User Manual

FIBER GASTROINTESTINAL ENDOSCOPE

XS-20

XS-30

AGF-40

Precautions

Prior to using the fiber gastrointestinal endoscope, be sure to undertake sufficient practice in correct sequences, not least read this manual carefully to have full understanding of each content to avoid serious adverse consequences to the patients or users. Meanwhile, it is also necessary to carefully read the operating manuals of other devices and accessories associated with this manual and handling issues.

The hazards it may bring during the operation of fiber gastrointestinal endoscope normally include: perforation, electric burns and stimulation, bleeding, infection, rupture, etc. Knowing that incompliance with the User Manual may damage the fiber gastrointestinal endoscope or cause malfunction.

Shanghai Aohua Photoelectricity Endoscope Co., LTD

Important Notice

The fiber gastrointestinal endoscope has been elaborately developed by our company to satisfy the demand of both domestic and foreign physicians for their clinic therapeutic needs. The fiber gastrointestinal endoscope is useful in routine diagnosis and treatment for patients' upper digestive tract. Be sure not to use the fiber gastrointestinal endoscope for any other purpose.

Before using this instrument, carefully read this User Manual, which contains most appropriate descriptions in terms of maintenance and operation of the fiber gastrointestinal endoscope. Even so, as to the fiber gastrointestinal endoscope per se, it actually belongs to precise instrument. Therefore, proper operation and cleaning following the methods revealed in this manual will definitely reduce the possibility of malfunction, also prolong the lifetime of new instrument.

This manual is to address the preparation and ideal procedures required for instrumental examination. It is neither intended to give detailed guide pertaining to clinical examination, nor purported to make beginners become acquainted with the technique of fiber gastrointestinal endoscope examination along with medical knowledge. This instrument is only for the use of those physicians who have a good command of fiber gastrointestinal endoscope technology and have got trained.

The security of fiber gastrointestinal endoscope is not only dependent on itself but also the auxiliary instruments used together with it. In order to assure the compatibility, it is recommended to use the auxiliary equipments acknowledged by our company.

After purchase, please take out the fiber gastrointestinal endoscope and its accessories from the package, and safely keep them in accordance with "Storage" contained in this manual. The fiber gastrointestinal endoscope suitcase is not suitable for the use of safekeeping fiber gastrointestinal endoscope but for loading or transporting only.

This instrument does not contain any user–serviceable parts. Do not disassemble, modify or attempt to repair it; patient or operator injury, equipment damage and/or the failure to obtain the expected functionality can result. This instrument should be repaired by personnel authorized by Aohua only.

In case of doubt or you have any question relating to the contents in this manual or operation and security of the fiber gastrointestinal endoscope, please contact our company or our authorized service station nearby.

Warning

The fiber gastrointestinal endoscope can generate powerful light rays when it is in combined use with intense light source (especially with Xenon light). When the head end of fiber gastrointestinal endoscope is too close to the mucosa, there will be strong light rays concentrating in a quite small area whose surface temperature will naturally rise in consequence of long-time light irradiation, and may cause ambustion when exceeding 41 °C. The surface temperature of fiber gastrointestinal endoscope may surpass 41 °C and up to maximum 50 °C.

reduce the observation time on a fixed point in a close range as the cold light source has a lack of automatic light adjustment function. Once the light bulb of flashlight is burned out during operation, there will be no image showing up in the FOV, and blind operation will cause certain harm to the patient. So, resume the operation after replacement of light bulb.

It can pose increased burn risk under the following conditions:

1. Take too long time to approach the mucosa or observe one fixed point.
2. Advance slowly the fiber gastrointestinal endoscope in the narrow lumen.

In order to lessen the burn risk, following methods are recommendable.

1. Attempt to avoid fixed-point observation as far as possible.
2. Turn off the lighting switch when out of use, to avoid accident.

Note: Use is prohibited when the instrument is in the state of charging.

Before inserting the endoscope into the human body, the angulation lock should be positioned on “F” level, and then confirm if the distal end can freely removed without let or hindrance. If abnormal hindrances encounter when guiding the endoscope into or operating the angulation knob, do not use the endoscope and please immediately contact with our company or our company’s maintenance center nearby.

Contents

Chapter 1 Signal words

1.1 Warnings and attentions

The following signal words are used throughout this manual:

Warning

It indicates a potentially hazardous situation, if not be avoided, could result in death or serious injury.

Attention

It indicates a potentially hazardous situation, if not be avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

Follow the warnings and cautions below when handling this instrument.

★After using this instrument reprocess and store it according to the User Manual.
★Before endoscopy, remove any metallic objects (watch, glasses, necklace, ect.) from the patient.
★Do not strike, bend, hit, pull, twist, or drop the endoscope's distal end, insertion tube, bending section, control section, universal cord, or light guide connector of the endoscope with excessive force.

★Never perform angulation control forcibly or abruptly.

★Never insert or withdraw the endoscope's insertion tube while the bending section is locked in position.

★Never perform flexibility adjustment, operate the bending section, feed air or perform suction, insert or withdraw the endoscope's insertion tube, or use endo-therapy accessories without viewing the endoscopic image.

★Do not touch the light guide connector immediately after removing it from the light source because it is extremely hot.

★If it is difficult to insert the endoscope, do not forcibly insert the endoscope and stop the endoscopy.

★Do not pull the universal cord during an examination.

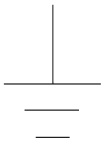
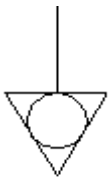
★Do not apply shock to the distal end of the insertion tube, particularly the objective lens surface at the distal end.

★Do not twist or bend the bending section with your hands.

★Do not squeeze the bending section forcefully.

★Electromagnetic interference may occur on this instrument near equipment marked with the following symbol or other portable and mobile RF communications equipment.

1.2 Labels and Symbols

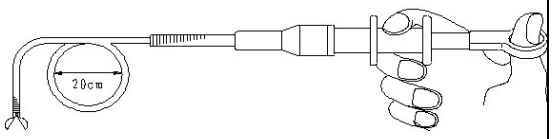
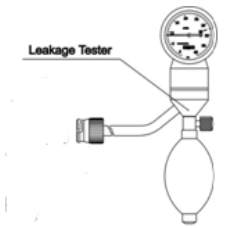
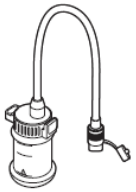
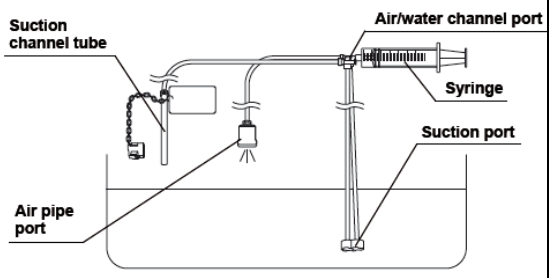
	Category tags: BF type class I
	Ground terminal
	Attention! Consult the accompanying document.
	Potential equalization terminal

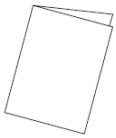
Note

(1)The equipment is water-resistant.
(2)Water-resistant: IPX7
(3)Manufacturer: **Shanghai AOHUA Photoelectricity Endoscope Co., LTD. (abbreviated "AOHUA")**

1.3 Package Contents Check

Match all items in the package with the components shown below. Inspect each item for damage check. If a component is missing or damaged, please contact Aohua.

