

Instructions For Use

PENTAX Medical Video Colonoscope

Model Name:

EC38-V10cM

EC38-V10cL

Instructions for Use

This Instructions for Use (hereinafter referred to as "IFU") contains essential information, such as operating procedures and handling precautions, on using this endoscope safely and effectively. Before use, fully understand the contents of, and properly follow, this IFU and the instruction manuals of all equipment that are going to be used in combination. Do not use this endoscope for any purpose other than its intended use. Inappropriate use of the product may result in damage to the equipment or injuries, including, but not limited to, burns, electric shock, perforation, infection, and bleeding.

Prior to use of the instrument, it is important for operators to have received sufficient training in clinical endoscopic techniques and to be familiar with the intended use, warnings, cautions, indications and contraindications mentioned in this IFU.

This IFU does not describe specific endoscopic procedures. The specific procedures should be determined according to the discretion of a medical professional.

If you have any questions or concerns about any information in this IFU, contact your local PENTAX Medical service facility.

The content of the IFU may be changed without prior notice.

Unauthorized reproduction of any part of this IFU is prohibited.

Keep this IFU and all related instruction manuals in a safe, accessible location.

Signal Words and Symbols

Signal Words

The following signal words are used throughout this IFU.



Warning

Indicates a situation that could result in death or serious injury if not avoided.



Caution

Indicates a potentially hazardous situation that could result in minor or moderate injury or damage to equipment if not avoided.



Note

Indicates supplementary or useful information regarding use.

Symbols

The meaning(s) of the symbol(s) on the endoscope, accessories, and/or on their packaging are as follows:

Symbol	Title
	Manufacturer
	Authorized representative in the European Community / European Union
	Date of manufacture
	Serial number
	Importer
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Temperature limit
	Caution
	Medical device
	Unique device identifier
	Refer to instruction manual/booklet (This symbol is colored blue on the product.)
	Stacking limit by number

Symbol	Title
	This way up
	The CE mark confirms the compliance to applicable European (EU) requirements.
	Type BF applied part

Contents

Instructions for Use	3
Signal Words and Symbols	3
Important Information — Please Read Before Use	8
Product Summary	8
Intended Use	8
Indications	8
Contraindications	8
Intended User	8
Notice to the User and/or Patient	8
Instrument Compatibility	9
Spare Equipment	9
Repair and Modification	9
Warnings and Cautions	9
Reprocessing before the Initial Use, Reprocessing, and Storage after Use	10
Other Announcements	12
1 Checking the Package Contents	14
2 Nomenclature and Functions	16
2-1. Nomenclature	16
2-2. Functions	17
2-3. Specifications	18
3 Preparation and Inspection	20
3-1. Preparation of the Equipment	20
3-2. Inspection of the Endoscope	25
3-3. Endoscopic Image Check	27

4	Operation	28
4-1.	Insertion	29
4-2.	Specific Operation	31
4-3.	Using an Endoscopic Device	34
4-4.	Use of the Electrosurgical Snare	37
4-5.	Withdraw the Endoscope	37
4-6.	Transportation of the Endoscope	38
4-7.	Transportation and Storage of the Endoscope	39
4-8.	Disposal	39
5	Cleaning and Disinfection	40
5-1.	Initial Treatment at the Point of Use	40
5-2.	Preparation before Cleaning	41
5-3.	Manual Cleaning	42
5-4.	Rinsing after Manual Cleaning	44
5-5.	Disinfection	45
5-6.	Rinsing after Disinfection	46
5-7.	Drying	46
5-8.	Automatic Cleaning and Disinfection	47
5-9.	Maintenance, Inspection, and Testing	47
5-10.	Packaging and Sterilization	48
5-11.	Storage and Additional Information	48
6	Troubleshooting	50
	EMC Information	52

Important Information — Please Read Before Use

Product Summary

This endoscope visualizes subjects under illumination transmitted from a dedicated video processor with a CMOS image sensor located at the distal end of the endoscope and provides images for observation of the target anatomy through the images reproduced on the video monitor via the video processor. It can be used with endoscopic devices which are introduced from the instrument channel inlet of the control body. The endoscope also allows for angulation operation of the bending sections via operation of the angulation control knob; air/water feeding from the distal end of the endoscope via operation of the air/water feeding valve; and suction through the channel at the end of the endoscope via operation of the suction control valve.

Intended Use

This instrument is intended to be used with PENTAX Medical VIDEO PROCESSOR VERSA EPK-V1500c for the lower G.I. video observation for the purpose of performing diagnosis and treatment. Do not use this video colonoscope for any purpose other than its intended use.

Indications

This device is commonly used in the evaluation or treatment of unusual abdominal pain, abdominal bloating, cervical cancer assessment, functional colopathy, dyspepsia, hemorrhoidal disease, or dysenteric syndrome. Physicians may also use the device to obtain biopsies or perform other procedures.

Contraindications

Patients with the following contraindications are prohibited with the colonoscopy.

1. Patients with severe heart disease, serious arrhythmia, especially with low ventricular rate, acute myocardial infarction, severe cardiac failure
2. Patients implanted with cardiac pacemaker
3. Patients with acute perforation of organs
4. Patients with complete intestinal obstruction
5. Patients with pregnancy or menstruation
6. Patients with severe active colitis
7. Patients unable to cooperate due to obnubilation or psychiatric disorders

Intended User

The operator of this instrument must be a trained and qualified gastroenteric physician or endoscopic physician.

Notice to the User and/or Patient

As per the Regulation (EU) 2017/745 (EU-MDR), any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Instrument Compatibility

Using incompatible equipment can result in patient or operator injury and/or equipment damage. Before use, please refer to this manual to confirm that this instrument is compatible with the ancillary equipment.

Spare Equipment

Be sure to prepare another endoscope to avoid that the examination will be interrupted due to equipment failure or malfunction.

Repair and Modification

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

Warnings and Cautions

Follow the warnings and cautions below when handling this instrument.



Warning

- After using this instrument reprocess and store it according to the instructions.
- Before endoscopy, remove any metallic objects (watch, glasses, necklace, etc.) from the patient.
- Does 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.
- 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 while the image is frozen.
- Do not touch the light guide connector immediately after removing it from the video processor because it is extremely hot.
- When the endoscopic image does not appear on the monitor, the image device may have been damaged. Turn the video processor OFF immediately.
- If it is difficult to insert the endoscope, do not forcibly insert the endoscope and stop the endoscopy.



Caution

- Do not pull the universal cord during an examination.
- Do not touch the electrical contacts inside the electrical connector.
- 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.
- Turn the video processor OFF before connecting or disconnecting the videoscope from the video processor.
- Do not hit or bend the electrical contacts on the light guide connector.
- Electromagnetic interference may occur on this instrument near equipment marked with the following symbol or other portable and mobile RF communications equipment.



Reprocessing before the Initial Use, Reprocessing, and Storage after Use

■ Reprocessing before the initial use

The endoscope identified in this IFU is a reusable semi-critical device. Since it is packaged non-sterile, it must be processed according to the Chapter 5 of this IFU before initial use. Insufficient reprocessing may increase the risk of infection.



Note

The wording “high-level disinfection” in this IFU defines the disinfection of the endoscope and the accessories with a completely virucidal disinfectant.

■ Reprocessing

After use, the endoscope must be appropriately processed and stored. Perform processing according to the Chapter 5 of this IFU. Insufficient and/or incomplete processing of this endoscope may result in its non-optimal function of and/or damage to the endoscope and may pose a risk of infection to the patient and/or users.



Warning

When using an endoscope and its accessories on patients with Creutzfeldt-Jakob disease (CJD) or variant Creutzfeldt-Jakob disease (vCJD), use only dedicated instruments and equipment. The instruments and equipment used on these patients must be discarded so that they cannot be used again on another patient. The pathogenic agents that cause this disease, which are called “prions”, cannot be destroyed or inactivated using the cleaning, disinfection, and sterilization methods presented in this IFU. Please consult the guidelines that apply to your country or region for more detailed information regarding the handling of prion-contaminated instruments.



Note

- The equipment is water-resistant.
- Water-resistant: ISO 8600-7
- Manufacturer: PENTAX-Aohua Medical Technologies Co., Ltd.

■ Storage after use



Warning

Adhere to the following guidelines. Failure to do so may result in contamination of the endoscope with bacteria or pose a risk of infection to patients and/or users.

- Ensure that all removable accessories, such as air/water feeding valve, suction control valve, inlet seal, cleaning adapter, and water resistant cap are removed from the endoscope when storing.
- Do NOT store the endoscope in areas of high humidity or high temperature.
- Do NOT store the endoscope, its components, and accessories in the carrying case.
- Ensure that the endoscope, its components, and accessories are completely moisture-free before storage.
- Before the next use, the endoscope, its components, and accessories that have been stored inappropriately or for a prolonged period of time must be subjected to appropriate cleaning, high-level disinfection, and/or sterilization processes according to the Chapter 5 of this IFU.



Caution

Observe the following precautions when storing the endoscopes, its accessories, or device. Failure to do so may result in damage to property.

- Endoscope insertion portion, umbilical cord, and endoscopic devices should be kept as straight as possible during storage.
- Keep away from chemicals, direct sunlight, or ultraviolet rays.
- Maintain adequate distances between the endoscope, its accessories, and devices, so that they do NOT hit against each other.



Note

It is recommended to store the endoscope hanging down straight in a well-ventilated room or cabinet dedicated for endoscope storage.

For cleaning prior to storage, also refer to the Chapter 5 of this IFU.

Other Announcements



Caution

To prevent infection and ensure the safety of all maintenance personnel, ensure to clean and strictly disinfect the video endoscope before sending the defected endoscope back to PENTAX Medical for repair. If the endoscope is used by any HA positive patient or patient with other infectious diseases, inform the personnel of PENTAX Medical in advance.

- When insert, withdraw, or store the video endoscope, ensure the angulation lock has been freed.
- The internal structure of video endoscope is very delicate. Do not forcibly bend, fold, twist, or collide the endoscope.
- Do not store the video endoscope in a high temperature, humid, and dusty environment.
- If the video endoscope is exposed in X-ray, aging and color change of the internal sensor and other delicate components may result. Limit the usage of X-ray to the minimum level.
- Do not align the distal end of the video endoscope with strong light (e.g., sunlight, emergent light of light source, etc.). Damage may be caused to the light-sensitive and precise device.
- If the video endoscope does not function normally, stop using it immediately and shut OFF the grid power supply and contact your local PENTAX Medical service facility timely.
- Comply with relevant waste disposition regulations to dispose of the endoscope and its internal components needed to be discarded.

Checking the Package Contents



Caution

Match all items in the package with the components shown below. Inspect each item for damage. If a component is missing or damaged, please contact your local PENTAX Medical service facility.

■ EC38-V10cL

Item code	Item	Quantity
–	EC38-V10cL	1
GM00261	Air/water valve	1
GM00259	Suction valve	1
GS00003	Cleaning kit	1
MF00004	Biopsy valve	3
GS00045	Cleaning plug	1
GS00017	Plug label	1
GM00906	Water resistant cap	1
AGS00228	Cleaning brushes	5
GF00027	Leakage tester	1
GS00006	Water bottle	1
DX00293	IFU (EC)	1

■ EC38-V10cM

Item code	Item	Quantity
–	EC38-V10cM	1
GM00261	Air/water valve	1
GM00259	Suction valve	1
GS00003	Cleaning kit	1
MF00004	Biopsy valve	3
GS00045	Cleaning plug	1
GS00017	Plug label	1
GM00906	Water resistant cap	1
AGS00228	Cleaning brushes	5
GF00027	Leakage tester	1
GS00006	Water bottle	1
DX00293	IFU (EC)	1



Note

Above accessories are dedicated to PENTAX MEDICAL V10c series endoscope. Do not use other accessories out of above table with V10c series endoscopes.

