OLYMPUS®

OPERATION MANUAL

INSTRUCTIONS

EVIS EUS

EVIS EUS ULTRASOUND BRONCHOFIBERVIDEOSCOPE

OLYMPUS BF-UC190F

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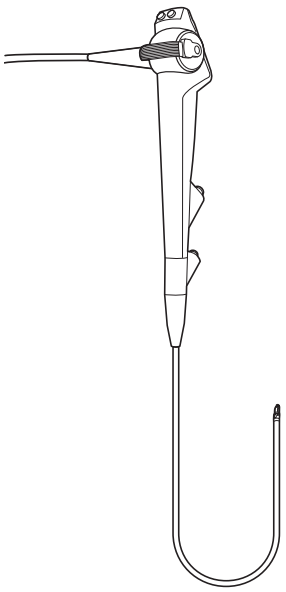
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CAUTION: Balloons used with this product contain natural rubber latex, which may cause allergic reactions.

Refer to the endoscope's companion manual, the "REPROCESSING MANUAL" with your endoscope model listed on the cover, for reprocessing information.

CE 0197

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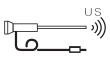
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Symbols

The meaning(s) of the symbol(s) shown on the component packaging, the back cover of the instruction manual, and/or the instrument are as follows:

Symbol	Description
	Refer to instructions.
	Caution
	TYPE BF applied part
	Single use only
	Do not resterilize
LOT	Lot number
	Use by (expiration date)
STERILE LOT	Sterilization lot number
STERILE R	Sterilized using irradiation
	Manufacturer
EC REP	Authorized representative in the European Community
SN	Serial number
IPX7	Ingress protection rating is 7. (except for connectors)
	Ultrasound endoscope

Symbols

Symbol	Description
	Keep away from sunlight
	Keep dry
	Do not use if package is damaged
	Contains or Presence of Natural Rubber Latex
	Lock the ultrasound cable connector
	Release the ultrasound cable connector
	Translation
	Importer (into European Union)
	Date of Manufacture

Important Information — Please Read Before Use

■ Intended use

This instrument has been designed to be used with diagnostic ultrasound system, video system center, light source, documentation equipment, display monitor, EndoTherapy accessories such as an aspiration biopsy needle.

This instrument is designed for endoscopic real-time ultrasound imaging, for performing endoscopic ultrasound guided needle aspiration within the airways, tracheobronchial tree, esophagus and surrounding organs.

■ Applicability of endoscopy and endoscopic treatment

If there are official standards on the applicability of endoscopy and endoscopic treatment that are defined by the healthcare facilities administrations or other official institutions, such as academic societies on endoscopy, follow those standards. Before starting endoscopy and endoscopic treatment, thoroughly evaluate its properties, purposes, effects, and possible risks (their nature, extent, and probability). Perform endoscopy and endoscopic treatment only when its potential benefits are greater than its risks.

Fully explain to the patient the potential benefits and risks of the endoscopy and endoscopic treatment as well as any examination/treatment methods that can be performed in its place, and perform the endoscopy and endoscopic treatment only after obtaining the consent of the patient.

Even after starting the endoscopy and endoscopic treatment, continue to evaluate the potential benefits and risks, and immediately stop the endoscopy/treatment and take proper measures if the risks to the patient become greater than the potential benefits.

■ *Instruction manual*

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals for all the equipment that will be used during the procedure and use the equipment as instructed.
Note that the complete instruction manual set for this endoscope consists of this manual and the “REPROCESSING MANUAL” with your endoscope model listed on the cover. It also accompanied the endoscope at shipment.
Keep this and all related instruction manuals in a safe, accessible location.
If you have any questions or comments about any information in this manual, contact Olympus.

❍ Terms used in this manual

WLI (White Light Imaging) observation

This is observation using white light.

Image sensor

The image sensor is a device that converts light into electrical signals.

Elastography

Mode for displaying the relative elasticity information of a tissue using color images. For more details, refer to the instruction manual for the ultrasound instrument that elastography is available.

■ *User qualifications*

If there are official standards for user qualifications to perform endoscopy and endoscopic treatment that are defined by the healthcare facilities medical administrators or other official institutions, such as academic societies on endoscopy, follow those standards. If there are no official qualification standards, the operator of this instrument must be a physician approved by the medical safety manager of the healthcare facility or person in charge of the department (department of internal medicine, etc.).

The physician should be capable of safely performing the planned endoscopy and endoscopic treatment following guidelines set by the academic societies on endoscopy, etc., and considering the difficulty of endoscopy and endoscopic treatment. This manual does not explain or discuss endoscopic procedures.

■ *Instrument compatibility*

Refer to “Combination equipment” on page 97 to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient or operator injury and/or equipment damage.

This instrument complies with the EMC standard for medical electrical equipment, edition 4 (IEC 60601-1-2: 2014).
When connecting to an instrument that complies with a previous edition of the EMC standard for medical electrical equipment edition, the EMC characteristics could be vulnerable.

■ *Reprocessing before the first use/reprocessing and storage after use*

This instrument was not reprocessed before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in the endoscope’s companion “REPROCESSING MANUAL” with your endoscope model listed on the cover.
After using this instrument, reprocess and store it according to the instructions given in the endoscope’s companion reprocessing manual. Improper and/or incomplete reprocessing or storage can pose an infection control risk, cause equipment damage, or reduce performance.
The balloons are disposable, and are intended for a single use only; a new one must be used for each patient. Do not attempt to reuse or resterilize a balloon.

■ *Spare equipment*

Be sure to prepare another endoscope to avoid interruption of the examination due to equipment failure or malfunction.

■ *Maintenance management*

The probability of failure of the endoscope and ancillary equipment increases as the number of procedures performed and/or the total operating hours increase. In addition to the inspection before each procedure, the person in charge of medical equipment maintenance in each healthcare facility should inspect the items specified in this manual periodically following regulations, guidelines, etc. required of you. An endoscope with an observed irregularity should not be used, but should be inspected by following Section 5.2, “Troubleshooting guide”. If the irregularity is still observed after inspection, contact Olympus.

■ *Prohibition of improper repair and modification*

This instrument does not contain any user-serviceable parts. Do not disassemble, modify, or attempt to repair it; patient or operator injury and/or equipment damage may result.
Equipment that has been disassembled, repaired, altered, changed, or modified by persons other than Olympus' own authorized service personnel is excluded from Olympus' limited warranty and is not warranted by Olympus in any manner.

■ *Signal words*

The following signal words are used throughout this manual:

WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.
NOTE	Indicates additional helpful information.

■ *Warnings and cautions*

Follow the warnings and cautions given below when handling this endoscope. This information is to be supplemented by the warnings and cautions given in each chapter.

WARNING

- Do not use this endoscope for any purpose other than its indications for use. Patient or operator injury and/or equipment damage may result.
- After using this endoscope, reprocess and store it according to the instructions given in the endoscope's companion "REPROCESSING MANUAL" with your endoscope model listed on the cover. Using improperly or incompletely reprocessed or stored instruments may cause patient cross-contamination and/or infection.
- This endoscope has a "forward oblique" view. There is a difference between the direction of view and the insertion direction of the endoscope. The insertion direction appears in the lower portion of the endoscopic view, and the visible area in that direction is limited. Always view the endoscopic image carefully, and insert the endoscope prudently. Otherwise, patient injury may occur.

WARNING

- This endoscope is incompatible with laser cauterization. Performing laser cauterization may cause patient injury and/or equipment damage.
- Never use high-frequency EndoTherapy accessories, because the distal end of this instrument is not isolated.
  Using high-frequency accessories places the patient at risk of an electric shock.
- Do not strike, hit, or drop the endoscope's distal end, insertion tube, bending section, control section, universal cord, or endoscope connector. Also, do not bend, pull, or twist the endoscope's distal end, insertion tube, bending section, control section, universal cord, or endoscope connector with excessive force. The endoscope may be damaged and could cause patient injury, burns, bleeding, and/or perforations. It could also cause parts of the endoscope to fall off inside the patient.
- Never perform angulation control forcibly or abruptly. Never forcefully pull, twist, or rotate the angulated bending section. Patient injury, bleeding, and/or perforation may result. It may also become impossible to straighten the bending section during an examination.
- Never perform high-suction continuously. Patient injury can result.
- Never insert or withdraw the endoscope's insertion section while the bending section is locked in position. Patient injury, bleeding, and/or perforation may result.
- Never operate the bending section, perform suction, insert or withdraw the endoscope's insertion section or use EndoTherapy accessories while no endoscopic image is observed or the endoscopic image is frozen. Patient injury, bleeding, and/or perforation may result.
- Never insert or withdraw the endoscope's insertion section with excessive force or while an optimum field of view cannot be obtained. Patient injury, bleeding, and/or perforation may result. If it is difficult to insert the endoscope, do not forcibly insert the endoscope; stop the endoscopy. Forcible insertion can result in patient injury, bleeding, and/or perforation.
- Never insert or withdraw the insertion section abruptly or with excessive force. Patient injury, bleeding, and/or perforation may result.
- Do not touch the light guide on the endoscope connector immediately after removing it from the light source because it is extremely hot. Operator or patient burns can result.

WARNING

- Although the illumination light emitted from the endoscope's distal end is required for endoscopic observation, it may also cause alteration of living tissues such as protein denaturation of living tissue and perforation of the tissue through improper usage. Observe the following warnings for illumination.
  - Always set the minimum required brightness. The brightness of the image on a monitor may differ from the actual brightness at the distal end of the endoscope. Pay attention to the brightness level setting of the light source, particularly when operating the electrical shutter function of a video system center. When using a light source and video system center that are compatible with the light source's automatic brightness control function, make sure to use the automatic brightness control function. This function can better maintain the illumination level. Refer to the instruction manual for the light source and the video system center for further details.
  - Always maintain a suitable distance necessary for adequate viewing while using the minimum level of illumination for the minimum amount of time. Do not use close stationary viewing or leave the distal end of the endoscope close to the mucous membrane for a long time without necessity.
  - When the endoscope will not be used for a long period, be sure to turn OFF the light source or activate the light shield function (standby mode, etc.) so that the endoscope is not illuminated unnecessarily.
- Do not connect the endoscope connector while the electrical contacts are wet and/or dirty, which may result in an electric shock, causing severe damage to the endoscope and compromising patient and/or operator safety.
- If the endoscopic image becomes dimmer during the procedure, it may indicate that blood or mucus is adhering to the light guide lens on the distal end of the endoscope. Immediately withdraw the endoscope from the patient, remove blood or mucus, and confirm that the light guide lens has no irregularities to use it again. If you continue to use the endoscope with the obstructed light guide lens, the temperature at the distal end may rise, which may cause patient injury or operator and/or patient burns.
- When the endoscopic image does not appear on the monitor, the image sensor may have been damaged. Turn the video system center OFF immediately. Continued power supply in such a case will cause the distal end to become hot and could cause operator and/or patient burns.

WARNING

- When performing transnasal insertion with the endoscope, follow the warnings below.
  - The shape and size of the nasal cavity and its suitability for transnasal insertion may vary from patient to patient. No endoscope, including this one, can always be inserted transnasally into all patients. Before proceeding, always be sure to confirm that transnasal insertion is possible with the patient by considering both the size of the patient's nasal cavity as well as the size of the endoscope's insertion section. Patient injury can result or the endoscope could become lodged and difficult to withdraw.
  - Transnasal insertion is accompanied by the risk of inflammation of the nasal cavity. If this happens, the nasal passage will be constricted, making it more difficult to withdraw the endoscope. In this case, do not use force to withdraw the endoscope because patient injury, bleeding, and/or perforation may result.
  - Transnasal insertion is accompanied by the risk of bleeding in the nasal cavity. Be sure to be prepared to deal with any bleeding. When withdrawing the endoscope, observe the inside of the nasal cavity to ensure that there is no bleeding. Even when the endoscope has been withdrawn without bleeding, do not allow the patient to blow his or her nose strongly because this could cause it to start bleeding.
  - Before transnasal insertion, apply the appropriate pretreatment and lubrication to the patient to enlarge the nasal cavity. Otherwise, patient injury can result or the endoscope could become lodged and difficult to withdraw. When applying a pretreatment agent through a tube, insert the tube into the same path as the path planned for the endoscope's insertion. Otherwise, the treatment will have no effect. The effects of the pretreatment agent and lubricant will decrease the longer the procedure lasts. Apply the pretreatment agent or lubricant as required during the procedure – for example, when withdrawal seems to be difficult.
  - Transnasal insertion of the endoscope should be performed carefully. If resistance to insertion is felt, or the patient reports pain, stop the insertion immediately. Patient injury can result or the endoscope could become lodged and difficult to withdraw.
  - If it becomes impossible to withdraw the transnasally inserted endoscope, detach the ultrasound cable from the ultrasound cable connector, pull its distal end out of the mouth, cut the flexible tube using wire cutters, and after ensuring that the cut section will not injure the body cavity or nasal cavity of the patient, withdraw the endoscope carefully. Therefore, always prepare wire cutters in advance.

WARNING

- When using the electronic zoom function of the video system center, never insert or withdraw the endoscope's insertion section or use EndoTherapy accessories while the image is electronically zoomed. Patient injury, bleeding, and/or perforation can result.
- The bending section will only bend to the UP or DOWN direction. To insert or withdraw, operate the endoscope by considering the direction in which the bending section is angulated. Never apply excessive force to the RIGHT or LEFT direction when inserting or withdrawing the endoscope. Patient injury, bleeding, and/or perforation can result.
- Before each use or after a change of viewing modes/settings, check to ensure the view observed through the endoscope provides a live image (rather than a stored one) and has the correct image orientation. Otherwise, patient injury, bleeding, and/or perforation can result.
- Never tie the elastic opening of both sides of the balloon with a thread. This may cause the balloon to rupture or come off the distal end of the endoscope when inflating it excessively. This can result in patient injury.
- Never inflate the balloon to a diameter of more than 20 mm when using the endoscope in the trachea. This could result in suffocation of the patient.
- Never withdraw the endoscope while the balloon is still inflated. Otherwise, the balloon may burst or come off the distal end of the endoscope. If the balloon cannot be deflated, insert the channel cleaning brush (BW-400B) into the irrigation port. Using slow, short strokes, carefully feed the brush to remove debris. After that, the balloon can be deflated.
- When withdrawing the endoscope, make sure that the balloon is completely deflated, using the ultrasound image and endoscopic field of view. Withdrawing the endoscope while the balloon is inflated could result in patient injury.
- If any irregularity in the ultrasound image is observed, turn the endoscopic ultrasound center OFF immediately. Continued ultrasound radiation will cause the distal end to become hot and could cause operator and/or patient burns.
- Elastography[*1] uses the pulsation of a living body. The intentional pressurization is not necessary. Compression onto the tissue by operating the bending section and inserting or withdrawing the endoscope may cause tissue damage, bleeding, or perforation.

  *1 Elastography is not available with the diagnostic ultrasound system (Hitachi, Ltd.) ProSound F75 in Canada.

- Be sure that this instrument is not used adjacent to or stacked with other equipment (other than the components of this instrument or system) to avoid electromagnetic interference.

WARNING

- Electromagnetic interference may occur on this endoscope near equipment marked with the following symbol or other portable and mobile RF (Radio Frequency) communications equipment, such as cellular phones. If electromagnetic interference occurs, mitigation measures may be necessary, such as reorienting or relocating this endoscope, or shielding the location.



CAUTION

- Do not pull the universal cord during an examination. The endoscope connector will be pulled out from the output socket of the light source and the endoscopic image will disappear.
- Do not coil the insertion tube or universal cord with a diameter of less than 12 cm. Equipment damage may result.
- Do not attempt to bend or twist the endoscope's insertion section with excessive force. The insertion section may be damaged.
- Do not apply shock to the distal end of the insertion section, in particular the objective lens surface at the distal end. Visual irregularities may result.
- If the endoscope is dropped or the distal end of the endoscope receives a hard impact, the endoscope may be damaged even if no visible damage of the lens on the distal end can be found. In this case, stop using the endoscope, and contact Olympus.
- Do not twist or bend the bending section with your hands. Equipment damage may result.
- Do not squeeze the bending section forcefully. The covering of the bending section may stretch or break and cause water leakage.
- Do not put or press the endoscope connector on the insertion section when transporting or reprocessing. The insertion section may be damaged.
- Turn the video system center ON only when the endoscope connector is connected to the light source. In particular, confirm that the video system center is OFF before connecting or disconnecting the endoscope connector. Failure to do so can result in equipment damage, including destruction of the image sensor.
- The endoscope's remote switches cannot be removed from the control section. Pressing, pulling, or twisting them with excessive force can break the switches and/or cause water leakage.
- Do not hit or bend the electrical contacts on the endoscope connector. The connection to the light source may be impaired and faulty contact can result.

CAUTION

- When using an endotracheal tube with the endoscope, select the tube that gives a sufficient gap between the insertion section of the endoscope and itself. A narrow gap may make it difficult for a patient to breathe and/or damage the endoscope.
- Before inserting the endoscope with an endotracheal tube into the patient, confirm that the insertion section of the endoscope can be inserted to the endotracheal tube smoothly by running it back and forth over the entire length of the insertion section and that the tube does not damage the endoscope. Any protrusions may damage the bending section cover or strip the external surface of the insertion section. When using lubrication, make above confirmation before applying lubrication.
- Be sure that this endoscope is not used adjacent to or stacked with other equipment (other than the components of this endoscope or system) to avoid electromagnetic interference.
- Do not touch the electrical contacts in the ultrasound cable connector. Equipment damage can result.
- Do not pull, twist, or tightly coil the ultrasound cable. Noise can develop in the ultrasound image.
- To prevent unnecessary patient exposure to ultrasound radiation, follow the “as-low-as-reasonably achievable” (ALARA) principle when using Olympus ultrasound equipment. Freeze the image whenever you are not actively viewing the “live” ultrasound image. When the equipment is in the FREEZE mode, no ultrasound energy is emitted.

NOTE

- This endoscope contains a memory chip that stores information about the endoscope and communicates this information to the video system center CV-190.
- When the endoscope gets strong static electricity, noise may be observed in the endoscopic image. This does not indicate a malfunction.
- It is highly desirable that a backup ultrasound cable be available to continue clinical procedures in case of a malfunction.

■ *Precaution for disappeared or frozen endoscopic image*

WARNING

- If the endoscopic image disappears unexpectedly or the frozen image cannot be restored during an examination, immediately stop using the endoscope and withdraw it from the patient as described in Section 5.3, “Withdrawal of the endoscope with an irregularity”. Continued use of the endoscope under this condition could result in patient injury, bleeding, and/or perforation.
- Follow the precautions given below. Otherwise, the endoscopic image may disappear unexpectedly or the frozen image may not be restored during the examination.
  - Connect the endoscope connector to the light source completely by pushing the endoscope connector until it clicks. Otherwise, faulty contact can result.
  - Do not bend, hit, pull, or twist the insertion section, bending section, control section, universal cord, and endoscope connector. The endoscope may be damaged, and water leaks and/or breakage of internal parts like the image sensor cable can result.
  - Before connecting the endoscope connector to the light source, confirm that the endoscope connector, including the electrical contacts, is completely dry and clean. If the endoscope is used with the electrical contacts wet and/or dirty, the endoscope and light source may malfunction.
  - If air bubbles emerge from the endoscope continuously during the leakage test, do not use the endoscope. Water may enter the endoscope and cause a short circuit. This may result in image sensor damage.
  - When inserting the endoscope through the mouth, place the mouthpiece in the patient’s mouth as necessary before inserting the endoscope to prevent the patient from accidentally biting the insertion section. Biting the insertion section may result in breakage of the cable or malfunction of the light guide.

■ *Examples of inappropriate handling*

Details on clinical endoscopic technique are the responsibility of trained specialists. Patient safety in endoscopic examinations and endoscopic treatment can be ensured through appropriate handling by the physician and the medical facility. Examples of inappropriate handling are described below.

- Applying suction with the distal end in contact with the mucosal surface, with higher suction pressure than required or with prolonged suction time may cause bleeding and/or lesions.
- The endoscope has not been designed for use in retroflexed observation. Performing retroflexed observation in a narrow lumen may make it impossible to straighten the angle of the bending section and/or withdraw the endoscope from the patient. In case the patient moves due to coughing and other reasons while the endoscope is angulated in the narrow lumen, the bending section of the endoscope may be pushed into the lumen and be retroflexed.
  Pretreatment to control patient's coughing reflex and other possible unexpected moves is the responsibility of trained specialists.
  Retroflexed observation should be performed only when the usefulness of doing so is determined to be greater than the risk that is posed to the patient.
- Inserting, withdrawing, and using EndoTherapy accessories without a clear endoscopic image may cause patient injury, burns, bleeding, and/or perforation.
- Inserting or withdrawing the endoscope, rotating the insertion section, applying suction, or operating the bending section without a clear endoscopic image may cause patient injury, bleeding, and/or perforation.

■ *Natural rubber latex medical alert*

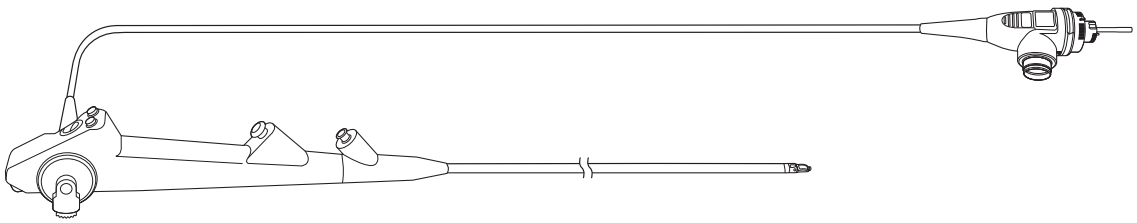
Balloons used with this instrument contain natural rubber latex that may cause allergic reactions in some patients.
Do not use this instrument on a latex sensitive patient.

Chapter 1 Checking the Package Contents

1.1 Checking the package contents

Match all items in the package with the components shown below. Inspect each item for damage. If the endoscope is damaged, a component is missing, or you have any questions, do not use the items; immediately contact Olympus.

❍ Endoscope



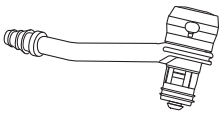
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■ *Packaged items*

❍ Packaged items



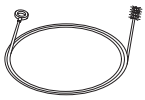
Suction cleaning adapter (MAJ-222)



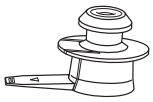
Single use suction valve (MAJ-209, 20 pcs (1 box))



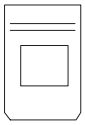
Single use combination cleaning brush (BW-411B, 3 pcs)



Single use single-ended cleaning brush (BW-400B, 3 pcs)



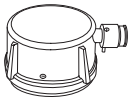
Single-use adapter biopsy valve (MAJ-1414, 10 pcs, sterile)



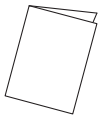
Balloon (MAJ-1351, 20 pieces, sterile)



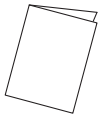
Balloon applicator (MAJ-1352)



US connector cap (MAJ-2295)



Operation manual



Reprocessing manual

1.2 Ultrasound cable

The ultrasound cable (MAJ-2056, optional) is necessary to use this endoscope (BF-UC190F) and may be purchased from Olympus.

❍ For the Olympus ultrasound center and the diagnostic ultrasound system (Hitachi, Ltd.) ProSound F75

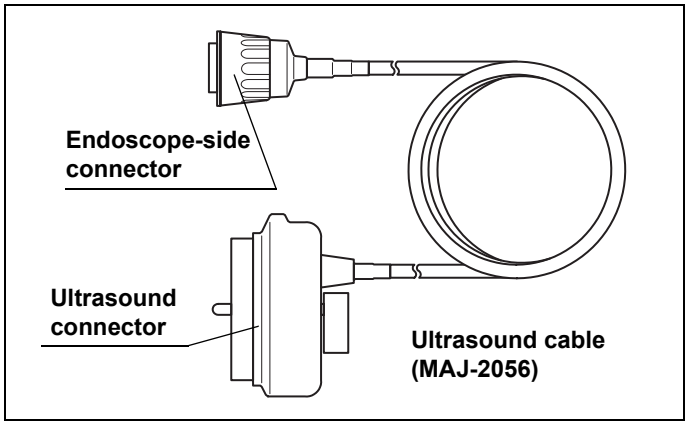


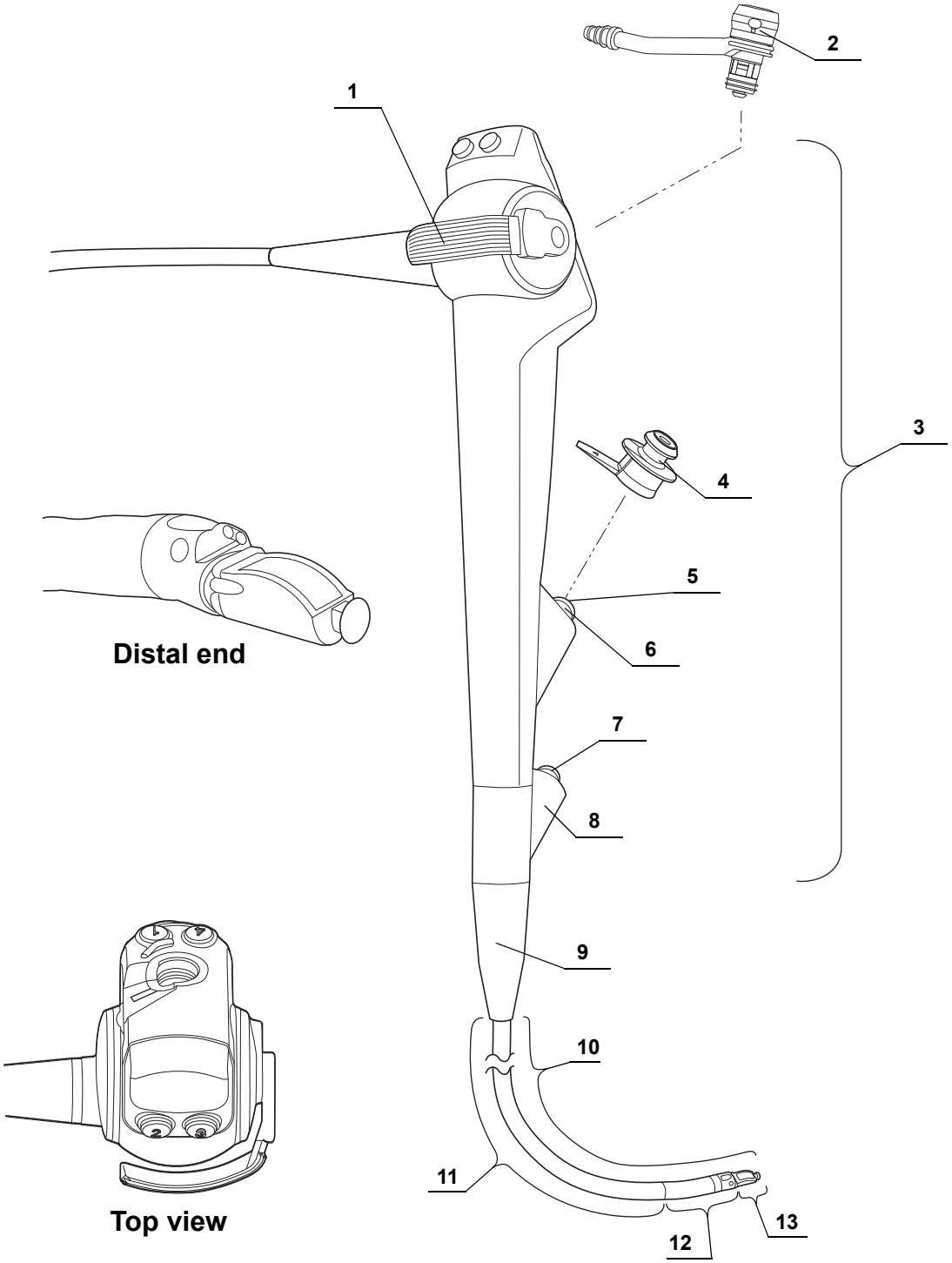
Figure 1.1

Chapter 2 Instrument Nomenclature and Specifications

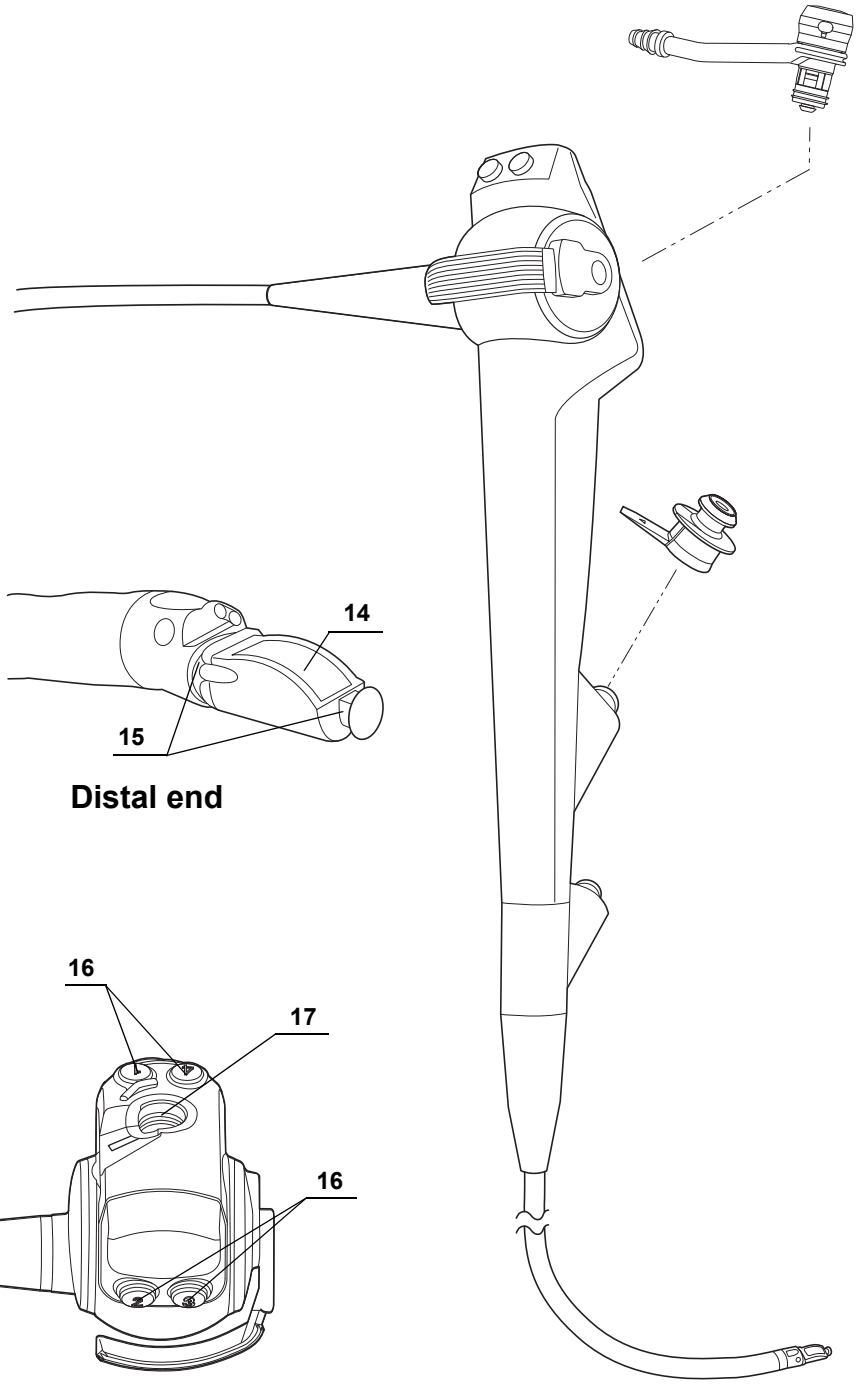
The instrument nomenclature, functions, and specifications are described in this chapter.

