps to clean and disinfect the endoscope.



5.1 Detergent, Disinfectant, and Flushing Fluid



- Use effective and legally marketed detergent and disinfectant in accordance with the local regulations.
- Use the detergent, disinfectant, and flushing fluid recommended by the manufacturer, and ensure that the concentration and the immersion 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, contact the manufacturer.
- Prepare, use, store and dispose the detergent and disinfectant according to the instructions provided by manufacturers.
- Do not use expired detergent and disinfectant.
- Do not perform steam sterilization (autoclaving) for the endoscope.
- Do not dry any disinfectant on the endoscope in air.

- Do not immerse the endoscope into the anhydrous ethanol or wipe the endoscope with the anhydrous ethanol.

■ Disinfection Levels

The disinfection classification is defined as follows in Table 5-1.

Table 5-1 Disinfection Levels

Classification	Definition	Level of Disinfection	Application
Critical	A device that enters normally sterile tissue or the vascular system or through which blood flow should be sterile	Sterilization	Surgical instruments, injection needle, laparoscope, biopsy forceps, invasive sheaths, implants
Semi-critical	A device that comes in contact with intact mucous membrane and does not ordinarily penetrate sterile tissue	High-level disinfection	Gastrointestinal endoscope, bronchoscope, laryngoscope
Noncritical	A device that does not ordinarily touch the patient or touch only intact skin	Medium or low-level disinfection	Stethoscope, blood pressure meter, cuff

5.1.1 Detergent

Detergent can be used to dissolve and emulsify feculence and microbe, enhance the dirt-removing power, facilitate cleaning, and improve the cleaning quality. Detergent can be classified into the following types:

- Alkaline detergent: Its pH value is greater than or equal to 7.5. It functions well in dissolving various organics and it is slightly corrosive to metals.
- Neutral detergent: Its pH value ranges from 6.5 to 7.5, and it is not corrosive to metals.
- Acidic detergent: Its pH value is smaller than or equal to 6.5. It functions well in dissolving inorganic solid particles and it is slightly corrosive to metals.

5 Cleaning, Disinfection and Sterilization

- Detergent containing enzyme: The detergent that contains enzyme synergist contains one or multiple types of different enzyme. This type of detergent has strong dirt-removing power. It can be used to resolve various organic pollutants like protein. This type of detergent requires a certain contact time and temperature for its efficiency to reach the maximum. It must be used in proper conditions according to the product description of the manufacturer.

Low-foaming detergent containing enzyme is recommended.

NOTE:

- Don't use the detergent repeatedly.
- Excessive detergent foaming could cause inadequate contact between the interior of the channels and the detergent. Consequently, the endoscope cannot be cleaned completely.

5.1.2 Disinfectant

The manufacturer recommends that phthalic dicarboxaldehyde solution with a level of 0.55% (0.5%-0.6%), alkaline glutaraldehyde solution with a level not smaller than 2%, peroxyacetic acid solution with a level of 0.2%-0.35%, or acidic electrolyzed oxidizing water solution with an active chlorine level of (60±10) mg/L can be used for high-level disinfection of the endoscope.

NOTE:

The glutaraldehyde solution may incur stimulus or anaphylactic reaction of the endoscope cleaning and disinfection personnel. Therefore, this solution should be used in an area with adequate ventilation and stored in a sealed container.

5.1.3 Flushing Fluid

After high-level disinfection, you should completely rinse the endoscope, endoscope accessories, and cleaning and disinfection tools with sterile water to remove the residual of high-level disinfectant. If no sterile water is available, filtered or tap water may be used only when the rinse is followed by alcohol flushing and drying steps.

NOTE:

- Do not use running water as the flushing fluid.
- Do not use the flushing fluid repeatedly.

5.2 Cleaning and Disinfection Tools

Prepare the following items before cleaning and disinfection.

- Manual cleaning tank, rinse tank, disinfection/sterilization tank, and terminal rinse tank

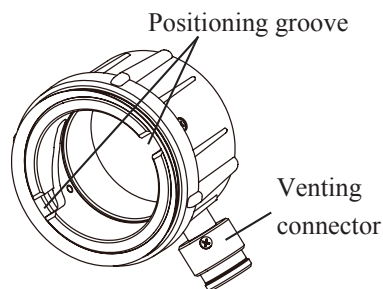
- Manual cleaning basin, rinse basin, disinfection/sterilization basin, and terminal rinse basin
- Waterproof cap
- Channel plug
- Injection tube
- Cleaning brush
- Channel-opening cleaning brush
- Shorter auxiliary water-feeding tube
- Leakage detector
- Water pressure gun
- Air pressure gun
- Suction pump
- Timer
- Transport container for endoscope and accessories
- Sterile mat
- Lint-free cloth (disposable)
- Sterile swab
- 30cm³ (30ml) syringe

5.3 Accessory Inspection and Connection

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

5.3.1 Waterproof Cap

The waterproof cap is used to protect the electrical connector from water entering the endoscope during cleaning and disinfection. Before a leakage test, the venting connector needs to be connected to the waterproof cap, as shown in the following figure.



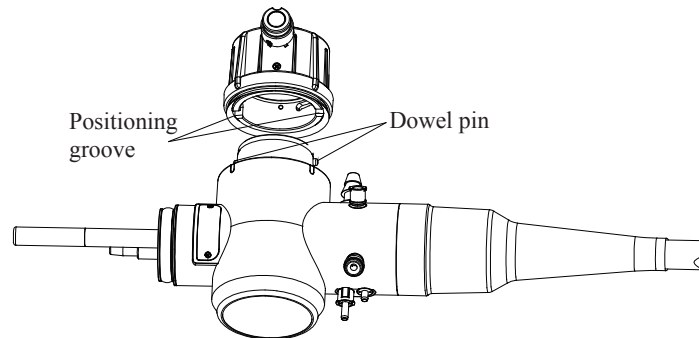
Before using the waterproof cap, perform the following inspections.

5 Cleaning, Disinfection and Sterilization

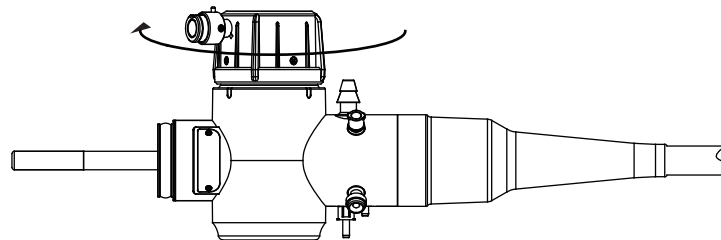
- Ensure that the inner wall of the waterproof cap is completely dry and there is no debris. If water drop or debris is found, wipe with a dry lint-free cloth.
- Ensure that there is no scratch, crack or debris on the sealing components of the waterproof cap.
- Ensure that the venting connector is connected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

Perform the following steps to attach the waterproof cap.

1. Align the dowel pin of the electrical connector with the positioning groove of the waterproof cap.



2. Press down and rotate the waterproof cap clockwise till the end. Ensure that the waterproof cap is firmly attached onto the endoscope.