2

Nomenclature and Functions

2

2-1. Nomenclature

Nomenclature and Functions

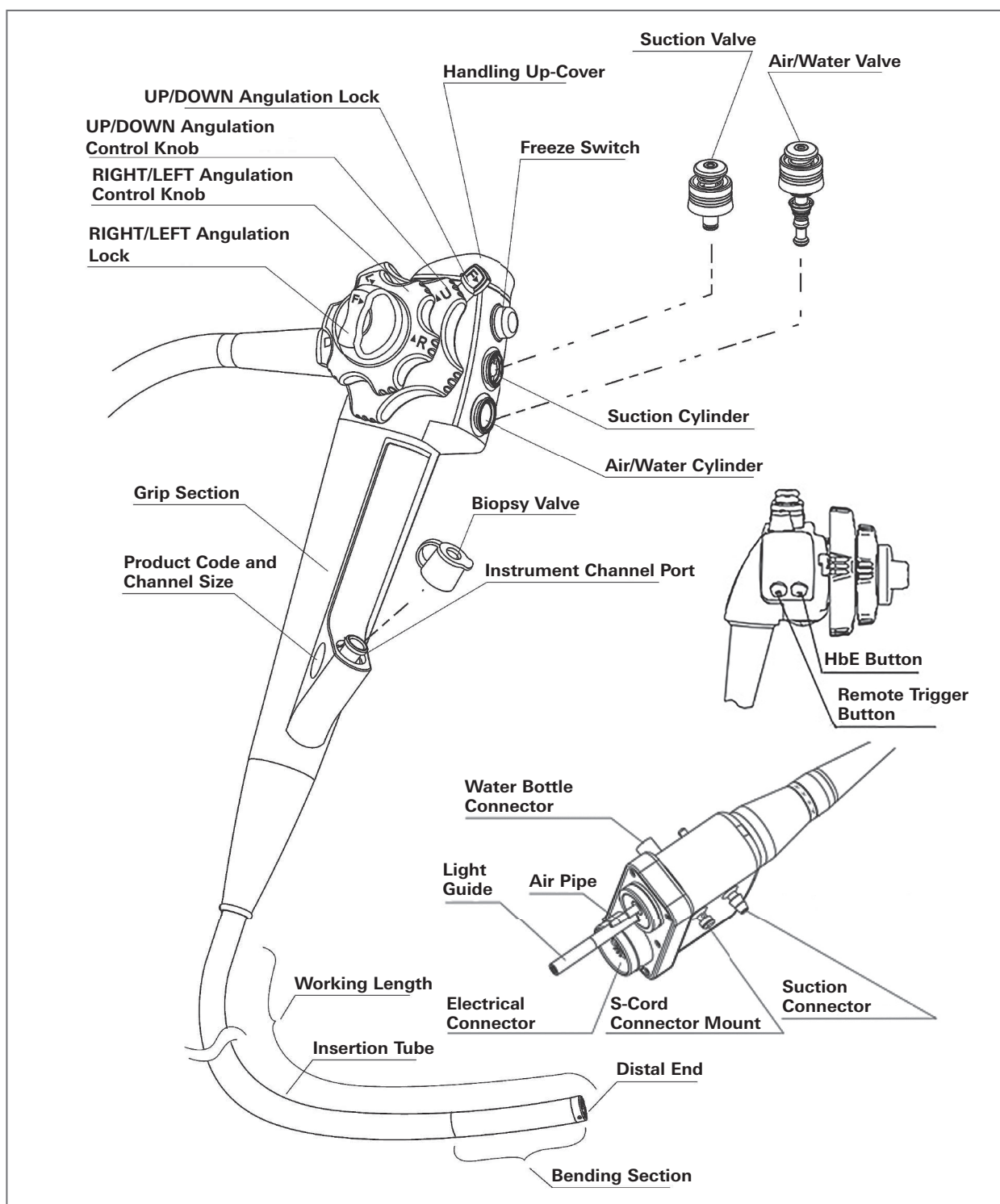


Figure 2.1

2-2. Functions

1. Suction connector

Connect the endoscope to the suction tube of the suction pump.

2. S-cord connector mount

Connect the endoscope with electrosurgical unit via the S-cord.

3. Water bottle connector

Connect the endoscope to the water container via the water container tube, to supply water to the distal end of the endoscope.

4. Light guide

Connect the endoscope to the output socket of the light source and transmits light from the light source to the endoscope.

5. Electrical connector

Connect the endoscope to the video processor via the videoscope cable.

6. UP/DOWN angulation control knob

Move the bending section UP/DOWN by operating it.

7. UP/DOWN angulation lock

Moving this lock in the "F▼" direction frees angulation.

8. Suction valve

This valve is pressed to activate suction.

9. Air/Water valve

The hole in this valve is covered to insufflate air and the valve is pressed 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.

10. Bending section

This section moves the distal end when the UP/DOWN and RIGHT/LEFT angulation control knobs are operated.

11. RIGHT/LEFT angulation lock

Turning this lock in the "F▼" direction frees angulation.

12. RIGHT/LEFT angulation control knob

When this knob is turned in the "R▲" direction, the bending section moves RIGHT.

2-3. Specifications

Operating environment

- Ambient temperature: 5 to 40°C
- Relative humidity: ≤80% (40°C)
- Atmospheric pressure: 700 to 1060 hPa

Specifications: EC38-V10cM

Item	Specification
Working length	1300 mm
Distal end outer diameter	Ø12.8 mm
Main flexible tube outer diameter	Ø12.8 mm
Maximum insertion portion diameter	Ø14 mm
Minimum instrument channel inner diameter	Ø3.7 mm
Bending angle	Up and down: 180°, Left and right: 160°
Field of view	140°
Angle of view	0° (forward)
Water supply amounts	≥ 45 mL/min
Gas supply amounts	≥ 800 mL/min
Suction amounts	≥ 400 mL/min
Depth of view	3 to 100 mm

Specifications: EC38-V10cL

Item	Specification
Working length	1650 mm
Distal end outer diameter	Ø12.8 mm
Main flexible tube outer diameter	Ø12.8 mm
Maximum insertion portion diameter	Ø14 mm
Minimum instrument channel inner diameter	Ø3.7 mm
Bending angle	Up and down: 180°, Left and right: 160°
Field of view	140°
Angle of view	0° (forward)
Water supply amounts	≥ 45 mL/min
Gas supply amounts	≥ 800 mL/min
Suction amounts	≥ 400 mL/min
Depth of view	3 to 100 mm

3

Preparation and Inspection

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



Warning

- Using an endoscope that is not functioning properly may compromise patients' or operators' safety and may result in more severe equipment damage.
- This instrument is not cleaned, disinfected or sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions.

3-1 . Preparation of the Equipment

Prior to use, the endoscope, video processor and endoscopic accessory instruments must be carefully inspected for cleanliness and proper function to determine that they are appropriate for patient use (see Figure 3.1 and Figure 3.2). For detailed operation requirements, refer to the instructions of the video processor and the monitor.



Note

PENTAX Medical video endoscopes contained in this IFU are only compatible with PENTAX Medical video processors VERSA EPK-V1500c.



Caution

To avoid discontinuation of endoscopic procedure, have an extra (spare) instrument available as a standby device. Should any unforeseen event or circumstance render the original instrument inoperable and/or unsafe for patient.

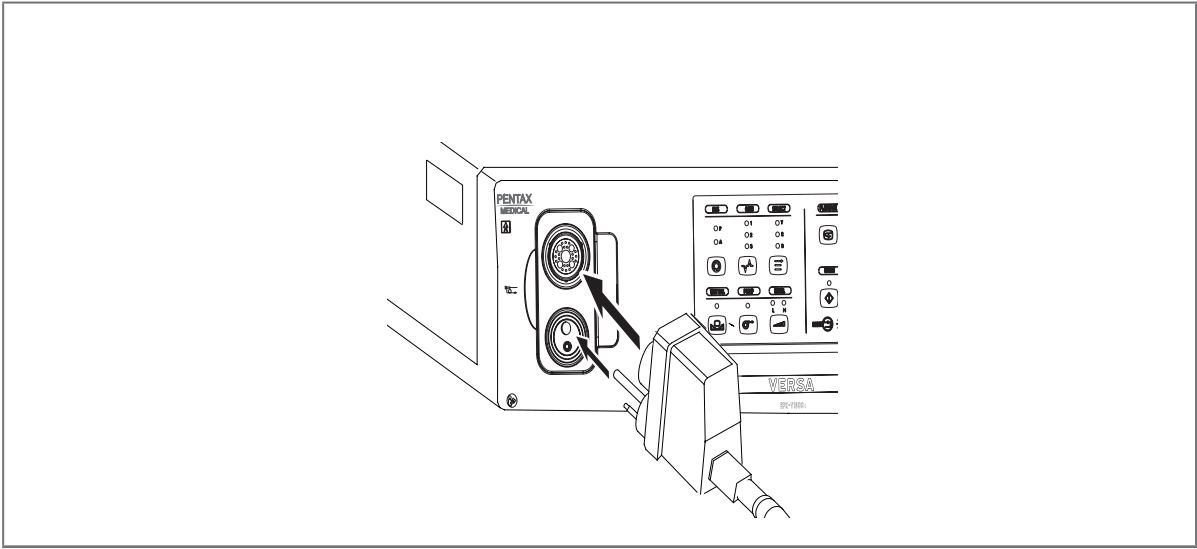


Figure 3.1

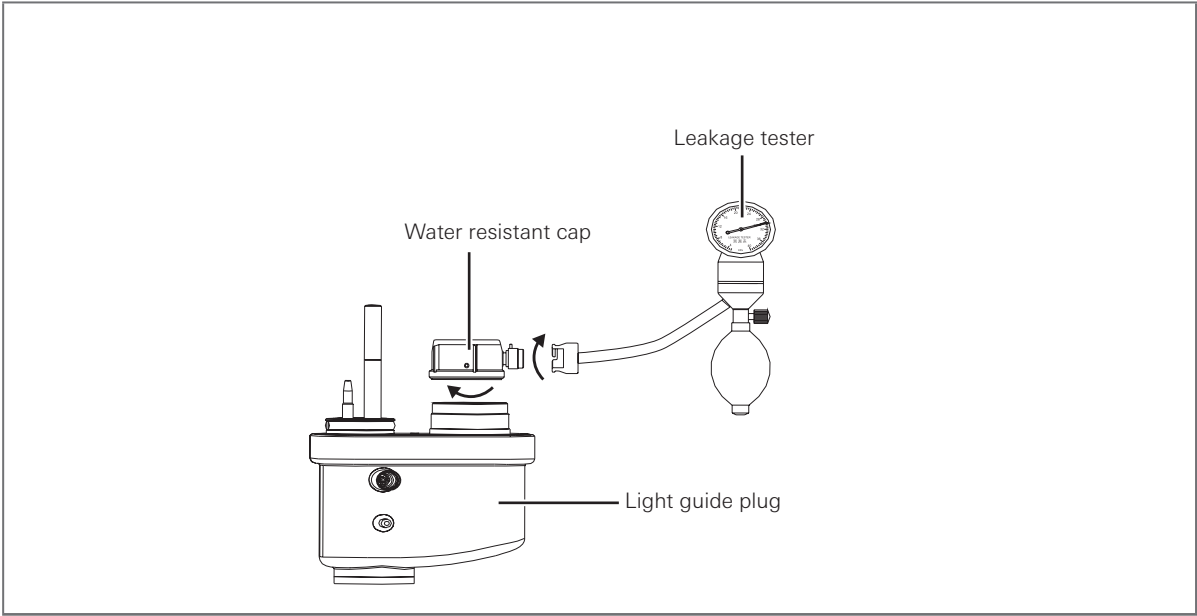


Figure 3.2

3.1.1 Attaching Accessories to the Endoscope



Caution

The air/water valve and the suction valve do not require lubrication. Lubricants can cause swelling of the valves' seals, which will impair valve function.