2.1 Nomenclature and functions

■ *Control section, insertion section*



No.	Nomenclature	Description
1	UP/DOWN angulation control lever	When this lever is operated in the “U” direction, the bending section moves UP; when the lever is operated in the “D” direction, the bending section moves DOWN.
2	Single use suction valve (MAJ-209) or suction valve (MAJ-207, optional)	The suction valve is depressed to activate suction. The valve is also used to remove any fluid or debris adhering to the objective lens.
3	Control section	Operates the endoscope, such as controlling angulation.
4	Single-use adapter biopsy valve (MAJ-1414) or single use biopsy valve (MAJ-210, optional)	Accessories may be inserted through the slit in this valve. A syringe may be inserted for the introduction of fluids.
5	Instrument channel	An EndoTherapy accessory can be inserted to this channel. The instrument channel is connected to the distal end of the endoscope. The instrument channel functions are as follows: • Channel for the insertion of EndoTherapy accessories • Suction channel • Fluid feed channel (from a syringe via the biopsy valve)
6	Instrument channel port	Attach the biopsy valve to this port.
7	Balloon channel	Feed water from the irrigation port through the balloon channel when necessary (e.g., observation of the ultrasound image).
8	Irrigation port	Connects an extension tube, a 3-way stopcock or a syringe to feed water into the balloon or suck water from the balloon through the balloon channel.
9	Boot	Protects the junction between the insertion tube and control section from bending.
10	Insertion section	This section is inserted into the patient body cavity.
11	Insertion tube	Connects the control section and bending section.
12	Bending section	The bending section moves the distal end of the endoscope when the UP/DOWN angulation control lever is operated.
13	Distal end	The objective lens and light guide lens are on this distal end.

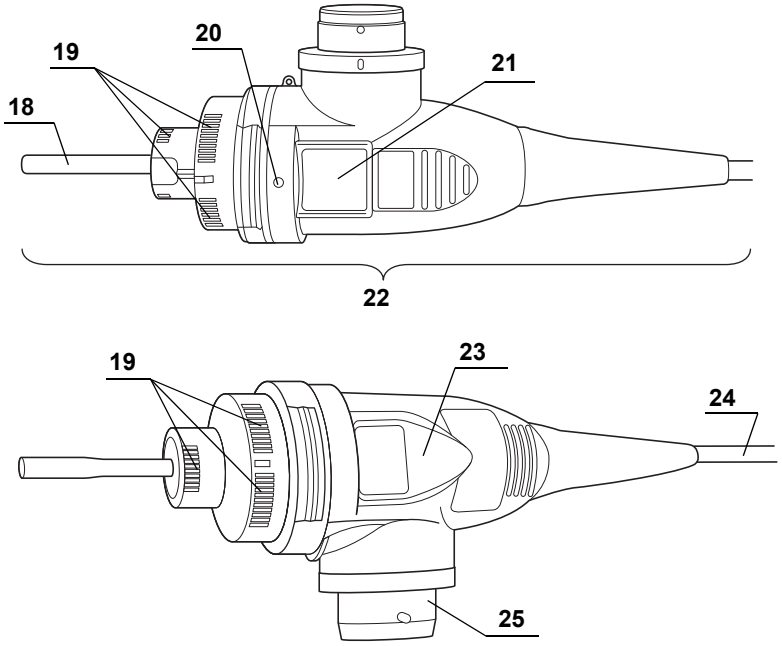


Distal end

Top view

No.	Nomenclature	Description
14	Ultrasound transducer	This ultrasound transducer emits and receives the ultrasound wave.
15	Balloon grooves	The balloon is attached to the balloon grooves.
16	Remote switches 1 to 4	The functions of the remote switches 1 to 4 can be selected on the video system center. Refer to the instruction manual for the video system center when setting these functions.
17	Suction cylinder	Attach the suction valve to this cylinder.

■ *Endoscope connector*



Rear side

No.	Nomenclature	Description
18	Light guide	Connects the endoscope to the light source and transmits light to the distal end of the endoscope.
19	Electrical contacts	Connect the light source and the endoscope electrically.
20	UP mark	When the endoscope connector is connected to the light source, the “O” mark (UP mark) faces upward.
21	Product ID plate	UDI Indication, The product name (model) and serial number are marked here.
22	Endoscope connector	Connects the endoscope to the light source to transmit light to the distal end of the endoscope and accessories are connected to this connector. The endoscope contains a memory chip that stores information about the endoscope and communicates this information to the video system center CV-190. For more details, refer to the instruction manual for the CV-190.
23	Scope ID mark	The RFID (radio frequency identification) chip for the endoscope identification information is embedded here.
24	Universal cord	Connects the endoscope connector and control section.
25	Ultrasound cable connector	This connector connects the ultrasound cable of the Olympus ultrasound center or the diagnostic ultrasound system (Hitachi, Ltd.) to the endoscope.

2.2 Specifications

NOTE

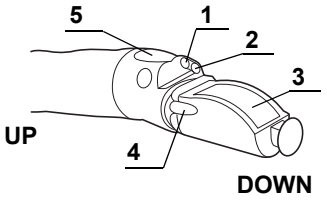
- This endoscope differs from a general videoscope. The endoscopic image is transmitted to the control section by the image guide and converted into an electrical signal by the image sensor in the control section.
- Only a limited type of EndoTherapy accessory is compatible with this endoscope compared with a general 2.2 mm channel endoscope. This is because it has a unique shaped instrument channel outlet. Refer to "■ System chart" on page 97 to confirm the details about the compatible EndoTherapy accessories.

■ Environment

Operating environment	**Ambient temperature**	10 – 40°C (50 – 104°F)
	Relative humidity	30 – 85%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)
Standard storage environment (e.g. within the healthcare facility)	**Ambient temperature**	5 – 40°C (41 – 104°F)
	Relative humidity	10 – 95%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)
Transportation environment (conditions during transportation and short-term storage)	**Ambient temperature**	–47 to +70°C (–52.6 to +158°F)
	Relative humidity	10 – 95%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)

■ *Specifications*

❍ Endoscope function

Model		BF-UC190F
Optical system	**Field of view**	80°
	Direction of view	20° (Forward oblique)
	Depth of field	2 – 50 mm
Insertion section	**Distal end enlarged** 1 Objective lens 2 Light guide lens 3 Ultrasound transducer 4 Balloon channel outlet 5 Instrument channel outlet	
	Distal end outer diameter	ø 6.6 mm
	Insertion tube outer diameter	ø 6.3 mm
	Insertion section working length	600 mm
Instrument channel	**Channel inner diameter**	ø 2.2 mm
	Minimum visible distance[*1]	3 mm
	Direction from which EndoTherapy accessories enter and exit the endoscopic image	
Bending section	**Angulation range**	UP 160° DOWN 70°
Total length		890 mm
Pre-freeze function[*2]		Available
Electronic zoom function[*2]		Not compatible
Electronic shutter function[*2]		Available
Records of endoscope's information[*2]		Available
NBI observation[*2]		Not compatible
High-frequency treatment		Not compatible
Laser treatment		Not compatible

*1 Distance from the distal end of the endoscope.

*2 For more details, refer to the instruction manual for the CV-190.

❍ Ultrasound function

Ultrasound method	Electronic curved linear array
Ultrasound direction	Parallel to the insertion direction
Nominal frequency	7 – 10 MHz
Contacting method	Balloon method, direct contact method

❍ Ultrasound function with Olympus universal endoscopic ultrasound center EU-ME1

Operation mode	B mode, color flow mode, power flow mode
Scanning range	60°
Transducer surface maximum temperature	< 43°C

❍ Ultrasound function with EVIS EUS endoscopic ultrasound center EU-ME2, EU-ME2 PREMIER*1, EU-ME2 PREMIER PLUS

Operation mode	**EU-ME2 PREMIER PLUS**	B mode, FLOW mode, PW mode, THE mode, CH-EUS mode, ELST mode
	EU-ME2 PREMIER*1	B mode, FLOW mode, PW mode, THE mode, CH-EUS mode
	EU-ME2	B mode, FLOW mode, PW mode
Scanning range		65°
Transducer surface maximum temperature		< 43°C

❍ Ultrasound function with diagnostic ultrasound system (Hitachi, Ltd.) ProSound F75

Operation mode	B mode, M mode, D mode, Flow mode, PW mode, Power flow mode, THE mode
Scanning range	65°
Transducer surface maximum temperature	< 43°C

*1 This equipment may not be available in some areas.

Common specifications

Medical Devices Directive		CE 0197 This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class II a
RoHS Directive		CE This device complies with the requirements of Directive 2011/65/EU concerning electrical and electronic equipment.
EMC	**Applied standard**	IEC 60601-1-2: 2001+A1 IEC 60601-2-37: 2001+A1+A2 IEC 60601-1-2: 2007 IEC 60601-1-2: 2014 IEC 60601-2-37: 2007 • This instrument complies with the EMC standard for medical electrical equipment, edition 4 (IEC 60601-1-2: 2014). When connecting to an instrument that complies with a previous edition of the EMC standard for medical electrical equipment edition, the EMC characteristics could be vulnerable. • CISPR 11 of emission: Group 1, Class B
Degree of protection against electric shock		TYPE BF applied part
Ingress protection rating		IPX7 This instrument complies with the standards for medical electrical equipment: IEC 60601-1: 2005+A1, IEC 60601-2-37:2007.
UDI Indication		The UDI Indication is required by some countries' regulations regarding the identification of a medical device also known as Unique Device Identification (UDI). The following information is being coded in the 2-dimensional barcode (GS1 Data Matrix): - (01) 14-digit GS1 Global Trade Item Number; - (11) 6-digit date of manufacture; - (21) 7-digit serial number.

Chapter 3 Preparation and Inspection

The equipment prepared before using this endoscope and procedures for the inspection of the endoscope and equipment are described in this chapter.

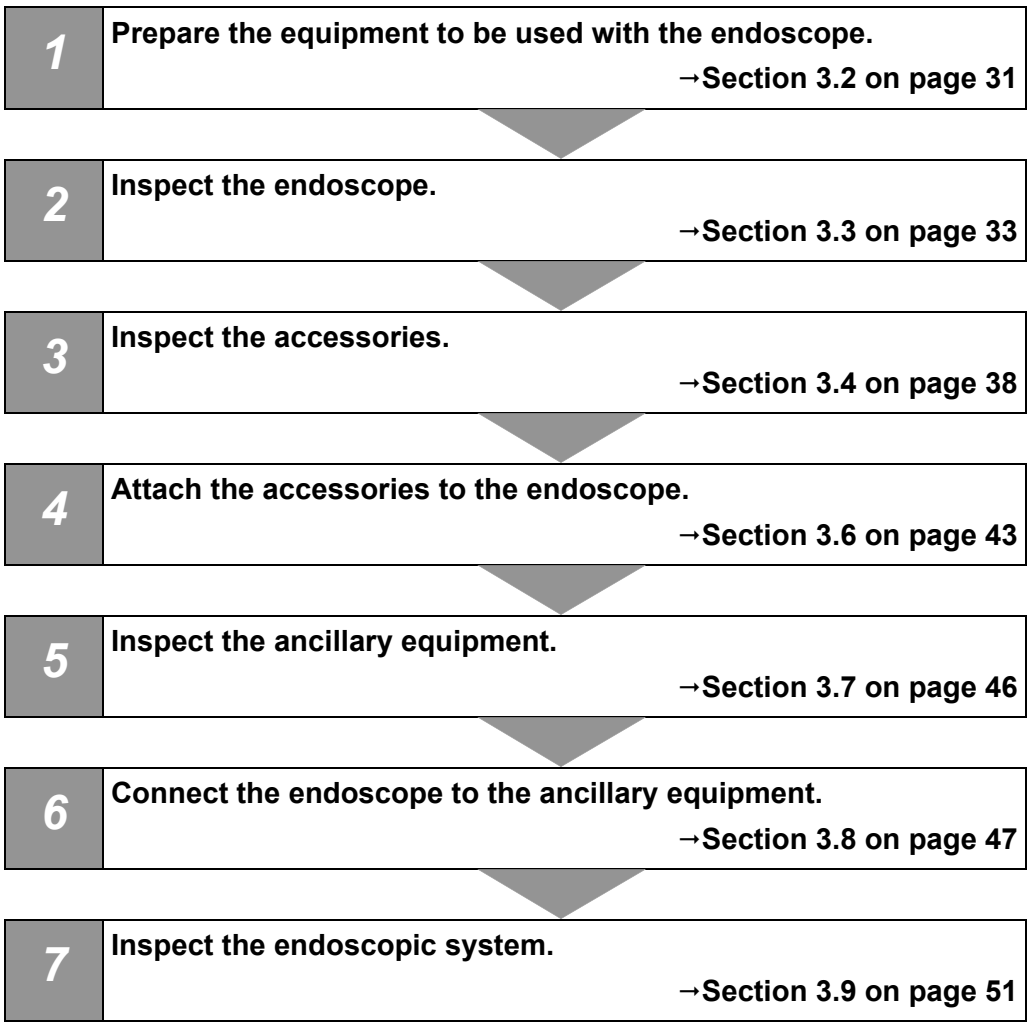
3.1 The workflow of preparation and inspection

The workflow of preparation and inspection is shown below.

Before each case, prepare and inspect this endoscope as instructed below. Inspect other equipment to be used with this endoscope as instructed in their respective instruction manuals. Should any irregularity be observed after inspection, follow the instructions as described in Chapter 5, “Troubleshooting”. If this endoscope malfunctions, do not use it. Return it to Olympus for repair as described in Section 5.4, “Returning the endoscope for repair”.

WARNING

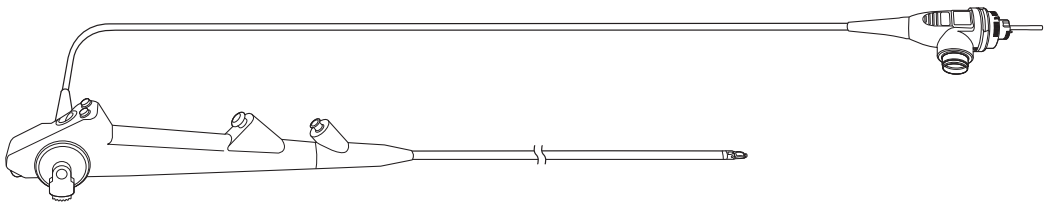
- Never use the endoscope on a patient if any irregularity is observed. The irregular endoscope may compromise patient or user safety and may result in more severe equipment damage. In addition, it may pose an infection control risk.
- This endoscope was not reprocessed before shipment. Before using this endoscope for the first time, reprocess it according to the instructions as described in the endoscope’s companion “REPROCESSING MANUAL” with your endoscope model listed on the cover.


1
Prepare the equipment to be used with the endoscope.
→Section 3.2 on page 31
2
Inspect the endoscope.
→Section 3.3 on page 33
3
Inspect the accessories.
→Section 3.4 on page 38
4
Attach the accessories to the endoscope.
→Section 3.6 on page 43
5
Inspect the ancillary equipment.
→Section 3.7 on page 46
6
Connect the endoscope to the ancillary equipment.
→Section 3.8 on page 47
7
Inspect the endoscopic system.
→Section 3.9 on page 51

3.2 Preparation of the equipment

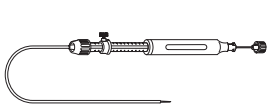
Prepare this endoscope, the accessories, the equipment, and all personal protective equipment as shown in Figure 3.1. Prepare the equipment in “Combination equipment” on page 97 in accordance with the intended use.
Also, refer to the respective instruction manuals for each piece of equipment before use.

❍ Endoscope

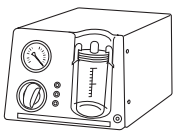


Endoscope*1

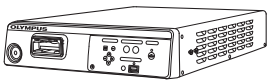
❍ Accessories and ancillary equipment



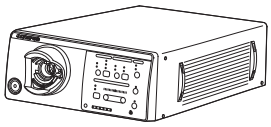
EndoTherapy accessories



Suction pump



Video system center



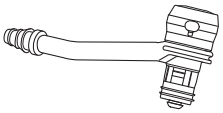
Light source



Monitor



The olympus ultrasound center or the diagnostic ultrasound system (Hitachi, Ltd.)



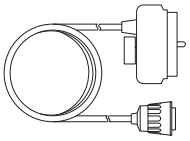
Single use suction valve (MAJ-209)



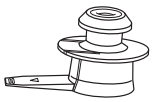
Single use biopsy valve (MAJ-210, optional)



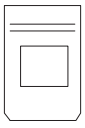
Mouthpiece (MA-651*1, optional)



Ultrasound cable (MAJ-2056, optional)



Single-use adapter biopsy valve (MAJ-1414, 10 pcs, sterile)



Balloon (MAJ-1351, 20 pieces, sterile)

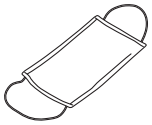


Balloon applicator (MAJ-1352)

❍ Personal protective equipment (e.g.)



Eyewear



Face mask



Moisture-resistant clothing



Chemical-resistant gloves

❍ Other

- **Clean lint-free cloths**
- **Containers for sterile water**
- **Trays**
- **Syringe**
- **Medical-grade, water-soluble lubricant**
- **Sterile de-aerated water**
- **Paper towels**
- **3-way stopcock**
- **Extension tube**

Figure 3.1

*1 Prepare the endoscope, suction valve, mouthpiece, and biopsy valve that have been reprocessed as described in the “REPROCESSING MANUAL” with your endoscope model listed on the cover.

3.3 Inspection of the endoscope

■ Inspection of the endoscope

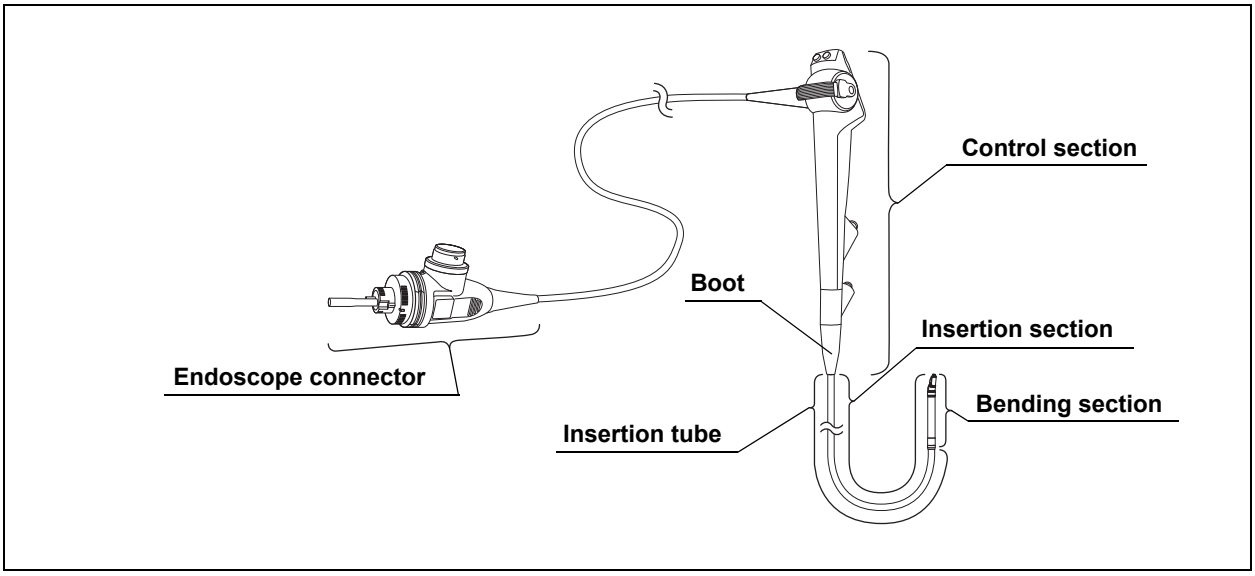


Figure 3.2

1 Inspect the control section and endoscope connector for any irregularities such as excessive scratching, deformation, and loose parts.

2 Inspect the boot and the insertion section near the boot for any irregularities such as bends, twists, tears, and cracks.

3 Inspect the external surface of the entire insertion section, including the bending section and the distal end for dents, bulges, swelling, scratches, peeling of coating, holes, sagging, transformation, bends, adhesion of foreign bodies, missing parts, protruding objects.

4 Holding the control section with one hand, carefully run your other hand back and forth over the entire length of the insertion section. Confirm that no objects or metallic wire protrude from the insertion section.
Also, confirm that the insertion tube is not abnormally rigid.

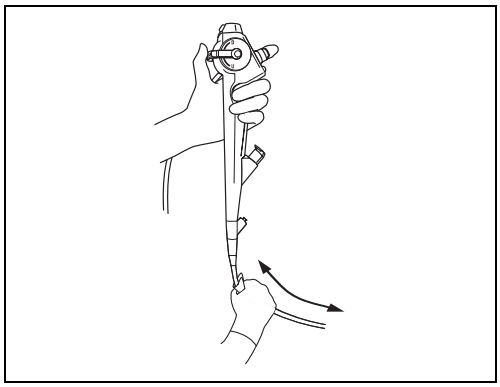


Figure 3.3

5 Using both hands, bend the insertion tube of the endoscope into a semicircle.
Then, moving your hands as shown by the arrows in Figure 3.4, confirm that the entire insertion tube can be smoothly bent to form a semicircle and that the insertion tube is pliable.

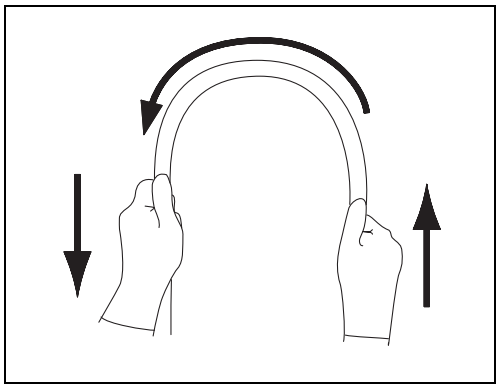


Figure 3.4

6 Gently hold the midpoint of the bending section and a point 10 cm from the distal end. Push and pull gently to confirm that the junction between the bending section and the insertion tube is not loose.

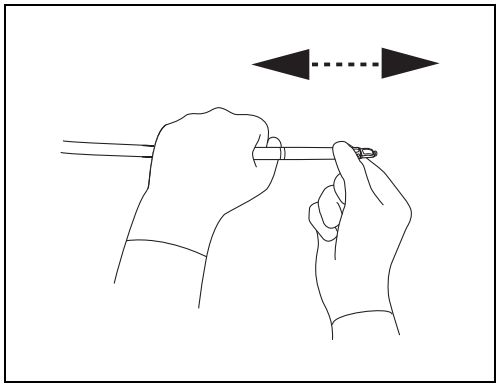


Figure 3.5

7 Inspect the entire distal end of the endoscope including the objective lens and light guide lens for any irregularities such as scratches, chips, cracks, stains, discoloration, deformation, and gaps around the lens.

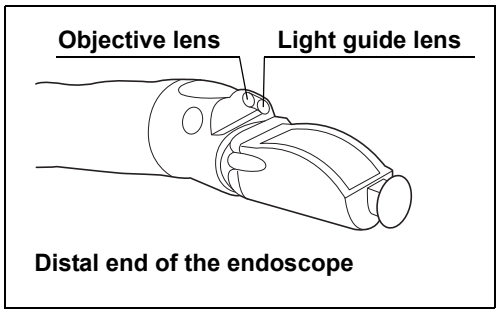


Figure 3.6

8 Inspect the ultrasound transducer surface at the distal end of the endoscope for any irregularities such as deterioration, scratches, cracks, bulges and dents.