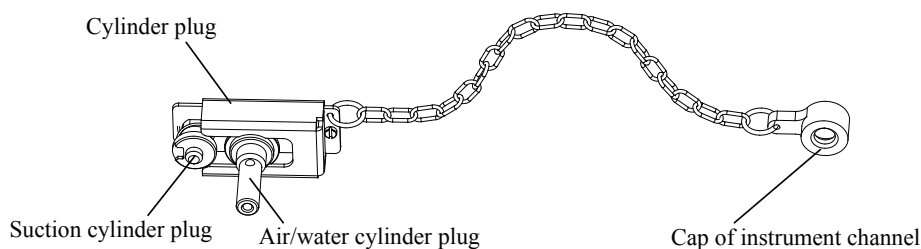


NOTE:

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

5.3.2 Channel Plug

Channel plugs are used to plug the instrument channel port, air/water feeding ports, and suction channel port during cleaning and disinfection of the endoscope. The following figure shows the channel plugs.

**NOTE:**

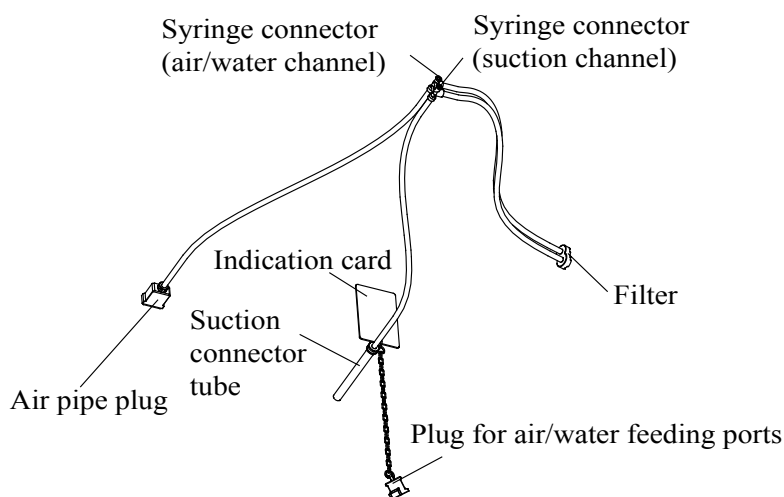
- Before using a channel plug, ensure that there is no crack, scratch, or debris on the plug.
- Ensure that the channel plug and the endoscope are firmly connected.

Perform the following steps to attach the channel plug.

1. Hold the cylinder plug, install the suction channel plug and air/water channel plug to the suction valve cylinder and air/water valve cylinder of the endoscope respectively.
2. Press the cylinder plug and ensure that the installation is firm.
3. Press the cap of the instrument channel into the instrument channel port, and ensure that the connection is firm.

5.3.3 Injection Tube

The injection tube is used to inject detergent solution, disinfectant solution, sterile water or alcohol into the air/water and suction channels. It is also used to feed air into the channels to discharge residual liquid. The following figure shows an injection tube.

**NOTE:**

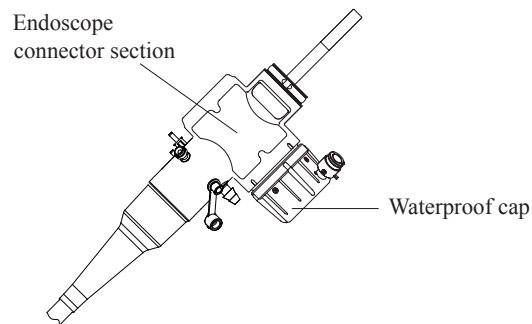
- Before using the injection tube, ensure that there is no crack, scratch, flaw, or debris on any component.
- Ensure that the filter mesh is intact.

5 Cleaning, Disinfection and Sterilization

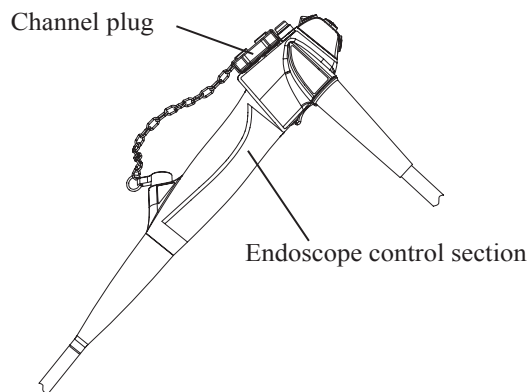
- Connect a 30cm³ (30 ml) syringe to the syringe connector (air/water channel). Immerse the filter in the clean water, pull out the plunger of the syringe, and ensure that clean water is aspirated into the syringe. Then, push the plunger, and ensure that clean water flows from the air pipe plug and no clean water flows from the filter.
- Connect a 30cm³ (30 ml) syringe to the syringe connector (suction channel). Immerse the filter in the clean water, pull out the plunger of the syringe, and ensure that clean water is aspirated into the syringe. Then, push the plunger, and ensure that clean water flows from the suction connector tube and no clean water flows from the filter.

Perform the following steps to connect the injection tube.

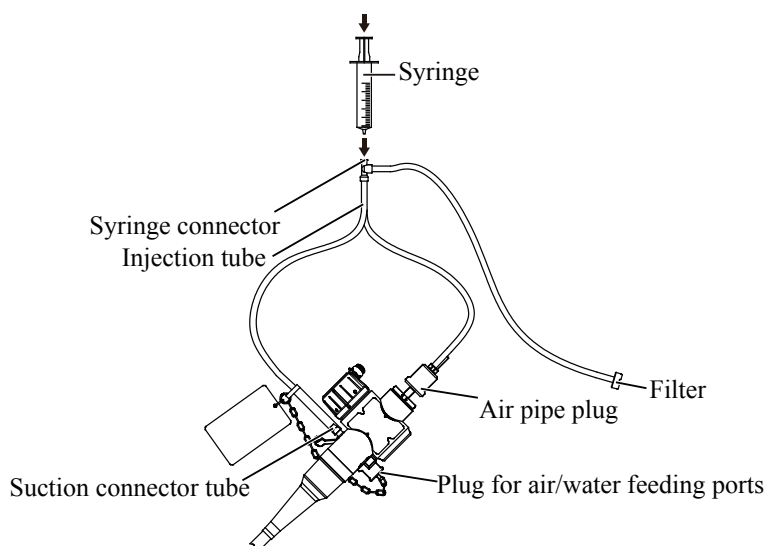
1. Connect the waterproof cap to the electrical connector of the endoscope.



2. Use channel plugs to plug the suction valve cylinder, air/water valve cylinder, and instrument channel port respectively.

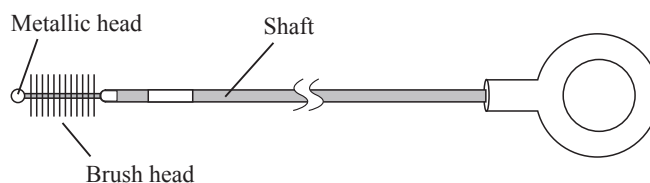


3. Connect the air pipe plug, suction connector tube, and plug for air/water feeding ports of the injection tube to the air pipe, suction connector, and air/water feeding ports of the endoscope connector section respectively.



5.3.4 Cleaning Brush

The cleaning brush is used to brush the inner parts of all endoscope channels. The following figure shows a cleaning brush.



Perform the following inspections before using the cleaning brush.