Name	Qty. (pcs)	Image
Cleaning brush	1	
Biopsy forceps	1	
Leakage tester	1	
Water bottle	1	
Seal ring	1	
Cleaning kit	1	
Cleaning plug	1	

Biopsy valve	3	
Mouthpiece	2	
Air/water valve	1	
Suction valve	1	
User Manual	1	

Chapter 2 Nomenclature and Functions

2.1 Nomenclature

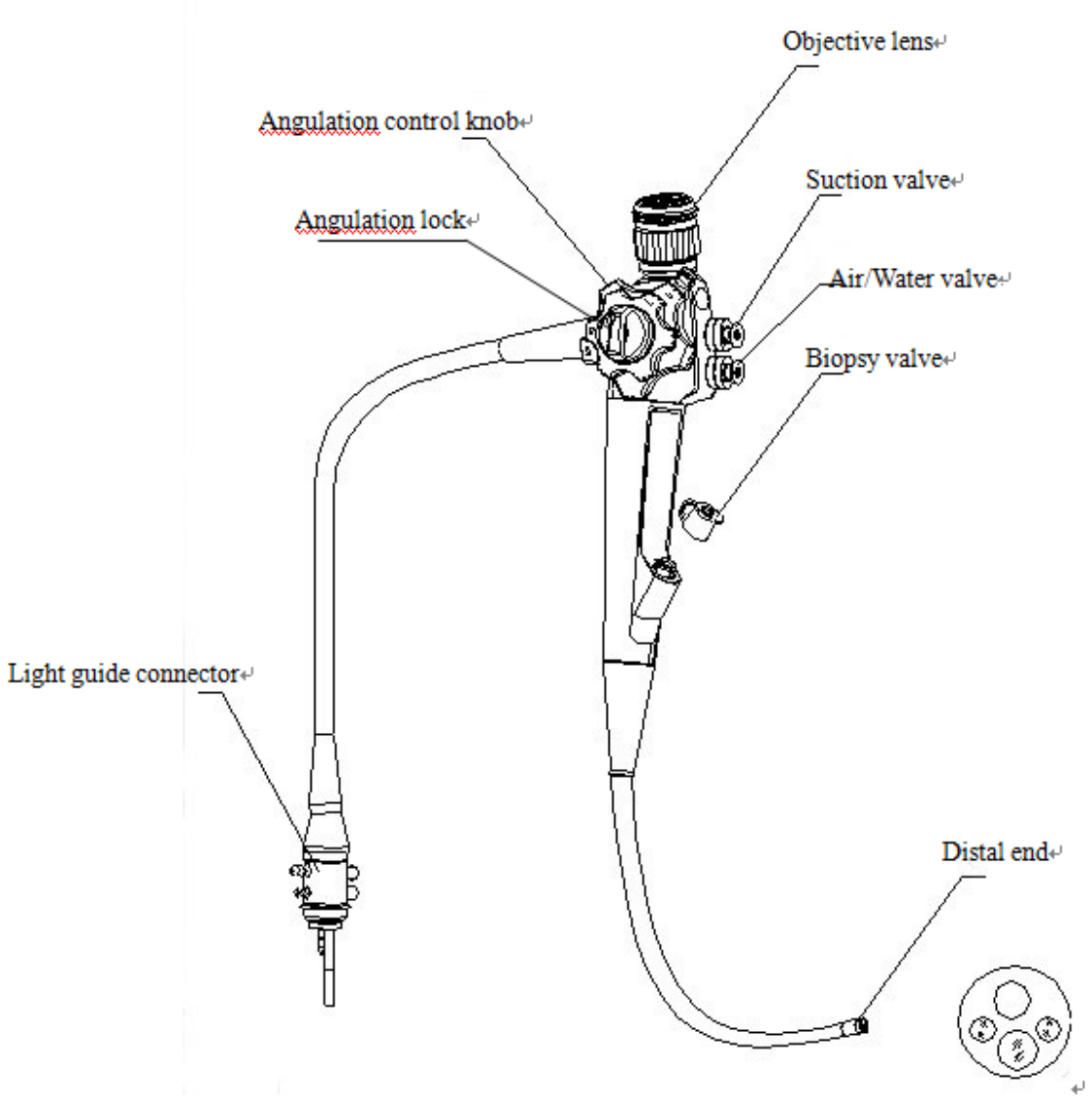


Figure 2.1 (split unit)

2.2 Functions

(1) Light guide connector

Connect the endoscope to the output socket of the light source and transmit light from the light source

to the endoscope.

(2) UP/DOWN angulation control knob
Move the bending section UP/DOWN by operating it.

(3) UP/DOWN angulation lock
Moving this lock in the "F▼"direction frees angulation.

(4)Objective lens

Observe the human body inside via this lens

(5) Suction valve
This valve is depressed to active suction.

(6) Air/Water valve
The hole in this valve is covered to insufflate air and the valve is depressed to feed water for lens washing. It also can be used to feed air to remove any fluid or debris adhering to the objective lens.

(7)Biopsy valve
Protect the instrument channel port

(8) Instrument channel
The instrument channel functions as:

△channel for the insertion of endo-therapy accessories

△suction channel

△fluid feed channel

2.3 Working conditions and application

2.3.1 Operating environment:
(1)Ambient temperature: 10℃ to 40℃

(2)Relative humidity: 30% to 85%

(3)Atmospheric pressure: 700 to 1060hPa

(4)Power supply: 220V±22V, 50Hz/60Hz±1Hz

2.3.2 Application:
This endoscope is used for routine diagnosis and treatment of patients' upper digestive tract.
2.3.3 Interconnected equipment:
Light sources manufactured by our company and monitors, LG150-2 cold light source is the one interconnected with it, it also is compatible with cold light source manufactured by Olympus.

2.4 Performance characteristic, main technical index and complete set of equipment:

2.4.1 Performance Characteristic:

(1)This gastrointestinal endoscope applies the advanced optical fiber image transmitting technology with the hexagonal honeycomb arrangement. Insertion tube is thin and soft and able to bend, therefore it is not only convenient to insert into human body but also will not make patients pain, the diameter of the insertion tube is just 9.8mm, be easy to accept by the patients. Upward angulation can be up to 180° , and if it is used with lift/right angulation simultaneously, it is able to reach intensive bending 210° and even if the intensive bending is reached , the channel for biopsies and other instruments is also unblocked, viable tissue can be collected and treatment can be performed at any location that is observable, which dramatically decreases blind areas when observing and diagnosing, thereby enhancing diagnosis accuracy and treatment maneuverability.

(2)The fiber gastrointestinal endoscope is equipped with biopsy & suction channel of Φ2.8mm, which is compatible to versatile biopsy forceps, cytobrush and other standard instruments.

(3)Electromagnetic air pump is contained in the light source, after it is started, automatic water/air input as needed can be achieved by controlling the water/air knob, and by connecting externally the suction pump and pressing the suction knob, residual in the channel can be aspirated out.