■ Attaching the Suction Valve

1. Align the two metal ridges on the underside of the suction valve with the two holes in the suction cylinder.
2. Attach the suction valve to the suction cylinder of the endoscope. Confirm that the valve fits properly without any bulging of the skirt. Also confirm that the valve cannot be rotated.



Note

Suction valve will make a whistling noise when it is dry; this does not indicate a malfunction.

■ Attaching the Air/Water Valve

1. Attach the air/water valve to the air/water cylinder of the endoscope.
2. Confirm that the valve fits properly without any bulging of the skirt.

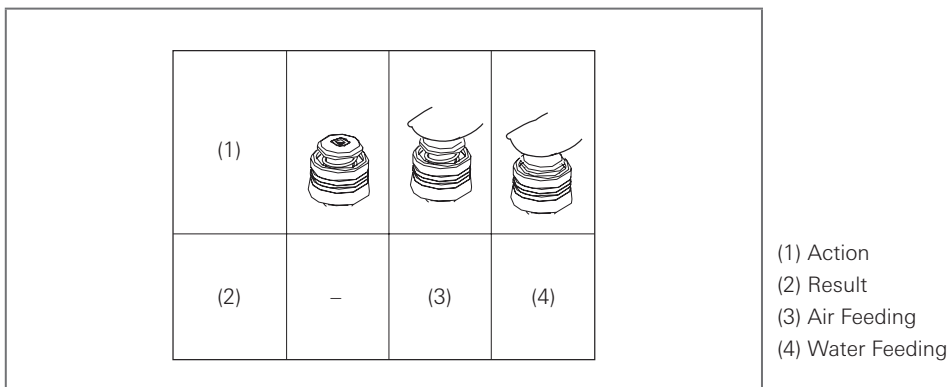


Figure 3.3



Note

The air/water valve may stick at first, but it should operate smoothly after it is pressed a few times.

■ Attaching the Biopsy Valve



Warning

- If a biopsy valve is not properly connected to the instrument channel port, it can reduce the efficacy of the endoscope's suction system and may cause patient debris to leak or spray from the endoscope.
- Attach the biopsy valve to the instrument channel port of the endoscope. Confirm that the biopsy valve fits properly.

3.1.2 Preparation before Suction

- Confirm that the place and suction performance of the suction pump is in good condition.
- Prepare the apparatus for living tissue sampling.
- Connect the suction flexible tube of the suction unit and the suction connector of the light guide connector of the video endoscope. Switch on the power supply of the suction unit, then dip the distal end of the endoscope in water, and control suction through the suction valve of the endoscope. (See Figure 3.4)

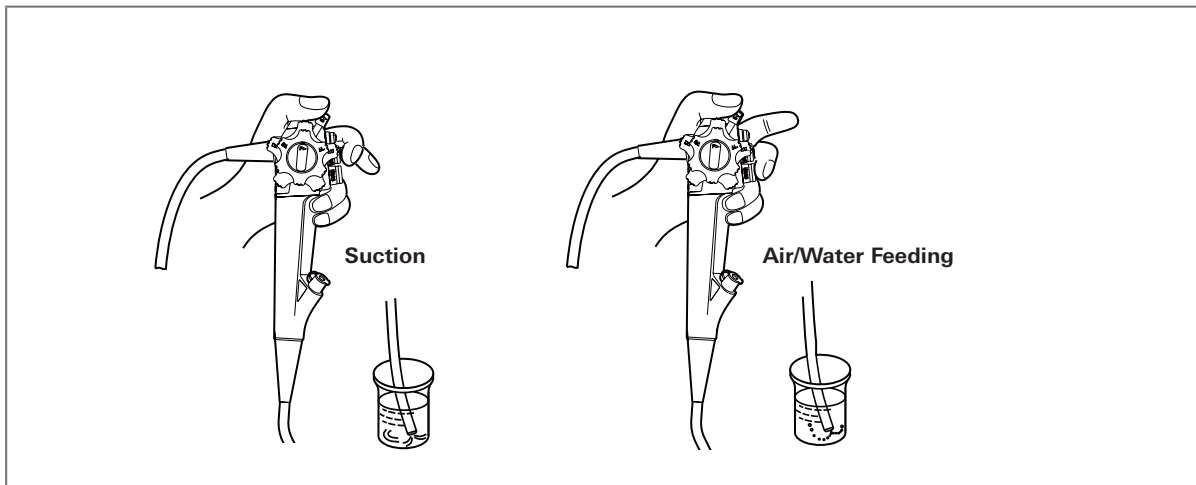


Figure 3.4

3.1.3 Preparation of Air/Water Feeding System

- 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 processor.
- Connect the bottle and the light guide connector.
- Turn on the air pump, operate the air/water valve to control air/water feeding, and make sure that the function is normal. (See Figure 3.4 (right figure))

3.1.4 Preparation of the TV Display System

- The video endoscope is applicable to 19-inch monitors.
- Make sure that the connections of the video processor system and the monitor, the printer, and the VCR are right and secure.
- Simulate and regulate the color and definition of the monitor.
- For the regulation of white balance and color, please consult the instructions of PENTAX Medical VIDEO PROCESSOR VERSA EPK-V1500c.
- **For the connection of the TV display system, see the instructions of monitor and video processor.**

3.1.5 Preparation of Electrosurgical Snare and HF Instrument

- Before use, carefully read information about how to use the electrosurgical snare and HF instrument to avoid accidents.
- Try not to use these two pieces of equipment together with other electrical equipment concurrently. If they are used along with the ECG, the electrode of the latter may be burned. When a person with a pace maker comes up, high frequency will confuse the signal of the pace maker, which may threaten life. So, keep that in mind.
- The video endoscope can work with OLYMPUS PSD type, UES type HF generator, and special electrosurgery instruments to conduct electrosurgery operations such as polyp removal of various positions of gastrointestinal tract (before using other branded electrosurgical snares and HF instruments, obtain the confirmation of our company in advance).
- To perform a HF electrosurgery operation, make sure that a doctor experienced in the operation of a video endoscope performs it with caution. Before starting an operation, fully prepare and inspect HF instruments and relevant accessories to ensure the operation is smooth and safe.
- According to the method shown in Figure 3.5, connect the electrosurgical snare and the video endoscope as well as the video processor. For detailed connection method, consult the instructions for the electrosurgical snare and the video processor.

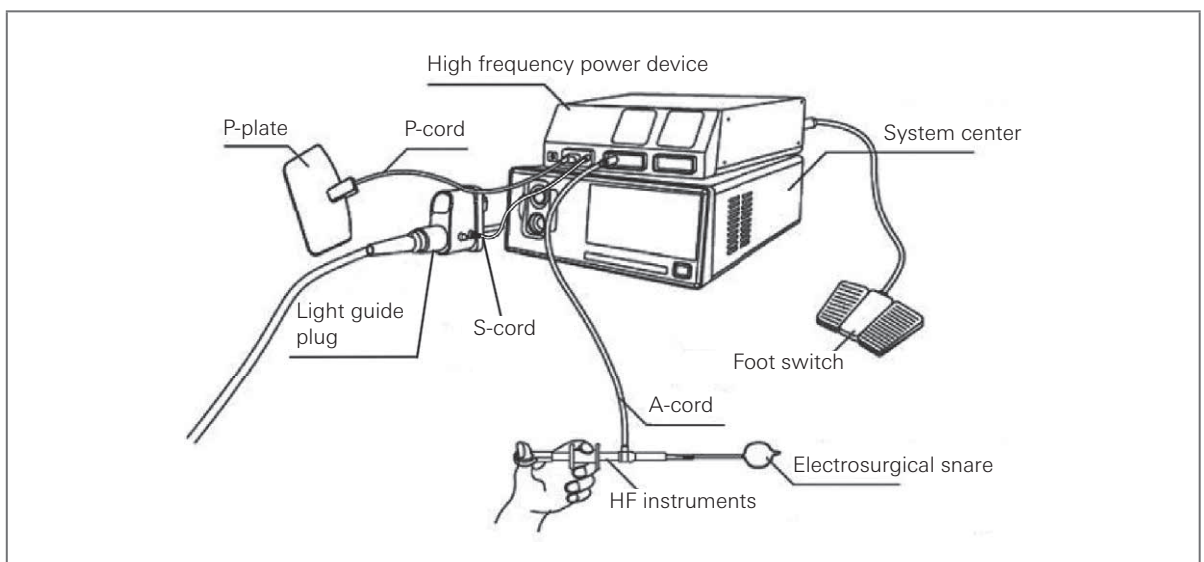


Figure 3.5

3-2. Inspection of the Endoscope

Clean and disinfect or sterilize the endoscope, then remove the water-resistant cap from the light guide connector.

3.2.1 Inspection of the Endoscope

1. Inspect the control section and the light guide connector for excessive scratching, deformation, loose parts or other irregularities.
2. Inspect the boot and the insertion tube near the boot for bends, twists or other irregularities.
3. Inspect the external surface of the entire insertion tube including the bending section and the distal end for dents, bulges, swelling, scratching, holes, sagging, transformation, bends, adhesion of foreign bodies, dropout of parts, any protruding objects or other irregularities.
4. 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. (See Figure 3.6)

- **For the bending section, do not bend or straighten a tube with your hands forcibly.**

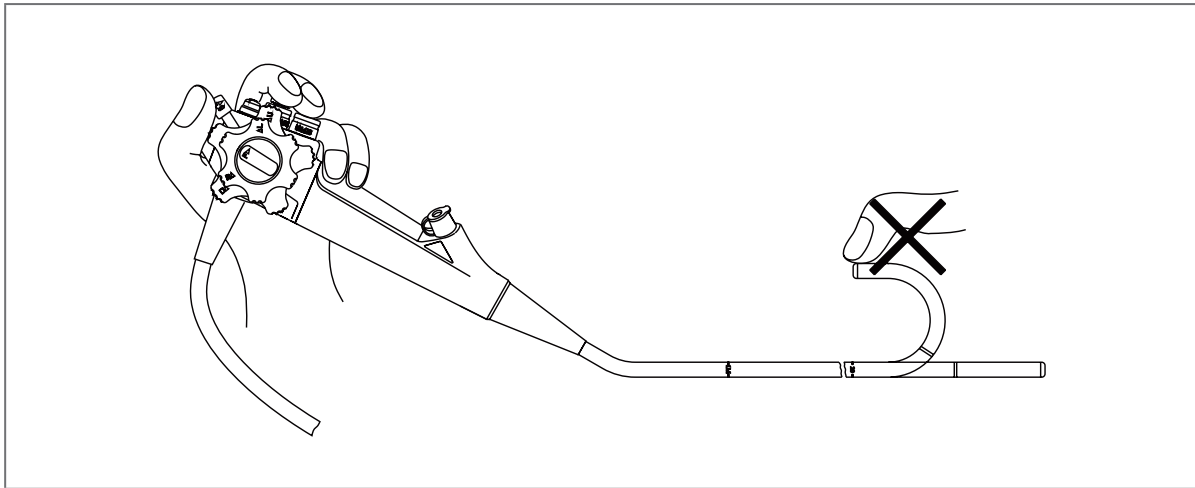


Figure 3.6

5. Inspect the sealing property of the video endoscope as described in “Chapter 5 Cleaning and Disinfection, Section 5-2. Leakage Detection”.
6. Inspect the objective lens and light guide lens at the distal end of the endoscope’s insertion tube for scratching, cracks, stains, or other irregularities.
7. Inspect the air/water nozzle at the distal end of the endoscope’s insertion tube for abnormal swelling, bulges, dents or other irregularities.
 - Press the air/water valve to confirm that air/water is supplied at the distal end. After loosening your hand, confirm that air/water feeding stops.
 - 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.