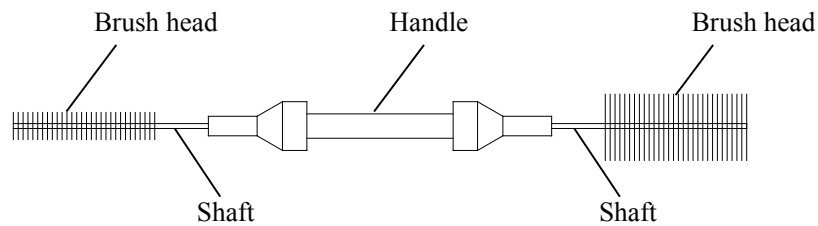
- Ensure that the brush head, metallic head, and bristle are firm.
- Ensure there is no bend, scratch, or damage on the brush shaft.
- Ensure that there is no debris on the brush shaft or bristle.

NOTE:

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

5.3.5 Channel-Opening Cleaning Brush

The channel-opening cleaning brush is used to brush the interior and opening of the air/water valve, suction valve, biopsy valve, suction valve cylinder or instrument channel port.

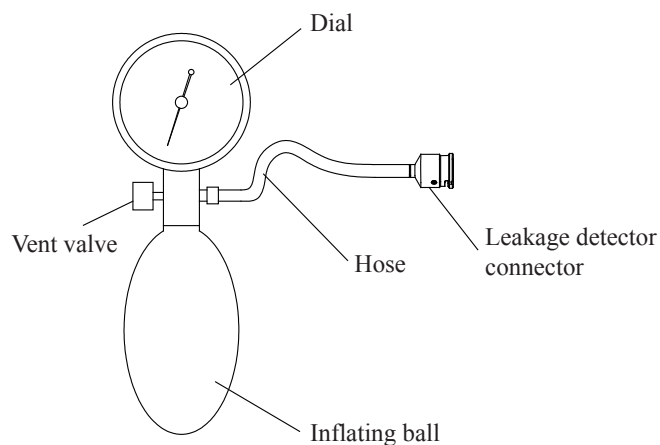


Perform the following inspections before using the brush.

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

5.3.6 Leakage Detector

The leakage detector is used to perform leakage test before cleaning and disinfecting the endoscope. The following figure shows a 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 pin on the venting connector of the waterproof cap with the groove on the leakage detector connector.
2. Rotate the leakage detector connector clockwise until it is locked.

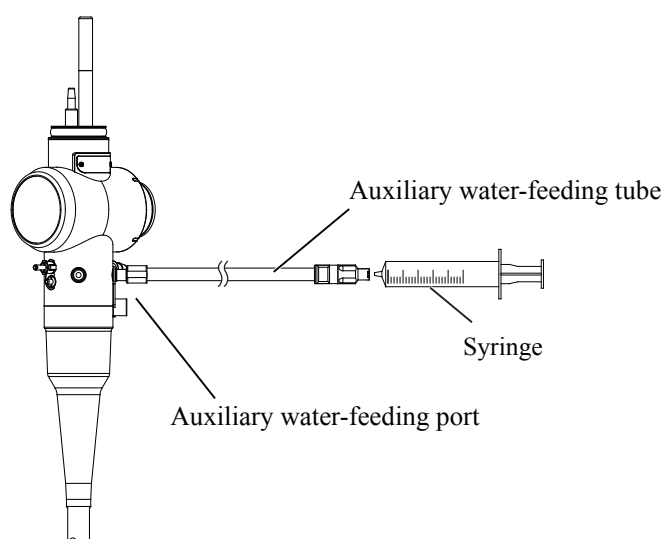
5.3.7 Auxiliary Water-feeding Tube

NOTE:

- Use the shorter auxiliary water-feeding tube to flush the auxiliary water-feeding channel.
- Ensure that there is no crack, scratch, flaw, or debris on the shorter auxiliary water feeding tube.

The shorter auxiliary water-feeding tube is used to inject detergent, disinfectant, flushing fluid or alcohol into the auxiliary water-feeding channel. It is also used to feed air into the channel to discharge residual liquid.

Connect the shorter auxiliary water-feeding tube as shown in the following figure:



5.4 Pre-cleaning



- After being withdrawn from the patient's body, the endoscope must 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 procedure. Otherwise, the residual debris may solidify. Consequently, cleaning and disinfection or sterilization of the endoscope will be difficult.
- Do not touch the light guide lens of endoscope and the endoscope port of light source after disconnecting the endoscope from the light source after each use. The temperature of the two parts is extremely high. Touching them may result in skin burns.

5.4.1 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.

Use a lint-free cloth dampened with detergent to wipe the surface of the endoscope insertion section to remove all visible soil after the endoscope is withdrawn from the patient's body.

5.4.2 Suction Channel

NOTE:

During aspiration, observe the liquid in the suction bottle carefully to avoid overflow. Otherwise, the suction pump may be damaged.

1. Power on the suction pump.
2. Install the biopsy valve.
3. Immerse the distal end of the endoscope in the detergent, and press the suction valve to aspirate detergent into the instrument channel for 30s.
4. Take out the distal end from the detergent, and press the suction valve to aspirate air for 10s.
5. Power off the suction pump.

5.4.3 Air/Water Channel

1. Immerse the distal end of the endoscope in the clean water.
2. Switch on the air pump of the light source, and adjust the air feeding pressure to the maximum.
3. Cover and press the air/water valve to feed water into the air/water channel for 10s.
4. Release the air/water valve to feed air into the air/water channel for 10s.
5. Power off the light source.

5.4.4 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. Use the shorter auxiliary water-feeding tube to flush the auxiliary water-feeding channel.

- You can directly use the water pump to rinse the auxiliary water-feeding channel if the water pump is used in the examination. Otherwise, use a syringe to rinse the auxiliary water-feeding channel.

Perform the following steps to rinse the auxiliary water-feeding channel.

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

5.4.5 Reusable Parts

1. Disconnect the endoscope from the image processor, and remove the endoscope cable, suction hose, and water bottle hose from the endoscope.
2. Disconnect the endoscope from the light source.
3. Remove the air/water valve, suction valve and biopsy valve, and place these valves into the transport container for accessories filled with detergent.
4. Transport the endoscope to the disinfection room with the transport container for endoscope.

5.5 Leakage Test

A leakage test should be performed before cleaning of the endoscope manually.



- Attach the waterproof cap onto the electrical connector of the endoscope firmly. Otherwise, the endoscope may be damaged.
- When leakage is found on the endoscope, do not use the endoscope. Otherwise, the endoscope may be damaged and an electric shock may be caused. In case of leakage, contact the local distributor.

NOTE:

- The endoscope should be pre-cleaned before the leakage test.
- Connect the leakage detector to the waterproof cap firmly. Otherwise, the pressure in the endoscope cannot be increased.
- It is normal that the rubber surface of the bending section starts swelling as the pressure in the endoscope increases.
- During the test, do not place the leakage detector into the liquid.

Perform the following steps to perform a leakage test.