2.4.2Product Features:

(1)Type of equipment: Type BF Applied Part

(2)Noxious liquid inlet resistance rating: IPX7

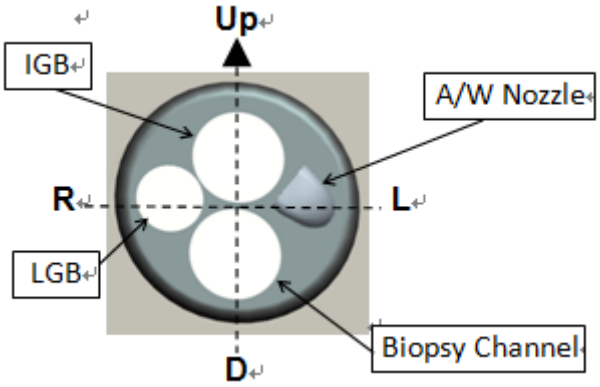
(3)Manufacturer: SHANGHAI AOHUA PHOTOELECTRICITY ENDOSCOPE CO., LTD.

(4)Working system: continuous operation

(5)Attention: Refer to accompanying documents

(6)Equipment cannot be used under circumstances of flammable anaesthetic mixed gas or N_2O

2.4.3 Main technical index

Model		XS-20	XS-30	AGF-40
Optical system	Field of view	120°	100°	120°
	Direction of view	Forward viewing		
	Depth of field	3-100 mm		
Insertion tube	Distal end outer diameter	Ø9.8mm		
				
	Insertion tube outer diameter	Ø9.8mm		
	Working length	1030mm		
Instrument channel	Channel inner diameter	Ø2.8mm		
Bending section	Angulation range	UP 210°, DOWN 90°		
		RIGHT 120°, LEFT 120°		

2.4.4Complete set of equipment

XS-20/XS-30/AGF-40	1set
Biopsy forceps port cap	2pcs
Suitcase	1pc
User Manual	1copy
Product warranty card	1pc

Chapter 3 Preparation and Inspection

Warning

★Before each case, prepare and inspect this instrument as instructed below.

★Using an endoscope that is not functioning properly may comprise patient or operator safety and may result in more severe equipment damage.

★This instrument was not cleaned, disinfected or sterilized before shipment. Before using this instrument for the first time, reprocess it according to the User Manual.

3.1 Fiber gastrointestinal endoscope sealing property check

★Before testing, the light guild plug of the endoscope must be unloaded from the cold light source, otherwise the endoscope will be damaged.

Inspect the sealing property of the fiber gastrointestinal endoscope as following steps:

(1)Connect the leakage tester (separately purchased part) to the endoscope according to the method shown in Figure 3.1.

(2)Press the leakage tester to reach 30 Kpa. Make sure that the reading indicated by the pointer falls after stop pressing.

(3)If the reading indicated by the pointer slowly falls, continue to slowly pressurize (**not exceed 30 Kpa, otherwise the fiber gastrointestinal endoscope will be damaged**). Meanwhile, put the fiber gastrointestinal endoscope in water, observing whether there are continuous bubbles on the surface of the endoscope or not (**normally, 3 or less bubbles per minute is acceptable**). If bubbles continuously appear, stop using this equipment, and contact After-sales Service Department of Aohua timely.

(4)If there is not any change of the leakage tester's pointer, that means the fiber gastrointestinal endoscope has a sound sealing property, the endoscope can be used normally or cleaned or disinfected.

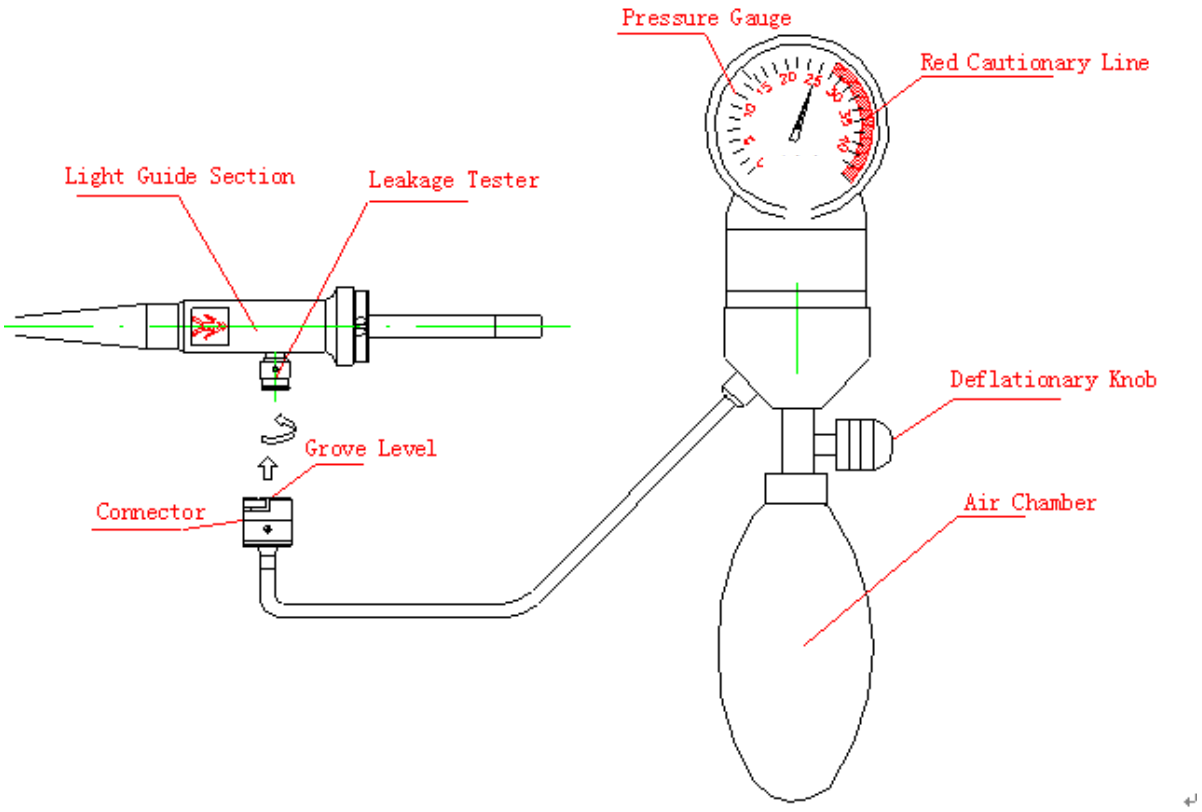


Figure 3.1

3.2 Preparation of light source

(1)Prepararion of light source device

As per the user mannual of light source device used. Especially indicate that the cold light source must be of grounding device.

1) confirm the power swith of the light source is on the “OFF” position, connect the power wire to the AC power supply with correct grounding, Any accidents resulted from either the power is connected to the non-standard power supply or grouding is unavaible, then the user is responsible for it.

2) turn on the light source and confirm the adjustbility of its brightness.

3)insert the head of the light guide plug solidly in the connecting socket in the light source (see Figure3.2).