8. Inspection of the biopsy forceps

- 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 3.7)

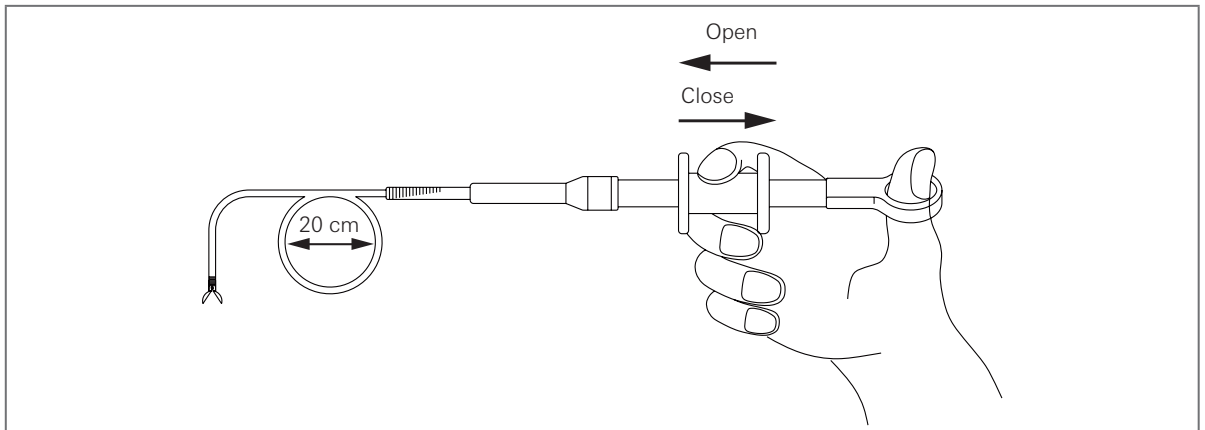


Figure 3.7

- Check the biopsy forceps according to the operation instructions for accessories, etc.
- When finding that the operation or appearance of the biopsy forceps goes wrong, be sure to replace it with a new one.
- 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.

3-3. Endoscopic Image Check



Warning

- Do not stare directly at the distal end of the endoscope while the light is ON. Otherwise, eye injury may occur.
- Turn the video processor, video monitor ON and check endoscopic image.
- Confirm that light is from the endoscope's distal end.
- While observing the palm of your hand, confirm that the endoscopic image is without noise, blur, fog or other irregularities.
- Angulate the endoscope and confirm that the endoscopic image does not momentarily disappear or displays any other irregularities.



Note

If the object cannot be seen clearly, wipe the objective lens using a clean lint-free cloth moistened with 70% ethyl or isopropyl alcohol.

4 Operation

The operator of this instrument must be physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique.



Warning

- Wear personal protective equipment to guard against dangerous chemicals and potentially infectious material during the procedure.
- Whenever possible, avoid close stationary viewing and do not leave the distal end of the endoscope close to the mucous membrane for a long time.
- Whenever possible, do not leave the endoscope illuminated before and/or after an examination.
- If an abnormal endoscopic image or function is observed, but quickly corrects itself, the endoscope may have malfunctioned.
- Never perform flexibility adjustment while the endo-therapy accessory extends from the distal end of the endoscope.
- Confirm cleaning and disinfection;
- Reconfirm the connection condition;
- Use a piece of lens paper to slightly apply silicone oil on the distal end observation window and the illuminating window;
- If required, apply lubricant on the appearance of the insertion tube on the bending section and the soft section. **Lubricant is free from grease substances. Otherwise, the rubber tube may be damaged. Don't apply too much lubricant on the observation window and the illuminating window. Otherwise, it will affect the clearness and brightness of view.**

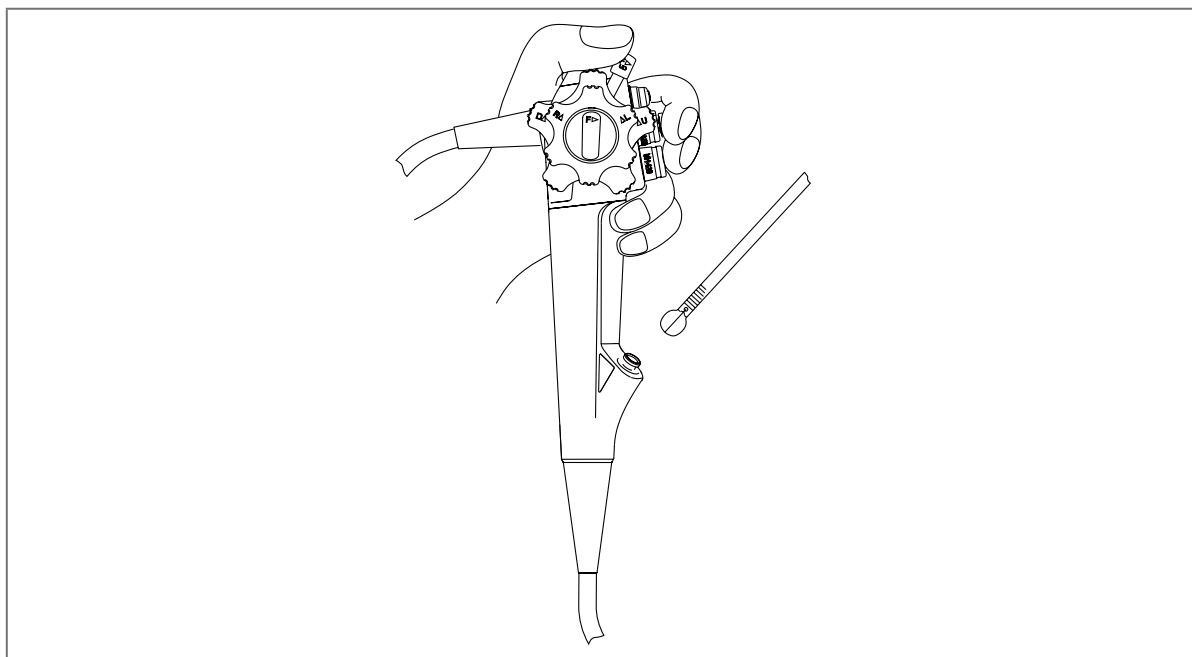


Figure 4.1

4-1 . Insertion

4.1.1 Holding and Manipulating the Endoscope

The control section of the endoscope is designed to be held in the left hand. The air/water and suction valves can be operated using the left index finger. The UP/DOWN angulation control knob can be operated using the left thumb. The right hand is free to manipulate the insertion tube and the RIGHT/LEFT angulation control knob. (See Figure 4.1)

4.1.2 Insertion of the Endoscope

The white balance adjustment is required to reproduce colors in their original tones.



Caution

- To prevent the patient from accidentally biting the insertion tube during an examination, it is strongly recommend that a mouthpiece be placed in the patient's mouth before inserting the endoscope.
- To prevent the patient from accidentally loosing dental prosthesis; make sure that the patient removes them before the examination.
- Do not apply olive oil or products containing petroleum-based lubrications. These products may cause stretching and deterioration of the bending section's covering.
- Do not allow the insertion tube to be bent within a distance of 10cm or less from the junction of the boot. Insertion tube damage can occur.

4.1.3 Insertion and Observation

- Switch on the power supply of the video processor.
- Press the white balance button of the video processor, and adjust the reflected real color. Please refer to the PENTAX Medical VERSA EPK-V1500c Video Processor's IFU, White Balance Adjustment Section for further details.
- Turn on the Light Button and adjust the IRIS mode of the video processor to make the luminance field suitable for observation. Please refer to the PENTAX Medical VERSA EPK-V1500c Video Processor's IFU, Functions Section, Light Button and IRIS Mode Button.
- As required, supply air and water, operate the angulation hand wheel, adjust the angulation to move the distal end of the video endoscope to the place to be observed, and slowly insert the distal end when observing.
- If images become vague due to mucus, etc., press the water valve to wash the lens surface. Then, you can quickly make images clear by both air feeding and suction.

4.1.4 Angulation of the Distal End



Caution

Avoid forcible or excessive angulation, as this imposes load on the wire controlling the bending section. This may cause stretching or tearing of the wire, which could impair the movement of the bending section.

1. Operate the angulation control knobs as necessary to guide the distal end for insertion tube and observation.
2. The endoscope's angulation locks are used to hold the angulated distal end in position.



Note

- When passing an endo-therapy accessory through the instrument channel while the angulation is locked, the angle of the distal end may change. When it is necessary to keep the angulation stationary, hold the angulation control knob in place with your hand. If the insertion is not straight when accessory insertion, it might break or puncture the working channel and cause leakage.
- When operating the UP/DOWN or RIGHT/LEFT angulation lock, hold the angulation control knob stationary with your finger. If this is not held, the angulation will change.

4-2. Specific Operation

4.2.1 Turning the Hb Enhancement ON

The equipment can provide image with Hb enhancement. Hb enhancement is an image processing technique that highlights the blood vessels to make it easier to observe tissue with enriched blood supply.

1. Press the HbE button on the front panel of the video processor or HbE button on the handle of endoscope (see Figure 4.2) to turn ON the Hb enhancement. Press the HbE button on the front panel of the video processor or HbE button on the handle of endoscope again to turn OFF the HB enhancement.

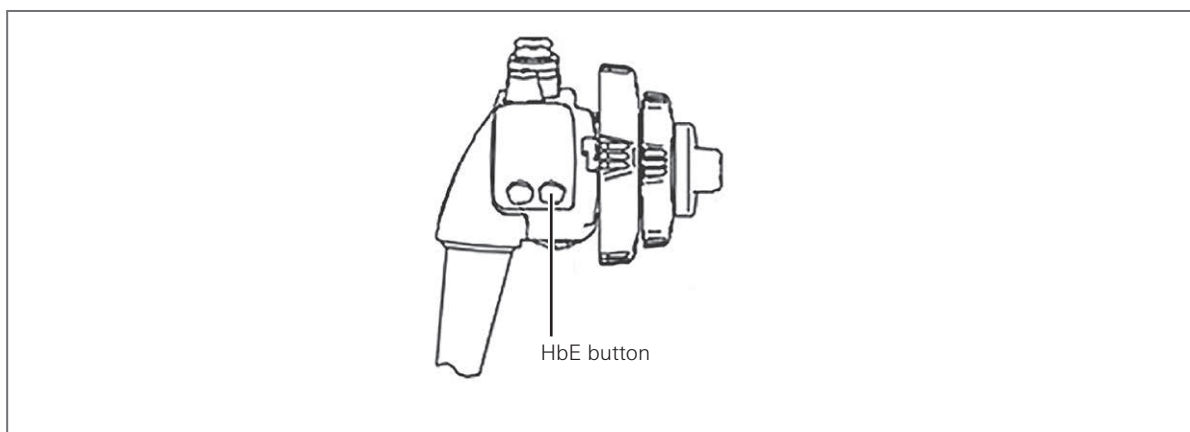


Figure 4.2

4.2.2 Freeze

The endoscopic image can be frozen for closer inspection.



Warning

If the image fails to freeze or defreeze, press the power switch to turn OFF the video processor, wait for 8 seconds, and then press the power switch to turn ON the video processor again.

If this fails to correct the problem, immediately stop using the equipment and remove the endoscope from the patient as directed in the endoscope's instruction manual.

1. Press the freeze button on the handle of the endoscope (see Figure 4.3) or press the freeze button on the front panel of the video processor to freeze the image.