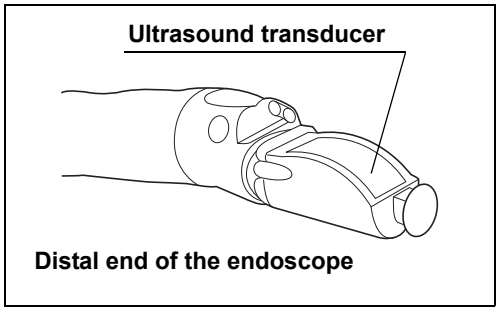


Figure 3.7

9 Inspect the adhesives attaching the bending section cover to the insertion section for any irregularities such as detrioration, pitting, cracking, and peeling.
Also, inspect the bending section cover for any irregularities such as bulges, swelling, scratches, and holes.

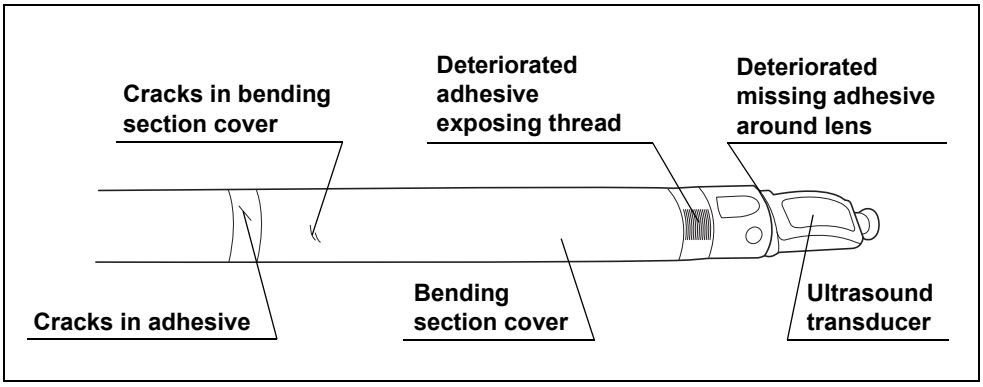


Figure 3.8

NOTE

The covering on both ends of the bending section is wound with thread. The adhesives cover them so that they are fixed. Therefore, the thread is exposed if the adhesives become chipped.

10 Wipe the light guide edge of the endoscope connector using clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol.

11 If foreign objects, such as detergent remnants, hard water residue, finger grease, dust, and lint may be on the electrical contacts on the endoscope connector (ex. wiping with lint-prone cloths, left unused for a long period of time), wipe the electrical contacts with clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol.
Also, confirm that the electrical contacts are completely dry and clean.

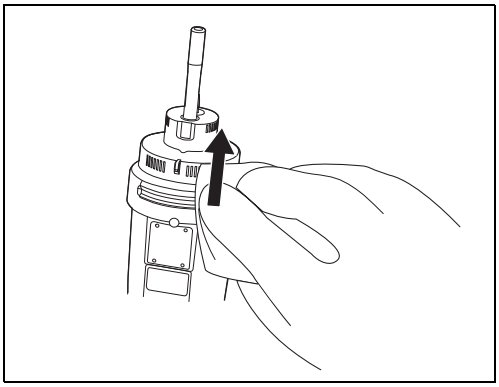


Figure 3.9

■ *Inspection of the bending mechanism*

Perform the following inspections while the bending section is straight.

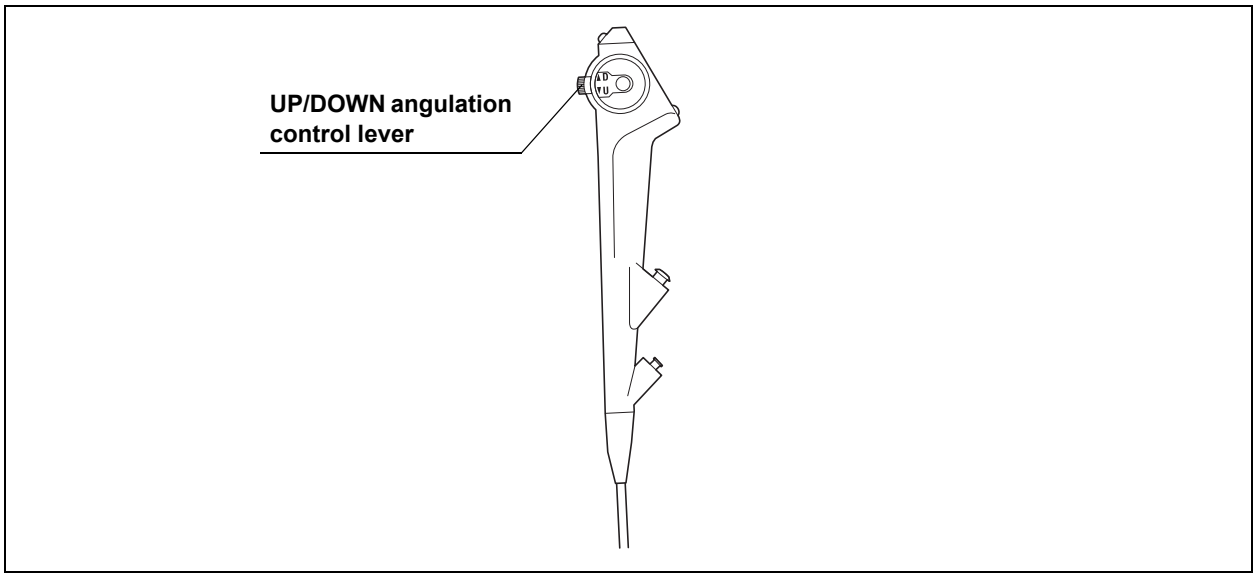


Figure 3.10

WARNING

If the movement of the UP/DOWN angulation control lever is loose and/or not smooth, or the bending section does not angulate smoothly, the bending mechanism may have an irregularity. In this case, do not use the endoscope because it may be impossible to straighten the bending section during an examination, and patient injury, bleeding, and/or perforation may result.

Inspection for smooth operation

1 Straighten the bending section.

2 Operate the UP/DOWN angulation control lever slowly in each direction until it stops.

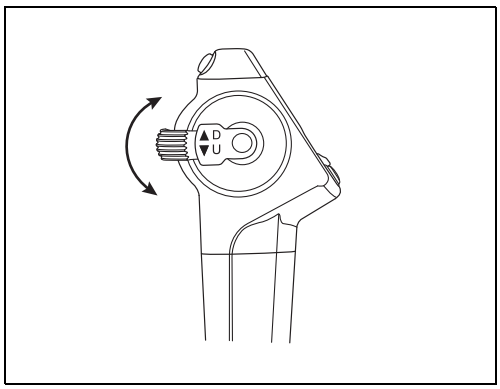


Figure 3.11

3 Confirm that the bending section angulates smoothly and correctly and the maximum angulation can be achieved.

4 Operate the UP/DOWN angulation control lever slowly to its straight (neutral) position. Confirm that the bending section returns smoothly to an approximately straight position.

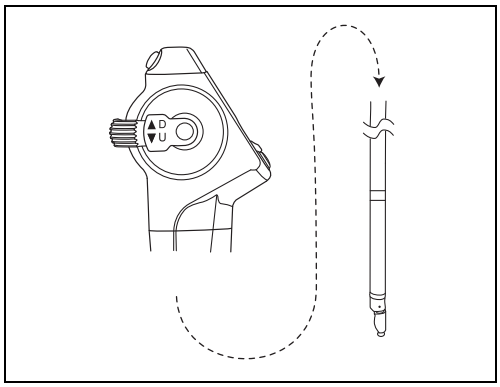


Figure 3.12

3.4 Inspection of accessories

■ Inspection of the single use suction valve (MAJ-209) or suction valve (MAJ-207, optional)

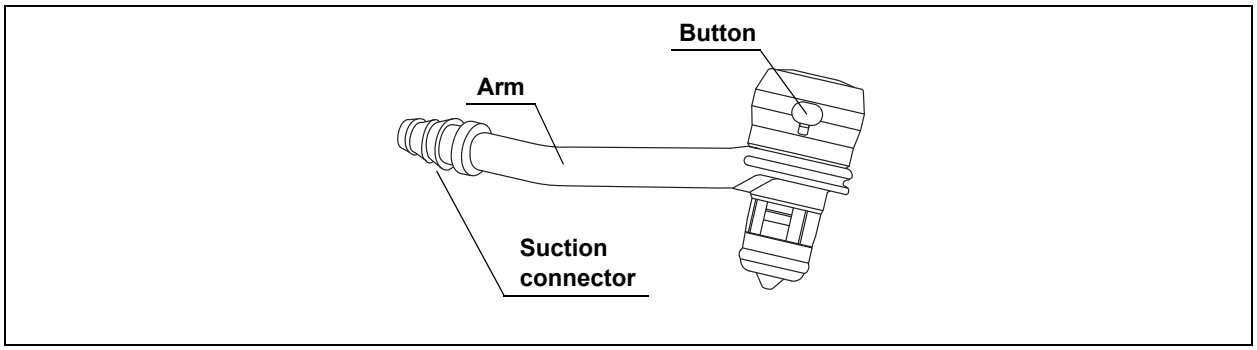


Figure 3.13

WARNING

- Do not use the suction valve (MAJ-207) for more than six procedures.
- The single use suction valve (MAJ-209) is disposable. Do not attempt to reuse or resterilize it. The suction valve is provided in a sterile condition. Do not open the package until ready to use.
- Do not use a single-use adapter biopsy valve after the expiration date displayed on the sterile package. Doing so may pose an infection control risk.

Inspection of the suction valve (MAJ-207) or the single use suction valve (MAJ-209) as described in the suction valve's instruction manual.

■ *Inspection of the single-use adapter biopsy valve (MAJ-1414)*

WARNING

- The single-use adapter biopsy valve (MAJ-1414) is disposable. Do not attempt to reuse or resterilize it. The adapter biopsy valve is provided in a sterile condition. Do not open the package until ready to use.
- Do not use a single-use adapter biopsy valve (MAJ-1414) after the expiration date displayed on the sterile package. Doing so may pose an infection control risk.

NOTE

This single-use adapter biopsy valve (MAJ-1414) corresponds to the aspiration needle indicated in the "■ Compatible EndoTherapy accessories" on page 100.

1 Inspect the sterile package for tears, inadequate sealing, or water damage.
If the sterile package shows any any irregularity, the sterile condition of the instrument may have been compromised. Use a spare instead.

2 Tear open the sterile package.

3 Inspect the biopsy valve for cracks or other damage.

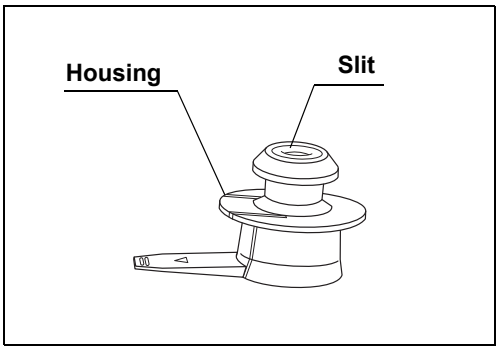


Figure 3.14

■ *Inspection of the single use biopsy valve (MAJ-210, optional)*

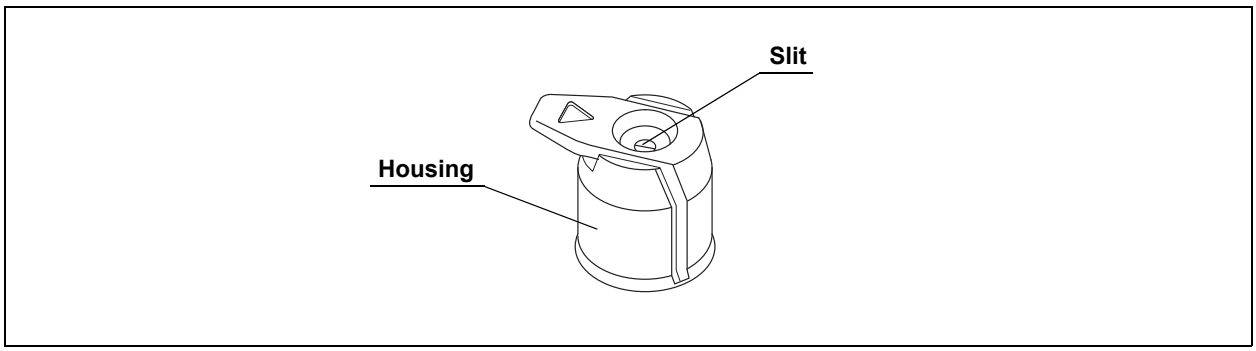


Figure 3.15

WARNING

- Do not use a single use biopsy valve (MAJ-210) after the expiration date displayed on the sterile package. Doing so may pose an infection control risk.
- The single use biopsy valve (MAJ-210) is disposable. Do not attempt to reuse or resterilize it. This could pose an infection control risk or cause equipment damage.
- Do not use the single use biopsy valve (MAJ-210) with the single use aspiration needle the single-use adapter biopsy valve (MAJ-1414) corresponds to the aspiration needle indicated in the “■ Compatible EndoTherapy accessories” on page 100.

Inspect the single use biopsy valve (MAJ-210) as described in the single use biopsy valve’s instruction manual.

■ *Inspection of the mouthpiece (MA-651, optional)*

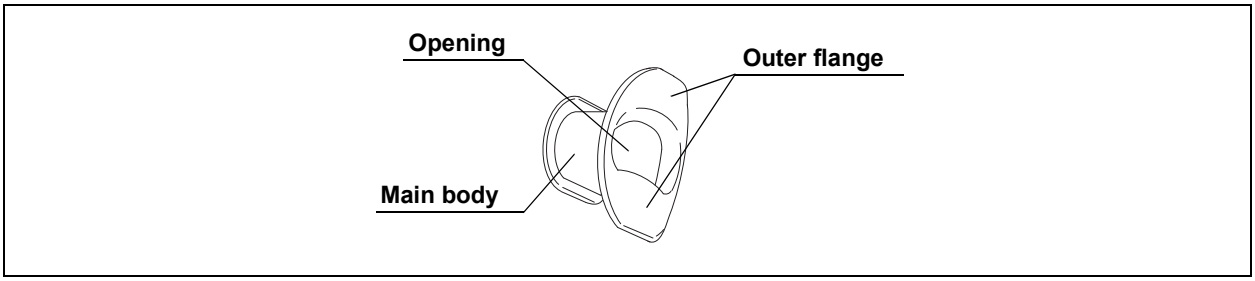


Figure 3.16

WARNING

Do not use a mouthpiece (MAJ-651) that is damaged, deformed or reveals other irregularities. Doing so may cause patient injury and/or equipment damage.

NOTE

Placing the mouthpiece (MAJ-651) in the patient's mouth before the procedure prevents the patient from biting and/or damaging the endoscope's insertion section.

1 Confirm that the mouthpiece (MAJ-651) is free from cracks, deformation, or discoloration.

2 Using your fingers, check all surfaces of the mouthpiece for scratches, cracks, or other irregularities.

3.5 Inspection of the ultrasound cable (MAJ-2056, optional)

■ Inspection of the ultrasound cable (MAJ-2056, optional)

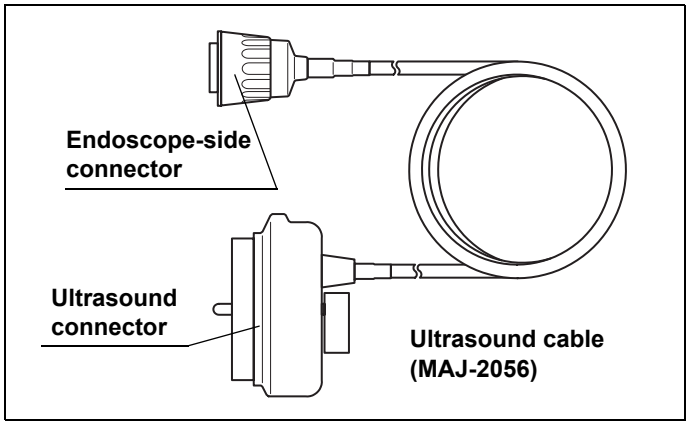


Figure 3.17

CAUTION

Do not use an ultrasound cable (MAJ-2056) that is damaged, deformed, or reveals other irregularities, which may cause equipment damage.

1. Confirm that the ultrasound cable (MAJ-2056) has no scratches, cracks, excessive wear, or deformation.
2. Confirm that the endoscope-side connector and the ultrasound connector have no scratches, cracks, or deformation.

3.6 Attaching accessories to the endoscope

■ Attaching the single use suction valve (MAJ-209) or suction valve (MAJ-207, optional)

WARNING

Firmly attach the suction valve to the instrument channel port. If the suction valve is attached to the endoscope improperly or a gap between the base of the suction valve and the top of the suction cylinder exists, the suction valve may detach from the endoscope and may cause patient debris to leak or spray from the gap.

CAUTION

The suction valve does not require lubrication. Lubricants can cause swelling of the valve's seals, and the valve function may be impaired.

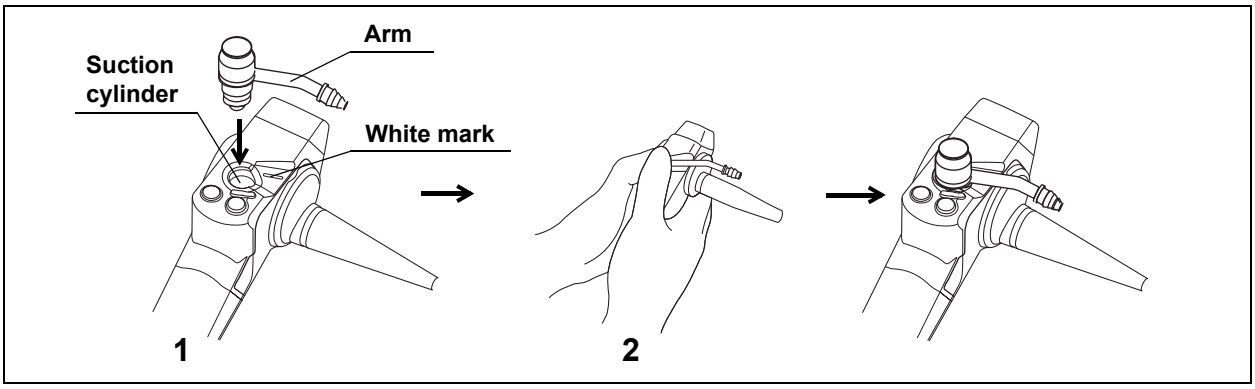


Figure 3.18

1 Place the suction valve into the suction cylinder, then align the arm of the main body with the white mark on the endoscope.

2 Press down on the suction valve's top surface with both thumbs until it "clicks" into place.

NOTE

Sometimes the suction valve will click before it is fully seated in the suction cylinder. Depress the suction valve into the suction cylinder until it fits completely to the suction cylinder without showing a gap.

3 Inspect and verify that the base of the valve is in contact with the suction cylinder properly. Improper attachment makes a gap between the base of the suction valve and the top of the suction cylinder.

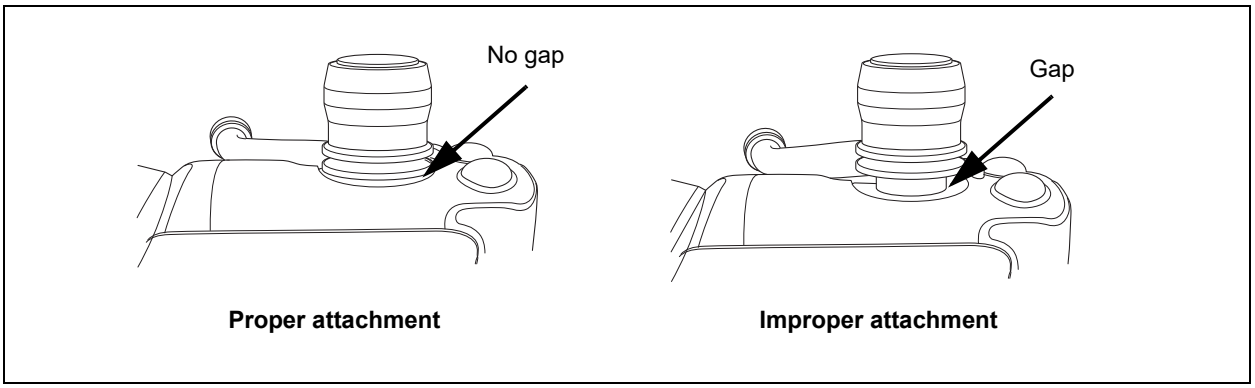


Figure 3.19

■ *Attaching the single-use adapter biopsy valve (MAJ-1414)*

WARNING

If the single-use adapter 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, posing an infection control risk.

Attach the single-use adapter biopsy valve to the instrument channel port of the endoscope. Confirm that the adapter biopsy valve is firmly attached to the instrument channel port of the endoscope.

NOTE

At low temperature, the housing may become stiff and difficult to attach.

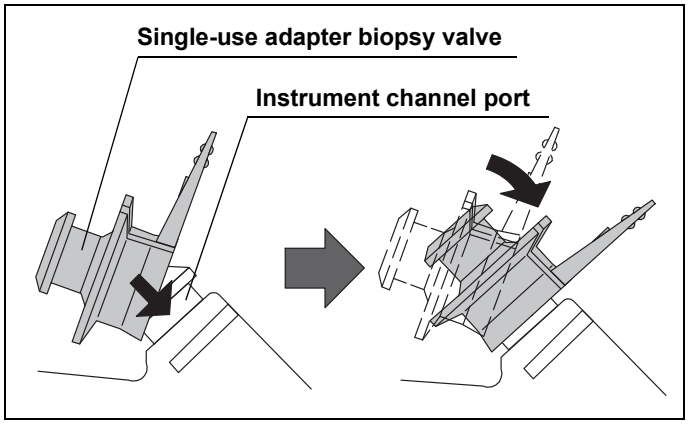


Figure 3.20

■ *Attaching the single use biopsy valve (MAJ-210)*

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.

1 Attach the biopsy valve to the instrument channel port of the endoscope.

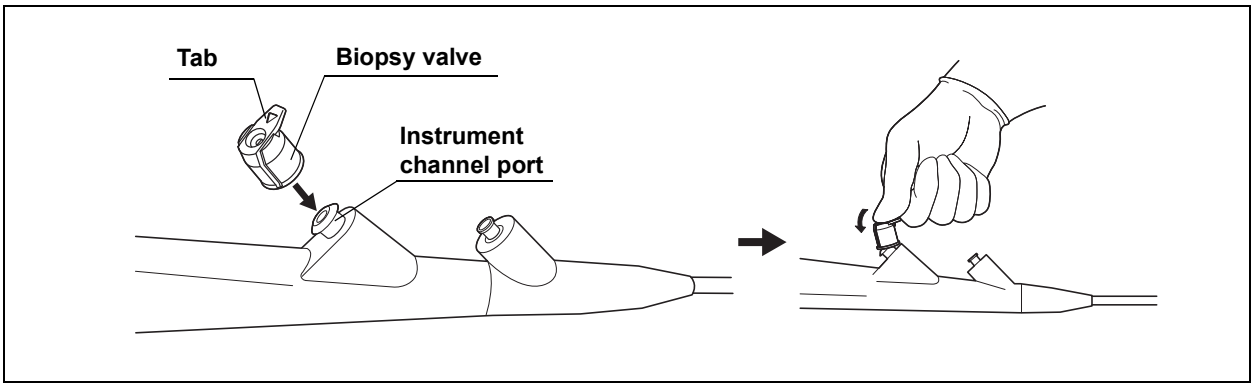


Figure 3.21

2 Confirm that the biopsy valve fits properly.

NOTE

At low temperature, the biopsy valve may become stiff and difficult to attach.

3.7 Inspection of ancillary equipment

Inspect the following equipment as described in their respective instruction manuals.

- Light source
- Video system center
- Monitor
- Suction pump
- EndoTherapy accessories
- Ultrasound center

3.8 Connection of the endoscope and ancillary equipment

Connect the ancillary equipment to the endoscope as described below.

■ Connection to the light source

WARNING

- If the endoscope connector and light source are not connected properly, the endoscopic image may flicker or may not be displayed. Continuous use of such an endoscope may cause patient injury, bleeding, and/or perforation.
- Firmly connect the suction tube from the suction pump to the suction connector on the suction valve. If the suction tube is not attached properly, debris may drip from the tube. The patient, operator, and/or equipment could be contaminated and equipment malfunction can result.

CAUTION

Before connecting the endoscope connector to the light source, confirm that the endoscope connector, including the electrical contacts, is completely dry and clean. If the endoscope is used with the electrical contacts wet and/or dirty, the endoscope and light source may malfunction.

1 If any ancillary equipment is ON, turn it OFF.

2 Hold the endoscope connector while the UP mark is facing upward.

3 Connect the endoscope connector completely into the output socket of the light source.

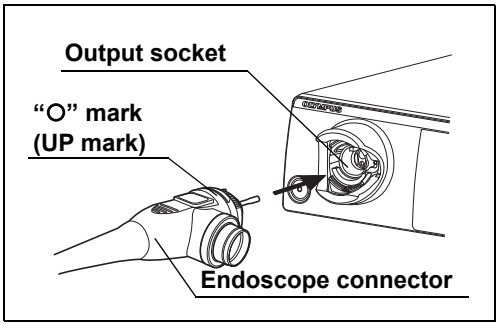


Figure 3.22

4 Push the connector until it clicks.

5 Confirm that the “O” mark (UP mark) on the endoscope connector is hidden by the light source.

■ *Connection of the suction tube*

WARNING

Firmly connect the suction tube from the suction pump to the suction connector on the suction valve. If the suction tube is not attached properly, debris may drip from the tube and can pose an infection control risk, cause equipment damage, and/or reduce suction capability.

Connect the suction tube from the suction pump to the suction connector on the suction valve.

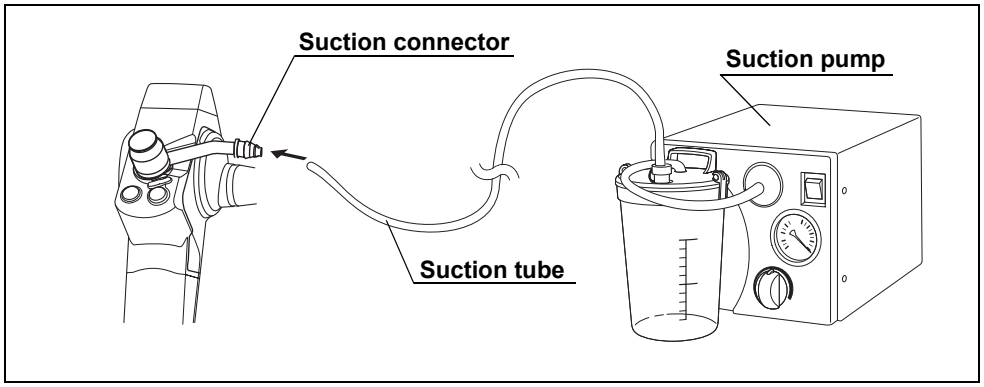


Figure 3.23

■ *Connection of the endoscope and the ultrasound cable (MAJ-2056)*

WARNING

The electrical contacts inside the ultrasound cable connector have sharp tips and may be damaged by handling. Do not touch the electrical contacts.

CAUTION

For more information on combining the endoscope with the ultrasound cable (MAJ-2056) refer to “■ System chart” on page 97.