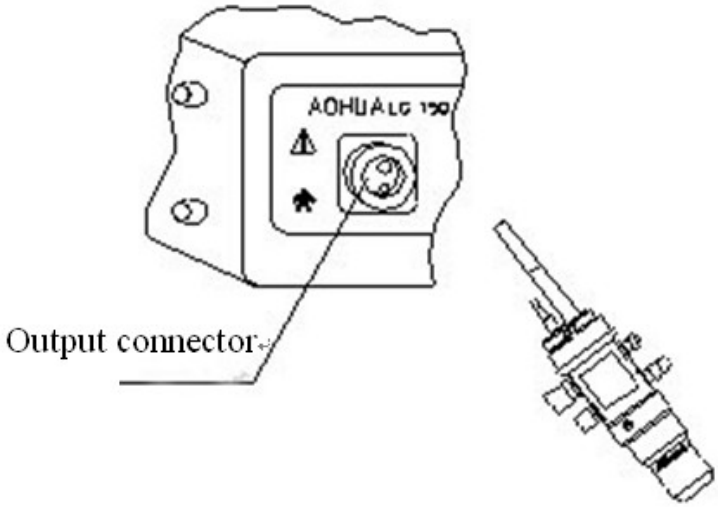


Figure 3.2

4)put purified water up to 80% of the water bottle, tighten the cap

5)connect the output termianl of the water bottle to the water input interface on the light guide plug,

6)make sure reliable grounding is avilable

7)set the swithes of both the air pump and the suction unit on the “ON” position

Power connection and disconnection

Chapter 4 Fiber gastrointestinal endoscope application method

4.1Preparation and check in early stage

(1) check and confirm the connection performance of each component

(2) wipe the insertion tube, bending section and distal end of the fiber gastrointestinal endoscope using the alcohol cotton carefully

4.1.1Preparation of suction

(1) connect the suction flexible tube of the suction unit and the suction connector in the light guide plug of the fiber gastrointestinal endoscope (See Figure 4.1)
(2) switch on the power supply of the suction unit,

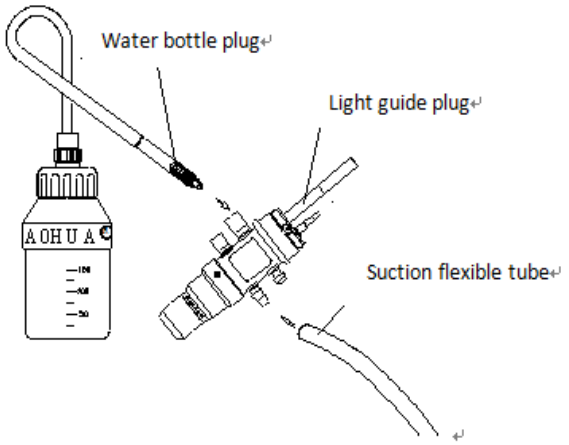


Figure 4.1

4.1.2Preparation of air/water feeding system

(1)Distilled water or purified water should occupy 80% of the bottle volume. Then, tighten the cap, and place the bottle at the location designated on the video system center.
(2)Connect the bottle and the light guide connector (See Figure 4.1)
(3)Turn on the air pump, the air pump has automatic air feeding function.

4.1.3Check of fiber gastrointestinal endoscope

(1)Check of the flexible insertion tube

1) visual check if the surface of the insertion tube has any defects, like dents, bulges and fractures, etc ..
2) touch the flexible insertion tube up and down several times by finger to check if the flexible tube has any defects, like dents and bulges or is loosen or has other abnormality

Note

The quality of the flexible insertion tube surface should have no defects that could hurt the patients, even if extremly tiny abnormality is found, please stop using the endoscope and get in touch with the after-slaes department of our company

(2)Check of bending tube

Slowly operate the angulation control knob to confirm that the bending section, the angulation control knob and the angulation lock are flexible, effective, reliable, and free from any jamming. Make sure that the bending angle meets the use of requirement.

(3)Check of the angulation hand wheel and the locking knob

When the locking knob "F" is on the locking position, it can fix the bending section on any angulation position, when it is on the loosening position, the angulation hand wheel can move freely. When the angulation hand wheel is released, bending section should return to original position.

Note

For the bending section, do not bend or straighten the tube with your hands forcibly(See Figure 4.2)

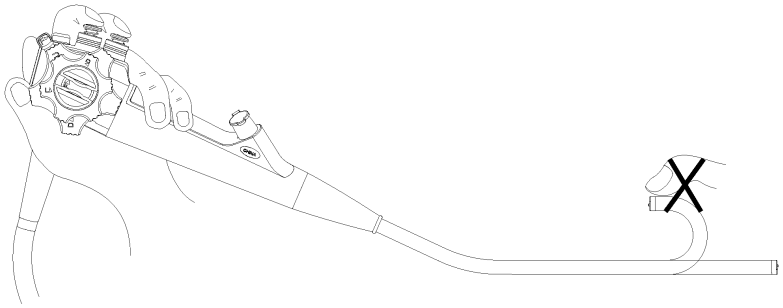


Figure 4.2

(4)Check of suction and air/water feeding function

1) Turn on the air pump, operate the air/water valve to control air/water feeding, and make sure that the function is normal.

2) Dip the distal end in water, and press the suction valve to confirm that water is aspirated. Loosen your hands, and make sure that such suction stops (See Figure 4.3)

3) Cover the hole of the air/water valve or press the air/water valve with your hand to confirm that air/water is supplied at the distal end. After loosening your hand, confirm that air/water feeding stops (See Figure 4.4)

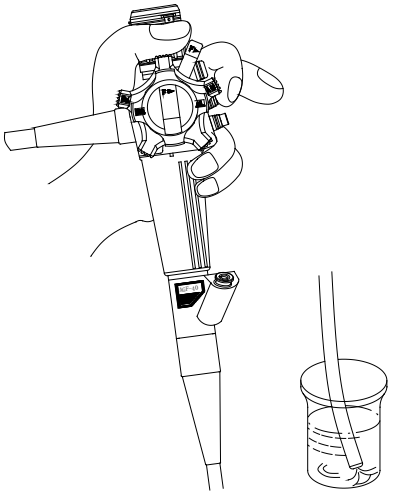


Figure 4.3

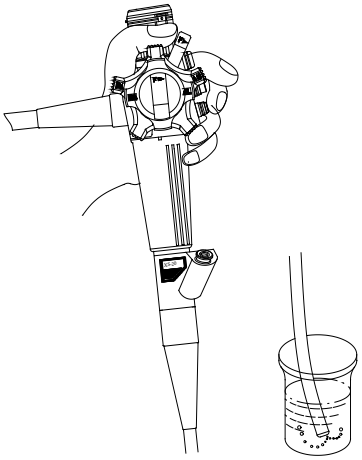


Figure 4.4

(5)Check of biopsy forceps

1) Bend the biopsy forceps into a circle with the diameter of 20 cm. When slightly operating the biopsy forceps, make sure that the head of the biopsy forceps can be opened or closed smoothly. (See Figure 4.4)

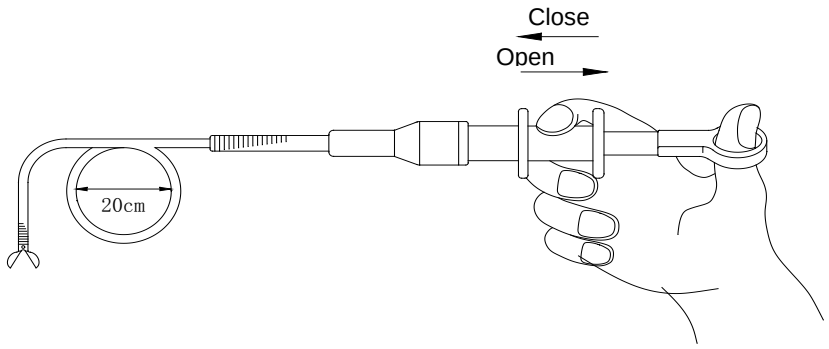


Figure 4.4

2) Check the biopsy forceps according to the operation instructions for accessories, etc.