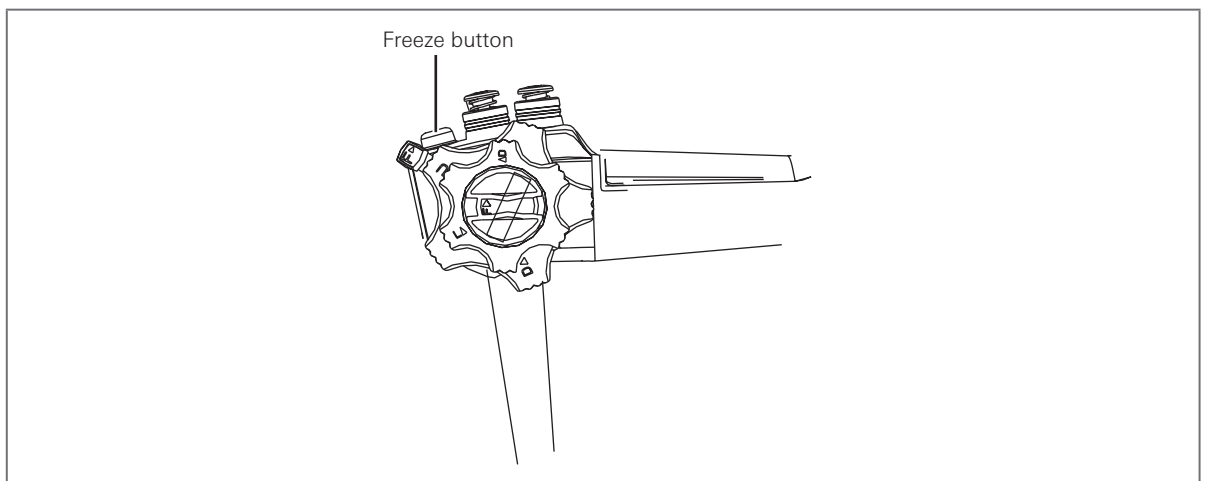


Figure 4.3

2. Press the playback button on the front panel of the video processor to view the frozen image on the screen frame by frame. If processor power is off, all saved images will be deleted from processor memory. To ensure desired images saved, connect a USB storage device always.
3. Press the freeze button on the handle or press the freeze button on the front panel of the video processor again to restore the real-time image.

4.2.3 Remote Printing

When compatible printer (SONY, UP-25MD) was connected as Figure 4.4 shows. The remote printing is workable.

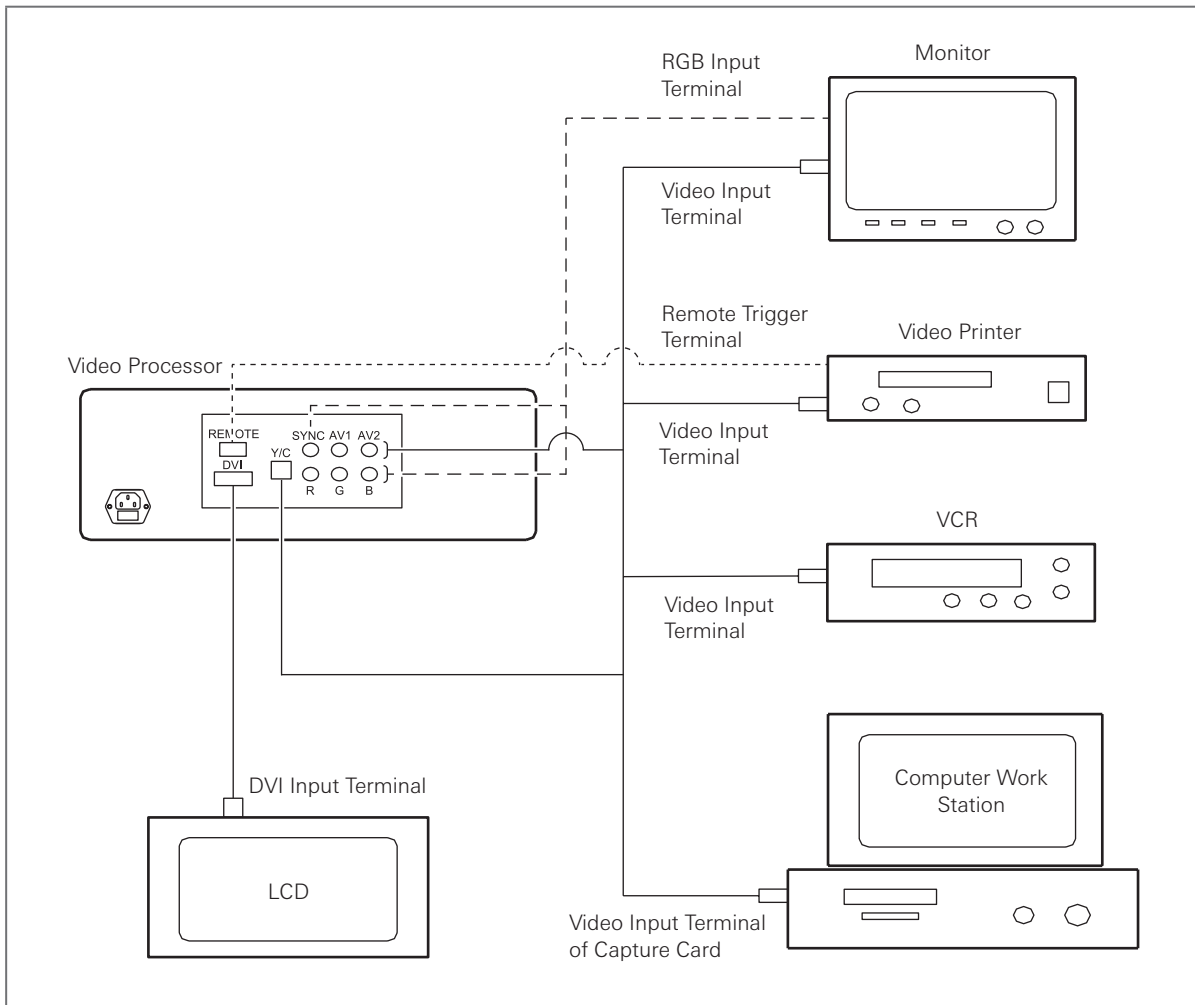


Figure 4.4

1. Press the remote trigger button on the handle of endoscope (see Figure 4.5) to trigger the image printing by compatible printer.

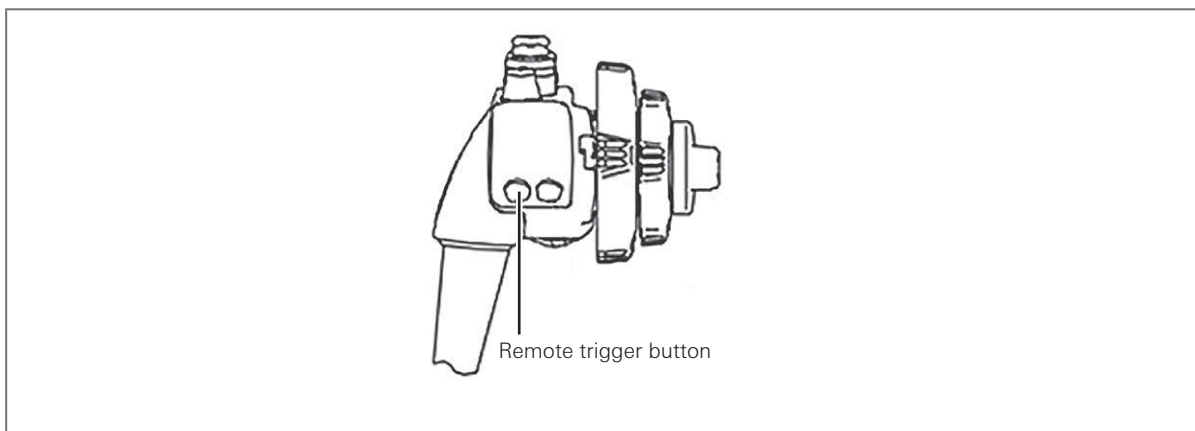


Figure 4.5

4-3. Using an Endoscopic Device

4

Operation



Warning

- NEVER use an endoscopic device showing signs of damage and/or operational abnormality. Doing so may result in endoscope malfunction or damage and/or patient injury.
- All reusable endoscopic devices must be cleaned or sterilized before initial use as well as before each subsequent use.
- Before using the endoscopic device, check its compatibility with the endoscope and read the respective IFU of the endoscopic device carefully. Incorrect use of the endoscopic device may result in damage to the endoscopic device and patient injury.
- When inserting or withdrawing the endoscopic device, ensure that its distal tip is closed or retracted within the sheath. Straighten the endoscopic device and slowly withdraw it. Failure to do so may result in inlet seal damage and/or falling of the broken inlet seal particle(s) into the patient's body cavity.
- Ensure that the distal tip of the endoscopic device is adequately projecting from the distal end of the endoscope before operating it. Failure to do so may result in damage to the instrument channel and/or falling of the broken instrument channel particle(s) inside the patient's body cavity.
- After the endoscopic device is inserted into the inlet seal, NEVER let it hang down. Ensure that the endoscopic device is supported with a hand and no load is applied to the inlet seal. Failure to do so may result in lowered suction function as well as potential reflux or dispersal of patient's body fluids, posing a risk of infection.
- Use only compatible endoscopic devices specified by PENTAX Medical. Using non-compatible endoscopic devices NOT specified by PENTAX Medical may result in clogging and/or damage to the instrument channel and/or endoscopic device. If a liquid such as sterile water or physiological saline is injected with a syringe from the instrument channel inlet while the instrument channel is clogged, the suction control valve may detach and result in potential reflux or dispersal of patient fluids, posing a risk of infection.
- Immediately stop the endoscopic procedure if the endoscopic device cannot be withdrawn from the endoscope. Do NOT attempt to forcefully withdraw the endoscopic device. Slowly and cautiously withdraw the endoscope in which the endoscopic device is inserted. Failure to do so may result in damage to the endoscopic device and/or instrument channel as well as potential reflux or dispersal of patient's body fluids, posing a risk of infection.



Caution

- Do NOT forcefully insert the endoscopic device when the instrument channel is clogged, as this may result in damage to the endoscope.
- Constantly check the endoscopic image while cautiously inserting and withdrawing the endoscopic device.
- Keep the endoscope bending section as straight as possible when inserting and withdrawing the endoscopic device. Forcefully inserting and withdrawing the endoscopic device may result in damage to the instrument channel and endoscopic device and/or patient injury.



Note

The instrument channel diameter is found on the model name label.

4.3.1 Insertion and Operation of the Endoscopic Device

1. Ensure that the distal tip of the endoscopic device is closed or retracted into the sheath. In case of biopsy forceps, operate the forceps to fully close the cups at the tip. There is a certain amount of resistance when inserting for the first time. Hold the shaft at approximately 5 cm away from its end, and press it in. (See Figure 4.6)

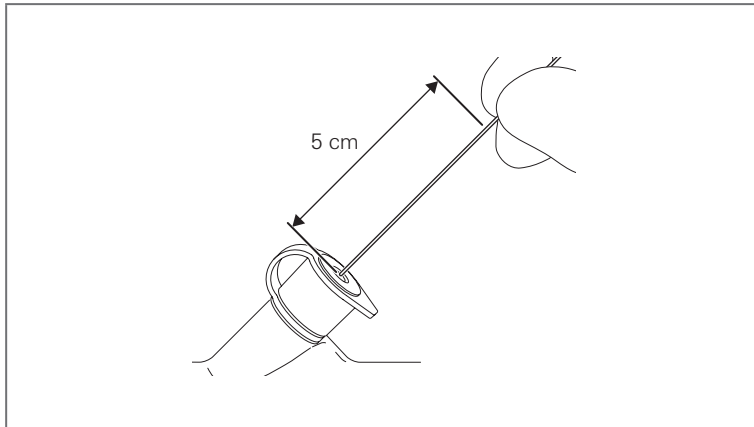


Figure 4.6

2. Slowly insert the endoscopic device, and check that the distal tip of the endoscopic device is within the field of view. (See Figure 4.7)

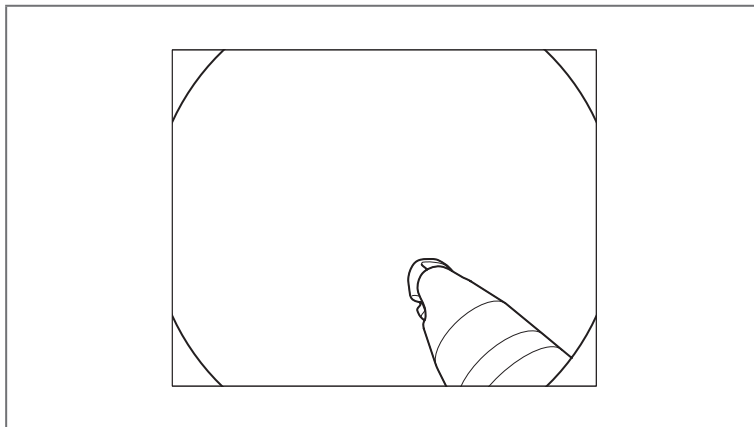


Figure 4.7

3. Operate the endoscopic device according to the IFU provided with it.

4.3.2 Withdrawal of the Endoscopic Device



Warning

- Do NOT forcefully withdraw the endoscopic device or in an oblique direction. Doing so may result in lowered suction function caused by inlet seal damage, falling of the broken inlet seal particle(s) into the patient's body cavity, and potential reflux or dispersal of patient's body fluids, posing a risk of infection. When withdrawing the endoscopic device, prevent the dispersal of patient's body fluids by covering the inlet seal with clean gauze, and withdraw the device slowly in a straight direction against the inlet seal.
- Immediately stop the therapeutic procedure if significant resistance is encountered when withdrawing the endoscopic device or if the endoscopic device cannot be withdrawn from the endoscope. Do NOT attempt to forcefully withdraw the endoscopic device. Failure to do so may result in equipment damage. Close or retract the distal tip of the endoscopic device and slowly withdraw the endoscope into which the endoscopic device is inserted.