1. Connect the leakage detector. For details, see section 5.3.6 Leakage Detector.

5 Cleaning, Disinfection and Sterilization

2. Rotate the vent valve of the leakage detector clockwise to fasten it, use an inflating ball to increase the pressure to 22kpa, and wait for 3 minutes. If the reading on the dial decreases continuously, the endoscope is leaky. In this case, contact the sales representative of the manufacturer.
3. Immerse the inflated entire endoscope in clean water and use a syringe to inject water into all channels to expel air. Use the angulation control pole to adjust the angle of the bending section upwards, downwards, leftwards and rightwards and wait for 3 minutes. Check if there are air bubbles generating at the insertion section, the control section or the connector
4. Take out the endoscope and leakage detector from the clean water.
5. Rotate the vent valve anticlockwise until the pointer on the dial goes back to the zero position again.
6. Disconnect the leakage detector and dry the endoscope completely.

5.6 Manual Cleaning



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

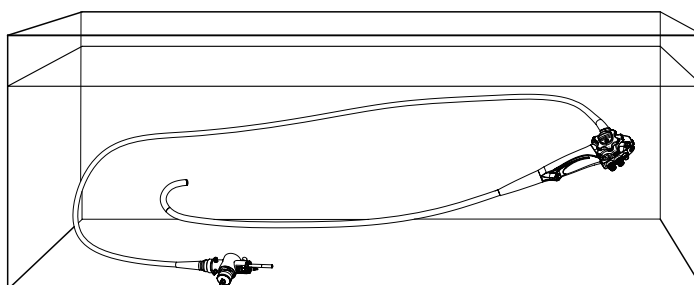
NOTE:

- The operator should gently pull out the cleaning brush from the instrument channel or suction channel to ensure that the shaft of the brush will not rub against the external opening of the suction valve. Otherwise, the brush may be damaged and the opening of the valve may be scratched, causing suction degradation or leakage.
- Do not attempt to insert the cleaning brush from the distal end of the insertion section or the suction connector. Otherwise, the cleaning brush could get stuck and cannot be pulled out.
- Do not immerse the endoscope together with its accessories to avoid damaging the endoscope.

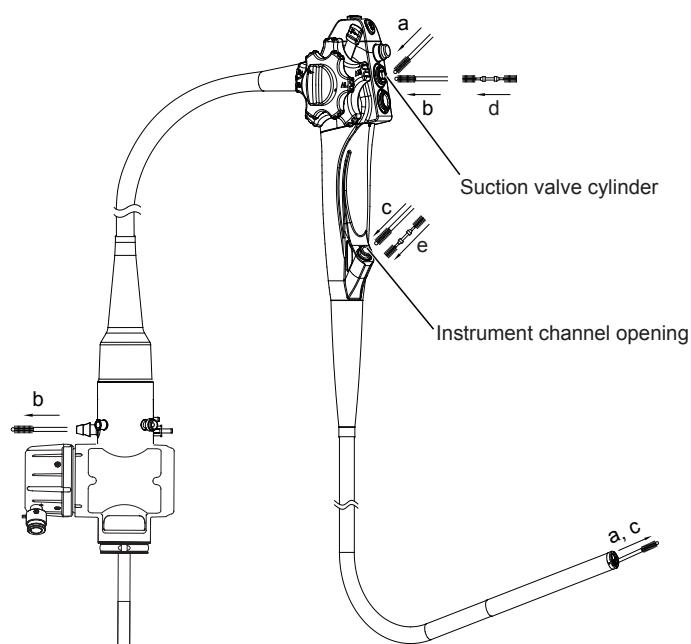
- To avoid endoscope leakage, clean the endoscope gently.

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

1. Immerse the entire endoscope in the detergent and remove the auxiliary water-feeding tube and the cap of the auxiliary water-feeding port from the endoscope.

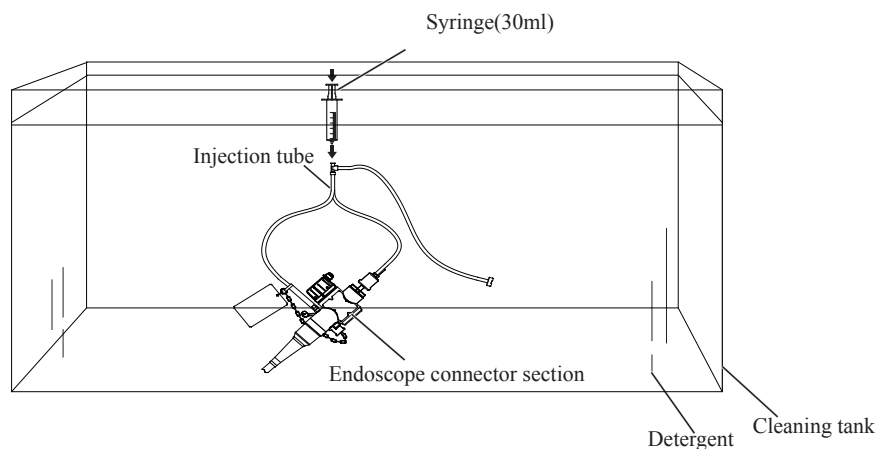


2. Use a lint-free cloth to wipe the outer surface of the entire endoscope in the detergent, especially the surface of the insertion section and control section of the endoscope. Ensure that the outer surface of the endoscope is cleaned completely.
3. Brush channels in steps, as shown in the following figure.



- To brush the suction channel from the control section to the distal end:**
Straighten the bending section of the endoscope, insert the cleaning brush at a 45° angle into the suction valve cylinder, slowly advance the brush until the brush head emerges from the distal end, clean the bristles with your fingertips in the detergent solution, and then pull out the brush from the suction valve cylinder carefully.

- b. **To brush the suction channel from the control section to the connector section:** Insert the cleaning brush straightly into the suction valve cylinder, slowly advance the brush until the brush head emerges from the suction connector, clean the bristles with your fingertips in the detergent solution, and then pull out the brush from the suction valve cylinder carefully. Clean the bristles with your fingertips again. Repeat the above steps several times until no debris is left.
 - c. **To brush the suction channel from the instrument channel opening to the distal end:** Straighten the bending section of the endoscope, insert the cleaning brush into the instrument channel, slowly advance the brush until the brush head emerges from the distal end, clean the bristles with your fingertips in the detergent, and then pull out the brush from the instrument channel opening carefully. Clean the bristles with your fingertips in the detergent again. Repeat the procedure at least 3 times to ensure that no debris is left.
 - d. **To brush the suction valve:** Insert the cleaning brush into the suction valve until half of the brush is inserted, rotate the brush once, pull out the brush, and clean the bristles with your fingertips in the detergent solution. Repeat the above steps several times until no debris is left.
 - e. **To brush the instrument channel:** Insert the cleaning brush into the instrument channel, pull out the brush, and clean the bristles with your fingertips in the detergent solution. Repeat the above steps several times until no debris is left.
4. Use a 30 ml syringe to inject detergent into the instrument channel of the endoscope at least 3 times (90 ml).
 5. Connect the injection tube, channel plugs and the shorter auxiliary water-feeding tube to the endoscope respectively. Ensure that the endoscope is completely immersed in the detergent.
 6. Use the power pump or 30 ml syringe to inject at least 180 ml of detergent respectively into the air/water and suction channels of the endoscope through the syringe connector of the injection tube.



7. Use the power pump or 30 ml syringe to inject at least 150 ml of detergent into the auxiliary water-feeding channel through the auxiliary water-feeding port.