3) When finding that the operation or appearance of the biopsy forceps goes wrong, be sure to replace it with a new one.

4) Hold the grip section, slightly insert the biopsy forceps into the instrument channel, and confirm that the instrument channel is clear and the biopsy forceps can smoothly be extended from the distal end.

(6)Check of biopsy forceps channel

1) Check if the biopsy forceps channel open valve has any foreign matters or water drops.

2) Put the biopsy forceps through the channel gently, make sure biopsy forceps channel is totally smooth without any blockages.

3) If the biopsy forceps cannot turn up from the biopsy forceps channel at the distal end, please do not force it to.

Note

If too strong force is used to push the biopsy forceps through the channel or the biopsy forceps is forced through the channnel, then damage could be brought about to the channle and causing other severe consequences.

(7)Check of optical system

1)Turn the diopter adjusting ring until the image can be clearly seen

2) Check whether the subject 10mm away from the objective lens can be clearly seen, the color code mark on the eyepiece is the reference mark for quickly adjusting and deciding the diopter

(8)Check of video device

1) The connectors of camera and TV that are suited for this fiberscope are DF-1 camera connector of Aohua, TV type display video connector, all camera and OTV connectors of OES series of Olympus.

2)Fix the video connector together with the camera to the eyepiece (align the red dot on the connector with the pulling pole on the eyepiece, after loading, rotate it 50 ° in the clockwise direction.

3) Via the camera viewfinder to observe whether or not imaging is clear

4) As per the instruction of the video connector, set the exposure of the camera to automatic mode and set corresponding exposure parameters as per the film applied.

5) Make the distal end of the endoscope face the targets away from it with different distances, press the shutter of the camera, confirm the lasting time of the shutter open is different as per the distance

between the distal end and the targets.
6) Unload the camera from the eyepiece. (Note: rotate it 50° in anticlockwise direction)

(9)Preparation and check of TV system

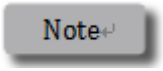
1) This endoscope is compatible with the OTV television system manufactured by our company.
2)Load the TV system on eyepiece of the endoscope, turn on the TV system, adjust the definition and color of the image to the satisfying degree.

(10)Check of other parts

1) Check if the flexible light guide tube has any damage(like fracture, crack, distortion or battering)
2) The air pump in the light source has automatic air feeding function, start the air pump, confirm the air pump works well and air outlet has air outputted
3) Make sure the working condition of the image processor, monitor and suction pump used simultaneously is safe and right
4) Please also refer to the instructions of accessories and other auxiliary devices

4.1.4Final preparation before use

(1)Cleaning and disinfection of the device
Please refer to the items in Maintenance and Disinfection to perform the cleaning and disinfection of the endoscope and other devices
(2)Method of lens cleaning and antifoggant usage
1) Keep the silicone maxes clean
2) Wet the clean gauze with lens detergent, wipe the eyepiece and the objective lens with it
3) Wipe softly away the additional detergent



Please do not let the lens detergent block the air/water nozzle. Wipe the nozzle align with the opening of the nozzle.
Please do not plaster lens detergent directly on the lens, otherwise it may be the cause for nozzle blocking
(3) Method of silicone oil (lubricant) usage
1) Plaster the clean water-soluble lubricant of medical grade to the flexible insertion tube, please do not plaster it on the lens of the distal end.
2) Please do not use olive oil, lidocaine cream, other petroleum bases or lubricant containing vaseline, these reagents will result in damages to some materials of the endoscope.

4.2 Insertion and observation

(1)Switch on the power supply of the video system center and turn on the light source.
(2)Press the white balance button of the video system center, and adjust the reflected real color.
(3)Adjust the luminance control knob of the video system center to make the luminance suitable for observation.
(4)As required, supply air and water, operate the angulation hand wheel, adjust the angulation to move the distal end of the fiber gastrointestinal endoscope to the place to be observed, and slowly insert the distal end when observing.
(5)If images become vague due to mucus, etc., press the water valve to wash the endoscope surface. Then, you can quickly make images clear by both air feeding and suction.

4.3 Use of biopsy forceps

(1)Open the protective rubber cap of the instrument channel port on the grip section of the fiber gastrointestinal endoscope;
(2)Close the biopsy forceps tightly and insert them in the instrument channel port slowly; (Figure 4.6)
(3)Hold the biopsy forceps while keeping the distance between the instrument channel port and your hand is 30mm, when 5mm of the head of the biopsy forceps stretches out the distal end, the biopsy forces will enter into the FOV;
(4)When observing an objective within field of vision, align the biopsy forceps with the desired objective, open the small bowl of the biopsy forceps to catch the objective;
(5)After catching any living tissue or foreign matter, closing the biopsy forceps tightly and pull out them of the biopsy mouth;
(6)If a foreign matter doesn't pass the biopsy channel due to its large size; withdraw the fiber gastrointestinal endoscope and the biopsy forceps from the mouth of the patient;
(7)After withdrawing the biopsy forceps or other instruments, cover the protective rubber cap of the instrument channel port.

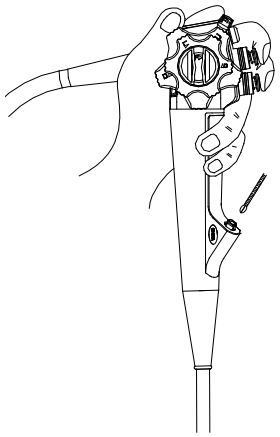


Figure 4.6

Note

To insert or withdraw the biopsy forceps or other instruments please close the small bowl or the moving part at the head of the biopsy forceps

4.4 Withdrawal of fiber gastrointestinal endoscope

1. Loosen the up/down angulation lock and left/right angulation lock and make the bending section straight, confirm that you can withdraw the fiber gastrointestinal endoscope from the mouth of the patient.
2. Aspirate accumulated air, blood, mucus, or other debris by depressing the suction valve.
3. Carefully withdraw the endoscope while observing the endoscopic image.

If blood unexpectedly adheres to the surface of the insertion tube of the withdrawn endoscope, carefully check the condition of the patient.

Chapter5 Cleaning, disinfection and storage of the endoscope

When each clinical check ends, detach the light guide connector of the endoscope from the cold light source and clean it, particularly the mucus on the distal end or in the tube, etc. If it isn't washed for a long time, it may make the performance of the endoscope abnormal. Before cleaning and disinfection, make sure to cover the light guide connector with the water-resistant cap to avoid water inflow or moisture.

★Whenever each clinical examination case ends, be sure to clean and disinfect the endoscope immediately.

The cleaning and disinfection method is determined by the operating doctor and hospital infection control committee, etc. On their own, or complies with the "Manipulation Specification for Cleaning and Disinfection of Endoscope" issued by the Ministry of Health of PRC.

The cleaning and disinfection include automatic and manual method. Our company only introduces how to manually clean and disinfect the fiber gastrointestinal endoscope. For the automatic method, consult the instructions for relevant equipment.

5.1 Cleaning of the fiber gastrointestinal endoscope

(1)Remove the air/water valve, suction valve and biopsy valve, wash them with clear water, and put them in disinfectant.