1 Make sure that the inside of the ultrasound cable connector is dry and free of debris.

2 Align the mark on the ultrasound cable (MAJ-2056) with mark A on the ultrasound cable connector, and push it until it stops. (See Figure 3.24)

3 Turn the endoscope-side connector of the ultrasound cable (MAJ-2056) clockwise until it stops. (See Figure 3.24)

4 Confirm that the mark on the ultrasound cable (MAJ-2056) is aligned with mark B on the ultrasound cable connector.

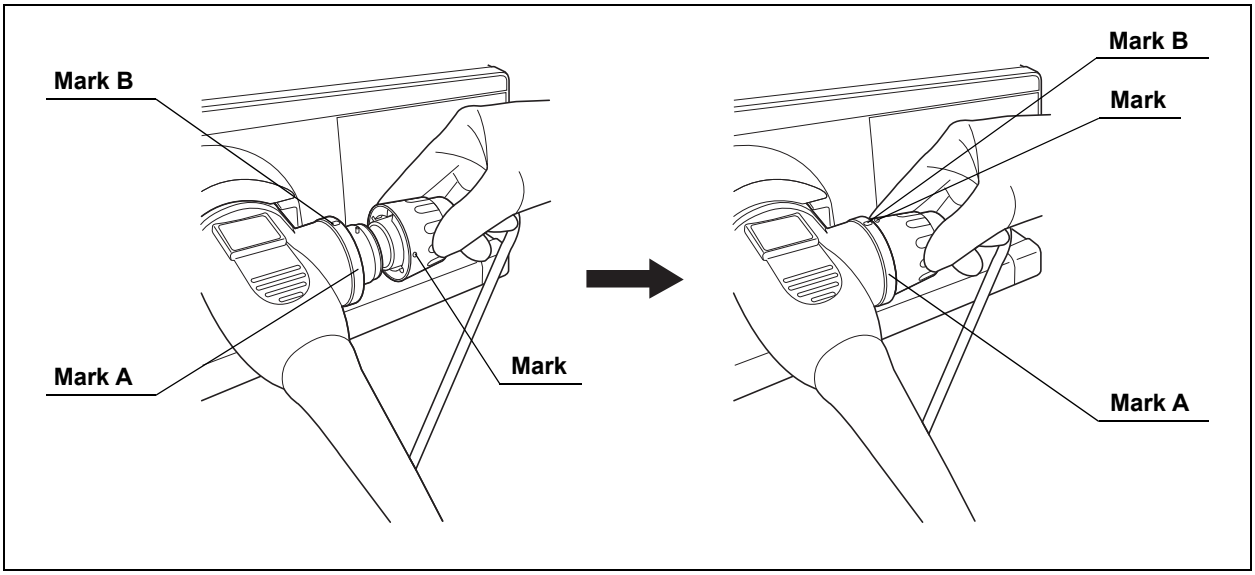


Figure 3.24

■ *Connection of the ultrasound cable (MAJ-2056) and the endoscopic ultrasound center*

Insert the ultrasound connector properly into the transducer port of the ultrasound center. Rotate the connector's lock handle 1/4 turn clockwise.

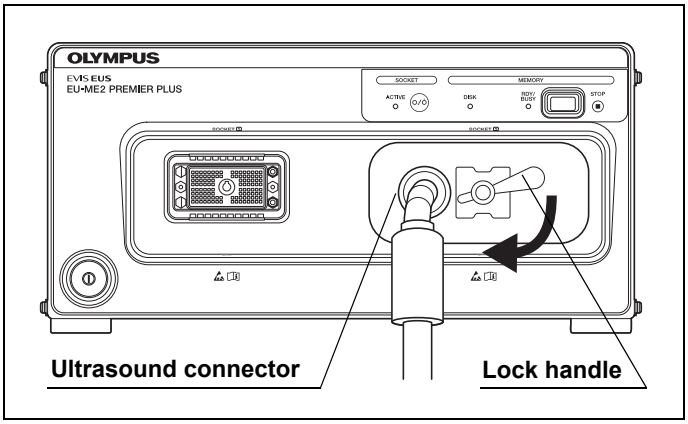


Figure 3.25

■ *Connection of the diagnostic ultrasound system (Hitachi, Ltd.) ProSound F75*

CAUTION

The electrical contacts inside the ultrasound connector have sharp tips and may be damaged by handling. Do not touch the electrical contacts.

Insert the ultrasound connector properly into the transducer port of the diagnostic ultrasound system. Rotate the connector's lock handle 1/4 turn clockwise. (See Figure 3.26)

CAUTION

Connect the ultrasound connector to one of the probe connectors on the lower side (PROBE 3 or 4) of the ProSound F75.
If the ultrasound connector is connected to one of the probe connectors on the upper side (PROBE 1 or 2), the operation panel of the ProSound F75 may hit the ultrasound connector, which may result in equipment damage. When adjusting the height, a horizontal and/or vertical position of the operation panel of the ProSound F75 with the ultrasound connector connected to the PROBE 1 or 2, move slowly the operation panel with visually confirming the position of the bottom of the operation panel.

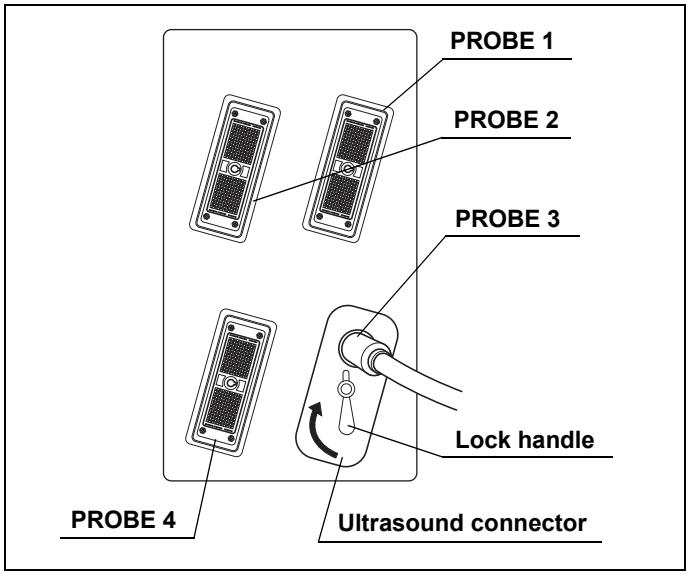
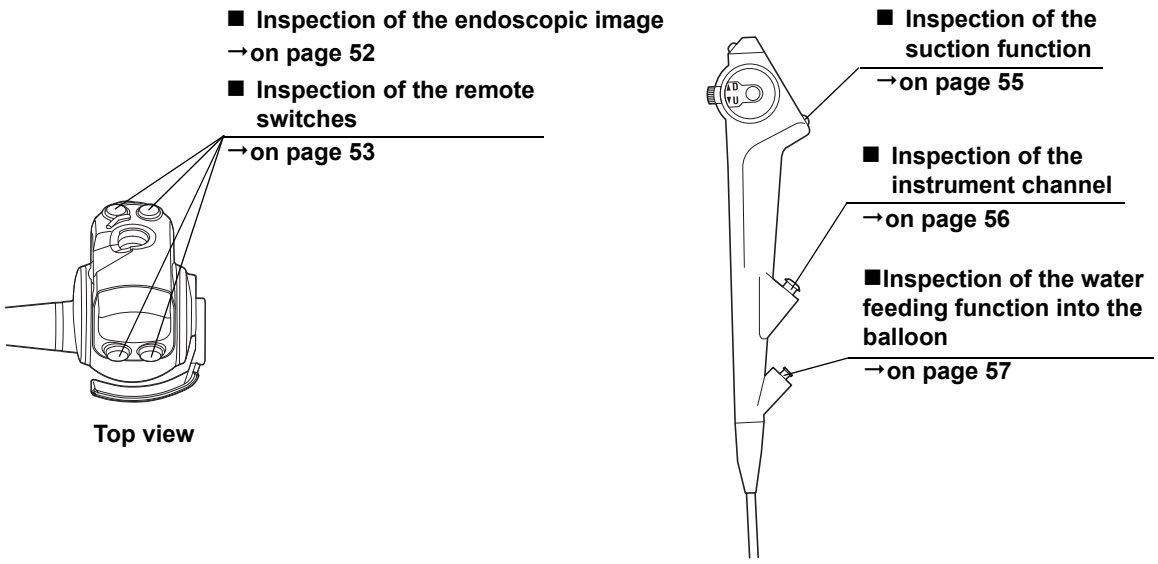


Figure 3.26

3.9 Inspection of the endoscopic system

■ Inspection summary



■ Inspection of the ancillary equipment

Turn ON the video system center, light source, and monitor. Inspect them as described in their respective instruction manuals.

■ *Inspection of the endoscopic image*

Confirm that the WLI endoscopic images are normal.

WARNING

Do not stare directly into the distal end of the endoscope while the examination light is ON. Eye injury may result.

1 Before inspection, wipe the objective lens with clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol.

2 Observe the palm of your hand in the WLI endoscopic images.

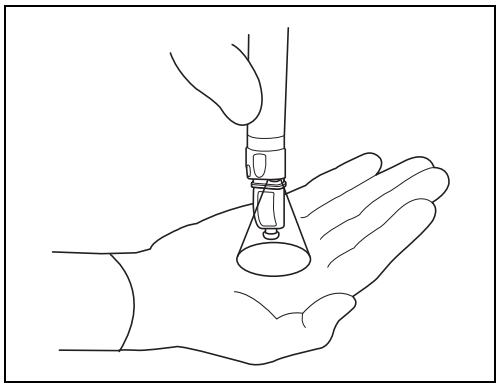


Figure 3.27

3 Confirm that light is outputting from the endoscope's distal end. (See Figure 3.27)

4 Adjust the brightness level as appropriate.

5 Confirm that the WLI endoscopic image is free from noise, blur, fog, or other irregularities.

6 Operate the UP/DOWN angulation control lever slowly in each direction until it stops.

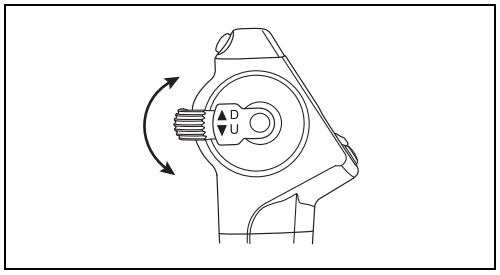


Figure 3.28

7 Confirm that the WLI endoscopic image does not momentarily disappear or display any other irregularities.

■ *Inspection of the remote switches*

WARNING

Check all remote switches to work normally even if they are not expected to be used. Otherwise, the endoscopic image may freeze, or other irregularities may occur during examination and may cause patient injury, bleeding, and/or perforation.

CAUTION

Detach the sterilization cap from the venting connector after gas sterilization (e.g., ethylene oxide gas sterilization, hydrogen peroxide low temperature plasma). Otherwise, the remote switches may not work normally due to a difference between internal and external pressures of the endoscope.

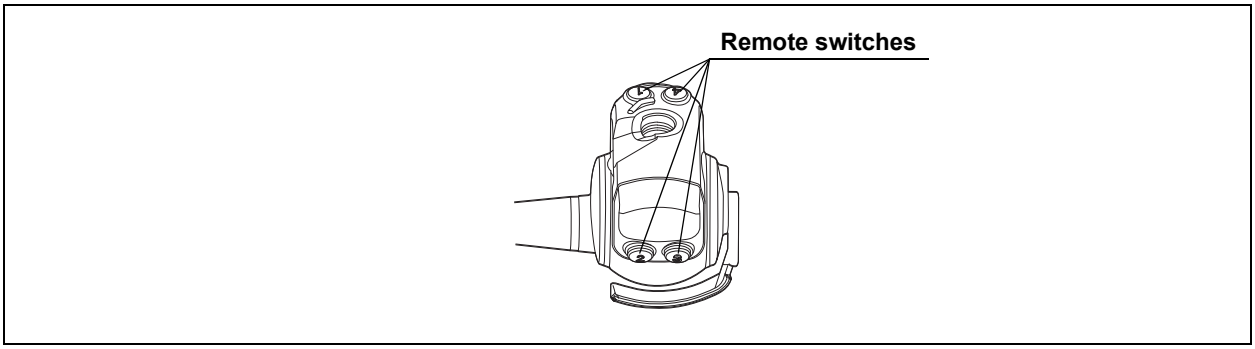


Figure 3.29

1 Depress every remote switch.

2 Confirm that the specified functions work normally.

■ *Inspection of the water feeding function*

1 Insert a syringe filled with sterile water into the biopsy valve.

2 Depress the plunger. Confirm that water is discharged from the distal end of the endoscope.

NOTE

- For proper operation, the syringe must be inserted fully and held perpendicular to the biopsy valve. Angled or incomplete insertion may result in fluid leakage from the biopsy valve.
- Do not depress the suction valve during water feeding. If the suction valve is depressed during water feeding, water will be aspirated into the suction tube instead of being discharged from the endoscope's distal end.
- If fluid is not discharged from the endoscope's distal end, flush air through the channel.

■ *Inspection of the suction function*

WARNING

- Set the aspiration pressure of the suction pump within the range of –34 kPa to 0 kPa. Excessive aspiration pressure may make it difficult to stop suction.
- If the suction valve does not operate smoothly, detach it and reattach it, or replace it with a new one. If the endoscope is used while the suction valve is not working properly, it may be impossible to stop suctioning, which could cause patient injury. If the reattached or replaced suction valve fails to operate smoothly, the endoscope may be malfunctioning; stop using it and contact Olympus.

1 Turn ON the suction pump.

2 Adjust the suction pressure within the range of –34 to 0 kPa.

3 Immerse the distal end of the insertion section in sterile water.

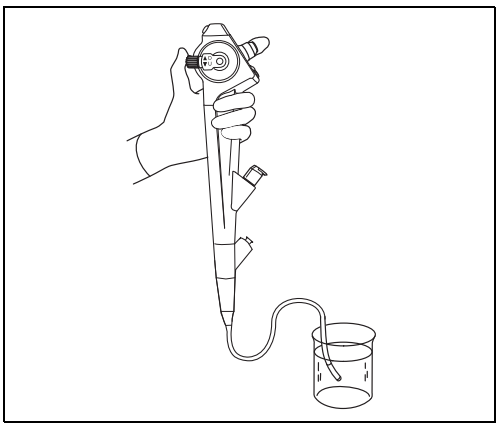


Figure 3.30

4 Depress the suction valve and confirm that water is continuously aspirated into the suction bottle on the suction pump.

5 Release the suction valve. Confirm that suction stops and that the suction valve returns smoothly to its original position.

6 Remove the distal end of the insertion section from the water.

7 Depress the suction valve and aspirate air for a few seconds to remove water from the instrument channel and suction channel.

■ *Inspection of the instrument channel*

WARNING

Keep your eyes away from the distal end when inserting EndoTherapy accessories. Extending the EndoTherapy accessory from the distal end could cause eye injury.

CAUTION

- If significant resistance is encountered and insertion becomes very difficult, straighten the bending section as much as possible without losing the endoscopic image. Inserting EndoTherapy accessories with excessive force may damage the endoscope and/or the EndoTherapy accessories.
- Confirm that the tip of the EndoTherapy accessory is closed or retracted into its sheath and slowly insert the EndoTherapy accessory into the forceps port of the forceps/irrigation plug. Do not open the tip of the EndoTherapy accessory or extend the tip of the EndoTherapy accessory from its sheath while inserting it into the channel. The endoscope and/or the EndoTherapy accessory may be damaged.

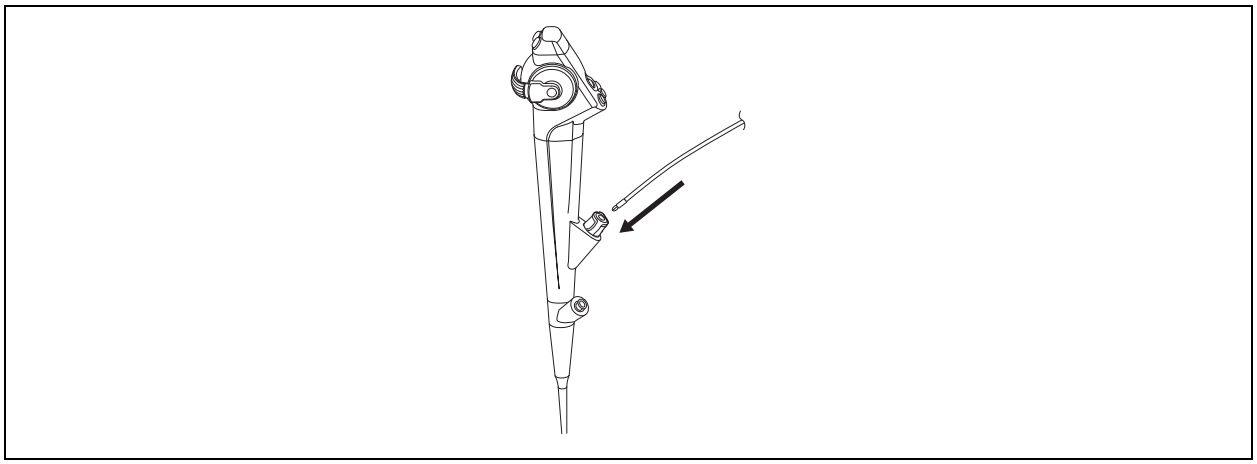


Figure 3.31

1. Straighten the insertion section of the endoscope.
2. Insert the EndoTherapy accessory straight through the biopsy valve while closing its distal end and retracting it into the sheath.
3. Confirm that the EndoTherapy accessory extends smoothly from the distal end of the endoscope. Also, make sure that no foreign objects come out of the distal end.
4. Confirm that the EndoTherapy accessory can be withdrawn smoothly from the biopsy valve.

■ *Inspection of the water feeding function into the balloon*

NOTE

If the balloon is over-inflated, sterile water will leak from the distal end to prevent balloon rupture or detachment. Therefore, it is desirable to use saline solution for avoiding patient coughs.

1 Connect the extension tube, 3-way stopcock, and syringe to the irrigation port as shown in Figure 3.32.

2 Fill the syringe with 10 to 15 cm^3 (10 to 15 ml) of sterile, de-aerated water, or saline and connect it to the 3-way stopcock and depress the plunger.

3 Confirm that water is emitted from the distal end.

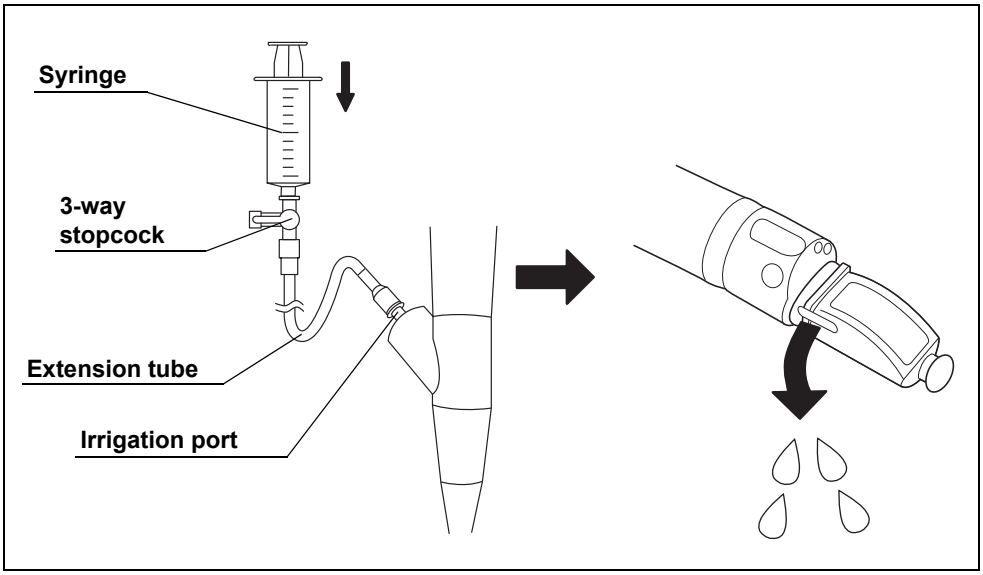


Figure 3.32

■ *Inspection of the ultrasound image with the Olympus universal endoscopic ultrasound center EU-ME1*

1 Turn on the ultrasound center.

NOTE

A progress bar is displayed after connecting the ultrasound endoscope. While the progress bar is displayed, information on the connected ultrasound endoscope will be updated on the endoscopic ultrasound center. Do not turn OFF the ultrasound center while the progress bar is displayed.

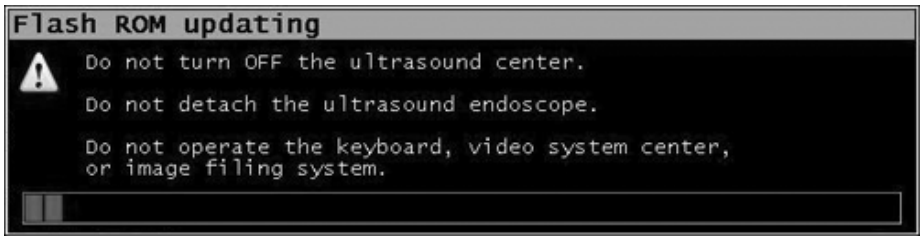


Figure 3.33

2 Inspect the endoscopic ultrasound center as described in its instruction manual.

3 When setting the frequency, choose the setting value CLA5, and then select the frequencies available with the keyboard. Refer to EU-ME1 instruction manual for instructions on how to set the frequency.

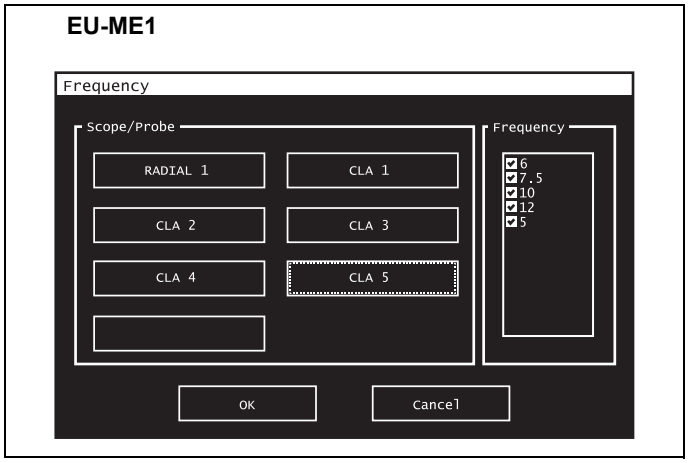


Figure 3.34

4 Press the “FREEZE” switch on the endoscopic ultrasound center to change the ultrasound image to the REAL-TIME mode.

5 Confirm that the ultrasound image is visible on the monitor.

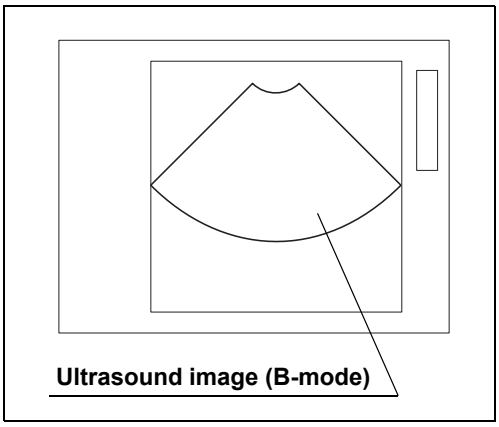


Figure 3.35

6 Press the “FREEZE” switch to change the ultrasound image to the FREEZE mode.

■ *Inspection of the ultrasound image with the EVIS EUS endoscopic ultrasound center EU-ME2 PREMIER PLUS, EU-ME2 PREMIER, EU-ME2*

1 Turn on the endoscopic ultrasound center.

2 Inspect the endoscopic ultrasound center as described in its instruction manual.

3 When setting the frequency, choose the setting value CLA5, and then the frequencies available with the keyboard. Refer to EU-ME2 PREMIER PLUS, EU-ME2 PREMIER, EU-ME2 instruction manual for instructions on how to set the frequency.

EU-ME2 PREMIER PLUS, EU-ME2 PREMIER, EU-ME2

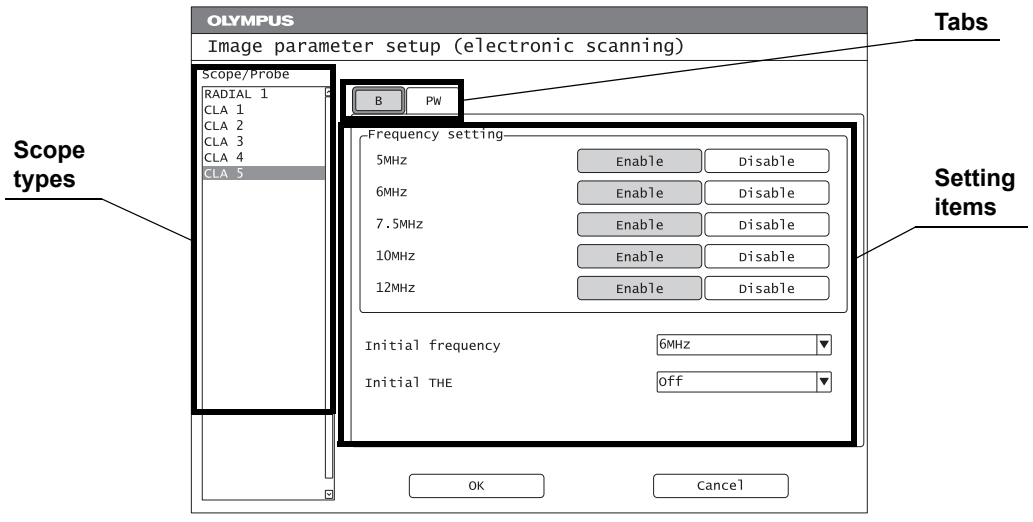


Figure 3.36

4 Press the “FREEZE” switch on the endoscopic ultrasound center to change the ultrasound image to the REAL-TIME mode.

5 Confirm that the ultrasound image is visible on the monitor.

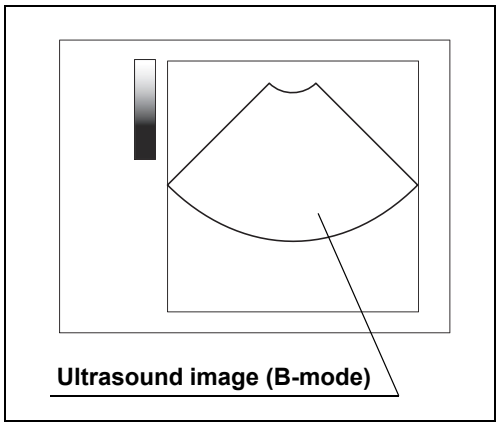


Figure 3.37

6 Press the “FREEZE” switch to change the ultrasound image to the FREEZE mode.

■ *Inspection of the ultrasound image with the diagnostic ultrasound system (Hitachi, Ltd.) ProSound F75*

1 Inspect the diagnostic ultrasound system as described in its instruction manual.

2 Turn the diagnostic ultrasound system ON.

3 Confirm that the ultrasound image is visible on the diagnostic ultrasound system.

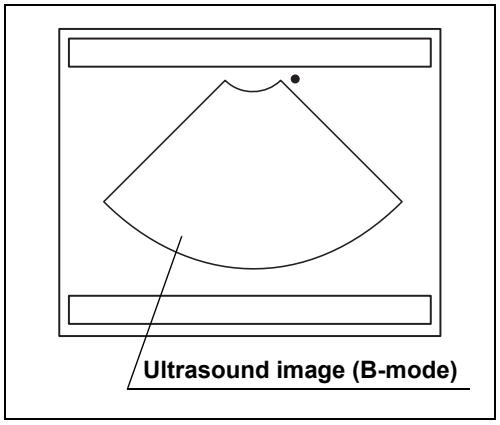


Figure 3.38

4 Press the “FREEZE” switch to change the ultrasound image to the FREEZE mode.

3.10 Preparation and inspection of the balloon

WARNING

- Balloons used with this instrument contain natural rubber latex that may cause allergic reactions in some individuals. Do not use the balloon on a latex-sensitive patient.
- The balloons are disposable and are intended for a single-use only. A new one must be used for each patient.
  Do not attempt to reuse or sterilize a balloon.
  This could pose an infection control risk or cause equipment damage.
- Confirm that the balloon applicator has been properly reprocessed as described in the “REPROCESSING MANUAL”
- If you find a peel pack that is open, damaged, or soiled, do not use the balloon in that pack.

CAUTION

- The balloon can easily tear, so beware of sharp objects.
- Store the balloon in a cool environment with low humidity.
- After opening the laminate package, reseal it securely. If the laminate package remains open, the efficacy of the deoxidizer will be reduced.