1. Ensure that the distal tip of the endoscopic device is closed or retracted into the sheath.
2. Slowly withdraw the endoscopic device in a straight direction against the inlet seal. (See Figure 4.8)

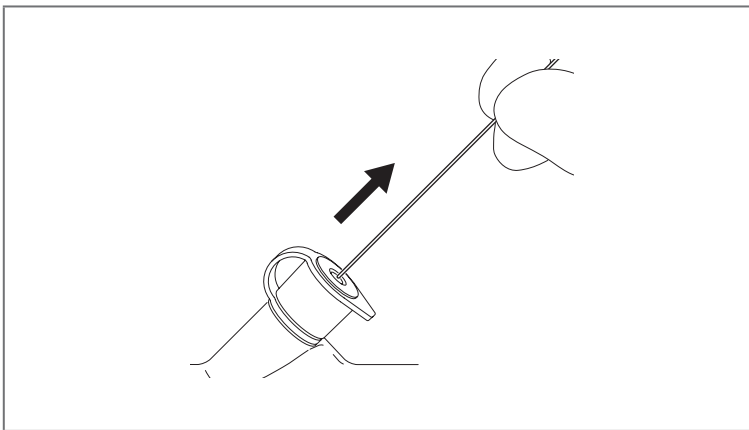


Figure 4.8

4-4. Use of the Electrosurgical Snare

- To ensure that a HF operation is safe, the insertion tube of the video endoscope is designed as insulated, and the insertion tube is isolated from the whole electric part of the above endoscope.
- To start operating, the user and his/her assistant must wear rubber gloves.
- The outer diameter of the HF instrument should not exceed Ø3.7 mm. For the insertion method, consult the operation instructions for the biopsy forceps and the HF instrument.
- To prevent any accidents, before performing a HF operation, make sure to operate the air valve of the video endoscope to repeatedly supply air to discharge any possibly existing combustion-supporting gas from inside the patient's stomach. Additionally, air feeding and suction should be provided to aspirate any waste gas caused by the HF operation.
- The power of the electrosurgical snare should not exceed 100 W (the output open-circuit voltage peak value should be not more than 1800 V).
- To perform a HF operation by use of a video endoscope, the operator should choose the right output power to achieve the expected purpose according to the actual clinical need and different burnt focuses (for example, the polyp size and the bleeding point size).
- HF operation involving a video endoscope may prolong blood coagulation time because of the incision or the use of the charged electrode of a conventional HF operation. If the output power is too low, this may injure the patient or harm the surrounding tissue due to overheating. Therefore, be particularly careful about adjustment of output power. (For detailed operations, consult the instructions for the electrosurgical snare and the HF instrument.)

4-5. Withdraw the Endoscope

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

1. Aspirate accumulated air, blood, mucus, or other debris by pressing the suction valve.
2. Turn the UP/DOWN and RIGHT/LEFT angulation locks to the "F▼" direction to release them.
3. Carefully withdraw the endoscope while observing the endoscopic image.

4.5.1 Withdrawal of the Video Endoscope

Loosen the up/down angulation lock and left/right angulation lock, confirm that you can withdraw the video endoscope from the patient after making the bending section straight.

1. After using the video endoscope, be sure to switch off the power supply of the video processor, and disconnect the light guide connector from the video processor.
 - Since the video processor causes the surface temperature of the exit window at the front end of the light guide connector may exceed 41°C, you cannot immediately touch it with your hands or skin as soon as withdrawing the light guide of this endoscope; After a while (at least two minutes), you can touch it on the hand or skin to prevent from being scalded.

4-6. Transportation of the Endoscope

4.6.1 Transporting within the Hospital

- Set the insertion tube to the most-flexible condition.
- When carrying the endoscope by hand, loop the universal cord, hold the light guide connector together with the control section in one hand and hold the distal end of the insertion tube securely, but gently without squeezing, in the other hand.

4.6.2 Transporting outside the Hospital

Transport the endoscope in the carrying case.



Warning

Always clean, disinfect or sterilize the endoscope after removing it from the carrying case. If the endoscope is not cleaned, disinfected or sterilized, it could pose an infection-control risk.



Caution

- The carrying case cannot be cleaned, disinfected or sterilized. Clean and disinfect or sterilize the endoscope before placing it in the carrying case.
- Do not attach the water-resistant cap when transporting the endoscope, to avoid damage to the endoscope caused by changes in air pressure.
- Before putting the endoscope in the carrying case, always make sure that the insertion tube is set to the most-flexible condition. Putting the endoscope in the carrying case while the insertion tube is rigid could damage the endoscope.

4-7 . Transportation and Storage of the Endoscope

Transportation and storage conditions

- Ambient temperature range: -40 to +55°C
- Relative humidity range: ≤93% (40°C)
- Atmospheric pressure range: 595 to 1060 hPa
- The video endoscope should be stored in an indoor environment with no corrosive gas and good ventilation.
- Before storage, make sure to completely dry the video endoscope and try to keep it straight, and store the insertion tube in an environment without any external force influence.
- The endoscope box is not for safeguard. Do not safeguard the video endoscope in an endoscope box to avoid any infection.

4-8 . Disposal



Warning

Follow the national or local laws/guidelines to appropriately dispose of the consumables.
Failure to do so may create a risk of cross contamination or infection.

Contact your local PENTAX Medical service facility when disposing of the endoscope(s).

5

Cleaning and Disinfection

If the endoscope was not cleaned for a long time, cross-contamination may occur, and the endoscope may not be working properly. Every 150 processing cycles, the product must be returned to PENTAX Medical facility for checking.



Warning

- After every endoscopy, cleaning and disinfection should be conducted immediately.
- Do not immerse the endoscope for too long time, since frequent or long-time immersion in the disinfectant will increase inner humidity of the endoscope and destroy imaging system, which results in lens blur, or even damage to the sensor.
- It is strictly prohibited to disinfect the endoscope by ultrasonic cleaner or autoclave.



Note

The instructions provided below have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials, and personnel in the processing facility, achieves the desired result. This requires verification, validation or both and routine monitoring of the process.

5-1 . Initial Treatment at the Point of Use

1. Before the endoscope is removed from the video processor, immediately use a clean lint-free cloth dampened with detergent to remove all visible dirt after endoscopy. Lint-free cloth should be one-time use.
2. Switch on the air pump of the video processor, and adjust the air feeding pressure to the maximum, cover and press the air/water valve to feed water into the air/water channel for 30s and release the air/water valve to feed air into the air/water channel for 10s.
3. Switch on the suction pump. Install the biopsy valve. Immerse the distal end of the endoscope in the detergent and press the suction valve to aspirate detergent into the instrument channel for 30s. Then take out the distal end from the detergent and press the suction valve to aspirate air for 10s.



Note

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

4. Switch off the suction pump.
5. Use a 50 mL syringe to inject sterile water into the auxiliary water-feeding channel through the auxiliary water-feeding port at least 4 times (200 mL) then inject air into the auxiliary water-feeding channel at least 8 times (400 mL) (applied only to the waterjet endoscope).
6. Remove the suction hose and auxiliary water hose (applied only to the waterjet endoscope) from the endoscope, disconnect the endoscope from the video processor and remove the water bottle hose, the air/water valve, suction valve, and biopsy valve from the endoscope.
7. Attach the water-resistant cap onto the endoscope, put the endoscope, air/water valve, suction valve, and biopsy valve into a delivery container and transport them to the processing room.

5-2. Preparation before Cleaning

The endoscope is a totally waterproof product (after installing the water-resistant cap). It can be immersed and cleaned thoroughly. But before immersing, the sealing of the endoscope should be inspected.

1. Connect the leakage tester to the endoscope according to the method as follows. (See Figure 5.1)

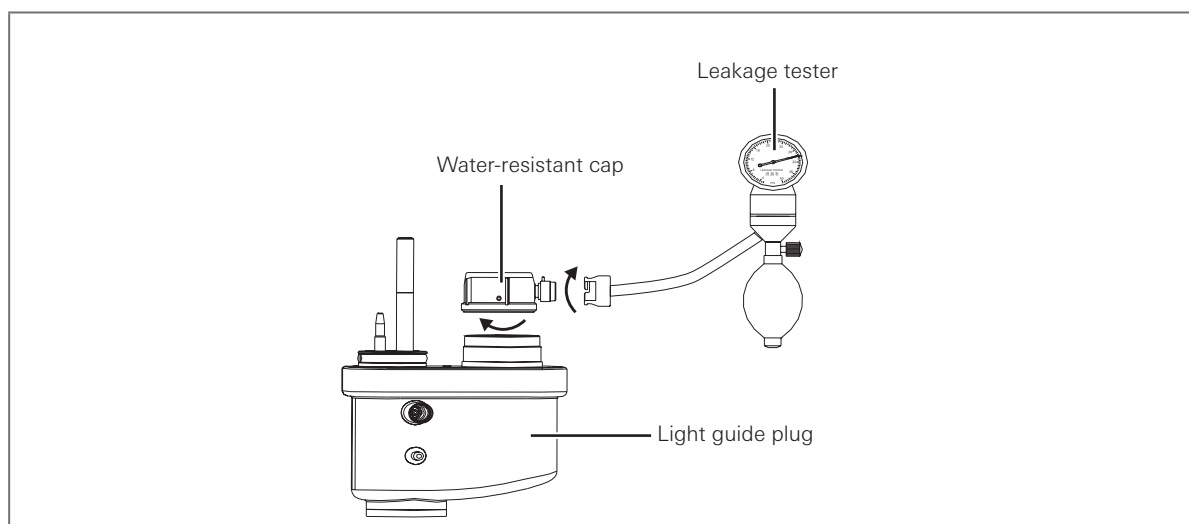


Figure 5.1

2. Stop inflating the leakage tester until the pointer of the gauge reaches the red line.
3. If the pointer slowly falls, then continue to slowly inflate the endoscope (not exceed 30 kPa, otherwise the endoscope will be damaged), and put the endoscope in water to observe whether there are bubbles continuously bubbling up from the surface of the endoscope or not (normally, 3 or less bubbles per minute is acceptable).

If there is not any change of the leakage tester's pointer, it means the endoscope has a sound sealing performance and the endoscope is available for cleaning.



Caution

- Ensure the firm connection between the water-resistant cap and the endoscope connector..
- The continuous bubbles indicate leakage. Immediately stop using the endoscope and contact your local PENTAX Medical facility.
- To avoid discontinuation of endoscopic procedure, have an extra (spare) instrument available as a standby device. Should not be any unforeseen event or circumstance render the original instrument inoperable and/or unsafe for patient.