(2)Clean the insertion tube with gauze or soft sponge in clear water.

(3)Immerse the insertion tube in detergent solution, cleaning the insertion flexible tube slightly and repeatedly with gauze or soft sponge.

(4)Insert a cleaning brush into the instrument channel and the suction cylinder to brush the inner wall of the instrument channel. (See Figure 5.1)

★Do not move the cleaning brush backward until the head of the brush is completely exposed at the distal end to avoid damaging the inner wall of the channel.

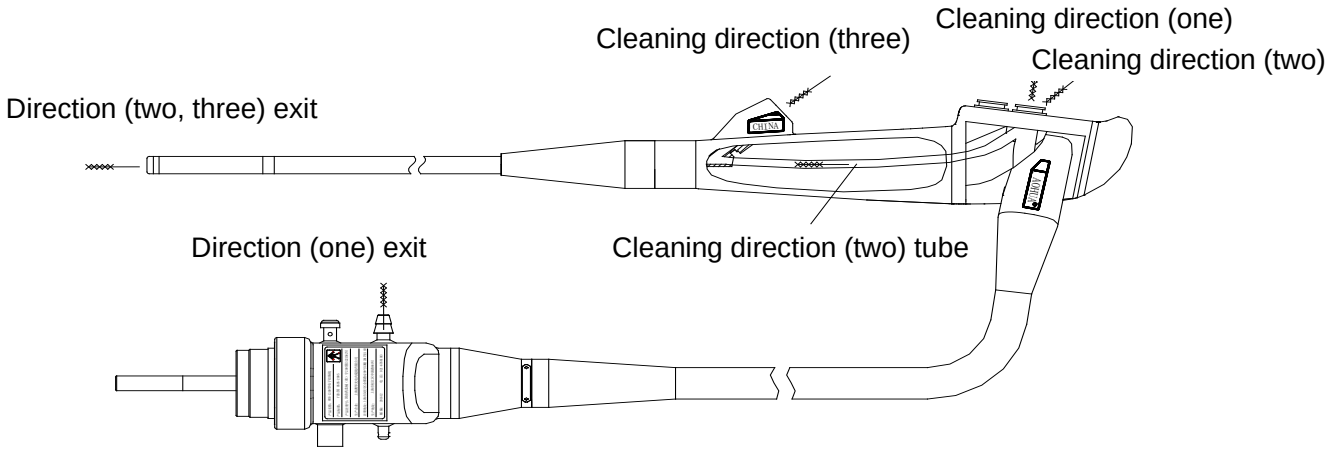


Figure5.1

(5)Before cleaning the air/water channel, connect the purge pipe of the tube cleaner (disinfector) to the air feeding joint at the light guide connector. Meanwhile, use the matching plug of the tube cleaner (disinfector) to block the water bottle connector and the air/water cylinder of the endoscope. Then, put the inlet valve of the tube cleaner (disinfector) in detergent solution, and repeatedly aspirate the syringe to wash the air/water channel. (For the connection and operation method, see Figure 5.2 Tube Cleaning and Disinfection)

(6)Before cleaning the suction and instrument channel, connect the purge pipe of the tube cleaner (disinfector) to the suction connector on the light guide connector. Meanwhile, use the matching plug of the tube cleaner (disinfector) to block the suction cylinder and the biopsy port of the endoscope. Then, put the inlet valve of the tube cleaner (disinfector) in detergent solution, and repeatedly aspirate the syringe to wash the suction and instrument channel. (For the connection and operation method, see Figure 5.2 Tube Cleaning and Disinfection.)

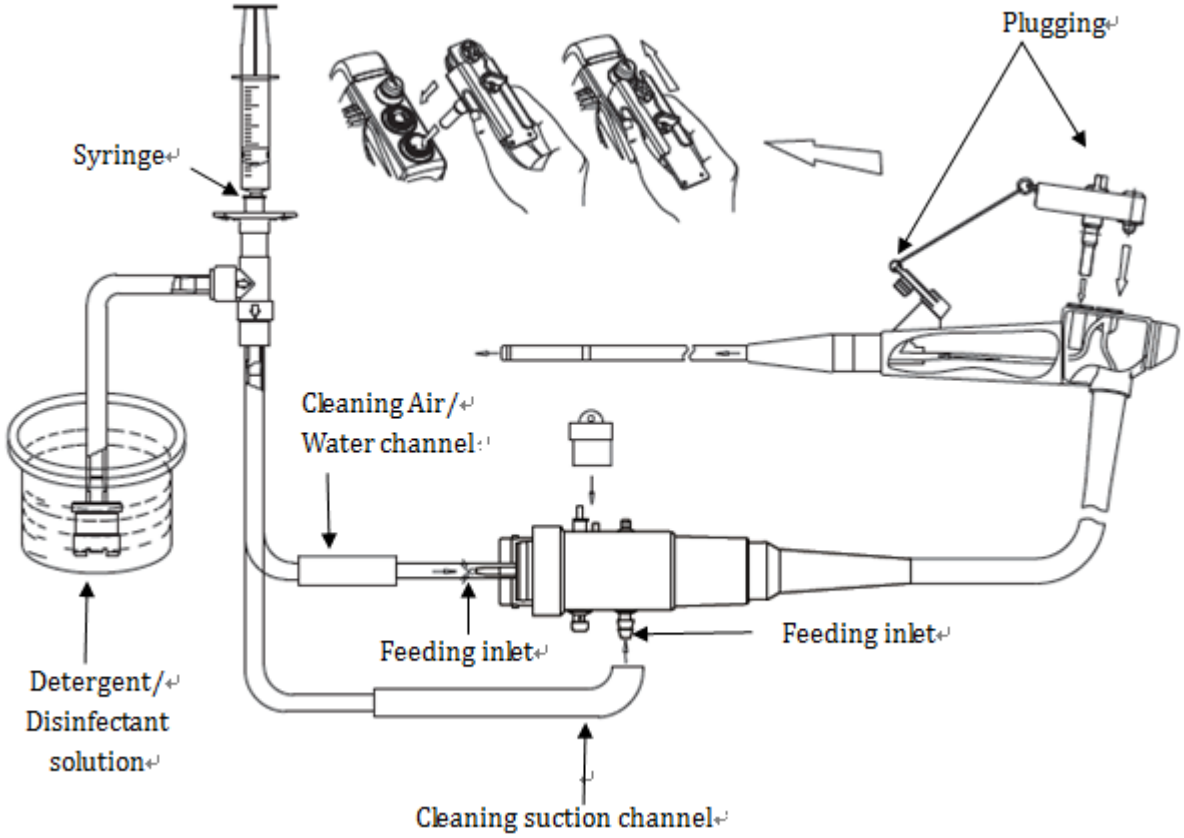


Figure 5.2

Announcements for cleaning the endoscope channel:

(1) Prior to cleaning the air/water channel, detach the light guide connector of the endoscope from the cold light source.

(2) When cleaning the air/water channel, block the air/water cylinder and the water bottle connector, cleaning fluid and detergent solution should be inputted from air feeding channel at the light guide connector of the endoscope.

(3) When cleaning the suction channel, the suction cylinder and the opening of biopsy forceps channel should be blocked, cleaning fluid and detergent solution should be inputted from suction connector.