8. Disconnect all channel plugs, the injection tube and the shorter auxiliary water-feeding tube from the endoscope and immerse them in the detergent.
9. Use a lint-free cloth or channel-opening cleaning brush to clean the outer surface and connectors of the endoscope until no debris is left.
10. Cover the manual cleaning tank with a sealing cover to reduce detergent volatilization.
11. Immerse the endoscope, and all the cleaning, disinfectant and sterilization tools in accordance with the period, temperature, and detergent concentration recommended by the detergent manufacturer.

5.7 Rinsing

After manual cleaning, perform the following steps to rinse the endoscope.

1. Transfer the endoscope, channel plugs, the injection tube and the shorter auxiliary water-feeding tube into the rinsing tank.
2. Use a lint-free cloth to wipe the outer surface of the entire endoscope completely.
3. Connect the channel plugs, the injection tube and the shorter auxiliary water-feeding tube to the endoscope.
4. Use the power pump or water pressure gun to inject running water into the air/water channel and suction channel respectively for at least 30 seconds.
5. Use the power pump or water pressure gun to inject running water into the auxiliary water-feeding channel for at least 30 seconds.
6. Rinse the outer surfaces of the endoscope and all its accessories with running water.
7. Take out the endoscope and all its accessories from the water.
8. Use a lint-free cloth to cover the distal end and control section of the endoscope.
9. Use the power pump or air pressure gun to inject air into the air/water channel and suction channel respectively for at least 30 seconds.
10. Use the power pump or air pressure gun to inject air into the auxiliary water-feeding channel for at least 30 seconds.
11. Remove the lint-free cloth from the distal end and control section.
12. Disconnect the channel plugs, the injection tube and the shorter auxiliary water-feeding tube from the endoscope.
13. Use a lint-free cloth to wipe up the outer surface of the endoscope and all its accessories.
14. Ensure that no residual debris is left on the endoscope or any of its accessories. Otherwise, repeat the operations of 5.7 Manual Cleaning and 5.8 Rinsing.

5.8 High-Level Disinfection

5.8.1 Automatic Disinfection

After initial rinsing, connect the endoscope to the automatic disinfection machine for high-level disinfection.

For the detailed operations of the automatic disinfection machine, refer to the user manual of the machine.

5.8.2 Manual Disinfection



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

After rinsing the endoscope for the first time, perform the following steps to disinfect the endoscope at high level.

1. Move the endoscope, channel plugs, the injection tube and the shorter auxiliary water-feeding tube into the disinfection tank.
2. Immerse the entire endoscope and all its accessories in the disinfectant.
3. Connect the channel plugs, the injection tube and the shorter auxiliary water-feeding tube to the endoscope firmly.
4. Use the power pump or 30 ml syringe to inject at least 180 ml of disinfectant respectively into the air/water channel and suction channel through the injection tube.
5. Use the power pump or 30 ml syringe to inject at least 150 ml of disinfectant into the auxiliary water-feeding channel through the shorter auxiliary water-feeding tube.

NOTE:

- Ensure that the syringe connector of the injection tube is completely immersed in the disinfectant solution.
 - Ensure that all channels of the endoscope are filled with disinfectant solution.
6. Take down the channel plugs, the injection tube and the shorter auxiliary water-feeding tube, and immerse them completely in the disinfectant.
 7. If bubbles are attached on the endoscope surface or the tools, wipe the bubbles off with a lint-free cloth.
 8. Cover the disinfection tank with a sealing cover to reduce disinfectant volatilization.

9. Immerse the endoscope and all its accessories by using the method recommended in Table 5-2 for high-level disinfection.

Table 5-2 Recommended high-level disinfection method

Disinfectant	High-Level Disinfection Parameter	Contact Period	Contact Type	Precautions
Phthalic dicarboxaldehyde (OPA)	Level: 0.55% (0.5%-0.6%)	≥ 5min	Immersion	<ul style="list-style-type: none"> The cloth, skin, and instrument are prone to dyeing. Steam of this disinfectant may stimulate the respiratory tract and eyes.
Glutaraldehyde (GA)	Level: ≥ 2% (alkaline)	≥ 10min Extend the contact period not lesser than 45 minutes if the endoscope is used by patients carrying mycobacterium tuberculosis or other mycobacterium bacteria.	Immersion	<ul style="list-style-type: none"> This disinfectant has sensitization and irritation on the skin, eye, and respiratory tract. In addition, it can cause dermatitis, conjunctivitis, nasal cavity inflammation, and occupational asthma. It is suitable for use in the automatic disinfection machine. This disinfectant is easy to condense on the endoscope and cleaning and disinfection devices.
Peroxyacetic acid (PAA)	Level: 0.2%-0.35% (W/V)	≥ 5min	Immersion	This disinfectant has irritation on the skin, eye, and respiratory tract.

Disinfectant	High-Level Disinfection Parameter	Contact Period	Contact Type	Precautions
Acidic electrolyzed oxidizing water (AEOW)	Active chlorine level: (60±10) mg/L, pH value: 2.0-3.0, chlorination reduction potential: 1100mV, residual chloride ion level: < 1000mg/L	3-5min	Immersion	<ul style="list-style-type: none"> When organic matters exist, the disinfection effect decreases sharply. The endoscope should be cleaned completely before the disinfection. For endoscopes that are heavily contaminated or difficult to be cleaned such as the colonoscope, the cleaning frequency should be increased and the rinsing period should be extended. Flowing immersion method should be adopted for disinfection. The endoscope should be rinsed with sterile or filtered water for 30 seconds after disinfection.

NOTE:

- For the preparation, usage, storage, and disposal of the disinfectant solution, refer to the instructions of the detergent and disinfectant manufacturers.
- The disinfectant selected must have a hygienic license (within its validity period) or a test report, national health security assessment report, and disinfectant production license issued by an authoritative institution. The parameter values in the preceding table are for your reference. When they differ from those on the health permission approval document, the values on the approval document shall prevail. When the disinfectant usage differs from that on the health permission approval document, the usage on the approval document shall prevail.

10. Before taking out the endoscope and its accessories from the disinfectant, connect the channel plug, the injection tube and the shorter auxiliary water-feeding tube to the endoscope.
11. Take out the filter of the injection tube from the disinfectant solution.
12. Use the power pump or air pressure gun to inject air into the air/water channel and suction channel respectively for at least 30 seconds to remove the disinfectant in the channels.
13. Use the power pump or air pressure gun to inject air into the auxiliary water-feeding channel for at least 30 seconds to remove the disinfectant in the channel.
14. Take out the endoscope and all its accessories from the disinfectant.
15. Disconnect the channel plugs, the injection tube and the shorter auxiliary water-feeding tube from the endoscope.

5.9 Sterilization

After the endoscope enters the sterile human tissue and organ and contacts damaged tissue, damaged mucous membrane, and blood (for example, in a surgery), it needs to be sterilized.

Perform the following steps to sterilize the endoscope.

1. Move the endoscope, channel plugs, the injection tube and the shorter auxiliary water-feeding tube into the sterilization tank.
2. Immerse the entire endoscope and all its accessories in the sterilant.
3. Connect the channel plugs, the injection tube and the shorter auxiliary water-feeding tube to the endoscope firmly.
4. Use the power pump or 30 ml syringe to inject at least 180 ml of sterilant respectively into the air/water channel and suction channel through the injection tube.
5. Use the power pump or 30 ml syringe to inject at least 150 ml of sterilant into the auxiliary water-feeding channel through the shorter auxiliary water-feeding tube.