■ *Attaching the balloon*

1 Prepare the balloon and the balloon applicator.

2 Inspect the balloon and confirm that it has no holes, no swelling, no color changes, or no other irregularities. If an irregularity is detected, do not use the balloon; use a spare instead, inspecting it thoroughly before use.

3 Grab the tip of the balloon with the applicator. Fold the rear band back onto the applicator.

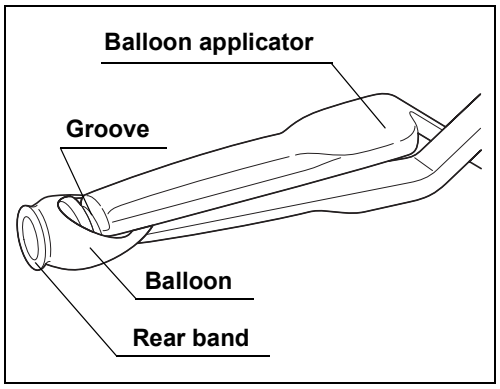


Figure 3.39

4 Position the rear band onto the groove of the applicator.

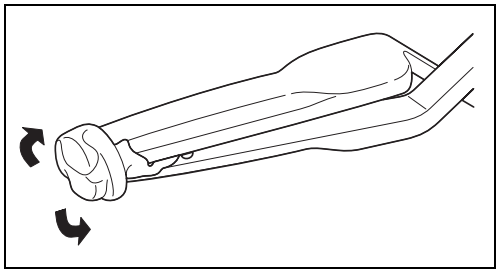


Figure 3.40

5 Open the applicator wide enough to fit the ultrasound transducer of the endoscope into it.

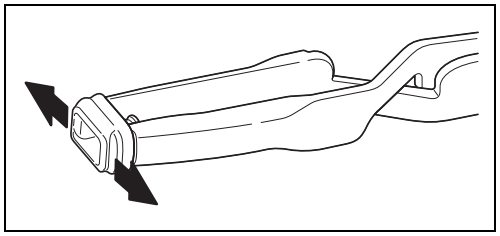


Figure 3.41

CAUTION

In Step 6 to 8 below, do not apply excessive force to or bend the distal end of the endoscope. Instrument damage may occur.

6 Insert the ultrasound transducer of the endoscope into the balloon.

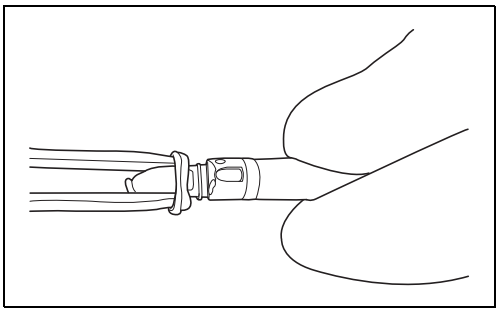


Figure 3.42

7 Put the rear band of the balloon into the rear balloon groove of the endoscope. Then, move the applicator DOWN, away from the distal end of the endoscope.

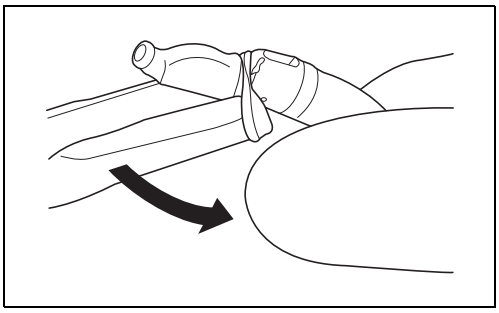


Figure 3.43

8 After performing the steps above, the balloon should be attached to the scope.

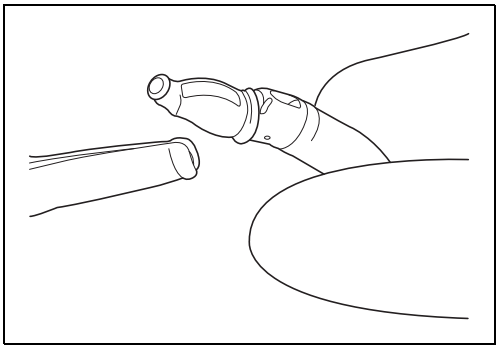


Figure 3.44

9 Fill the syringe with sterile de-aerated water or saline.

10 Connect the syringe to the 3-way stopcock and depress the plunger to inflate the balloon. While inflating the balloon, point the distal end of the endoscope upward.

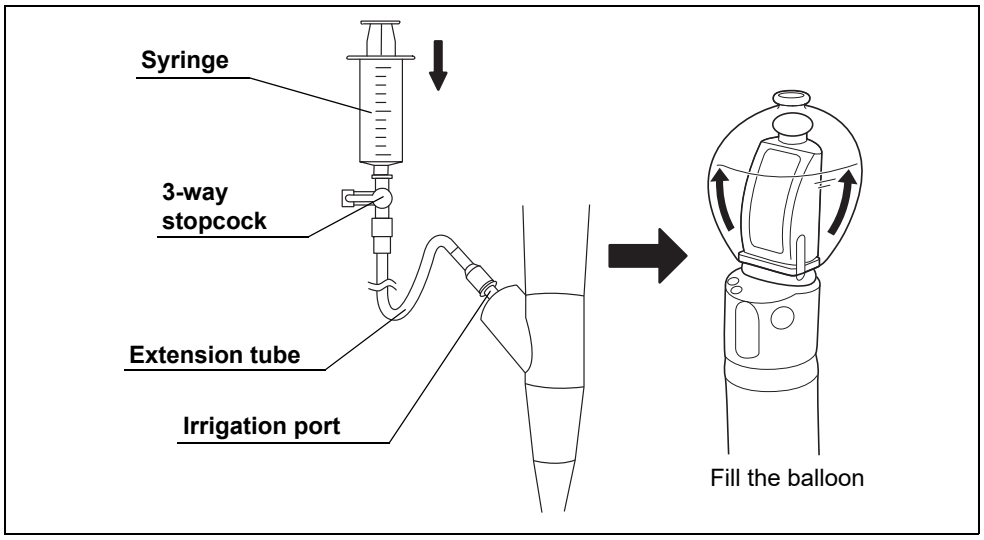


Figure 3.45

NOTE

In Step 10, the balloon's front band is not attached to the endoscope's balloon attachment groove. Therefore, water will be emitted from the front end of the balloon. Place the distal end of the endoscope in a beaker or any other container to prevent the floor from getting wet.

11 Gently grip the balloon with your fingers and squeeze out air bubbles from the front end of the balloon.

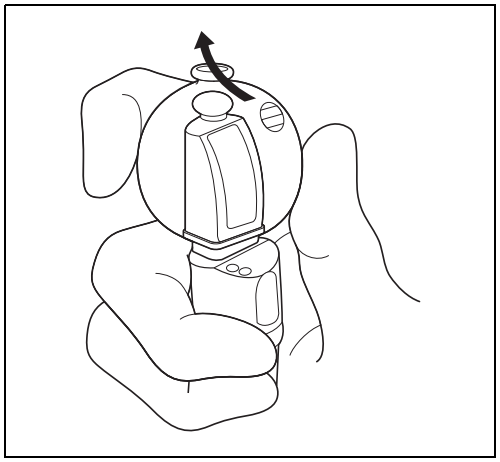


Figure 3.46

CAUTION

Do not apply excessive force to or bend the distal end of the endoscope. Instrument damage may occur.

12 Attach the front band of the balloon to the endoscope's balloon attachment groove using your finger.

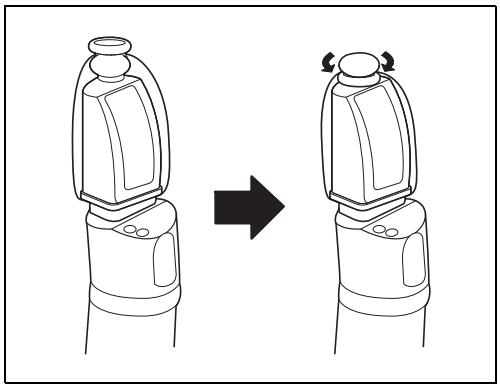


Figure 3.47

■ *Inspection of the balloon and expelling air*

1 Inflate the balloon to a diameter of about 15 mm by pushing the syringe's plunger. Confirm that there is no water leakage in the balloon.

2 Visually confirm that there are no air bubbles in the balloon. (See Figure 3.49)

3 If the balloon has no air bubbles and no water leakage has been detected, deflate the balloon by pulling the syringe's plunger. Turn the 3-way stopcock to stop feeding water.

4 If the water leaks from the band of the balloon, press the band into the balloon groove.

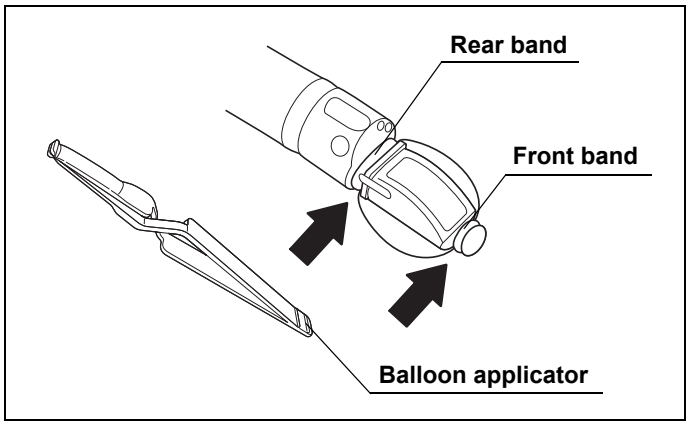


Figure 3.48

5 If air bubbles are observed in the balloon, lower the distal end of the endoscope. Deflate the balloon by pulling the syringe's plunger to remove the bubbles.

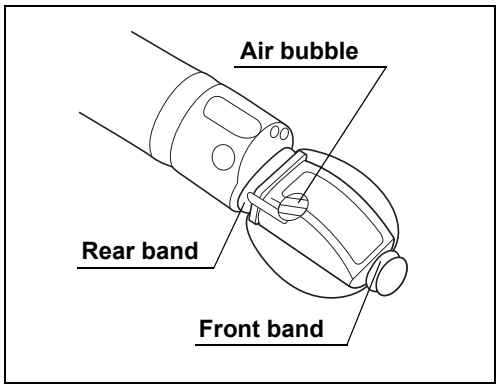


Figure 3.49

6 After confirming that there are no water leakage and no air bubbles in the balloon, deflate the balloon by pulling the syringe's plunger. Turn the 3-way stopcock to stop feeding water.

WARNING

Never tie both ends of the balloon with sterile cotton thread. This may cause the balloon to rupture or come off the distal end of the endoscope when over-inflated. This can result in patient injury.

Chapter 4 Operation

This manual does not explain or discuss clinical endoscopic procedures. It only describes basic operation and precautions related to the operation of this endoscope.

4.1 Precautions

WARNING

- To guard against dangerous chemicals and potentially infectious material during the procedure, wear personal protective equipment, such as eyewear, face mask, moisture-resistant clothing, and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed.
- The temperature of the distal end of the endoscope may exceed 41°C (106°F) and reach 50°C (122°F) due to intense endoscopic illumination. Surface temperatures over 41°C (106°F) may cause mucosal burns. Always maintain a suitable distance necessary for adequate viewing while using the minimum level of illumination for the minimum amount of time. Do not use close stationary viewing or leave the distal end of the endoscope close to the mucous membrane for a long time without necessity.
- Whenever possible, do not leave the endoscope illuminated before and/or after an examination. Continued illumination will cause the distal end of the endoscope to become hot and could cause operator and/or patient burns.
- If significant resistance is felt during insertion, do not insert, withdraw, or turn the insertion tube of the endoscope with excessive force. Patient injury, bleeding, and/or perforation may occur.
- Never insert or withdraw the endoscope under any of the following conditions. Patient injury, bleeding, and/or perforation can result.
  - While the EndoTherapy accessory extends from the distal end of the endoscope.
  - While the bending section is locked in position.
  - Insertion or withdrawal with excessive force.
- Transnasal insertion is accompanied by the risk of inflammation of the nasal cavity. If this happens, the nasal passage will be constricted, making it more difficult to withdraw the endoscope. In this case, do not use force to withdraw the endoscope because patient injury, bleeding, and/or perforation may result.

WARNING

- Transnasal insertion is accompanied by the risk of bleeding in the nasal cavity. Be sure to be prepared to deal with any bleeding. When withdrawing the endoscope, observe the inside of the nasal cavity to ensure that there is no bleeding. Even when the endoscope has been withdrawn without bleeding, do not allow the patient to blow his or her nose strongly because this could cause it to start bleeding.
- Before transnasal insertion, apply the appropriate pretreatment and lubrication to the patient to enlarge the nasal cavity. Otherwise, patient injury can result or the endoscope could become lodged and be difficult to withdraw. When applying a pretreatment agent through a tube, insert the tube into the same path as the path planned for the endoscope's insertion. Otherwise, the treatment will have no effect. The effects of the pretreatment agent and lubricant will decrease as the procedure lasts longer. Apply the pretreatment agent or lubricant as required during the procedure – for example, when withdrawal seems to be difficult.
- If any of the following conditions occur during an examination, immediately stop the examination and withdraw the endoscope from the patient as described in Section 5.3, "Withdrawal of the endoscope with an irregularity".
  - If any irregularity is observed with the functionality of the endoscope.
  - If the endoscopic image on the monitor disappears or freezes unexpectedly.
  - If the endoscopic image on the monitor appears blurry or foggy unexpectedly.
  - If the UP/DOWN angulation control lever does not move.
  - If the angulation control mechanism is not functioning properly.

  Continued use of the endoscope under these conditions could result in patient injury, bleeding, and/or perforation.
- If an abnormal endoscopic image appears or an abnormal function occurs but quickly corrects itself, the endoscope may have malfunctioned. In this case, stop using the endoscope because the irregularity can occur again and the endoscope may not return to its normal condition. Stop the examination immediately and slowly withdraw the endoscope while viewing the endoscopic image. Otherwise, patient injury, bleeding, and/or perforation can result.
- When a part of the endoscopic image, normal colors, or a whole image is not displayed, the image sensor may be damaged. Using the damaged image sensor continuously for a long time makes the distal end of the endoscope extremely hot. Immediately turn OFF the video system center and light source. Otherwise, operator or patient burns may result.

WARNING

- Turn the video system center ON to operate the light source's automatic brightness function. When the video system center is OFF, it cannot operate the light source's automatic brightness function, and the light intensity may be set to the maximum level. In this case, the distal end of the endoscope can become hot and could cause operator and/or patient burns.
- Never force the insertion section if resistance is encountered. Patient injury, perforation, and/or equipment damage may occur.
- Always lubricate the balloon before insertion. Otherwise, the balloon could rupture or come off. This could result in patient injury.
- When using this instrument, never block the trachea with the balloon. This could result in suffocation.
- Deflate the balloon before withdrawing the endoscope from the patient. Withdrawing the endoscope while the balloon is inflated could result in patient injury.

CAUTION

- If the endoscope is dropped or the distal end of the endoscope receives a hard impact, the endoscope may be damaged even if a crack or chip of the lens on the distal end cannot be found. Stop using the endoscope and contact Olympus.
- Before disconnecting the ultrasound cable (MAJ-2056, optional) from the endoscope, confirm that the ACTIVE lamp is not lit. Equipment damage may result if the endoscope or the ultrasound cable is connected or disconnected while the ACTIVE lamp illuminates.

NOTE

Set the brightness of the light source to the minimum level necessary to perform the procedure safely. If the endoscope is used for a prolonged period at or near maximum light intensity, vapor may be observed in the endoscopic image. This is caused by the evaporation of organic material (blood, etc.) due to heat generated by the light guide near the light guide lens. If this vapor continues to interfere with the examination, remove the endoscope, wipe the distal end with lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol, reinsert the endoscope, and continue the examination.

4.2 Insertion

■ Holding and manipulating the endoscope

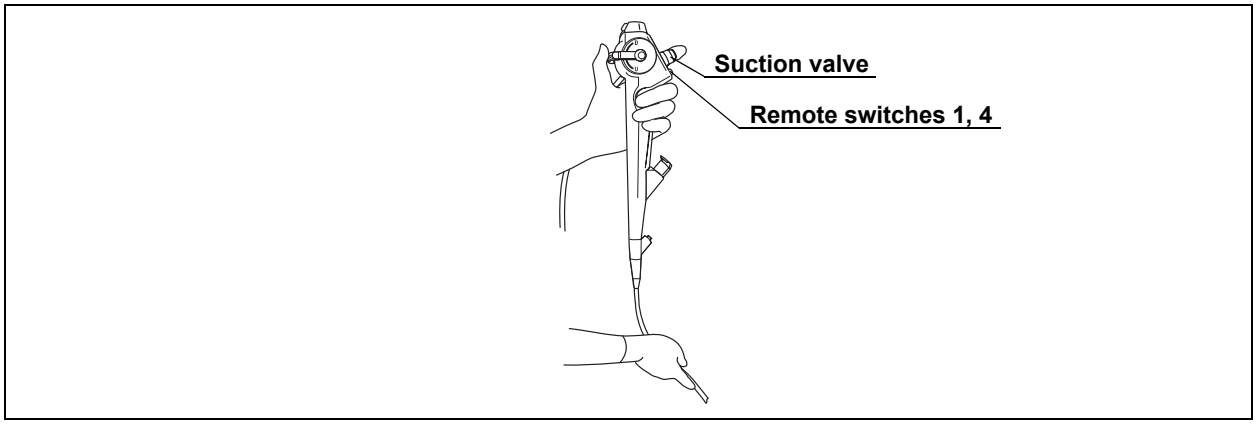


Figure 4.1

1 The control section of the endoscope is designed to be held in the left hand. The suction valve can be operated using the left index finger. The UP/DOWN angulation control lever can be operated using the left thumb.

2 Maintain the insertion section using the right hand.

■ *Insertion of the endoscope*

WARNING

- The shape and size of the nasal cavity and its suitability for transnasal insertion may vary from patient to patient. No endoscope, including this one, can always be inserted transnasally into all patients. Before proceeding, always be sure to confirm that transnasal insertion is possible with the patient by considering both the size of the patient's nasal cavity as well as the size of the endoscope's insertion section. Otherwise, patient injury can result or the endoscope could become lodged and difficult to withdraw.
- Transnasal insertion of the endoscope should be performed carefully. If resistance to insertion is felt, or the patient reports pain, stop the insertion immediately. Otherwise, patient injury can result or the endoscope could become lodged and difficult to withdraw.

CAUTION

- When inserting the endoscope through the mouth, place the mouthpiece in the patient's mouth as necessary before inserting the endoscope to prevent the patient from accidentally biting the insertion section. Biting the insertion section may result in breakage of the cable or malfunction of the light guide.
- When the patient has dental prostheses, remove them from the patient's mouth before placing a mouthpiece. Otherwise, the dental prostheses or mouthpiece may loosen during the examination.
- Confirm the patient's dental condition before using the mouthpiece. If any irregularity, such as teeth under treatment or lack of teeth is observed, the teeth may be broken.
- Do not apply olive oil or products containing petroleum-based lubricants (e.g., Vaseline®) to the endoscope. These products may cause stretching and deterioration of the bending section's covering.
- Do not apply silicone oil to the ultrasound transducer surface.
  Silicone oil may cause deterioration of the ultrasound transducer surface.

CAUTION

- Do not allow the insertion section to be bent within a distance of 10 cm or less from the junction of the boot. Insertion section damage can occur.

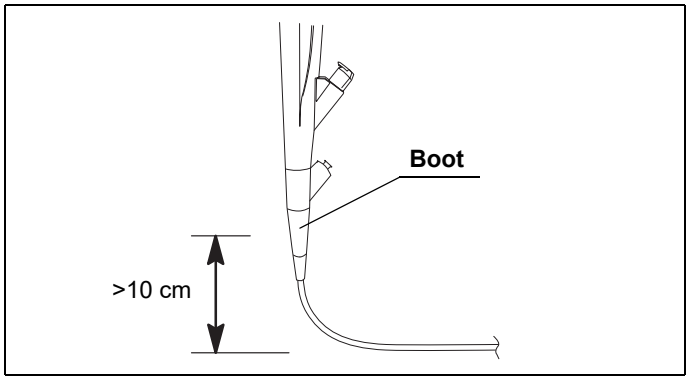


Figure 4.2

1 If necessary, apply a medical-grade, water-soluble lubricant to the insertion section and balloon.

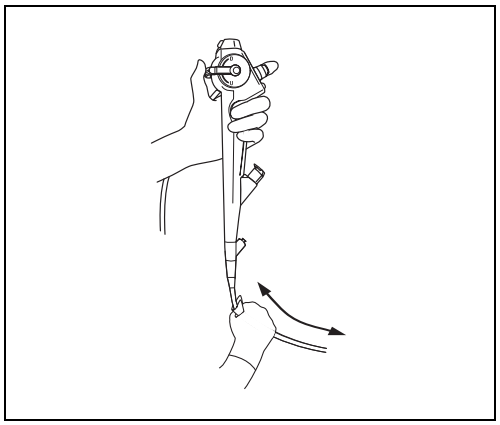


Figure 4.3

2 If necessary, insert the flexible endotracheal tube into the trachea to lead the endoscope smoothly.

NOTE

The recommended inner diameter of the endotracheal tube is 8.0 mm or more.

3 Place the mouthpiece between the patient's teeth or gums, with the outer flange on the outside of the patient's mouth.

4 Insert the distal end of the endoscope through the opening of the mouthpiece, then from the mouth to the pharynx, while viewing the endoscopic image. When using an endotracheal tube, insert the endoscope into the endotracheal tube.

■ *Angulation of the distal end*

WARNING

- If the angulation control mechanism or any other part of the system is not functioning properly, stop the examination immediately. Then carefully withdraw the endoscope while observing the endoscopic image. If the endoscope cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope carefully. If the endoscope cannot be withdrawn from the patient, consider removing it through open surgery and take proper measures. Forcibly withdrawing the endoscope may cause patient injury, bleeding, and/or perforation. If any irregularity with the endoscope is observed, contact Olympus.
- Operate the UP/DOWN angulation control lever slowly while observing the endoscopic image. Otherwise, patient injury may result.

CAUTION

Avoid forcible or excessive angulation, as this imposes load on the wire controlling the bending section and may cause stretching or tearing of the wire and trouble in the action of the bending section.

Operate the UP/DOWN angulation control lever slowly to guide the distal end for insertion and observation.

■ *Feeding fluids*

CAUTION

Do not depress the suction valve while feeding fluids. The fluids will be aspirated into the suction pump.

1 Securely insert a syringe into the slit of the biopsy valve.

2 Depress the plunger to feed fluids.

■ *Suction*

WARNING

- When aspirating, attach the biopsy valve to the instrument channel port. If the valve is not attached properly, it can reduce the efficacy of the endoscope's suction system and may cause patient debris to leak or spray. It can pose an infection control risk.
- When aspirating, maintain the suction pressure at the lowest level necessary to perform the procedure. Excessive suction pressure could cause aspiration of and/or injury to the mucous membrane. In addition, patient fluids could leak or spray from the biopsy valve, posing an infection control risk.
- Avoid aspirating solid matter or thick fluids; channel or suction valve clogging can occur. If the suction valve clogs and suction cannot be stopped, disconnect the suction tube from the suction connector on the suction valve. Then turn the suction pump OFF, detach the suction valve and remove solid matter or thick fluids.

CAUTION

During the procedure, make sure that the suction bottle does not fill completely or overflow. Aspirating fluids into a full bottle may cause the suction pump to malfunction.

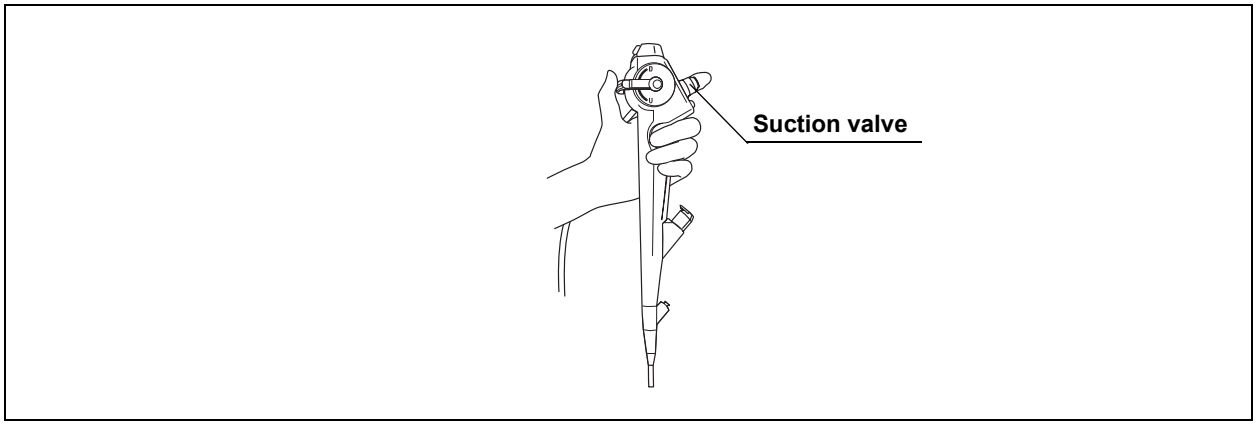


Figure 4.4

Depress the suction valve to aspirate excess fluid or other debris obscuring the endoscopic image.

■ *Observation of the endoscopic image*

NOTE

Unlike general videoscopes, which have Charge-Coupled Device (CCD) in the distal end of the insertion section, this endoscope has a different mechanism: The endoscopic image is transmitted to the camera section via the image guide and converted into an electrical signal with the CCD in the camera section. Therefore, tiny black dots may appear in the endoscopic image if the image guide fibers are damaged. This is similar to what happens with standard fiberscopes.

Refer to the light source's instruction manual for instructions on how to adjust the brightness.

■ *Observation of the ultrasound image*

WARNING

Never inflate the balloon to a diameter of more than 20 mm when using the endoscope in the trachea. This could result in suffocation of the patient.

NOTE

If the balloon is over-inflated, sterile water will leak from the balloon attachment groove to prevent balloon rupture or detachment from the endoscope.

1 Position the distal end of the endoscope beyond the target site and press the “FREEZE” switch on the ultrasound system to change the ultrasound image to REAL-TIME mode.

2 Turn the 3-way stopcock and inflate the balloon to the desired diameter by pushing the syringe’s plunger. When inflation is complete, turn the 3-way stopcock again to stop water feeding.

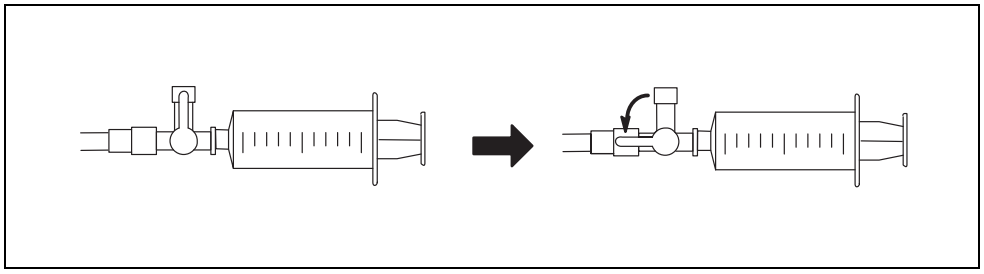


Figure 4.5

3 When the ultrasound image of the target appears, adjust the ultrasound system as described in its instruction manual to obtain a suitable image.

4 Use the endoscope’s angulation mechanism to bring the balloon into full contact with the tracheal or bronchial wall. Move the distal end of the endoscope to the target site.

CAUTION

Deflate the balloon and keep the endoscopic ultrasound center in the FREEZE mode, except during ultrasound observation.

4.3 Using EndoTherapy accessories

For more information on combining the endoscope with particular EndoTherapy accessories, refer to "■ Compatible EndoTherapy accessories" on page 100 and the instruction manuals for the accessories. Also, refer to their respective instruction manuals for operating the accessories.