Warning

If inputting cleaning fluid and detergent solution from air feeding channal, detaching the light guide plug from the cold light source is necessory, otherwise cleaning fulid and detergent solution will be inputted into air pump, and damage the air pump.

5.2 Disinfection of the fiber gastrointestinal endoscope

As a waterproof endoscope, this product can be entirely immersed to undergo disinfection. Before immersing the endoscope, check its sealing property (Check method please refer to fiber

gastrointestinal endoscope sealing property check procedures, Figure 3.1).

Warning

Immerse the fiber gastrointestinal endoscope in the disinfectant solution, as per the procedures following:

(1)Immerse the fiber gastrointestinal endoscope in disinfectant solution; clean the insertion flexible tube slightly and repeatedly with gauze or soft sponge.

(2)Put the inlet valve of the tube cleaner (disinfector) in disinfectant solution. Disinfect the air/water tube, instrument channel tube and suction tube of the endoscope respectively according to the cleaning method of them.

(3)After disinfecting the endoscope, rinse it with clear water to remove the disinfectant residual. Meanwhile, get rid of the disinfectant residual in the tube according to the cleaning method of the air/water tube, instrument channel tube and suction tube of the endoscope.

(4)Use dry gauze to wipe the surface of the fiber gastrointestinal endoscope.

(5)Seal the water bottle connector on the light guide connector and the air/water cylinder on the grip section, then connect the light guide connector to the video system center, and turn on the air pump to thoroughly dry the air/water channel tube (See Figure 5.3).

(6)Seal the instrument channel connector and suction cylinder, connect the suction tube, switch on the suction pump to completely dry the instrument channel, and then detach the light guide connector from the video system center (See Figure 5.3).

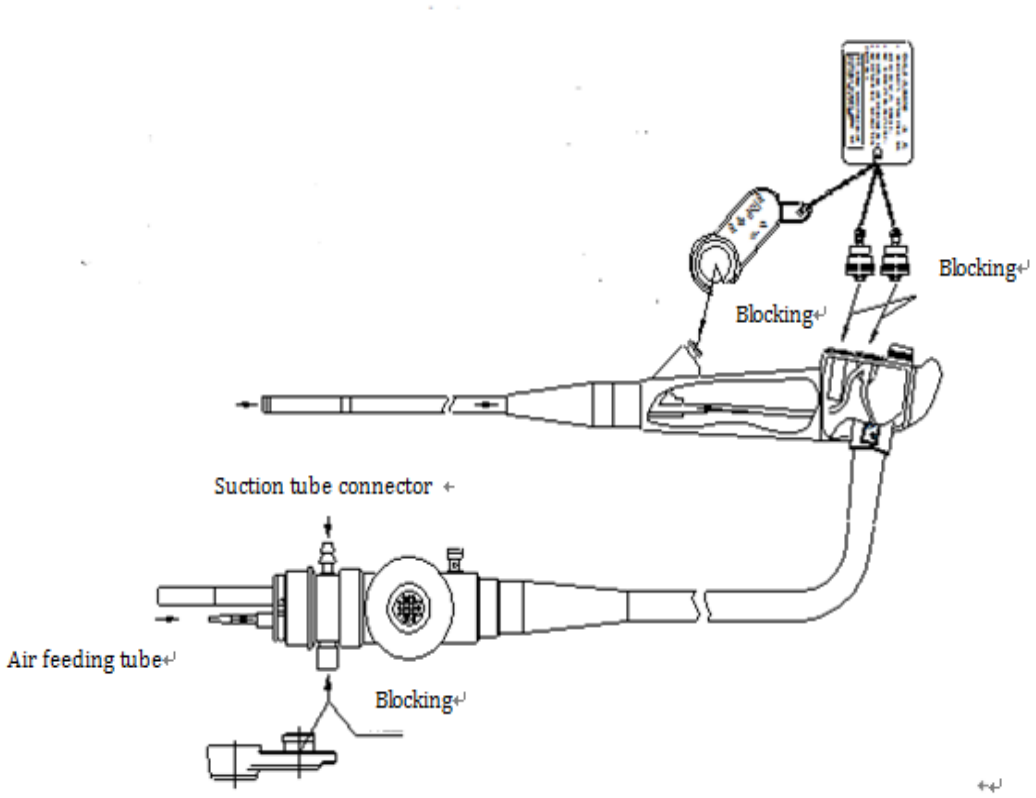


Figure 5.3

(7)Use clear water to rinse the air/water valve, suction valve and biopsy valve, wipe them with dry gauze, and then install them on the corresponding connectors.

(8)Use gauze with alcohol (70%) to clean the surface of the whole fiber gastrointestinal endoscope.

Attention

(1)Some disinfectant may damage some materials (e.g., synthetic resin and rubber, etc.) used in the fiber gastrointestinal endoscope. Before using any disinfection, fully ensure the safety of the fiber gastrointestinal endoscope.

(2)According to the long–term test and clinical use, the following disinfectant solution will do no harm to the fiber gastrointestinal endoscope if it is correctly used:

Chlorhexidine solution

Glutaraldehyde solution

Attention

(3) ***The following disinfection methods, which will CAUSE MAJOR FAULT to the fiber gastrointestinal endoscope, SHOULD BE PROHIBITIVE!***

- Heating and pressing EGO disinfection at the atmospheric pressure of over 1.5 and the temperature of over 40℃.
- USC or disinfection
- Scalding
- Disinfection by drying
- Steam disinfection
- Disinfection by cresol solution or formaldehyde
- Clean by using chlorobenzene and disinfect by the disinfectant solution not diluted

(4)During disinfection or when the fiber gastrointestinal endoscope isn't used, put the water-resistant cap on the light guide connector to avoid water inflow or moisture.

(5)To prevent water leakage from badly damaging the fiber gastrointestinal endoscope or avoid more repair expenses, check the sealing property of the endoscope before cleaning and disinfecting the endoscope.

5.3 Storage of the endoscope

(1)Before the storage, the endoscope should be completely dry, input enough air to the various channels to dry the inner wall of the channels. Especially pay attention to the distal end and the surface of the lens. Carefully wipe the eyepiece and the lens with dry cotton swab to be dry. Softly wipe the surface of the lens with a piece of gauze plastered with lens detergent (silicone maxes), which will prevent the residual water drop on the lens from forming remaining trace.

(2) The storage site should be clear, dry and has good ventilation and keeps the normal temperature. Avoid direct sunlight, high temperature, high humidity and the radiation of X-ray.

(3) Try to keep the flexible insertion tube straight when storage. If it has to be winded to disk shape for storage, please keep it more loosened than or equal to the condition when it is in the endoscope.

(4) Please do not use the suitcase to store the endoscope, the design of the suitcase is only for transportation. Under damp or dark environment or environment of inferior ventilation condition, routine storage using endoscope suitcase will result in problems to infection management. Accessories (like biopsy) should also be totally dried before storage, and please do not wind it to be tight.

5.4 Cleaning, Disinfection or Sterilization of other accessories

(1) Before disinfecting accessories (e.g., the biopsy forceps, the cytology brush, etc.), carefully clean them according to their instructions.

(2)Ideally, conduct the physical cleaning by the USC at the grain level. If possible, sterilize these accessories with ethylene oxide gas, and clean them by rushing gas to get rid of toxic gas. If not disinfecting these accessories, please immerse them to disinfect, then rinse and dry them completely.