NOTE:

- Ensure that the syringe connector of the injection tube is completely immersed in the sterilant solution.
 - Ensure that all channels of the endoscope are filled with sterilant solution.
6. Take down the channel plug, the injection tube and the shorter auxiliary water-feeding tube, and immerse them completely in the sterilant solution.
 7. If bubbles are attached on the endoscope surface or the tools, wipe the bubbles off with a lint-free cloth.
 8. Cover the sterilization tank with a sealing cover to reduce sterilant volatilization.

9. Immerse the endoscope and all its accessories by using the method recommended in Table 5-3 for sterilization.

Table 5-3 Recommended sterilization method

Sterilant	Sterilization Parameter	Contact Period	Contact Type	Precautions
Glutaraldehyde (GA)	Level: $\geq 2\%$ (alkaline)	$\geq 10\text{h}$	Immersion	<ul style="list-style-type: none"> • This disinfectant has sensitization and irritation on the skin, eye, and respiratory tract. In addition, it can cause dermatitis, conjunctivitis, nasal cavity inflammation, and occupational asthma. • This disinfectant is easy to condense on the endoscope and cleaning and disinfection devices.

NOTE:

- For the preparation, usage, storage, and disposal of the sterilant solution, refer to the instructions of the sterilant manufacturer.
 - The sterilant selected must have a hygienic license (within its validity period) or a test report, national health security assessment report, and sterilant production license issued by an authoritative institution. The parameter value in the preceding table is for your reference. When it differs from that on the health permission approval document, the value on the approval document shall prevail. When the sterilant usage differs from that on the health permission approval document, the usage on the approval document shall prevail.
10. Before taking out the endoscope and its accessories from the sterilant solution, connect the channel plug, the injection tube and the shorter auxiliary water-feeding tube to the endoscope.
 11. Take out the filter of the injection tube from the sterilant solution.
 12. Use the power pump or air pressure gun to inject air into the air/water channel and suction channel respectively for at least 30 seconds to expel sterilant solution in the channel.
 13. Take out the endoscope and all its accessories from the sterilant solution.
 14. Remove all accessories from the endoscope.
 15. Disconnect the channel plugs, the injection tube and the shorter auxiliary water-feeding tube from the endoscope.

5.10 Terminal Rinsing

After high-level disinfection, you should completely rinse the outer surface and all channels of the endoscope with sterile water to remove the residual of high-level disinfectant. If no sterile water is available, filtered or tap water may be used only when the rinse is followed by alcohol flushing and drying steps.

5.10.1 Using Sterile Water

Perform the following steps to terminally rinse the endoscope with sterile water.

1. Fill the terminal rinsing tank with sufficient sterile water.
2. Immerse the entire endoscope, channel plugs, the injection tube and the shorter auxiliary water-feeding tube in the sterile water.
3. Use a lint-free cloth to wipe the outer surface of the entire endoscope completely.
4. Connect the channel plugs, the injection tube and the shorter auxiliary water-feeding tube to the endoscope.
5. Use the power pump or water pressure gun to inject sterile water into the air/water channel and suction channel for at least 2 minutes. Ensure that no residual disinfectant or sterilant is left in the endoscope channels.
6. Use the power pump or water pressure gun to inject sterile water into the auxiliary water-feeding channel for at least 2 minutes. Ensure that no residual disinfectant or sterilant is left in the auxiliary water-feeding channel.
7. Rinse the outer surface of the endoscope and all its accessories with sterile water.
8. Take out the endoscope and all its accessories from the water.
9. Disconnect the channel plugs, the injection tube and the shorter auxiliary water-feeding tube from the endoscope. And wipe up the outer surface of the endoscope and its all accessories with a lint-free cloth.

5.10.2 Using Filtered Water (or Tap Water) and Alcohol Flushing

Perform the following steps to terminally rinse the endoscope with filtered water (or tap water).

1. Fill the terminal rinsing tank with sufficient filtered water (or tap water).
2. Immerse the entire endoscope, channel plugs, the injection tube and the shorter auxiliary water-feeding tube in the water, and use a lint-free cloth to completely wipe the outer surface of the entire endoscope.
3. Perform the step 3 to step 12 of Subsection 5.10.1 Using Sterile Water.
4. Fill a basin with 70% - 80% alcohol.
5. Connect the channel plug and injection tube to the endoscope and immerse the filter of the injection tube in the alcohol.

5 Cleaning, Disinfection and Sterilization

6. Use a lint-free cloth to cover the distal end and control section of the endoscope.
7. Use a 30ml syringe to inject alcohol into the air/water channel of the endoscope through the injection tube at least 2 times (60ml).
8. Use the 30ml syringe to inject alcohol into the suction channel of the endoscope through the injection tube at least 4 times (120ml).
9. Take out the filter of the injection tube from the alcohol, and use a 30 ml syringe to respectively inject air into the air/water channel and suction channel of the endoscope through the injection tube at least 6 times (180 ml).
10. Use the 30 ml syringe to inject alcohol into the auxiliary water-feeding channel through the auxiliary water-feeding port at least 2 times (60 ml).
11. Use the 30 ml syringe to inject air into the auxiliary water-feeding channel through the auxiliary water-feeding port at least 5 times (150 ml).
12. Remove the lint-free cloth from the distal end and control section.
13. Disconnect the channel plugs and injection tube from the endoscope, and wipe up the outer surface of the endoscope and the accessories with a lint-free cloth.
14. Use a lint-free cloth dampened with alcohol to wipe the outer surface of the endoscope and the accessories thoroughly.
15. Wipe up the air/water valve cylinder, suction valve cylinder and inner side of the instrument channel opening with sterile cotton swabs.

5.11 Drying



- After cleaning and 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 to dry the endoscope.

1. Place the endoscope and its all accessories on a sterile mat which is placed on the medical drying table.
2. Fill a container with 70% - 80% alcohol.
3. Connect the channel plugs, the injection tube and the shorter auxiliary water-feeding tube to the endoscope, and place the filter of injection tube into the alcohol.
4. Use a lint-free cloth to cover the distal end and control section of the endoscope.
5. Use a 30ml syringe to inject alcohol into the air/water channel of the endoscope through the injection tube at least once (30ml).
6. Use the 30ml syringe to inject alcohol into the suction channel of the endoscope through the injection tube twice (60ml).

7. Use the 30 ml syringe to inject the alcohol into the auxiliary water-feeding channel through the shorter auxiliary water-feeding tube at least once (30 ml).
8. Use the air pressure gun to inject air into the air/water channel, suction channel and auxiliary water-feeding channel of the endoscope respectively for at least 30 seconds.
9. Take away the lint-free cloth on the distal end and control section.
10. Take down all the accessories from the endoscope.
11. Dry the outer surface of the endoscope and all its accessories completely with the air pressure gun and a lint-free cloth dampened with alcohol.
12. Wipe up the air/water valve, suction valve, and inner side of the instrument channel port with sterile cotton swabs.
13. Dry the endoscope and its all accessories.