WARNING

- When using EndoTherapy accessories, keep the distance between the distal end of the endoscope and the mucous membrane greater than the endoscope's minimum visible distance so that the EndoTherapy accessory remains visible in the endoscopic image. If the distal end of the endoscope is placed closer than its minimum visible distance, the position of the accessory cannot be seen in the endoscopic image. This could cause serious patient injury and/or equipment damage. The minimum visible distance depends on the type of endoscope being used. Refer to Section 2.2, "Specifications".
- When inserting or withdrawing an EndoTherapy accessory, confirm that its distal end is closed or completely retracted into the sheath. Insert or withdraw the EndoTherapy accessory slowly and straight into or from the slit of the biopsy valve. Otherwise, the biopsy valve or instrument channel may be damaged and pieces of it could fall off. It may cause patient injury.
- If insertion or withdrawal of EndoTherapy accessories is difficult, straighten the bending section as much as possible without losing the endoscopic image. Inserting or withdrawing EndoTherapy accessories with excessive force may damage the instrument channel or EndoTherapy accessories and could cause some parts to fall off and/or cause patient injury.
- If the distal end of an EndoTherapy accessory is not visible in the endoscopic image, do not open the distal end or extend needle of the instrument. This could cause patient injury, bleeding, perforation, and/or equipment damage.
- If the EndoTherapy accessory cannot be withdrawn from the endoscope, close the tip of the EndoTherapy accessory or retract the tip of the EndoTherapy accessory into its sheath. Then carefully withdraw both the endoscope and the EndoTherapy accessory together while observing the endoscopic image. Inserting or withdrawing EndoTherapy accessories with excessive force may damage the instrument channel or EndoTherapy accessories and/or cause patient injury.
- Do not use the channel cleaning brush for cytologic tissue sampling or other diagnostic or therapeutic purposes. Patient injury, cross-contamination, and/or equipment damage may occur.
- Ultrasound guided needle aspiration should only be performed when the needle is visible in the ultrasound image.

WARNING

- If the ultrasound image disappears or the needle is not visible in the ultrasound image while using the needle, stop the procedure immediately and withdraw the needle from the tissue.
- Ultrasound guided needle aspiration should only be performed when the needle is visible in the ultrasound image.
- This endoscope is incompatible with laser cauterization. Performing laser cauterization may cause patient injury and/or equipment damage.
- Never use high-frequency EndoTherapy accessories, because the distal end of this instrument is not isolated.

CAUTION

- Select the EndoTherapy accessories compatible with the endoscope by referring to “Channel inner diameter” in “■ Specifications” on page 26.
- When using a biopsy forceps with a needle, confirm that the needle is not bent excessively. A bent needle could protrude from the closed cups of the biopsy forceps. Using such a biopsy forceps could damage the instrument channel and/or cause patient injury.
- When using an injector, be sure not to extend or retract the needle from the catheter of the injector until the injector is extended from the distal end of the endoscope. The needle could damage the instrument channel if extended inside the channel, or if the injector is inserted or withdrawn while the needle is extended.

NOTE

When using EndoTherapy accessories, the image might become dark. In that case, adjust the brightness of the light source.

■ *Insertion of EndoTherapy accessories into the endoscope*

WARNING

- Do not insert EndoTherapy accessories forcibly or abruptly. The EndoTherapy accessory may extend from the distal end of the endoscope abruptly, which could cause patient injury, bleeding, and/or perforation.
- Do not let the EndoTherapy accessory hang down from the biopsy valve, which can create a space between the accessory and the valve's slit or hole. This can damage the valve, which can reduce the efficacy of the endoscope's suction system and may leak or spray patient debris or fluids, posing an infection control risk.
- When inserting an EndoTherapy accessory, hold it close to the biopsy valve and insert it slowly and straight into the biopsy valve. Otherwise, the EndoTherapy accessory and/or biopsy valve could be damaged. This can reduce the efficacy of the endoscope's suction system and may leak or spray patient debris or fluids, posing an infection control risk.

CAUTION

- When the bending section of the endoscope angulates significantly and insertion of an EndoTherapy accessory becomes very difficult, straighten the bending section as much as possible. Inserting the EndoTherapy accessory with excessive force may damage the instrument channel and/or the EndoTherapy accessory.
- Hold the EndoTherapy accessory close to the slit of the biopsy valve and insert it straight into the slit using slow short strokes. Otherwise, the EndoTherapy accessory could bend or break.
- Do not open the tip of the EndoTherapy accessory or extend the tip of the EndoTherapy accessory from its sheath while the accessory is in the instrument channel. The instrument channel and/or the EndoTherapy accessory may become damaged.

CAUTION

- When the endoscope is bent at a sharp angle and the bending section and/or the insertion tube appear in the endoscopic image, be sure not to extend the EndoTherapy accessory from distal end of the endoscope. Equipment damage may result.
- When using the aspiration needle (NA series), refer to the instruction manuals for the aspiration needle (NA series). Otherwise, the instrument channel and/or the EndoTherapy accessory may become damaged.

1 Select EndoTherapy accessories compatible with the endoscope from "■ Compatible EndoTherapy accessories" on page 100 and the accessories' instruction manuals for operating instructions.

2 Hold the UP/DOWN angulation control lever stationary.

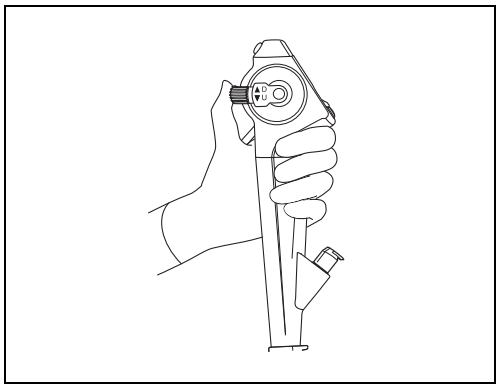


Figure 4.6

3 Confirm that the tip of the EndoTherapy accessory is closed or retracted into its sheath.

4 Insert the EndoTherapy accessory slowly and straight into the slit of the biopsy valve.

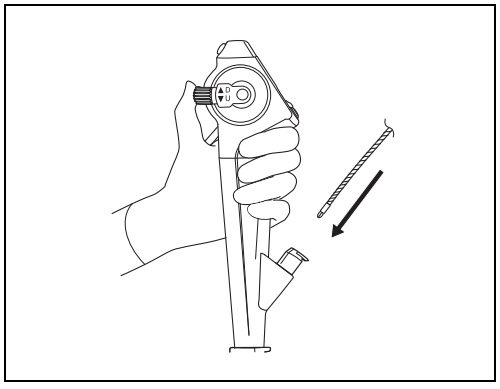


Figure 4.7

5 Hold the EndoTherapy accessory at a point approximately 4 cm from the slit of the biopsy valve and advance it slowly and straight into the slit using short strokes while observing the endoscopic image.

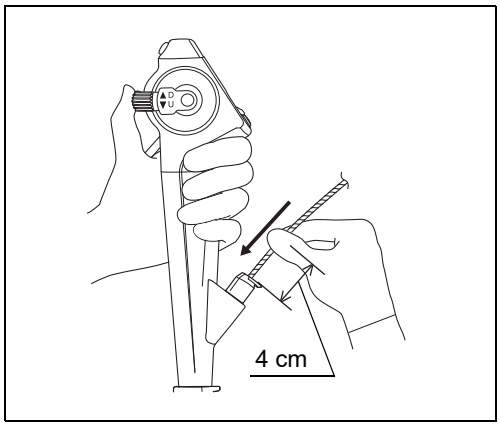


Figure 4.8

NOTE

When the tip of the EndoTherapy accessory extends approximately 1 cm from the distal end of the endoscope, the accessory will appear in the endoscopic image.

■ *Operation of EndoTherapy accessories*

Operate the EndoTherapy accessory according to the directions given in its instruction manual.

■ *Withdrawal of EndoTherapy accessories*

WARNING

- Do not withdraw the EndoTherapy accessory if the tip is open or extended from its sheath; patient injury, bleeding, perforation, and/or endoscope damage may occur.
- Fluid might spray when the EndoTherapy accessories are withdrawn from the biopsy valve. To prevent this, hold a piece of gauze around the accessory and the slit of the biopsy valve during withdrawal.
- Withdraw the EndoTherapy accessory slowly and straight out of the biopsy valve. Otherwise, the biopsy valve could be damaged. This can reduce the efficacy of the endoscope's suction system, and may leak or spray patient debris, posing an infection control risk.
- If the EndoTherapy accessory cannot be withdrawn from the endoscope, close the EndoTherapy accessory and/or retract it into its sheath. Then carefully withdraw both the endoscope and the EndoTherapy accessory together under endoscopic observation. Take care not to cause tissue trauma.

Withdraw the EndoTherapy accessory slowly while the tip of the EndoTherapy accessory is closed and/or retracted into its sheath.

■ *High-frequency cauterization treatment*

WARNING

Never use the high-frequency EndoTherapy accessories for the BF-UC190F, because the distal end of the BF-UC190F is not insulated.
Patient injury may result.

■ *Laser cauterization*

WARNING

The BF-UC190F is incompatible with laser cauterization. Performing laser cauterization may cause patient injury and/or equipment damage.

■ *Bronchoalveolar lavage*

❍ Using the BAL (bronchoalveolar lavage) kit

1 Disconnect the suction tube from the suction valve. Connect the suction tube to the suction connector of a commercially available BAL kit. Connect the BAL kit's suction line to the suction connector of the suction valve.

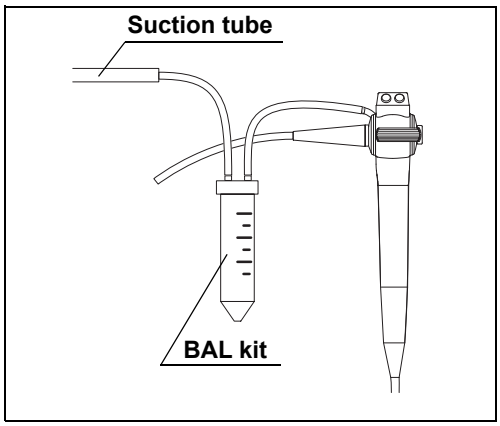


Figure 4.9

2 Securely insert a syringe filled with lavage fluid (e.g., saline) into the slit of the biopsy valve and press the plunger to feed lavage fluid.

3 Depress the suction valve to aspirate lavage fluid.

❍ Using a syringe

CAUTION

Angled or incomplete insertion may result in leakage of solution from the valve.

1 Securely insert a syringe into the slit of the biopsy valve.

2 Press the plunger to feed lavage fluid.

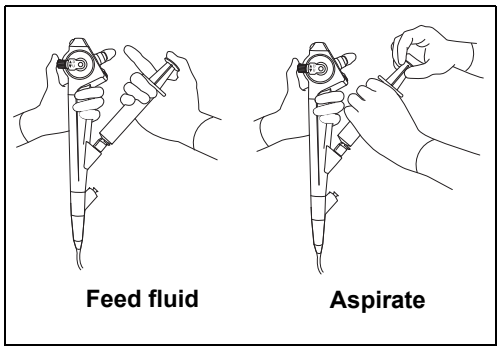


Figure 4.10

3 With the syringe attached, slowly withdraw the plunger to aspirate lavage fluid.

4.4 Withdrawal of the endoscope

WARNING

- If blood unexpectedly adheres to the surface of the insertion section of the withdrawn endoscope, carefully check the condition of the patient.
- If it becomes impossible to withdraw the transnasally inserted endoscope, pull its distal end out of the mouth, cut the flexible tube using wire cutters, and after ensuring that the cut section will not injure the body cavity or nasal cavity of the patient, withdraw the endoscope carefully. Therefore, always prepare wire cutters in advance.
- If the endoscope or EndoTherapy accessory cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope carefully. If the endoscope cannot be withdrawn from the patient, consider removing it through open surgery and take proper measures. Forcibly withdrawing the endoscope or EndoTherapy accessory may cause patient injury, bleeding, and/or perforation. If any irregularity with the endoscope is observed, contact Olympus.
- Avoid patient fluids adhering to the withdrawn endoscope from coming in contact with the bed or floor. The patient fluids may pose an infection control risk to the patient and/or medical personnel.
- Observe the endoscopic image or the ultrasound image on the monitor and confirm that the balloon deflates properly. Otherwise, patient injury may occur.
- If the balloon does not deflate even when the extension tube is removed from the endoscope, insert the channel cleaning brush (BW-7B) into the irrigation port to remove debris. The balloon will be automatically deflated.

1. Open the 3-way stopcock.
2. Deflate the balloon by pulling the syringe's plunger.
3. FREEZE the ultrasound image.
4. When using the electronic zoom function of the video system center, release the function.
5. Aspirate blood, mucus, or other debris by depressing the suction valve.
6. Carefully withdraw the endoscope while observing the endoscopic image.
7. Remove the mouthpiece from the patient's mouth.
8. Remove the balloon as described in Section 4.5, "Removal of the balloon" and discard it.

9 Reprocess the endoscope and accessories after the procedure as described in the “REPROCESSING MANUAL” with your endoscope model listed on the cover.

4.5 Removal of the balloon

CAUTION

- Do not hold the ultrasound transducer when holding the insertion tube. The ultrasound transducer can be damaged, resulting in an abnormal ultrasound image.
- Do not squeeze the ultrasound transducer forcefully. The ultrasound transducer can be damaged, resulting in an abnormal ultrasound image.
- Do not remove the balloon with equipment such as forceps, needle holder, or hemostat that may scratch the surface of the ultrasound transducer. The ultrasound transducer can be damaged, resulting in an abnormal ultrasound image.
- Do not pinch the ultrasound transducer surface and balloon together when removing the balloon. The ultrasound transducer can be damaged, resulting in an abnormal ultrasound image.

NOTE

Picking up the balloon with a clean lint-free cloth makes it easier to remove the balloon.

1 Using a clean lint-free cloth, gently wipe and dry the balloon surface.

2 Roll up the rear end of the balloon with your fingers. (See Figure 4.11)

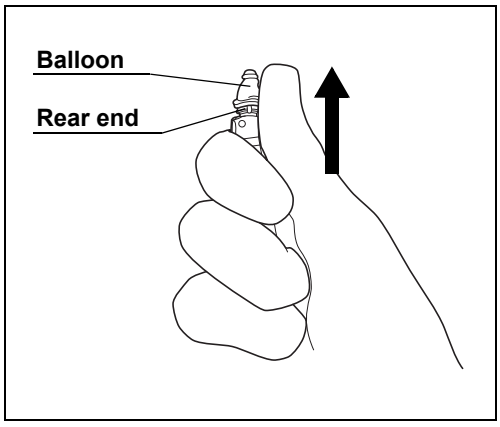


Figure 4.11

3 Gently detach the front band from the balloon attachment groove. (See Figure 4.12)

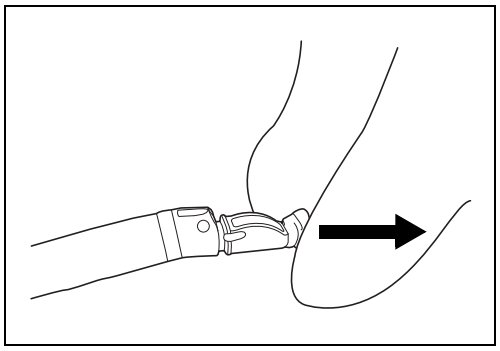


Figure 4.12

4 After the removal of the balloon, confirm that the surface of the ultrasound transducer is free from scratches. In case the ultrasound transducer surface is scratched, stop using the instrument and contact Olympus.

4.6 Transportation of the endoscope

■ Transporting within the healthcare facility

When carrying the endoscope by hand, loop the universal cord, hold the endoscope connector 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.

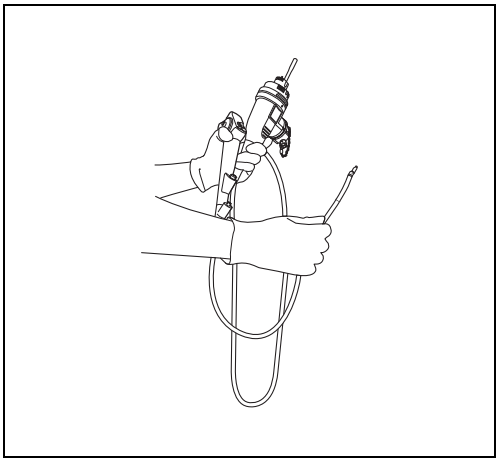


Figure 4.13

■ Transporting outside the healthcare facility

WARNING

Always reprocess the endoscope after removing it from the carrying case. If the endoscope is not reprocessed, it could pose an infection control risk.

CAUTION

- Use a dedicated carrying case. Transporting the endoscope in another carrying case may cause equipment damage.
- The carrying case cannot be reprocessed. Reprocess the endoscope before placing it in the carrying case.
- Do not attach the US connector cap (MAJ-2295) when transporting the endoscope, to avoid damage to the endoscope caused by changes in air pressure.

Transport the endoscope in the carrying case.

Chapter 5 Troubleshooting

The countermeasures against troubles are described in this chapter.

5.1 Troubleshooting

If any irregularity is observed during the inspection described in Chapter 3, “Preparation and Inspection”, do not use the endoscope and solve the problem as described in Section 5.2, “Troubleshooting guide”.

If the problem still cannot be resolved, send the endoscope to Olympus for repair as described in Section 5.4, “Returning the endoscope for repair”.

Also, should any irregularity be observed while using the endoscope, stop using it immediately and withdraw the endoscope from the patient as described Section 5.3, “Withdrawal of the endoscope with an irregularity”.

WARNING

- Never use the endoscope on a patient if any irregularity is observed. The irregular endoscope may compromise patient or user safety and may result in more severe equipment damage. In addition, it may pose an infection control risk.
- If any parts of the endoscope fall off inside the patient body due to equipment damage or failure, stop using the endoscope immediately and retrieve the parts in an appropriate way.

The accessories are consumables. Olympus does not repair accessory parts. If an accessory part becomes damaged, contact Olympus to purchase a replacement.

5.2 Troubleshooting guide

The following table shows the possible causes of and countermeasures against troubles that may occur due to equipment setting errors or deterioration of consumables.
Troubles or failures due to other causes than those listed below should be serviced. As repair performed by persons who are not qualified by Olympus could cause patient or user injury and/or equipment damage, be sure to contact Olympus for repair following the instructions given in Section 5.4, “Returning the endoscope for repair”.

■ *Image quality or brightness*

Irregularity description	Possible cause	Solution
An image is not displayed.	Not all equipment is ON.	Turn ON all equipment.
	The endoscope connector is not connected securely.	Connect the endoscope connector securely until it stops and clicks.
	Foreign objects such as detergent remnants, hard water residue, finger grease, dust, and lint are on the electrical contacts on the endoscope connector.	Wipe the electrical contacts on the endoscope connector using clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol and completely dry them as described in Section 3.3, “Inspection of the endoscope”. After drying them, connect the endoscope to the light source and confirm that a proper image is displayed when twisting the endoscope connector left and right.
An image is not clear.	The objective lens at the distal end of the endoscope is dirty.	Wipe the objective lens with clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol.
An image is excessively dark or bright.	The light guide lens at the distal end of the endoscope is dirty.	Wipe the light guide lens with clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol.
	The glass at the endoscope connector end is dirty.	Wipe the glass with clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol.
	The light source is not set properly.	Adjust the light source’s setting as described in its instruction manual.
An image is not proper.	An incompatible video system center is being used.	Use a compatible video system center.
	An incompatible light source is being used.	Use a compatible light source.
	Foreign objects such as detergent remnants, hard water residue, finger grease, dust, and lint are on the electrical contacts on the endoscope connector.	Wipe the electrical contacts on the endoscope connector using clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol and completely dry them as described in Section 3.3, “Inspection of the endoscope”. After drying them, connect the endoscope to the light source and confirm that a proper image is displayed when twisting the endoscope connector left and right.
A black point is shown in an endoscopic image.	An image guide fiber has broken.	When the image to be observed is not visible, send the endoscope to Olympus for repair.

■ *Water feeding*

Irregularity description	Possible cause	Solution
The fluid is leaking from the biopsy valve.	The biopsy valve is attached incorrectly.	Attach it correctly.
	The syringe is not inserted securely.	Insert it securely.
The biopsy valve cannot be attached.	An incorrect biopsy valve is used.	Use a correct biopsy valve.
	The biopsy valve is damaged.	Replace it with a new one.

■ *Suction*

Irregularity description	Possible cause	Solution
The suction is absent or insufficient.	The biopsy valve is not attached incorrectly.	Attach it correctly.
	The biopsy valve is damaged.	Replace it with a new one.
	The suction pump is not set properly.	Adjust the suction pump's setting as described in its instruction manual.
	The suction valve is damaged.	Replace it with a new one.
The suction valve is sticking.	The suction valve is damaged.	Replace it with a new one.
The suction valve does not return to its original position.	The aspiration pressure is too high.	Lower the aspiration pressure.
The suction valve cannot be attached.	An incorrect suction valve is used.	Use a correct suction valve.
	The suction valve is damaged.	Replace it with a new one.

■ *EndoTherapy accessories*

Irregularity description	Possible cause	Solution
An EndoTherapy accessory does not pass through the instrument channel smoothly.	An incompatible EndoTherapy accessory is being used.	Refer to "■ System chart" on page 97 and select a compatible EndoTherapy accessory. Confirm that the color code on the EndoTherapy accessory matches that on the endoscope.
	The bending section angulates sharply.	Straighten it as much as possible.

■ *Ultrasound (display monitor image)*

Irregularity description	Possible cause	Solution
Echo appears where there is no object.	Multiple echoes generated from an object with strong reflection.	Move the endoscope's distal end to another position and check to see if the echo in question moves to a greater degree than other echoes. If this happens, multiple echoes have coalesced and disturbed the ultrasound image. Keep the endoscope's distal end away from an object with strong reflection.

■ *Balloon water feeding and aspiration*

Irregularity description	Possible cause	Solution
Water feeding to the balloon and/or aspiration from the balloon does not work.	Balloon water supply channel is dirty.	Reprocess the channel.

■ *Others*

Irregularity description	Possible cause	Solution
The remote switch does not work.	The wrong remote switch is operated.	Operate the correct remote switch.
	The remote switch function has been set improperly.	Set the remote switch function correctly as described in the video system center's instruction manual.
	The remote switch is left depressed due to a difference between internal and external pressures of the endoscope that is made in the pressure reduction process of gas sterilization.	If the sterilization cap is attached to the venting connector, detach it. If not, attach the sterilization cap to the venting connector once and then detach it.
Air bubble is leak between the endoscope and US connector cap (MAJ-2295).	The seal of water-resistant cap is damaged.	Replace the water-resistant cap with a new one.

5.3 Withdrawal of the endoscope with an irregularity

If an irregularity occurs while the endoscope is in use, take proper measures as described in either "■ Withdrawal when the WLI endoscopic images appear on the monitor" or "■ Withdrawal when no endoscopic image appears on the monitor or a frozen image cannot be restored" on page 95. After withdrawal, return the endoscope for repair as described in Section 5.4, "Returning the endoscope for repair".

WARNING

If the endoscope or EndoTherapy accessory cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope carefully. If the endoscope cannot be withdrawn from the patient, consider removing it through open surgery and take proper measures. Forcibly withdrawing the endoscope or EndoTherapy accessory may cause patient injury, bleeding, and/or perforation. If any irregularity with the endoscope is observed, contact Olympus.

■ Withdrawal when the WLI endoscopic images appear on the monitor

1. Turn all equipment OFF except the video system center, light source, and monitor.
2. When using the electronic zoom function of the video system center, release the function.
3. When using an EndoTherapy accessory, close the tip of the EndoTherapy accessory and/or retract it into its sheath. Then withdraw the EndoTherapy accessory slowly.
4. Aspirate accumulated air, blood, mucous or other debris by depressing the suction valve.
5. Carefully withdraw the endoscope while observing the endoscopic image.
6. Remove the mouthpiece from the patient's mouth.

■ *Withdrawal when no endoscopic image appears on the monitor or a frozen image cannot be restored*

1 Turn all equipment OFF except the video system center, light source, and monitor.

2 Turn the video system center and light source OFF and then ON again. If the WLI endoscopic image appears or the frozen image is restored, follow the procedure given in "■ Withdrawal when the WLI endoscopic images appear on the monitor" on page 94, beginning from Step 2.
If the WLI endoscopic image still do not appear or the frozen image cannot be restored, perform the following steps.

3 Operate the video system center, light source, and monitor OFF.

4 When using an EndoTherapy accessory, close the tip of the EndoTherapy accessory and/or retract it into its sheath. Then withdraw the EndoTherapy accessory slowly.

5 Operate the UP/DOWN angulation control lever to its neutral position and release the angulation control lever.

6 Withdraw the endoscope from the patient carefully.

7 Remove the mouthpiece from the patient's mouth.

5.4 Returning the endoscope for repair

WARNING

Thoroughly reprocess the endoscope before returning it for repair. Improperly reprocessed equipment poses an infection control risk to each person who handles the endoscope within the healthcare facility and at Olympus.

CAUTION

Olympus is not liable for any injury or damage that occurs as a result of repairs attempted by non-Olympus personnel.

Before returning the endoscope for repair, contact Olympus. With the endoscope, include a description of the malfunction or damage and the name and telephone number of the individual at your location who is most familiar with the problem. Also, include a repair purchase order. When returning the endoscope for repair, follow the instructions given in “■ Transporting outside the healthcare facility” on page 87.

Appendix

The compatible equipment with this endoscope and the EMC information are described in this Appendix.

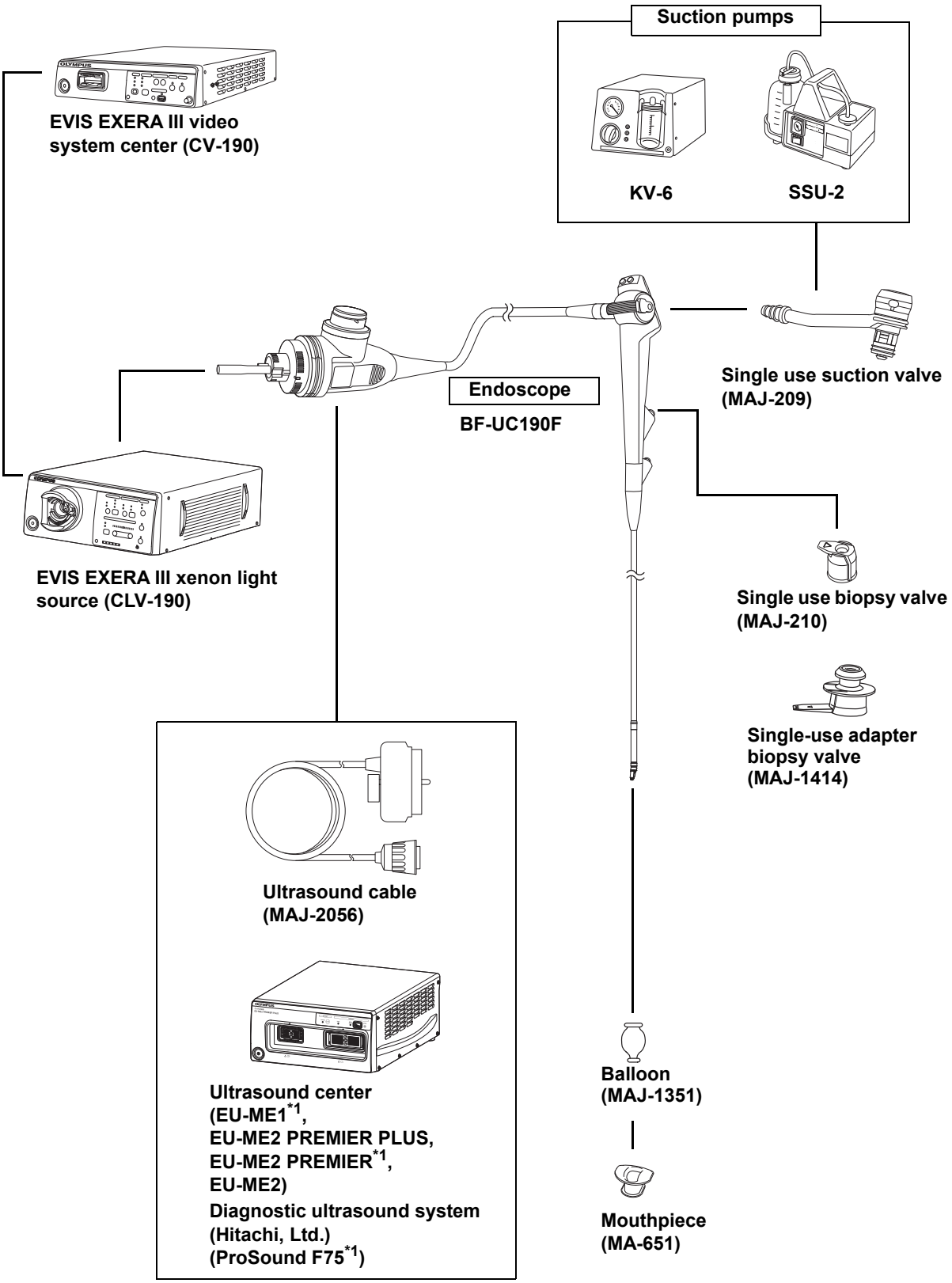
Combination equipment

■ System chart

The recommended combinations of equipment and accessories that can be used with this endoscope are listed below. Some items may not be available in some areas. New products released after the introduction of the endoscope may also be compatible for use in combination with the endoscope. For further details, contact Olympus.