5-3. Manual Cleaning

1. Immerse the entire endoscope, air/water valve, suction valve, and biopsy valve in the detergent.
2. Use a clean lint-free cloth to wipe the outer surface of the entire endoscope in the detergent, especially the insertion section and control section. Ensure that the outer surface is cleaned completely.
3. According to the following steps, brush the suction channel, suction cylinder, instrument channel port, air/water valve, suction valve, and biopsy valve (as shown in Figure 5.2):

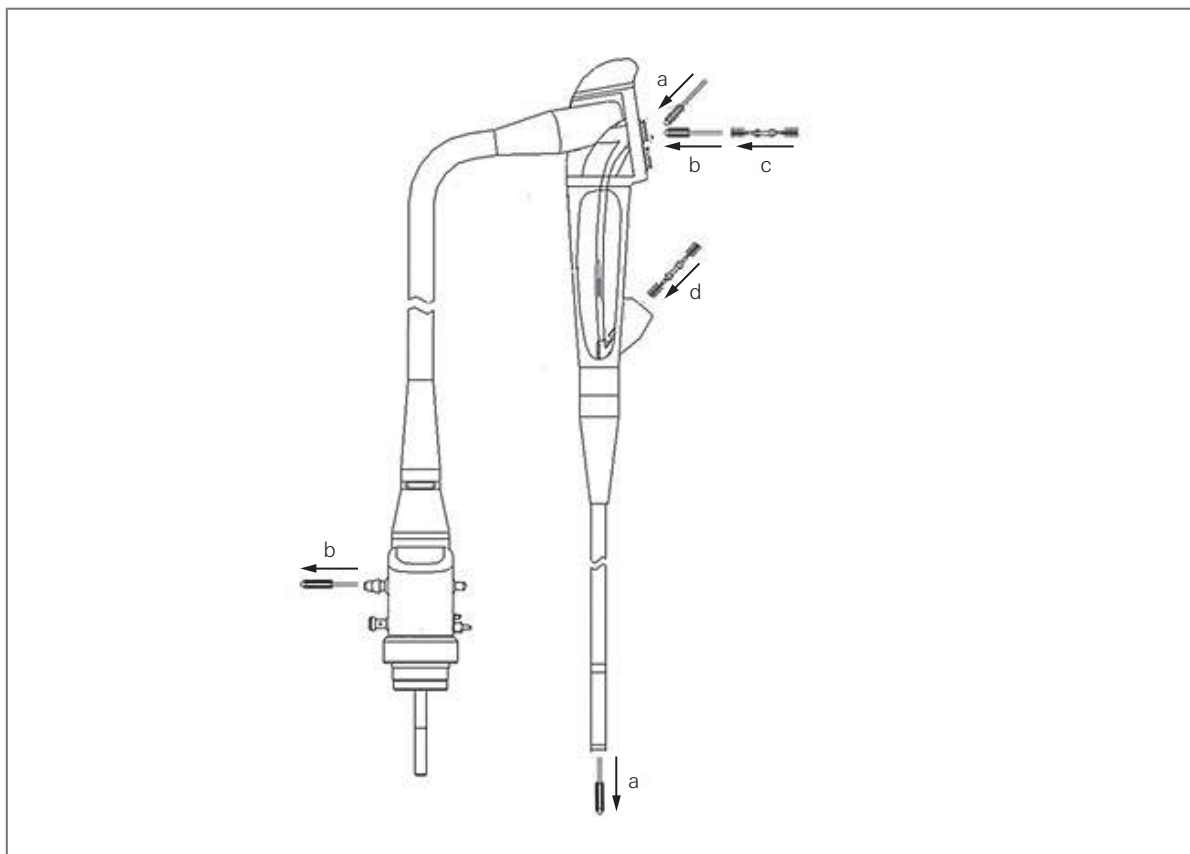


Figure 5.2



Caution

- If observed that the device is not completely cleaned when the cleaning step is completed, repeat the cleaning step.
- The cleaning brush should not be in reverse motion, it should be pulled back until the head completely exposed from the distal end. Otherwise, it will damage the internal surface of the channel.
- Lint-free cloth should be for one-time use.
- The detergent should be replaced after each use.

To brush the suction channel from the control section to the distal end (a)

- a. Straighten the bending section of the endoscope.
- b. Insert the cleaning brush at a 45° angle into the suction cylinder, slowly advance the brush until the brush head emerges from the distal end.
- c. Clean the channel cleaning brush with your fingertips in the detergent, and then pull out the brush from the suction cylinder carefully.
- d. Clean the channel cleaning brush with your fingertips in the detergent again.
- e. Operate the procedure at least 3 times to ensure that no debris is left.

To brush the suction channel from the control section to the light guide plug (b)

- a. Insert the cleaning brush straightly into the suction cylinder, slowly advance the brush until the brush head emerges from the suction connector.
- b. Clean the channel cleaning brush with your fingertips in the detergent, and then pull out the brush from the suction cylinder carefully.
- c. Clean the channel cleaning brush with your fingertips again.
- d. Operate the procedure at least 3 times to ensure that no debris is left.

To brush the suction cylinder (c)

- a. Insert the channel-opening cleaning brush into the suction cylinder until half of the brush reaches the cylinder.
- b. Rotate the channel-opening cleaning brush once.
- c. Pull out the channel-opening cleaning brush and clean the brush with your fingertips in the detergent.
- d. Operate the procedure at least 3 times to ensure that no debris is left.

To brush the air/water valve, suction valve, and biopsy valve (d)

- a. Scrub the air/water valve and the suction valve thoroughly with the channel-opening cleaning brush until all the debris is removed.
 - b. Scrub the inside and opening of the biopsy valve thoroughly with the channel-opening cleaning brush until all debris is removed.
4. Inject detergent into each channel.
- a. Plug the suction cylinder, air/water cylinder, and instrument channel port with the channel plug. Plug the water bottle connector with sealing plug. Connect the injection tube to the suction cylinder and instrument channel port of the endoscope and ensure that the endoscope is thoroughly immersed in the detergent.
 - b. Use a 50 mL syringe to respectively inject detergent into the air/water channel and suction channel of the endoscope through the injection tube at least 4 times (200 mL) (as shown in Figure 5.3). Use a 50mL syringe to inject detergent into the auxiliary water channel through the auxiliary water port at least 4 times (200 mL) (applied only to the waterjet endoscope).
 - c. Disconnect all the channel plugs and injection tube from the endoscope and immerse them in the detergent.

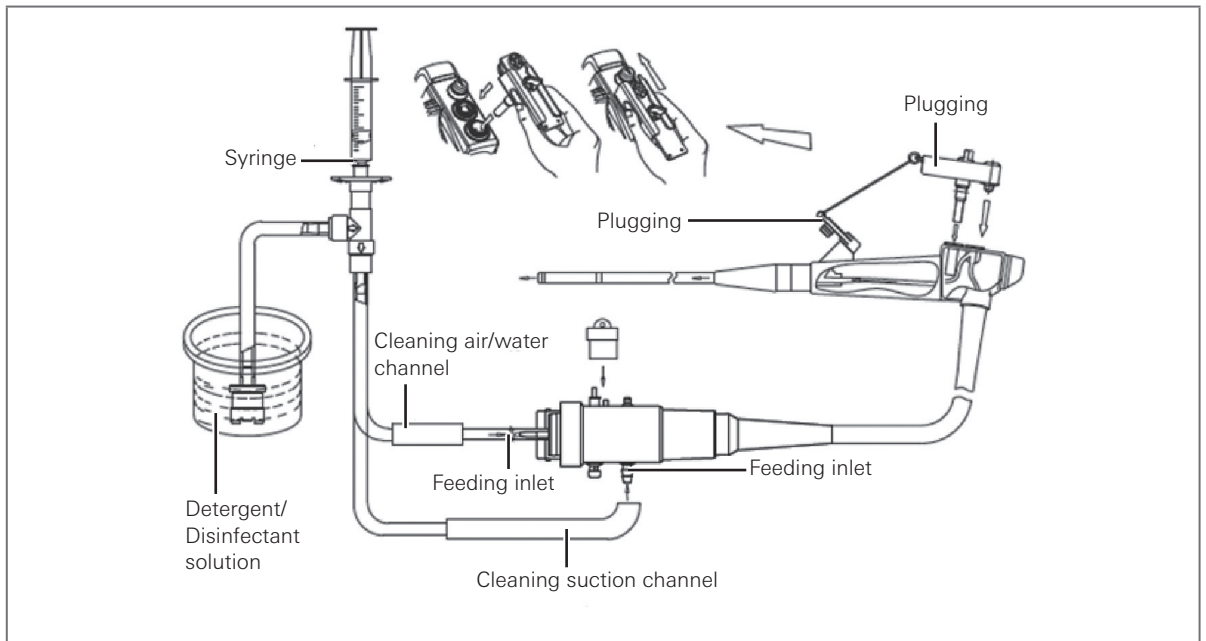


Figure 5.3

5. Cover the manual cleaning tank with a seal cover to reduce detergent volatilization.
6. Immerse the entire endoscope, air/water valve, suction valve, biopsy valve, and all ancillary components in accordance with the immersion time, temperature, and detergent concentration recommended by the manufacturer.

Cleaning reagent: neodisher® MediClean forte

Concentration: 5 to 30 mL per 1 L water

Temperature: 40°C at maximum

Soaking time: 2 to 10 min.

5-4. Rinsing after Manual Cleaning

1. Transfer the cleaned endoscope, air/water valve, suction valve, and biopsy valve into the rinse tank.
2. Plug the suction cylinder, air/water cylinder, instrument channel port with the channel plug. Plug the water bottle connector with the sealing plug. Connect the injection tube to the endoscope.
3. Use a 50 mL syringe to respectively inject sterile water into the air/water channel of the endoscope through the injection tube at least 4 times (200 mL) and into the suction channel of the endoscope through the injection tube at least 8 times (400 mL). Use a 50 mL syringe to inject sterile water into the auxiliary water channel through the auxiliary water port at least 4 times (200 mL) (applied only to the waterjet endoscope).
4. Wash the outer surface of the endoscope, air/water valve, suction valve, and biopsy valve with running water, and place them in a sterile container.
5. Use a 50 mL syringe to respectively inject air into the air/water channel of the endoscope through the injection tube at least 8 times (400 mL) and into the suction channel of the endoscope through the injection tube at least 16 times (800 mL).
6. Disconnect all ancillary components from the endoscope.
7. Dry the outer surface of the endoscope, air/water valve, suction valve, and biopsy valve with a clean lint-free cloth. The used lint-free cloth should be replaced.
8. Check endoscope and other cleaning and sterilizing components for residue. If there is still debris, wipe the surface again until there is no debris left.

5-5. Disinfection



Warning

- The immersion disinfection time of endoscope should be no less than 5 minutes, but do not immerse the endoscope for too long time. Since frequent or long-time immersion in the disinfectant will increase inner humidity of the endoscope and destroy imaging system, which results in lens blur, or even damage to the sensor.
- It is strictly prohibited to disinfect the endoscope by ultrasonic cleaner or autoclave.

1. Transfer the dried endoscope, air/water valve, suction valve, and biopsy valve to the disinfection tank, and immerse them in the disinfectant.
2. Plug the suction cylinder, air/water cylinder, instrument channel port with the channel plug. Plug the water bottle connector with the sealing plug. Connect the injection tube to the endoscope and ensure that the endoscope is thoroughly immersed in the disinfectant.
3. Use a 50 mL syringe to respectively inject disinfectant into the air/water channel and suction channel of the endoscope through the injection tube at least 4 times (200 mL). Use a 50 mL syringe to inject disinfectant into the auxiliary water channel through the auxiliary water port at least 4 times (200 mL) (applied only to the waterjet endoscope). Make sure no bubbles pop out of the head.