5.12 Reusable Parts and Cleaning, Disinfection, or Sterilization Tools



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

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

- Air/water valve
- Suction valve
- Biopsy valve
- Longer auxiliary water-feeding tube
- Cap for auxiliary water-feeding tube
- Cleaning brush
- Channel-opening cleaning brush

5.12.1 Manual Cleaning

NOTE:

- Ensure that the parts and tools immersed in the detergent are not in contact with each other.
 - Ensure that the sealing rings are not scratched.
 - Remove the cap from the main body of biopsy valve. Otherwise, the biopsy valve is not completely cleaned, and disinfected or sterilized.
1. Place the parts and tools into the manual cleaning basin.

5 Cleaning, Disinfection and Sterilization

2. Fill the manual cleaning basin with sufficient detergent, and ensure that all the parts and tools can be immersed in the detergent.
3. Use a lint-free cloth to wipe up the outer surface of the parts and tools in the detergent.
4. Brush the openings of air/water valve and suction valve completely with the channel opening cleaning brush to remove all the debris.
5. Brush the interiors and openings of biopsy valve and cap of auxiliary water-feeding tube with the channel-opening cleaning brush.
6. Use the power pump or 30 ml syringe to inject at least 90 ml of detergent into the longer auxiliary water-feeding tube.
7. Use the 30 ml syringe to rinse the interiors and openings of all the parts and tools completely to remove all bubbles.
8. During the immersion, press and release the pistons of air/water valve and suction valve 3 times to remove all bubbles.
9. Clean the bristles of cleaning brush and channel-opening cleaning brush completely to remove all bubbles.
10. Cover the manual cleaning basin with a sealing cover to reduce detergent volatilization. Immerse the parts and tools in accordance with the period, temperature, and concentration recommended by the manufacturer.
11. Take out all the parts and tools from the basin, and ensure that no debris is left on the parts and tools.

5.12.2 Rinsing

1. Move all the parts and tools after cleaned into the rinsing basin.
2. Use a lint-free cloth to clean the outer surfaces of parts and tools in the running water.
3. Use the power pump or water pressure gun to inject running water into the longer auxiliary water-feeding tube for at least 30 seconds.
4. Take out the longer auxiliary water-feeding tube, and use the power pump or water pressure gun to inject air into the longer auxiliary water-feeding tube for at least 30 seconds.
5. Rinse the interiors and openings of parts and tools with running water until no bubble exists.
6. During the immersion, press and release the pistons of air/water valve and suction valve at least 3 times to remove all bubbles.
7. Clean the bristles of cleaning brush and channel-opening cleaning brush to remove all bubbles.
8. Take out all the parts and tools and use a lint-free cloth to wipe up the outer surfaces of parts and tools.

9. Ensure that no residual debris is left on all the parts and tools. Otherwise, repeat the operations of 5.13.1 Manual Cleaning and 5.13.2 Rinsing.

5.12.3 High-level Disinfection



- Ensure all the bubbles adhered to the parts and tools are removed. Otherwise, it may degrade the disinfection effect.
 - Disinfection process should be performed when all parts and tools are immersed in the disinfectant. For sufficient disinfection, ensure that all parts and tools are in full contact with the disinfectant.
1. Move all the parts and tools into the disinfection basin.
 2. Fill the disinfection basin with sufficient disinfectant, and ensure that all the parts and tools can be immersed in the disinfectant.
 3. Use a lint-free cloth to wipe up the outer surface of the parts and tools in the disinfectant.
 4. Use the power pump or 30 ml syringe to inject at least 90 ml of disinfectant into the auxiliary water-feeding tube.
 5. Use a 30 ml syringe to completely rinse the interiors and openings of all the parts and tools to remove all bubbles.
 6. During the immersion, press and release the pistons of air/water valve and suction valve 3 times to remove all bubbles.
 7. Clean the bristles of cleaning brush and channel-opening cleaning brush completely to remove all bubbles.
 8. Cover the disinfection basin with a sealing cover to reduce disinfectant volatilization. Immerse all the parts and tools by using the method recommended in Table 5-2 Recommended high-level disinfection method for high-level disinfection.
 9. Take out all the parts and tools and use a lint-free cloth to wipe up the outer surface of the parts and tools.

5.12.4 Sterilization

1. Move the parts and tools into the sterilization basin.
2. Fill the sterilization basin with sufficient sterilant, and ensure that all the parts and tools can be immersed in the sterilant.
3. Use a lint-free cloth to wipe up the outer surface of the parts and tools in the sterilant.
4. Use the power pump or 30 ml syringe to inject at least 90 ml of sterilant into the longer auxiliary water-feeding tube.
5. Use a 30 ml syringe to completely rinse the interiors and openings of all the parts and tools to remove all bubbles.

5 Cleaning, Disinfection and Sterilization

6. During the immersion, press and release the pistons of air/water valve and suction valve 3 times to remove all bubbles.
7. Clean the bristles of cleaning brush and channel-opening cleaning brush completely to remove all bubbles.
8. Cover the sterilization basin with a sealing cover to reduce sterilant volatilization. Immerse all the parts and tools by using the method recommended in Table 5-3 Recommended sterilization method.
9. Take out all the parts and tools and use a lint-free cloth to wipe up the outer surface of the parts and tools.

5.12.5 Terminal Rinsing

After high-level disinfection, you should completely rinse the reusable parts and cleaning and disinfection tools with sterile water to remove the residual of high-level disinfectant. If no sterile water is available, filtered or tap water may be used only when the rinse is followed by alcohol flushing and drying steps.

■ Using Sterile Water

Perform the following steps to terminally rinse the parts and the tools with sterile water.

1. Fill the terminal rinsing basin with sufficient sterile water.
2. Move the parts and tools into the terminal rinsing basin.
3. Immerse the parts and the tools in the water, and gently agitate to completely clean the parts and the tools.
4. Use a lint-free cloth to clean the outer surfaces of the parts and the tools in the water.
5. Use a 30 ml syringe to inject water into the auxiliary water-feeding tube at least 3 times (90 ml).
6. Use the 30 ml syringe to rinse the interiors and openings of the parts and the tools until no bubble exists.
7. During the immersion, press and release the pistons of the air/water valve and the suction valve at least 3 times to remove all bubbles.
8. Clean the bristles of cleaning brush and channel-opening cleaning brush to remove all bubbles.
9. Take out all the parts and the tools.
10. Use the 30 ml syringe to inject air into the auxiliary water-feeding tube at least 3 times to dry the tube (90 ml).
11. Use a lint-free cloth to wipe up the outer surfaces of the parts and the tools.

■ Using Filtered Water (or Tap Water) and Alcohol Flushing

Perform the following steps to terminally rinse the parts and the tools with filtered water (or tap water).

1. Fill the terminal rinsing tank with sufficient filtered water (or tap water).
2. Immerse the parts and the tools in the water and gently agitate to completely clean the parts and the tools.
3. Perform the steps 3 to 10 of Using Sterile Water
4. Fill a basin with 70% - 80% alcohol.
5. Immerse the parts and the tools in the alcohol and gently agitate the alcohol.
6. Use a 30 ml syringe to inject alcohol into the auxiliary water-feeding tube at least 2 times (60 ml).
7. Use the 30 ml syringe to rinse the interiors and openings of the parts and the tools with alcohol until no bubble exists.
8. During the immersion, press and release the pistons of the air/water valve and the suction valve at least 3 times to remove all bubbles.
9. Clean the bristles of cleaning brush and channel-opening cleaning brush to remove all bubbles.
10. Take out all the parts and the tools.
11. Use the 30 ml syringe to inject air into the auxiliary water-feeding tube at least 3 times (90 ml) to dry the tube.
12. Use a lint-free cloth to wipe up the outer surfaces of the parts and the tools.