WARNING

Be sure to use the equipment in one of the recommended combinations.
If combinations of equipment other than those shown below are used, the full responsibility is assumed by the medical treatment facility.

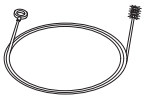


*1 These products may not be available in some areas.

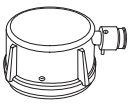
■ *Reprocessing equipment*



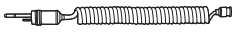
Single use combination cleaning brush (BW-411B)



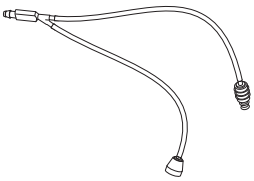
Single use single-ended cleaning brush (BW-400B)



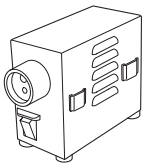
US connector cap (MAJ-2295)



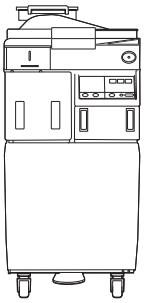
Leakage tester (MB-155)



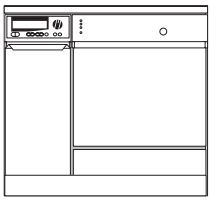
Suction cleaning adapter (MAJ-222)



Maintenance unit (MU-1)



Endoscope reprocessor (OER-AW*1)



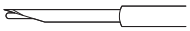
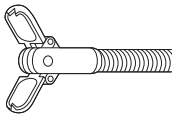
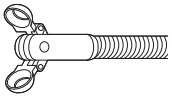
Washer-disinfector (ETD4, ETD-double)

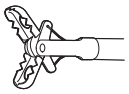
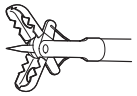
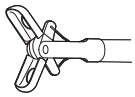
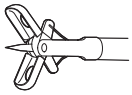
*1 OER-AW is not available in member states of the EU.

■ *Compatible EndoTherapy accessories*

❍ EndoTherapy accessories

Note that some of the accessories may not be available in some areas.

	Aspiration needle	Biopsy forceps (fenestrated)	
	Disposable	Rat tooth	Standard type
Endoscope			
BF-UC190F	NA-201SX-4021 NA-201SX-4022 NA-U401SX-4021 NA-U401SX-4022 NA-U403SX-4019 NA-U401SX-4025N	FB-56D-1	FB-19C-1 FB-19CR-1

	Single use biopsy forceps with swing jaws (fenestrated)			
	Alligator jaws type	Alligator jaws type (with needle)	Standard type	Standard type (with needle)
Endoscope				
BF-UC190F	FB-211D	FB-221D	FB-231D	FB-241D

Inspection of the endoscope after cleaning, disinfection, or sterilization in accordance with IEC 60601-2-37

After cleaning, disinfection or sterilization this instrument, check the parts or accessories that can be contaminated through contact with the patient, with body fluids, or with expired gases according to the “Method of inspection” listed below.

■ *Inspection of the endoscope after cleaning, disinfection, or sterilization*

Timing of inspection	Pertinent parts, components or functions	Method of inspection
After precleaning	Waterproof	Refer to the Section 5.4, “Leakage testing of the endoscope” in REPROSESSING MANUAL.
After cleaning, disinfection or sterilization	Inspection of the endoscope	Refer to “■ Inspection of the endoscope” on page 33.
	Bending mechanisms	Refer to “■ Inspection of the bending mechanism” on page 36.
	Suction valve	Refer to “■ Inspection of the single use suction valve (MAJ-209) or suction valve (MAJ-207, optional)” on page 38.
	Biopsy valve	Refer to “■ Inspection of the single-use adapter biopsy valve (MAJ-1414)” on page 39 and “■ Attaching the single use biopsy valve (MAJ-210)” on page 46.
	Mouthpiece	Refer to “■ Inspection of the mouthpiece (MA-651, optional)” on page 41.
	Attaching the suction valve	Refer to “■ Attaching the single use suction valve (MAJ-209) or suction valve (MAJ-207, optional)” on page 43
	Attaching the biopsy valve	Refer to “■ Attaching the single-use adapter biopsy valve (MAJ-1414)” on page 45 and “■ Attaching the single use biopsy valve (MAJ-210)” on page 46.
	Connection of the suction tube	Refer to “■ Connection of the suction tube” on page 48.

Inspection of the endoscope after cleaning, disinfection, or sterilization in accordance with IEC 60601-2-37

Timing of inspection	Pertinent parts, components or functions	Method of inspection
After cleaning, disinfection or sterilization	Connection of the ultrasound cable	Refer to "■ Connection of the endoscope and the ultrasound cable (MAJ-2056)" on page 48.
	Endoscopic image	Refer to "■ Inspection of the endoscopic image" on page 52.
	Remote switches	Refer to "■ Inspection of the remote switches" on page 53.
	Water feeding function into the balloon	Refer to "■ Inspection of the water feeding function into the balloon" on page 57.
	Suction function	Refer to "■ Inspection of the suction function" on page 55.
	Instrument channel	Refer to "■ Inspection of the instrument channel" on page 56.
	Ultrasound image	Refer to "■ Inspection of the ultrasound image with the Olympus universal endoscopic ultrasound center EU-ME1" on page 58.
	Balloon	Refer to Section 3.10, "Preparation and inspection of the balloon".

EMC information

Guidance and manufacturer's declaration — Electromagnetic emissions

This model is intended for use by medical personnel in healthcare facility environments and for use in the electromagnetic environment specified below. The customer or the user of this model should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment — Guidance
RF emissions CISPR 11	Group 1	This instrument uses RF (Radio Frequency) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated emissions CISPR 11	Class B	This instrument's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Main terminal conducted emissions CISPR 11		
Harmonic emissions IEC 61000-3-2	Class A	This instrument's harmonic emissions are low and are not likely to cause any problem in the typical commercial power supply connected to this instrument.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	This instrument stabilizes its own radio variability and has no effect such as flicker in lighting apparatus.

Radio spectrum test	Compliance	Description
AS/NZ 4268 ETSI EN 300 330	Complies  	This instrument has an inbuilt RFID that meets the requirements of Radiocommunications (Short Range Devices) standards.

Guidance and manufacturer's declaration — Electromagnetic immunity

This model is intended for use by medical personnel in healthcare facility environments and for use in the electromagnetic environment specified below. The customer or the user of this model should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 (2014) test level	IEC 60601-1-2 (2007, 2001) test level	Compliance level	IEC 60601-1-2 (2007, 2001) Electromagnetic environment — Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air: ±2, ±4, ±8, ±15 kV	Contact: ±2, ±4, ±6 kV Air: ±2, ±4, ±8 kV	Same as left	Floors should be made of wood, concrete, or ceramic tile that hardly produces static. If floors are covered with synthetic material that tends to produce static, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Same as left	Mains power quality should be that of a typical commercial (original condition feeding the facilities) or healthcare facility environment.
Surge IEC 61000-4-5	Differential mode: ±0.5, ±1 kV Common mode: ±0.5, ±1, ±2 kV for signal input/ output lines: ±2 kV	Differential mode: ±0.5, ±1 kV Common mode: ±0.5, ±1, ±2 kV	Same as left	Mains power quality should be that of a typical commercial or healthcare facility environment.

Immunity test	IEC 60601-1-2 (2014) test level	IEC 60601-1-2 (2007, 2001) test level	Compliance level	IEC 60601-1-2 (2007, 2001) Electromagnetic environment — Guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle/1 cycle	< 5% U_T (> 95% dip in U_T) for 0.5 cycle	Same as left	Mains power quality should be that of a typical commercial or healthcare facility environment. If the user of this instrument requires continued operation during power mains interruptions, it is recommended that this instrument be powered from an uninterruptible power supply or a battery.
	–	40% U_T (60% dip in U_T) for 5 cycle		
	70% U_T (30% dip in U_T) for 25 cycle (50 Hz)/ 30 cycle (60 Hz) Phase angle causing voltage dips: 0°	70% U_T (30% dip in U_T) for 25 cycle		
	0% U_T (100% dip in U_T) for 250 cycle (50 Hz)/ 300 cycle (60 Hz)	< 5% U_T (> 95% dip in U_T) for 5 seconds		
	U_T is the a.c. mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (50 Hz or 60 Hz)	3 A/m (50 Hz, 60 Hz)	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current.

<table>
<tr><th>Immunity test</th><th>IEC 60601-1-2 (2014) test level</th><th>IEC 60601-1-2 (2007, 2001) test level</th><th>Compliance level</th><th>IEC 60601-1-2 (2007, 2001) Electromagnetic environment — Guidance</th></tr>
<tr><td rowspan="3">Conducted RF
IEC 61000-4-6</td><td>3V
(150 kHz – 80 MHz)</td><td>3V (V_1)
(150 kHz – 80 MHz)</td><td>Same as left</td><td rowspan="2">Recommended separation distance
$d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$
Where “P” is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer and “d” is the recommended separation distance in meters [m].</td></tr>
<tr><td>6V
(ISM band of 150 kHz – 80 MHz)</td><td>–</td><td>Same as left</td></tr>
<tr><td colspan="4">ISM (industry, science, and medical care) band of 6.765 MHz – 6.795 MHz, 13.553 MHz – 13.567 MHz, 26.957 MHz – 27.283 MHz, and 40.66 MHz – 40.70 MHz between 0.15 MHz and 80 MHz</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3V/m (80 MHz – 2.7 GHz)</td><td>3V/m (E_1)
(80 MHz – 2.5 GHz)</td><td>Same as left</td><td rowspan="2">Recommended separation distance
$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$
80 MHz – 800 MHz
$d = \left[\frac{7}{E_1}\right]\sqrt{P}$
800 MHz – 2.5 GHz
Where “P” is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer and “d” is the recommended separation distance in meters [m].</td></tr>
<tr><td>Proximity magnetic field from RF communication equipment
IEC 61000-4-3</td><td>Refer to the table of the next page.</td><td>–</td><td>Same as left</td></tr>
</table>

NOTE

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- Electromagnetic interference may occur in the vicinity of high-frequency electrosurgical equipment and/or other equipment marked with the following symbol:



NOTE

- Field strength from fixed RF transmitters as determined by an electromagnetic site survey[a)] should be less than the compliance level in each frequency range[b)].

  a) Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this model is used exceeds the applicable RF compliance level above, this model should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this model.

  b) Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Test frequency [MHz]	Band [MHz]	Modulation*1	Maximum power [W]	Immunity test level [V/m]
385	380 – 390	Pulse modulation*1 18 Hz	1.8	27
450	430 – 470	FM ±5 kHz deviation 1 kHz sine	2	28
710	704 – 787	Pulse modulation*1 217 Hz	0.2	9
745				
780				
810	800 – 960	Pulse modulation*1 18 Hz	2	28
870				
930				
1720	1700 – 1990	Pulse modulation*1 217 Hz	2	28
1845				
1970				
2450	2400 – 2570	Pulse modulation*1 217 Hz	2	28
5240	5100 – 5800	Pulse modulation*1 217 Hz	0.2	9
5500				
5785				

*1 The carrier shall be modulated using a 50% duty cycle square wave signal.

WARNING

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 this instrument, including cables specified by Olympus. Otherwise, degradation of the performance of this equipment could result.

❍ Guidance and manufacturer's declaration — Cables used for EMC compliance testing

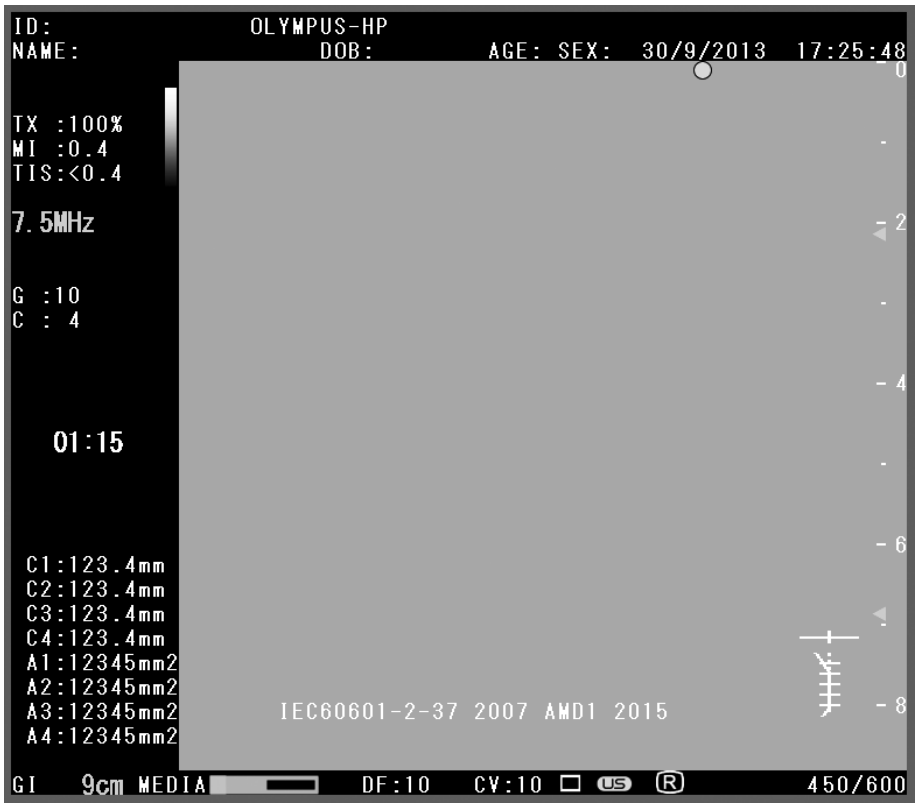
Refer to the instruction manuals for each piece of equipment.

Acoustic output information in accordance with IEC 60601-2-37

■ Acoustic output table with EVIS EUS endoscopic ultrasound center EU-ME2 PREMIER PLUS, EU-ME2 PREMIER, EU-ME2

In the case of the following conditions, confirm that “IEC60601-2-37 2007 AMD1 2015” is displayed on the screen.

- When the Ultrasound Center is turned ON.
- At the end of the examination.
- When the ACTIVE switch is OFF.



App.

When “IEC60601-2-37 2007 AMD1 2015” is not displayed.
Refer to sound data listed in “Appendix Acoustic output information in accordance with IEC 60601-2-37” sections “Symbol key (IEC 60601-2-37)” and “Acoustic output Reporting table (IEC 60601-2-37) (EU-ME2)”.

When “IEC60601-2-37 2007 AMD1 2015” is displayed.
Refer to sound data listed in “Appendix Acoustic output information in accordance with IEC 60601-2-37” sections “Symbol key (IEC 60601-2-37:2007+A1:2015)” and “Acoustic output table (IEC 60601-2-37:2007+A1:2015) (EU-ME2)”.

Symbol key (IEC 60601-2-37)

MI	Mechanical Index (MI) is given by $MI = \frac{p_{r\alpha} f_{awf}^{-1/2}}{C_{MI}}$ where C_{MI}=1MPaMHz-1/2; $p_{r\alpha}$ is the attenuated peak-rarefaction pressure in megapascals (MPa): f_{awf} is the acoustic working frequency in megahertz (MHz).
TI	Thermal Index (TI) is the ratio of attenuated acoustic power at a specified point to the attenuated acoustic power required to raise the temperature at that point in specific tissue model by 1°C
TIS_{scan}	Thermal Index related to soft tissues in autoscanning mode.
$TIS_{non\text{-}scan}$	Thermal Index related to soft tissues in non autoscanning mode.
TIB	Thermal Index for applications, such as fetal (second and third trimester) or neonatal cephalic (through the fontanelle), in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of a bone.
TIC	Thermal Index for applications, such as paediatric and adult cranial applications, in which the ultrasound beam passes through bone near the beam entrance into the body.
A_{aprt}	Area of the ultrasound beam derived from the –12 dB output beam dimensions (cm^2).
p_r	Peak-rarefactional acoustic pressure (p_r) is maximum of the modulus of the negative instantaneous acoustic pressure in an acoustic field during an acoustic repetition period (MPa).
$p_{r,\alpha}$	Attenuated peak-rarefactional acoustic pressure is the value of the peak-rarefactional acoustic pressure after attenuation and at a specified point (MPa).
P	Output power (P) is the time-average power radiated by an ultrasound transducer into an approximately free field under specified conditions in a specified medium, preferably water (mW).
$P_{\alpha(z_s)}$	Value of acoustic output power after attenuation and at zs from the transducer (mW).
$I_{spta,\alpha}$	Value of attenuated spatial-peak temporal-average intensity.
$I_{ta,\alpha(z_s)}$	Value of the temporal-average intensity after attenuation and at zs from the transducer (mW/cm^2).
$I_{pa,\alpha}$	Value of the acoustic pulse-average integral after attenuation and at a specified point (W/cm^2).
$I_{pi,\alpha}$	Value of the pulse intensity integral after attenuation and at a specified point (mJ/cm^2).

z_s	Depth for soft-tissue Thermal Index (zs) is the distance from the plane where the –12 dB output beam dimensions are determined along the beam alignment axis to the plane at which the lower value of the attenuated output power and the product of the attenuated spatial-peak temporal-average intensity and 1 cm^2 is maximized over the distance range equal to, or more than, 1.5 times the equivalent aperture diameter (diameter of a circle whose area is the –12 dB output beam area) (cm).
z_{bp}	Break-point depth (zbp) is the value equal to 1.5 times the equivalent aperture diameter (cm).
z_b	Depth for bone Thermal Index (zb) is the distance from the plane where the –12 dB output beam dimensions are determined along the beam alignment axis to the plane where the product of attenuated output power and attenuated pulse-intensity integral is maximum (cm).
$d_{eq\ (z_b)}$	Value of the diameter of the acoustic beam at the distance zb in terms of the equivalent beam area (value of the area of the acoustic beam at a specified point) (cm).
f_{awf}	Acoustic working frequency (fawf) is the arithmetic mean of the most separated frequencies f_1 and f_2 at which the amplitude of the pressure spectrum of the acoustic signal is 3 dB lower than the peak amplitude (MHz).
X,Y	–12 dB output beam dimensions (X,Y) are dimensions of the ultrasound beam (–12 dB pulse beam width) in specified directions normal to the beam alignment axis and at the transducer output face (cm).
t_d	Pulse duration (td) is 1.25 times the interval between the time when the time integral of intensity in an acoustic pulse at a point reaches 10% and when it reaches 90% of the pulse intensity integral (µs).
prr	Pulse repetition rate (prr) is inverse of the time interval between two successive acoustic pulses (Hz).
FL	The focal length, or azimuthal (x) and elevational (y) lengths, if different (cm).

Symbol key (IEC 60601-2-37:2007+A1:2015)

MI	Mechanical Index (MI) is given by $MI = \frac{p_{r,\alpha}(Z_{MI}) f_{awf}^{-1/2}}{C_{MI}}$ where C_{MI}=1MPa·MHz$^{-1/2}$ $P_{r,\alpha}(Z_{MI})$ is the attenuated peak-rarefactional acoustic pressure at the depth Z_{MI} f_{awf} is the acoustic working frequency.
TI	Thermal Index (TI) is the ratio of attenuated output power at a specified point to the attenuated output power required to raise the temperature at that point in a specific tissue model by 1°C
TIS	Soft tissue thermal index (TIS) is the thermal index related to soft tissues.
TIB	Thermal index for applications such as foetal (second and third trimester), in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.
TIC	Thermal index for applications in which the ultrasound beam passes through bone near the beam entrance into the body, such as paediatric and adult cranial or neonatal cephalic applications.
p_r	Peak-rarefactional acoustic pressure (pr) is the maximum of the modulus of the negative instantaneous acoustic pressure in an acoustic field or in a specified plane during an acoustic repetition period.
$p_{r,\alpha}$	Attenuated peak-rarefactional acoustic pressure is the value of the peak-rarefactional acoustic pressure after attenuation at a specified point (MPa).
z_{MI}	Depth for mechanical index (Z_{MI}) is the depth on the beam-axis from the external transducer aperture to the plane of maximum attenuated pulse intensity integral (pii_α).
P	Output power (P) is the time-average ultrasonic power emitted by an ultrasonic transducer into an approximately free field under specified conditions in a specified medium, preferably water.
P_{1x1}	Bounded-square output power (P_{1x1}) is the maximum value of the time average acoustic output power emitted from any one-centimetre square region of the active area of the transducer, the one-centimetre square region having 1 cm dimensions in the x- and y-directions.
I_{spta}	Spatial-peak temporal-average intensity (I_{spta}) is the maximum value of the temporal-average intensity in an acoustic field or in a specified plane.
$I_{spta,\alpha}$	Attenuated spatial-peak temporal-average intensity is the value of the spatial-peak temporal-average intensity after attenuation, at a specified distance from the external transducer aperture.
$I_{pa,\alpha}$	Attenuated pulse-average intensity is the value of the acoustic pulse-average intensity after attenuation and at a specified point.
z_s	Depth for TIS non-scanning is the distance along the beam axis from the external transducer aperture to the plane at which the lower value of the attenuated output power and the product of the attenuated spatial-peak temporal-average intensity and 1 cm^2 is maximized over the distance range equal to, or greater than, the break-point depth, zbp.
z_b	Depth for TIB non-scanning is the distance along the beam axis from the external transducer aperture to the plane where the product of attenuated output power and attenuated spatial-peak temporal-average intensity is a maximum over the distance range equal to, or greater than, the break-point depth, zbp.

z_{pii}	Depth for peak pulse-intensity integral (zpii) is the position of maximum spatial-peak temporal-average intensity for non-scanning mode components, determined beyond the break-point depth, zbp, on the beam-axis.
$z_{pii, \alpha}$	Depth for peak attenuated pulse-intensity integral ($z_{pii, \alpha}$) is the position of maximum attenuated spatial-peak temporal-average intensity for non-scanning mode components, determined beyond the break-point depth, z_{bp}, on the beam-axis.
z_{sii}	Depth for peak sum of pulse-intensity integrals (z_{sii}) is the position of maximum spatial-peak temporal-average intensity for scanning mode components, determined beyond the break-point depth, z_{bp}, on the beam-axis.
$z_{sii, \alpha}$	Depth for peak sum of attenuated pulse-intensity integrals ($z_{sii, \alpha}$) is the position of maximum attenuated spatial-peak temporal-average intensity for scanning mode components, determined beyond the break-point depth, zbp, on the beam-axis.
f_{awf}	Arithmetic-mean acoustic-working frequency (fawf) is the arithmetic mean of the most widely separated frequencies f_1 and f_2, within the range of three times f_1, at which the magnitude of the acoustic pressure spectrum is 3 dB below the peak magnitude.
prr	Pulse repetition rate (prr) is the reciprocal of the pulse repetition period.
srr	Scan repetition rate (srr) is the reciprocal of the scan repetition period.
n_{pps}	Number of pulses per ultrasonic scan line is the number of acoustic pulses travelling along a particular ultrasonic scan line.
TISas, sc	Soft tissue thermal index at surface, scanning
TISas, ns	Soft tissue thermal index at surface, non-scanning
TISbs, sc	Soft tissue thermal index below surface, scanning
TISbs, nc	Soft tissue thermal index below surface, non-scanning
TIBas, sc	Bone thermal index at surface, scanning
TIBas, ns	Bone thermal index at surface, non-scanning
TIBbs, sc	Bone thermal index below surface, scanning
TIBbs, nc	Bone thermal index below surface, non-scanning

■ *Acoustic output table with the Olympus universal endoscopic ultrasound center EU-ME1*

BF-UC190F will not exceed the statistical maximum of the global maximum MI of 1.9, the statistical maximum of the global maximum TI of 6.0, and the statistical maximum of the global maximum derated $I_{spta.\alpha}$ of 720 mW/cm^2 in any mode. In addition, the BF-UC190F will not exceed the global maximum displayed MI or TI of 1.0 in any mode.

■ *Acoustic output table with EVIS EUS endoscopic ultrasound center EU-ME2 PREMIER PLUS, EU-ME2 PREMIER, EU-ME2*

BF-UC190F will not exceed the statistical maximum of the global maximum MI of 1.9, the statistical maximum of the global maximum TI of 6.0, and the statistical maximum of the global maximum derated $I_{spta.\alpha}$ of 720 mW/cm^2 in any mode.

❍ Transducer/Mode Combination Summary (Whether the global maximum displayed MI or TI is greater than 1.0. or not)

The following table shows the transducer/mode combinations for which the global maximum displayed MI or TI is greater than 1.0.

Labeling " ↓ " shows that the global maximum displayed MI or TI is greater than 1.0

System : EU-ME2

	Mode of Operation						
Transducer Mode	**B**	**M[*1]**	**PWD**	**CWD[*1]**	**Color Doppler**	**Combined (Specify)**	**Other[*1] (Specify)**
BF-UC190F	↓		↓		↓	↓	

System : EU-ME2 PREMIER[*2]

	Mode of Operation						
Transducer Mode	**B**	**M[*1]**	**PWD**	**CWD[*1]**	**Color Doppler**	**Combined (Specify)**	**Other[*1] (Specify)**
BF-UC190F	↓		↓		↓	↓	

System : EU-ME2 PREMIER PLUS

	Mode of Operation						
Transducer Mode	**B**	**M[*1]**	**PWD**	**CWD[*1]**	**Color Doppler**	**Combined (Specify)**	**Other[*1] (Specify)**
BF-UC190F	↓		↓		↓	↓	

*1 These modes are not available with this system.

*2 This equipment may not be available in some areas.

Acoustic Output Reporting Table (IEC 60601-2-37:2007) (EU-ME2)

The following tables show global maximum acoustic output values for each possible system/transducer/mode combination.