Note

Ensure that the syringe connector of the injection tube is completely immersed in the disinfectant. Ensure that all channels of the endoscope are filled with disinfectant.

4. Disconnect all the channel plugs and injection tube from the endoscope and immerse them in the disinfectant.
5. If bubbles are attached on the endoscope surface or the tools, wipe the bubbles off with a clean lint-free cloth.
6. Cover the disinfection tank with a seal cover to reduce disinfectant volatilization.
7. Immerse the entire endoscope, air/water valve, suction valve, biopsy valve, and all cleaning and disinfecting accessories in accordance with the disinfection immersion time, temperature, and disinfectant concentration recommended by the manufacturer.
8. Replace the gloves and use a 50 mL syringe to respectively inject air into the air/water channel and suction channel of the endoscope through the injection tube at least 8 times (400 mL). Use a 50 mL syringe to inject air into the auxiliary water channel through the auxiliary water port at least 4 times (200 mL) (applied only to waterjet endoscope).

Cleaning reagent: CIDEX® OPA

Concentration: 0.55% o-Phthalaldehyde

Temperature: Room temperature

Soaking time: ≥5 min.

5-6. Rinsing after Disinfection

1. Transfer the endoscope, air/water valve, suction valve, and biopsy valve into the final rinse tank.
2. Plug the suction cylinder, air/water cylinder, and instrument channel port with the channel plug. Plug the water bottle connector with sealing plug. Connect the injection tube to the endoscope.
3. Use a 50 mL syringe to respectively inject sterile water into the air/water channel and suction channel of the endoscope through the injection tube at least 4 times (200 mL). Use a 50 mL syringe to inject sterile water into the auxiliary water channel through the auxiliary water port at least 4 times (200 mL) (applied only to the waterjet endoscope).
4. Wash the outer surface of the endoscope, air/water valve, suction valve, and biopsy valve with running water, and place them in a sterile container.
5. Use a 50 mL syringe to respectively inject air into the air/water channel of the endoscope through the injection tube at least 8 times (400 mL) and into the suction channel of the endoscope through the injection tube at least 16 times (800 mL). Use a 50 mL syringe to inject air into the auxiliary water channel through the auxiliary water port at least 8 times (400 mL) (applied only to the waterjet endoscope).
6. Disconnect the injection tube and connect the sterile suction tube on the suction pump to the suction connector of the endoscope. Turn on the suction pump to aspirate air at least 15s.
7. Turn off the suction pump and disconnect the suction pump and all ancillary components from the endoscope.

5

5-7. Drying

1. Place the endoscope, air/water valve, suction valve, and biopsy valve on the sterile towel. Sterile towel should be replaced every 4 hours.
2. Plug the suction cylinder, air/water cylinder, instrument channel port with the channel plug. Plug the water bottle connector with sealing plug. Connect the injection tube to the endoscope.
3. Use a 50 mL syringe to respectively inject 75 to 95% alcohol into the air/water channel and suction channel of the endoscope through the injection tube at least 4 times (200 mL). Use a 50 mL syringe to inject alcohol into the auxiliary water channel through the auxiliary water port at least 4 times (200 mL) (applied only to the waterjet endoscope).



Note

- The use of alcohol is OPTIONAL. Use alcohol ONLY in accordance with local regulations/guidance.
 - Alcohol is flammable and must be used safely.
4. Use a 50 mL syringe to respectively inject air into the air/water channel and suction channel of the endoscope through the injection tube at least 8 times (400 mL). Use a 50 mL syringe to inject air into the auxiliary water channel through the auxiliary water port at least 8 times (400 mL) (applied only to the waterjet endoscope).
 5. Dry the outer surface of the endoscope, air/water valve, suction valve, and biopsy valve with a sterile lint-free cloth.
 6. Dry the inner surface of the air/water cylinder, suction cylinder, and instrument channel port with sterile swab.
 7. Install the water/air valve, suction valve, and biopsy valve to the endoscope.

5-8. Automatic Cleaning and Disinfection

Cleaning reagent: neodisher® Mediclean forte

Concentration: 5 to 30 mL cleaner per 1 L water

Temperature: Maximum 40°C

Soaking time: 2 to 10 min.

1. Pre-cleaning: 2 to 10 min.
2. Cleaning: 2 to 10 min.
3. Rinsing 1: 5 to 10 min.
4. Rinsing 2: 5 to 10 min.

Disinfectant: PL 12 medical peracetic acid disinfectant

Concentration: 0.2 to 0.35% peracetic acid

Temperature: Room temperature

1. Disinfecting: 5 min.
2. Rinsing 1: 3 to 4 min.
3. Rinsing 2: 3 to 4 min.
4. Drying 1: 200 mL
5. Drying 2: 2 min.



Caution

Refer to the user manual of the washer disinfectant(s) for operation procedures including the connection specifications method also.

5-9. Maintenance, Inspection, and Testing

1. To prevent severe damage to the endoscope caused by water leakage and a large amount of repair expenses, check the endoscope's water tightness before cleaning and disinfecting it.
2. If the endoscope failed in leakage test, contact PENTAX Medical facility for repair.



Caution

The endoscope does not contain any user-serviceable parts. Do not disassemble, modify, or attempt to repair it. Otherwise, patient or operator injury, equipment damage, and/or the failure to obtain the expected functionality can result. The endoscope should be repaired by PENTAX Medical authorized personnel only.

5-10 . Packaging and Sterilization

1. After disinfection, the endoscope shall be used on the patient immediately. After storage at which sterility cannot be assured. Before use, the endoscope is required to be re-processed.
2. The endoscope has not been validated for sterilization and there is no mandatory requirement in EEA countries where products are put into use. Contact PENTAX Medical facility if sterilization is required.

5-11 . Storage and Additional Information

1. The angulation lock knob must be in free position. Hang the endoscope in a dust free and well-ventilated cabinet.
2. Put the water-resistant cap on the electric connector at the light guide plug to avoid water inflow or moisture.



Caution

- The hand-carry case is not for storage.
- Contact PENTAX Medical facility for proper hanging.

3. The following disinfection methods which will cause major faults to the endoscope should be prohibited.
 - Heating and pressing EGO disinfection at the atmospheric pressure of over 1.5 and the temperature over 40°C
 - USC or disinfection
 - Scalding
 - Disinfection by drying
 - Steam disinfection
 - Disinfection by cresol solution or formaldehyde
 - Cleaning by using chlorobenzene and disinfection by the disinfectant solution not diluted
4. According to the long-term test and clinical application, the following detergent and disinfectant are safe for the endoscope if correctly used.
 - Detergent: Medical low-foam enzyme detergent
 - Disinfectant: Glutaraldehyde/PAA-based reprocessing chemicals
5. During disinfection or when the endoscope is not used, put the water-resistant cap on the electric connector at the light guide plug to avoid water inflow or moisture.

6 Troubleshooting

Generally, the following troubles may happen to the video endoscope. If the problems cannot be resolved by described inspection method, stop using the video endoscope immediately and contact your local PENTAX Medical service facility.

Failure	Inspection method
An image is unclear or has interference.	Make sure that the voltage is stable, or the lens is clean.
Water drops or stripes	Contact your local PENTAX Medical service facility.
No illumination or dim light	Confirm that the video processor and the light guide connector are in place.
Inadequate angulation or angulation failing to actuate	Contact your local PENTAX Medical service facility.
Angulation lock malfunction	Contact your local PENTAX Medical service facility.
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	Make sure that the connection between 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 the insertion tube	Contact your local PENTAX Medical service facility.
Cracks on the observation window and the illuminating window	Contact your local PENTAX Medical service facility.



Caution

- Contraindications of a video endoscope: patients with contracting heart, liver, kidney, lung and hemorrhagic diseases.
- After being used a period of time, the distal end of the endoscope may burn human body if it touches human body inside, so keep an eye on this point at any time when using the endoscope.
- When use an endoscope with a strong light source, the video endoscope has a strong illuminating capacity. Once the distal end of it closes to mucosa, strong light will focus on a very small area. Thus, the surface temperature in this area can rise, may cause burns. Besides, the endoscope doesn't adjust light automatically, please manually reduce brightness while observing the equipment closely.

Under the following circumstances, growing risk of burns may result:

- Propel the video endoscope along the narrow lumen;
- Use the light source with high brightness.

To reduce the risk of burn, adopting the following methods:

- Manually turn down light to reach the minimum brightness necessary for full observation.
- Don't storage the video endoscope in a high temperature, humid, and dusty environment.
- If the video endoscope is exposed in X-ray, the internal CMOS and other meticulous component will be aged and change color.
- Do not align the distal end of the video endoscope with strong light (e.g., sunlight, emergent light of a light source, etc.) because CMOS as a sensitive, precision device is easily damaged.
- For equipment connecting with the endoscope, such as the video processor, 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).
- To use the video endoscope together with the video processor, better connect a voltage regulator with over 1000 W and automatic regulation function. Don't use a voltage regulator for household purpose on the video endoscope and the processor.
- As the video 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 video endoscope before sending the above endoscope back to our company for repair. If the endoscope is used by any Hepatitis A positive patient or those developing other infectious diseases, inform us in advance.

EMC Information

EMI Compliance Table

Table 1: Emission		
Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class A	Professional healthcare facility environment
Harmonic distortion	IEC 61000-3-2 Class A	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Professional healthcare facility environment



Note

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

EMS Compliance Table

Table 2: Enclosure port		
Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz–2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Table 3: Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380–390	Pulse modulation 18 Hz, 27 V/m
450	430–470	FM, ± 5 kHz deviation, 1 kHz sine, 28 V/m
710	704–787	Pulse modulation 217 Hz, 9 V/m
745		
780		
810	800–960	Pulse modulation 18 Hz, 28 V/m
870		
930		
1720	1700–1990	Pulse modulation 217 Hz, 28 V/m
1845		
1970		
2450	2400–2570	Pulse modulation 217 Hz, 28 V/m
5240	5100–5800	Pulse modulation 217 Hz, 9 V/m
5500		
5785		

Table 4: Input a.c. power port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 Vrms, 0.15 MHz–80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11	0% U_T ; 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% U_T ; 1 cycle and 70% U_T ; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T ; 250/300 cycles

Table 5: Signal input/output parts port		
Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 Vrms, 0.15 MHz–80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz

Table 6: Patient coupling port		
Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 Vrms, 0.15 MHz–80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz



Warning

1. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the EC38-V10cM/EC38-V10cL, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could occur.
2. The EC38-V10cM/EC38-V10cL is intended for use in Professional healthcare facility environment.
3. The installation and operation of the equipment shall be carried out in strict accordance with the EMC (electromagnetic compatibility) information provided in this IFU:
 - The essential performance of the video colonoscope enables the endoscope to display a complete outline and effective real-time image when the image processor and the cold light source of the endoscope work together, ensuring that there is no unacceptable risk if the image being observed by the operator has unexpected image orientation. When in use, a preliminary judgment is usually made on the basic performance of the equipment by visual inspection, so as to facilitate subsequent normal use.
 - Do not use the device with other non-supporting electronic devices to avoid electromagnetic interference.
 - Do not use the device in close proximity to or in a stack with other devices. If the device must be used in close proximity to or in a stack, observe and verify that the device can work properly under the configuration.
 - This device shall not be used in the same room with other devices such as life support devices, other devices that have a serious impact on the patient's life or treatment outcomes, or low-current measurement or treatment devices.
 - Do not use or keep the device away from portable and mobile communication devices, as this may affect the normal operation of the device.
 - Do not use cables and accessories that do not meet the specifications of the device. This may increase the emission of electromagnetic waves from the device or system and reduce the anti-interference capability of the device.

Contacts

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- TÜV Süd CE0123: Medical device class: IIa



- The product must be used only by healthcare professionals. Before usage and for detailed product specifications, please refer to the instructions for use (IFU).
- Product specifications are subject to change without notice or obligation.
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