5.12.6 Drying

1. Place the parts and tools on a sterile mat which is placed on a medical drying table.
2. Use a lint-free cloth to cover one end of longer auxiliary water-feeding tube.
3. Use a 30 ml syringe to inject 70% - 80% alcohol into the longer auxiliary water-feeding tube at least once (30 ml).
4. Use the power pump to inject clean compressed air into the longer auxiliary water-feeding tube for at least 30s to dry the tube completely.
5. Take away the lint-free cloth from the longer auxiliary water-feeding tube.
6. Use the air pressure gun or lint-free cloth dampened with alcohol to wipe up the outer surfaces of parts and tools completely.

This page is intentionally left blank.

6 Storage and Disposal

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



- Before storage, the endoscope should be cleaned and disinfected or sterilized 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 0.05% chlorine solution twice a week. The cabinet must be handled soon if it is contaminated.
- If the endoscope has been stored for more than 24 hours, it should be cleaned and disinfected or sterilized 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 to store the endoscope.

1. Take down all accessories from the endoscope, including the air/water valve, suction valve, biopsy valve, and waterproof cap.
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, biopsy valve, and waterproof cap 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 to transport the endoscope in the hospital.

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



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

Perform the following steps to transport the endoscope outdoors.

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

6.3 Disposal

The validity period of this product is five years. If the product is used with a low frequency and proper maintenance, the validity period can be extended properly. When the validity period expires or the product has been sterilized 20 times, dispose of it according to local laws and regulations.

For the detailed disposal information, consult the local distributor of the manufacturer. The manufacturer is not responsible for any system content or accessories that have been discarded improperly.

6.4 Customer Service

Only the service personnel of or authorized by the manufacturer can service the endoscope and its accessories. Any feedback or inquiries concerning our product or service should be directed to the following address.

Address: 4/F, 5/F, 8/F, 9/F & 10/F, Yizhe Building, Yuquan Road, Nanshan, Shenzhen, 518051, Guangdong, China

Zip Code: 518051

Tel: +86 755 2672 2890

Fax: +86 755 2672 2850

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, contact the sales representative of the manufacturer for replacement.

7 Troubleshooting

Item	Descriptions	Level	Cause	Solutions
Leakage	Leakage detector cannot pressurize the endoscope or bubbles appear continuously.	B	The rubber wrapping the bending section of the endoscope is damaged.	Stop using the endoscope.
		B	The sealing ring is aging.	
		B	The channel is broken.	
Image	No image	C	The endoscope cable is not connected firmly or the image processor is not powered on.	Check the connections. For details, refer to Chapter 3 Preparations.
		B/A	Others	
	Image is dimmer.	C	The brightness value of light source is too low.	Adjust the brightness of light source as described in the user manual.
	Image is blurred.	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 view field.	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.
	Cannot feed air.	C	The air/water valve is damaged.	Replace the air/water valve.

Item	Descriptions	Level	Cause	Solutions
Feed air	Cannot feed air.	C	The air pump does not function.	Enable 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 from the air/water nozzle.
		C	The water bottle cap is loose.	Fasten the cap of the water bottle.
	Cannot feed water.	C	There is no water in the bottle.	Pour the 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.	Enable 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 inner valve with a cotton swab.
		C	The suction valve is damaged.	Replace the suction valve.
		C	The channel is blocked.	Brush the suction channel as described in the user manual.
		C	The biopsy valve is damaged.	Replace the biopsy valve.
	The suction valve is sticky.	C	The suction valve is dirty.	Remove and rinse the suction valve, clean the opening of the valve with the cotton swab dampened with alcohol solution.

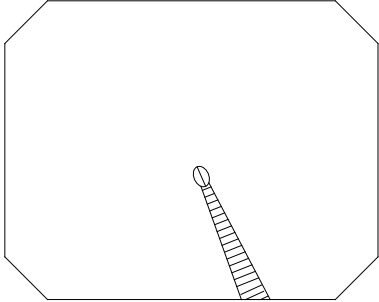
7 Troubleshooting

Item	Descriptions	Level	Cause	Solutions
Suction	The instrument channel leaks.	B	The instrument channel is damaged by improperly using the accessories such as biopsy forceps.	Stop using the endoscope.
	Liquid or air is leaked from the biopsy valve.	C	The biopsy valve is aging or damaged.	Replace the biopsy valve.
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 using for a long period.	Stop using the endoscope.
	The bending section cannot reach the maximum angle.	B		
	The bending section does not function.	A		
Accessories	The endoscope cable does not function.	B	Endoscope cable is damaged.	Stop using the endoscope.
	Other problems	B	/	Change a new one.

NOTE:

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

Appendix Specifications

Technical Parameter		Product Model			
		EC-430	EC-430L	EC-430T	EC-430L/T
Dimensions	Insertion section length	1350 mm, allowance: $\pm 10\%$		1700 mm, allowance: $\pm 10\%$	
	Min. inner diameter of the instrument channel	$\geq \Phi 3.8$ mm	$\geq \Phi 4.2$ mm	$\geq \Phi 3.8$ mm	$\geq \Phi 4.2$ mm
	Max. outer diameter of the insertion section	$\leq \Phi 13.8$ mm	$\leq \Phi 14.5$ mm	$\leq \Phi 13.8$ mm	$\leq \Phi 14.5$ mm
	Outer diameter of the bending section	$\Phi 12.5$ mm, allowance: + 10%, not considering lower limit	$\Phi 12.9$ mm, allowance: + 10%, not considering lower limit	$\Phi 12.5$ mm, allowance: + 10%, not considering lower limit	$\Phi 12.9$ mm, allowance: + 10%, not considering lower limit
	Outer diameter of the distal end	$\Phi 12$ mm, allowance: + 5%, not considering lower limit	$\Phi 12.9$ mm, allowance: + 5%, not considering lower limit	$\Phi 12$ mm, allowance: + 5%, not considering lower limit	$\Phi 12.9$ mm, allowance: + 5%, not considering lower limit
Imaging System	View field	140°, allowance: -10% to 10%			
	View depth	3 - 100 mm			
	Resolution	≥ 11 lp/mm (10 mm)			
	Biopsy entrance position				

Appendix Specifications

Technical Parameter		Product Model			
		EC-430	EC-430L	EC-430T	EC-430L/T
Water/air feeding & Suction System	The amount of fed water	≥ 40 mL/min			
	The amount of fed air	≥ 800 mL/min			
	Aspirated amount	≥ 400 mL/min			
Bending Section	Angle	Up 180°, Down 180°, Left 160°, Right 160° Allowance: - 10%, not considering upper limit			
Environment Requirements		Temperature	Relative Humidity	Atmosphere Pressure	
	Operation	5°C to 40°C	30% to 80%	700hPa to 1060hPa	
	Storage	-5°C to 40°C	30% to 80%	700hPa to 1060hPa	
	Transportation	-20°C to +55°C	20% to 90%	700hPa to 1060hPa	
Safety Types	Degree of protection against electric shock	Type BF applied part			
	Degree of protection against harmful liquid	IPX7			