(3)For the small bowl of the biopsy forceps, use silicone oil spray or liquid lubricant to lubricate and protect it to prevent adherency.

All the accessories included are NOT immune to autoclave sterilization.

Chapter6 Troubleshooting

Generally, the following troubles may happen to the fiber gastrointestinal endoscope. If the problems cannot be resolved by described inspection method, stop using the fiber gastrointestinal endoscope immediately and contact Aohua after-sales service department.

Failures	Inspection Method
●An image is unclear or has interference.	Confirm that the voltage is stable, or the lens is clean.
● Water drops or stripes	Tel: Contact Aohua after-sales service department.
● No illumination or dim light	Confirm that the light source device and the light guide connector are in place and the light fiber is undamaged.
● Inadequate angulation or angulation failing to actuate	Tel: Contact our after-sales service department.
● Angulation lock malfunction	Tel: Contact our after-sales service department.
● Fail to insert the biopsy forceps and other instruments	Confirm that no foreign matter falls in the tube.
● Weak water/air feeding or failure to supply water/air	Confirm that the connection between the video system center, the water bottle component and the water bottle connector and the light guide connector is secure, and the air pump is in good condition.
● Weak suction or suction failure	Inspect the suction pump, the suction tube, the suction connector and the instrument channel port.
●Needle-like protrusions or breakage or sinking on the surface of	Tel: Contact our after-sales service department.

the insertion tube

● Cracks on the observation window and the illuminating window Tel: Contact our after-sales service department.

Chapter7 Transportation, storage and maintenance

(1)Transportation and storage:

● Ambient temperature range: -40℃ to +55℃

● Relative humidity range: 10％ to 95％

● Atmospheric pressure range: 500hPa to 1060hPa

★The packaged fiber gastrointestinal endoscope should be stored in an indoor environment where relative humidity is not more than 80%, no corrosive gas exists and ventilation is good.

(2)Before storage, make sure to completely dry the fiber gastrointestinal endoscope and try to keep it straight, and store the insertion tube in an environment without any external force influence. The power switch of the imaging processor and the cold light source has to be closed before storage and unpin the power wire.

(3)The endoscope box is not for safeguard. Do not safeguard the fiber gastrointestinal endoscope in an endoscope box to avoid any infection.

(4)As of the purchase of the fiber gastrointestinal endoscope, enjoy “three guarantees" with a 1-year term. “three guarantees" should be on a basis that the invoice and the warranty card enclosed by the User Manual at the time of purchase act as the vouchers. If the fiber gastrointestinal endoscope is found to sustain a man-made damage, for example, the surface of the insertion tube bears some teeth marks left by the patient or signs of flatness bitten by the patient, or faults caused by the dismounting of the operator or the purchase organization, etc., this case should not apply to “three guarantees" repair.

Chapter8 Other announcements

(1) When insert, unload and store the fiber gastrointestinal endoscope, make sure if the angulation lock has been loosened.

(2) The internal structure of the fiber gastrointestinal endoscope is very delicate, do not forcibly bend, fold, reverse and collide it.

(3)Don’t storage the fiber gastrointestinal endoscope in a high temperature, humid, and dusty environment.

(4)For equipment connecting with the endoscope, such as the video system center, the suction pump and the electrosurgical snare, make sure to use three-pin plug and socket and connect the grounding cable to the power supply. (If such equipment triggers any electric shock, burn or other accidents due to violation of the operation standard, the full responsibility is assumed by the user).

(5)To use the fiber gastrointestinal endoscope together with the video system center, better connect a voltage regulator with over 1000 W and automatic regulation function. Don’t use a voltage regulator for household purpose on the fiber gastrointestinal endoscope and the system center.

(6)As the fiber gastrointestinal endoscope goes wrong, stop using it without delay and contact our after-sales service department, or contact the nearby franchised dealer or authorized maintenance station of our company.

★To prevent infection and ensure the safety of all apparatus maintenance personnel, make sure to

clean and strictly disinfect the fiber gastrointestinal endoscope before sending the above endoscope back to our company for repair. If the endoscope is used by any HA positive patient or those developing other infectious diseases, inform us in advance.
(7) When the endoscope and its internal components are scrapped, its disposition should comply with relative national waste residue disposition regulations.

Chapter9 Contraindications of the fiber gastrointestinal endoscope product

(1)Patients with severe heart disease: serious arrhythmia, low ventricular rate, acute myocardial infarction, severe cardiac failure.
(2) Patients who accepted cardiac pacemaker implantation.

(3)Patients with acute esophagus, gastric or duodenum perforation
(4)Patients suspicious with complete intestinal obstruction
(5)Women in the pregnancy or menstrual period
(6)Patients with severe active colonitis .
(7)Patients who refuse to cooperate due to obnubilation or psychiatric disorders.

(8) The other contraindications of gastrointestinal endoscopy

Chapter10 After sales services

(1)The endoscope image processor will enjoy the "three guarantees for quality" within 1 year from the date of purchase. The three guarantees service is dependent on the purchase invoice or product warranty bill or installation acceptance certificate. Quick-wear parts and give-aways are beyond the range of three guarantees.
(2)To any problem related to parts material and technology under normal use and maintenance condition occurred during service period, once proved and verified by AOHUA, our customer service center will provide free service.

Our company only commit to providing above mentioned warranty services if the product broke down under normal use condition. You may choose our paid service under following conditions. Our “service commitment” is limited to product hardware repair only.

1) After your product got repaired by our maintenance division, the original warranty is still applicable. Please pay a certain amount of service charge if the part to be repaired is beyond the warranty period. The service charge standard shall be provided by our maintenance division.
2) When you hope get warranty service, please bring forth the 3G certificate or purchase invoice. If not or the 3G certificate or purchase invoice is inconsistent with the product, we have the right to deny warranty service.

3) For any damage caused by non-compliance with the installation instruction given in the operating manual or operator error, we have the right to deny warranty service.
4) For any man-made damage, we have the right to deny warranty service.
5) For any damage caused by flood, fire or any natural disaster, we have the right to deny warranty service.

Special Hints

a) In case the product was not repaired, altered or dismounted by AOHUA's authorized service personnel, our company has the right to refuse providing warranty service.
b) You are supposed to ask for OPI (Open-Package Inspection) before product hand-over. Defect or fault discovered after the product hand-over shall be presumed to be not caused by our company.
c) Any additional commitment made to you by the retailer shall not considered part of our company's responsibility. In order to provide you with better after-sale services and guarantee your rights and interests, our company is welcoming you to exercise supervision over our work.
d) Once this product and its inside components and parts are determined to be scrapped, relevant national regulations concerning the disposal of waste residues should be followed.

Product Warranty Card

Customer information (in details)

Customer title:	
Detailed address:	
Product title:	Product No.:
Purchase place:	Purchase date:
Invoice No.:	Contact number:

Attention

* The warranty must be sent back to the company within one month from the purchase date.

Warranty way: Contact our maintenance center on the basis of the invoice (or copy). The warranty must be sent back to the company within one month from the purchase date.
Warranty condition: The company shall repair the product free of charge for any fault caused by manufacturing quality within one year from the purchase date.
Following conditions are beyond the warranty scope:

1. Damages caused by improper usage or preservation of the user
2. Disassembly or modification made by the user himself/herself.

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