Acoustic Output Reporting Table

System: **EU-ME2** Operating Mode: **B mode**
Transducer Model: **BF-UC190F**

Index label				MI	TIS			TIB	TIC
					Scan	Non-scan		Non-scan	
						A_{aprt}≤1cm²	A_{aprt}>1cm²		
Maximum Index Value				1.03	0.54	(1)	(1)	(1)	(2)
Associated acoustic parameters	$p_{r,a}$		(MPa)	2.53					
	P		(mW)		16.70	#		#	#
	Min of [$P_{\alpha}(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				#		
	z_s		(cm)				#		
	z_{bp}		(cm)				#		
	z_b		(cm)					#	
	z at max $I_{pi,\alpha}$		(cm)	0.76					
	$d_{eq}(z_b)$		(cm)					#	
	f_{awf}		(MHz)	6.07	6.80	#	#	#	#
	Dim of A_{aprt}	X	(cm)		1.09	#	#	#	#
		Y	(cm)		0.10	#	#	#	#
Other information	t_d		(μsec)	0.23					
	prr		(kHz)	8.07					
	p_r at max. I_{pi}		(MPa)	2.97					
	d_{eq} at max. I_{pi}		(cm)					#	
	Focal Length	FLx	(cm)		8.50	#	#		#
		FLy	(cm)		1.40	#	#		#
	$I_{pa,\alpha}$ at max.MI		(W/cm²)	319.27					
Operating control conditions	Mode			B	B	#	#	#	#
	Frequency			5.0M	6.0M	#	#	#	#
	Display Range		(cm)	2.0	2.0	#	#	#	#
	Focus Depth (B/THE/CH-EUS)		(cm)	1.3	8.5	#	#	#	#
	Location of PW cursor / ROI		(cm)	-	-	#	#	#	#
	Acoustic output		(%)	100	100	#	#	#	#
	View Angle		(°)	61	61	#	#	#	#
	ROI Angle(Flow)		(°)	-	-	#	#	#	#
	V-Range(PRF)		(kHz)	-	-	#	#	#	#

Notes:
(1) This index is not relevant to this operating mode.
(2) This probe is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table

System: **EU-ME2** Operating Mode: **PWD mode**
Transducer Model: **BF-UC190F**

Index label				MI	TIS			TIB	TIC
					Scan	Non-scan		Non-scan	
						A_{aprt}≤1cm²	A_{aprt}>1cm²		
Maximum Index Value				1.03	0.54	(1)	(1)	1.27	(2)
Associated acoustic parameters	$p_{r,a}$		(MPa)	2.53					
	P		(mW)		16.70	#		17.48	#
	Min of [$P_{\alpha}(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				#		
	z_s		(cm)				#		
	z_{bp}		(cm)				#		
	z_b		(cm)					0.76	
	z at max $I_{pi,\alpha}$		(cm)	0.76					
	$d_{eq}(z_b)$		(cm)					0.23	
	f_{awf}		(MHz)	6.07	6.80	#	#	5.32	#
	Dim of A_{aprt}	X	(cm)		1.09	#	#	0.65	#
		Y	(cm)		0.10	#	#	0.10	#
Other information	t_d		(μsec)	0.23					
	prr		(kHz)	8.07					
	p_r at max. I_{pi}		(MPa)	2.97					
	d_{eq} at max. I_{pi}		(cm)					0.23	
	Focal Length	*FLx*	(cm)		8.50	#	#		#
		FLy	(cm)		1.40	#	#		#
	$I_{pa,\alpha}$ at max.*MI*		(W/cm²)	319.27					
Operating control conditions	Mode			B	B	#	#	PW	#
	Frequency			5.0M	6.0M	#	#	5.0M	#
	Display Range		(cm)	2.0	2.0	#	#	-	#
	Focus Depth (B/THE/CH-EUS)		(cm)	1.3	8.5	#	#	-	#
	Location of PW cursor / ROI		(cm)	-	-	#	#	5.5	#
	Acoustic output		(%)	100	100	#	#	100	#
	View Angle		(°)	61	61	#	#	-	#
	ROI Angle(Flow)		(°)	-	-	#	#	-	#
	V-Range(PRF)		(kHz)	-	-	#	#	2.2	#

Notes:
(1) This index is not relevant to this operating mode.
(2) This probe is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table

System: **EU-ME2** Operating Mode: **Color Doppler mode**
Transducer Model: **BF-UC190F**

Index label				*MI*	*TIS*			*TIB*	*TIC*
					Scan	Non-scan		Non-scan	
						A_{aprt}≤1cm^2	A_{aprt}>1cm^2		
Maximum Index Value				1.03	0.58	(1)	(1)	(1)	(2)
Associated acoustic parameters	$p_{r,\alpha}$		(MPa)	2.53					
	P		(mW)		2.15/13.95	#		#	#
	Min of [$P_\alpha(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				#		
	z_s		(cm)				#		
	z_{bp}		(cm)				#		
	z_b		(cm)					#	
	z at max $I_{pi,\alpha}$		(cm)	0.76					
	$d_{eq}(z_b)$		(cm)					#	
	f_{awf}		(MHz)	6.07	6.80/7.71	#	#	#	#
	Dim of A_{aprt}	*X*	(cm)		1.09/0.65	#	#	#	#
		Y	(cm)		0.10	#	#	#	#
Other information	t_d		(μsec)	0.23					
	prr		(kHz)	8.07					
	p_r at max. I_{pi}		(MPa)	2.97					
	d_{eq} at max. I_{pi}		(cm)					#	
	Focal Length	*FLx*	(cm)		8.50/4.50	#	#		#
		FLy	(cm)		1.40	#	#		#
	$I_{pa,\alpha}$ at max.*MI*		(W/cm^2)	319.27					
Operating control conditions	Mode			B	B/H-FLOW	#	#	#	#
	Frequency			5.0M	6.0M/7.5M	#	#	#	#
	Display Range		(cm)	2.0	2.0	#	#	#	#
	Focus Depth (B/THE/CH-EUS)		(cm)	1.3	8.5	#	#	#	#
	Location of PW cursor / ROI		(cm)	-	4.5	#	#	#	#
	Acoustic output		(%)	100	100	#	#	#	#
	View Angle		(°)	61	61	#	#	#	#
	ROI Angle(Flow)		(°)	-	61	#	#	#	#
	V-Range(PRF)		(kHz)	-	20.0	#	#	#	#

Notes:
(1) This index is not relevant to this operating mode.
(2) This probe is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table

System: **EU-ME2** Operating Mode: **Combined mode**
Transducer Model: **BF-UC190F**

Index label				MI	TIS			TIB	TIC
					Scan	Non-scan		Non-scan	
						A_{aprt}≤1cm²	A_{aprt}>1cm²		
Maximum Index Value				1.03	0.58	(1)	(1)	1.27	(2)
Associated acoustic parameters	$p_{r,a}$		(MPa)	2.53					
	P		(mW)		2.15/13.95	#		17.48	#
	Min of [$P_\alpha(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				#		
	z_s		(cm)				#		
	z_{bp}		(cm)				#		
	z_b		(cm)					0.76	
	z at max $I_{pi,\alpha}$		(cm)	0.76					
	$d_{eq}(z_b)$		(cm)					0.23	
	f_{awf}		(MHz)	6.07	6.80/7.71	#	#	5.32	#
	Dim of A_{aprt}	X	(cm)		1.09/0.65	#	#	0.65	#
		Y	(cm)		0.10	#	#	0.10	#
Other information	t_d		(μsec)	0.23					
	prr		(kHz)	8.07					
	p_r at max. I_{pi}		(MPa)	2.97					
	d_{eq} at max. I_{pi}		(cm)					0.23	
	Focal Length	FLx	(cm)		8.50/4.50	#	#		#
		FLy	(cm)		1.40	#	#		#
	$I_{pa,\alpha}$ at max.MI		(W/cm²)	319.27					
Operating control conditions	Mode			B	B/H-FLOW	#	#	PW	#
	Frequency			5.0M	6.0M/7.5M	#	#	5.0M	#
	Display Range		(cm)	2.0	2.0	#	#	-	#
	Focus Depth (B/THE/CH-EUS)		(cm)	1.3	8.5	#	#	-	#
	Location of PW cursor / ROI		(cm)	-	4.5	#	#	5.5	#
	Acoustic output		(%)	100	100	#	#	100	#
	View Angle		(°)	61	61	#	#	-	#
	ROI Angle(Flow)		(°)	-	61	#	#	-	#
	V-Range(PRF)		(kHz)	-	20.0	#	#	2.2	#

Notes:
(1) This index is not relevant to this operating mode.
(2) This probe is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table (EU-ME2 PREMIER, EU-ME2 PREMIER PLUS)

Acoustic Output Reporting Table

System: **EU-ME2 PREMIER** / **EU-ME2 PREMIER PLUS** Operating Mode: **B mode**

Transducer Model: **BF-UC190F**

Index label				MI	TIS			TIB	TIC
					Scan	Non-scan		Non-scan	
						A_{aprt}≤1cm²	A_{aprt}>1cm²		
Maximum Index Value				1.03	0.54	(1)	(1)	(1)	(2)
Associated acoustic parameters	$p_{r,\alpha}$		(MPa)	2.53					
	P		(mW)		16.70	#		#	#
	Min of [$P_\alpha(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				#		
	z_s		(cm)				#		
	z_{bp}		(cm)				#		
	z_b		(cm)					#	
	z at max $I_{pi,\alpha}$		(cm)	0.76					
	$d_{eq}(z_b)$		(cm)					#	
	f_{awf}		(MHz)	6.07	6.80	#	#	#	#
	Dim of A_{aprt}	X	(cm)		1.09	#	#	#	#
		Y	(cm)		0.10	#	#	#	#
Other information	t_d		(μsec)	0.23					
	prr		(kHz)	8.07					
	p_r at max. I_{pi}		(MPa)	2.97					
	d_{eq} at max. I_{pi}		(cm)					#	
	Focal Length	FLx	(cm)		8.50	#	#		#
		FLy	(cm)		1.40	#	#		#
	$I_{pa,\alpha}$ at max.MI		(W/cm²)	319.27					
Operating control conditions	Mode			B	B	#	#	#	#
	Frequency			5.0M	6.0M	#	#	#	#
	Display Range		(cm)	2.0	2.0	#	#	#	#
	Focus Depth (B/THE/CH-EUS)		(cm)	1.3	8.5	#	#	#	#
	Location of PW cursor / ROI		(cm)	-	-	#	#	#	#
	Acoustic output		(%)	100	100	#	#	#	#
	View Angle		(°)	61	61	#	#	#	#
	ROI Angle(Flow)		(°)	-	-	#	#	#	#
	V-Range(PRF)		(kHz)	-	-	#	#	#	#

Notes:
(1) This index is not relevant to this operating mode.
(2) This probe is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table

System: **EU-ME2 PREMIER**
EU-ME2 PREMIER PLUS
Operating Mode: **PWD mode**
Transducer Model: **BF-UC190F**

Index label				*MI*	*TIS*			*TIB*	*TIC*
					Scan	Non-scan		Non-scan	
						A_{aprt}≤1cm^2	A_{aprt}>1cm^2		
Maximum Index Value				1.03	0.54	(1)	(1)	1.27	(2)
Associated acoustic parameters	$p_{r,\alpha}$		(MPa)	2.53					
	P		(mW)		16.70	#		17.48	#
	Min of [$P_{\alpha}(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				#		
	z_s		(cm)				#		
	z_{bp}		(cm)				#		
	z_b		(cm)					0.76	
	z at max $I_{pi,\alpha}$		(cm)	0.76					
	$d_{eq}(z_b)$		(cm)					0.23	
	f_{awf}		(MHz)	6.07	6.80	#	#	5.32	#
	Dim of A_{aprt}	X	(cm)		1.09	#	#	0.65	#
		Y	(cm)		0.10	#	#	0.10	#
Other information	t_d		(μsec)	0.23					
	prr		(kHz)	8.07					
	p_r at max. I_{pi}		(MPa)	2.97					
	d_{eq} at max. I_{pi}		(cm)					0.23	
	Focal Length	FLx	(cm)		8.50	#	#		#
		FLy	(cm)		1.40	#	#		#
	$I_{pa,\alpha}$ at max.MI		(W/cm^2)	319.27					
Operating control conditions	Mode			B	B	#	#	PW	#
	Frequency			5.0M	6.0M	#	#	5.0M	#
	Display Range		(cm)	2.0	2.0	#	#	-	#
	Focus Depth (B/THE/CH-EUS)		(cm)	1.3	8.5	#	#	-	#
	Location of PW cursor / ROI		(cm)	-	-	#	#	5.5	#
	Acoustic output		(%)	100	100	#	#	100	#
	View Angle		(°)	61	61	#	#	-	#
	ROI Angle(Flow)		(°)	-	-	#	#	-	#
	V-Range(PRF)		(kHz)	-	-	#	#	2.2	#

Notes:
(1) This index is not relevant to this operating mode.
(2) This probe is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table

System: **EU-ME2 PREMIER** **EU-ME2 PREMIER PLUS** Operating Mode: **Color Doppler mode**

Transducer Model: **BF-UC190F**

Index label				MI	TIS			TIB	TIC
					Scan	Non-scan		Non-scan	
						A_{aprt}≤1cm²	A_{aprt}>1cm²		
Maximum Index Value				1.03	0.58	(1)	(1)	(1)	(2)
Associated acoustic parameters	$p_{r,a}$		(MPa)	2.53					
	P		(mW)		2.15/13.95	#		#	#
	Min of [$P_{\alpha}(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				#		
	z_s		(cm)				#		
	z_{bp}		(cm)				#		
	z_b		(cm)					#	
	z at max $I_{pi,\alpha}$		(cm)	0.76					
	$d_{eq}(z_b)$		(cm)					#	
	f_{awf}		(MHz)	6.07	6.80/7.71	#	#	#	#
	Dim of A_{aprt}	X	(cm)		1.09/0.65	#	#	#	#
		Y	(cm)		0.10	#	#	#	#
Other information	t_d		(μsec)	0.23					
	prr		(kHz)	8.07					
	p_r at max. I_{pi}		(MPa)	2.97					
	d_{eq} at max. I_{pi}		(cm)					#	
	Focal Length	FLx	(cm)		8.50/4.50	#	#		#
		FLy	(cm)		1.40	#	#		#
	$I_{pa,\alpha}$ at max.MI		(W/cm²)	319.27					
Operating control conditions	Mode			B	B/H-FLOW	#	#	#	#
	Frequency			5.0M	6.0M/7.5M	#	#	#	#
	Display Range		(cm)	2.0	2.0	#	#	#	#
	Focus Depth (B/THE/CH-EUS)		(cm)	1.3	8.5	#	#	#	#
	Location of PW cursor / ROI		(cm)	-	4.5	#	#	#	#
	Acoustic output		(%)	100	100	#	#	#	#
	View Angle		(°)	61	61	#	#	#	#
	ROI Angle(Flow)		(°)	-	61	#	#	#	#
	V-Range(PRF)		(kHz)	-	20.0	#	#	#	#

Notes:
(1) This index is not relevant to this operating mode.
(2) This probe is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table

System: **EU-ME2 PREMIER** / **EU-ME2 PREMIER PLUS**
Operating Mode: **Combined mode**
Transducer Model: **BF-UC190F**

Index label				*MI*	*TIS*			*TIB*	*TIC*
					Scan	Non-scan		Non-scan	
						A_{aprt}≤1cm^2	A_{aprt}>1cm^2		
Maximum Index Value				1.03	0.58	(1)	(1)	1.27	(2)
Associated acoustic parameters	$p_{r,\alpha}$		(MPa)	2.53					
	P		(mW)		2.15/13.95	#		17.48	#
	Min of [$P_{\alpha}(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				#		
	z_s		(cm)				#		
	z_{bp}		(cm)				#		
	z_b		(cm)					0.76	
	z at max $I_{pi,\alpha}$		(cm)	0.76					
	$d_{eq}(z_b)$		(cm)					0.23	
	f_{awf}		(MHz)	6.07	6.80/7.71	#	#	5.32	#
	Dim of A_{aprt}	X	(cm)		1.09/0.65	#	#	0.65	#
		Y	(cm)		0.10	#	#	0.10	#
Other information	t_d		(μsec)	0.23					
	prr		(kHz)	8.07					
	p_r at max. I_{pi}		(MPa)	2.97					
	d_{eq} at max. I_{pi}		(cm)					0.23	
	Focal Length	FLx	(cm)		8.50/4.50	#	#		#
		FLy	(cm)		1.40	#	#		#
	$I_{pa,\alpha}$ at max.MI		(W/cm^2)	319.27					
Operating control conditions	Mode			B	B/H-FLOW	#	#	PW	#
	Frequency			5.0M	6.0M/7.5M	#	#	5.0M	#
	Display Range		(cm)	2.0	2.0	#	#	-	#
	Focus Depth (B/THE/CH-EUS)		(cm)	1.3	8.5	#	#	-	#
	Location of PW cursor / ROI		(cm)	-	4.5	#	#	5.5	#
	Acoustic output		(%)	100	100	#	#	100	#
	View Angle		(°)	61	61	#	#	-	#
	ROI Angle(Flow)		(°)	-	61	#	#	-	#
	V-Range(PRF)		(kHz)	-	20.0	#	#	2.2	#

Notes:
(1) This index is not relevant to this operating mode.
(2) This probe is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table

System: **EU-ME2 PREMIER** / **EU-ME2 PREMIER PLUS** Operating Mode: **Other mode**

Transducer Model: **BF-UC190F**

Index label				MI	TIS			TIB	TIC
					Scan	Non-scan		Non-scan	
						A_{aprt}≤1cm²	A_{aprt}>1cm²		
Maximum Index Value				0.97	0.34	(1)	(1)	(1)	(2)
Associated acoustic parameters	$p_{r,\alpha}$		(MPa)	2.07					
	P		(mW)		14.64	#		#	#
	Min of [$P_{\alpha}(z_s)$, $I_{ta,\alpha}(z_s)$]		(mW)				#		
	z_s		(cm)				#		
	z_{bp}		(cm)				#		
	z_b		(cm)					#	
	z at max $I_{pi,\alpha}$		(cm)	0.76					
	$d_{eq}(z_b)$		(cm)					#	
	f_{awf}		(MHz)	4.51	4.92	#	#	#	#
	Dim of A_{aprt}	X	(cm)		1.09	#	#	#	#
		Y	(cm)		0.10	#	#	#	#
Other information	t_d		(μsec)	0.37					
	prr		(kHz)	5.92					
	p_r at max. I_{pi}		(MPa)	2.33					
	d_{eq} at max. I_{pi}		(cm)					#	
	Focal Length	FLx	(cm)		5.40	#	#		#
		FLy	(cm)		1.40	#	#		#
	$I_{pa,\alpha}$ at max.MI		(W/cm²)	135.15					
Operating control conditions	Mode			CH-B	THE	#	#	#	#
	Frequency			CH-R	THE-P	#	#	#	#
	Display Range		(cm)	2.0	2.0	#	#	#	#
	Focus Depth (B/THE/CH-EUS)		(cm)	0.9	5.4	#	#	#	#
	Location of PW cursor / ROI		(cm)	-	-	#	#	#	#
	Acoustic output		(%)	100	100	#	#	#	#
	View Angle		(°)	61	61	#	#	#	#
	ROI Angle(Flow)		(°)	-	-	#	#	#	#
	V-Range(PRF)		(kHz)	-	-	#	#	#	#

Notes:
(1) This index is not relevant to this operating mode.
(2) This probe is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.

Acoustic Output Reporting Table (IEC 60601-2-37:2007+A1:2015) (EU-ME2)

The following tables show global maximum acoustic output values for each possible system/transducer/mode combination.

Acoustic Output Reporting Table (IEC 60601-2-37:2007+A1:2015)

System: **EU-ME2** Operating Mode: **B mode**
Transducer Model: **BF-UC190F**

Index Label			MI	TIS		TIB		TIC
				at surface	below surface	at surface	below surface	
Maximum Index Value			1.03	0.50		0.50		#
Index Component Value				0.50	0.50	0.50	0.50	
Associated Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.53					
	P	(mW)		16.70		16.70		#
	P_{1x1}	(mW)		15.35		15.35		
	z_s	(cm)			#			
	z_b	(cm)					#	
	z_{MI}	(cm)	0.76					
	$z_{pii,\alpha}$	(cm)	0.76					
	f_{awf}	(MHz)	6.07	6.80		6.80		#
Other Information	prr	(Hz)	8071					
	srr	(Hz)	123.04					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	319.27					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	47.51					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	64.20					
	p_r at z_{pii}	(MPa)	2.97					
Operating Control Conditions	Mode		B	B		B		#
	Frequency		5.0M	6.0M		6.0M		#
	Display Range	(cm)	2.0	2.0		2.0		#
	Focus Depth (B/THE/CH-EUS)	(cm)	1.3	8.5		8.5		#
	Location of PW cursor / ROI	(cm)	-	-		-		#
	Acoustic output	(%)	100	100		100		#
	View Angle	(°)	61	61		61		#
	ROI Angle(Flow)	(°)	-	-		-		#
	V-Range(PRF)	(kHz)	-	-		-		#

Acoustic Output Reporting Table (IEC 60601-2-37:2007+A1:2015)

System: **EU-ME2** Operating Mode: **PWD mode**
Transducer Model: **BF-UC190F**

Index Label			MI	TIS		TIB		TIC
				at surface	below surface	at surface	below surface	
Maximum Index Value			1.03	0.50		1.27		#
Index Component Value				0.50	0.50	0.44	1.27	
Associated Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.53					
	P	(mW)		16.70		17.48		#
	P_{1x1}	(mW)		15.35		17.48		
	z_s	(cm)			#			
	z_b	(cm)					0.76	
	z_{MI}	(cm)	0.76					
	$z_{pii,\alpha}$	(cm)	0.76					
	f_{awf}	(MHz)	6.07	6.80		5.32		#
Other Information	prr	(Hz)	8071					
	srr	(Hz)	123.04					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	319.27					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	47.51					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	64.20					
	p_r at z_{pii}	(MPa)	2.97					
Operating Control Conditions	Mode		B	B		PW		#
	Frequency		5.0M	6.0M		5.0M		#
	Display Range	(cm)	2.0	2.0		-		#
	Focus Depth (B/THE/CH-EUS)	(cm)	1.3	8.5		-		#
	Location of PW cursor / ROI	(cm)	-	-		5.5		#
	Acoustic output	(%)	100	100		100		#
	View Angle	(°)	61	61		-		#
	ROI Angle(Flow)	(°)	-	-		-		#
	V-Range(PRF)	(kHz)	-	-		2.2		#

Acoustic Output Reporting Table (IEC 60601-2-37:2007+A1:2015)

System: **EU-ME2** Operating Mode: **Color Doppler mode**
Transducer Model: **BF-UC190F**

Index Label			MI	TIS		TIB		TIC
				at surface	below surface	at surface	below surface	
Maximum Index Value			1.03	0.58		0.58		#
Index Component Value				0.58	0.58	0.58	0.58	
Associated Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.53					
	P	(mW)		2.15/13.95		2.15/13.95		#
	P_{1x1}	(mW)		1.97/13.95		1.97/13.95		
	z_s	(cm)			#			
	z_b	(cm)					#	
	z_{MI}	(cm)	0.76					
	$z_{pii,\alpha}$	(cm)	0.76					
	f_{awf}	(MHz)	6.07	6.80/7.71		6.80/7.71		#
Other Information	prr	(Hz)	8071					
	srr	(Hz)	123.04					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	319.27					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	47.51					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	64.20					
	p_r at z_{pii}	(MPa)	2.97					
Operating Control Conditions	Mode		B	B/H-FLOW		B/H-FLOW		#
	Frequency		5.0M	6.0M/7.5M		6.0M/7.5M		#
	Display Range	(cm)	2.0	2.0		2.0		#
	Focus Depth (B/THE/CH-EUS)	(cm)	1.3	8.5		8.5		#
	Location of PW cursor / ROI	(cm)	-	4.5		4.5		#
	Acoustic output	(%)	100	100		100		#
	View Angle	(°)	61	61		61		#
	ROI Angle(Flow)	(°)	-	61		61		#
	V-Range(PRF)	(kHz)	-	20.0		20.0		#

Acoustic Output Reporting Table (IEC 60601-2-37:2007+A1:2015)

System: **EU-ME2** Operating Mode: **Combined mode**
Transducer Model: **BF-UC190F**

Index Label			MI	TIS		TIB		TIC
				at surface	below surface	at surface	below surface	
Maximum Index Value			1.03	0.58		1.27		#
Index Component Value				0.58	0.58	0.44	1.27	
Associated Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.53					
	P	(mW)		2.15/13.95		17.48		#
	P_{1x1}	(mW)		1.97/13.95		17.48		
	z_s	(cm)			#			
	z_b	(cm)					0.76	
	z_{MI}	(cm)	0.76					
	$z_{pii,\alpha}$	(cm)	0.76					
	f_{awf}	(MHz)	6.07	6.80/7.71		5.32		#
Other Information	prr	(Hz)	8071					
	srr	(Hz)	123.04					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	319.27					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	47.51					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	64.20					
	p_r at z_{pii}	(MPa)	2.97					
Operating Control Conditions	Mode		B	B/H-FLOW		PW		#
	Frequency		5.0M	6.0M/7.5M		5.0M		#
	Display Range	(cm)	2.0	2.0		-		#
	Focus Depth (B/THE/CH-EUS)	(cm)	1.3	8.5		-		#
	Location of PW cursor / ROI	(cm)	-	4.5		5.5		#
	Acoustic output	(%)	100	100		100		#
	View Angle	(°)	61	61		-		#
	ROI Angle(Flow)	(°)	-	61		-		#
	V-Range(PRF)	(kHz)	-	20.0		2.2		#

Acoustic Output Reporting Table (IEC 60601-2-37:2007+A1:2015) (EU-ME2 PREMIER, EU-ME2 PREMIER PLUS)

Acoustic Output Reporting Table (IEC 60601-2-37:2007+A1:2015)

System: **EU-ME2 PREMIER** / **EU-ME2 PREMIER PLUS** Operating Mode: **B mode**

Transducer Model: **BF-UC190F**

Index Label			MI	TIS		TIB		TIC
				at surface	below surface	at surface	below surface	
Maximum Index Value			1.03	0.50		0.50		#
Index Component Value				0.50	0.50	0.50	0.50	
Associated Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.53					
	P	(mW)		16.70		16.70		#
	P_{1x1}	(mW)		15.35		15.35		
	z_s	(cm)			#			
	z_b	(cm)					#	
	z_{MI}	(cm)	0.76					
	$z_{pii,\alpha}$	(cm)	0.76					
	f_{awf}	(MHz)	6.07	6.80		6.80		#
Other Information	prr	(Hz)	8071					
	srr	(Hz)	123.04					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	319.27					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	47.51					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	64.20					
	p_r at z_{pii}	(MPa)	2.97					
Operating Control Conditions	Mode		B	B		B		#
	Frequency		5.0M	6.0M		6.0M		#
	Display Range	(cm)	2.0	2.0		2.0		#
	Focus Depth (B/THE/CH-EUS)	(cm)	1.3	8.5		8.5		#
	Location of PW cursor / ROI	(cm)	-	-		-		#
	Acoustic output	(%)	100	100		100		#
	View Angle	(°)	61	61		61		#
	ROI Angle(Flow)	(°)	-	-		-		#
	V-Range(PRF)	(kHz)	-	-		-		#

Acoustic Output Reporting Table (IEC 60601-2-37:2007+A1:2015)

System: **EU-ME2 PREMIER**
EU-ME2 PREMIER PLUS

Operating Mode: **PWD mode**

Transducer Model: **BF-UC190F**

Index Label			MI	TIS		TIB		TIC
				at surface	below surface	at surface	below surface	
Maximum Index Value			1.03	0.50		1.27		#
Index Component Value				0.50	0.50	0.44	1.27	
Associated Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.53					
	P	(mW)		16.70		17.48		#
	P_{1x1}	(mW)		15.35		17.48		
	z_s	(cm)			#			
	z_b	(cm)					0.76	
	z_{MI}	(cm)	0.76					
	$z_{pii,\alpha}$	(cm)	0.76					
	f_{awf}	(MHz)	6.07	6.80		5.32		#
Other Information	prr	(Hz)	8071					
	srr	(Hz)	123.04					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	319.27					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	47.51					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	64.20					
	p_r at z_{pii}	(MPa)	2.97					
Operating Control Conditions	Mode		B	B		PW		#
	Frequency		5.0M	6.0M		5.0M		#
	Display Range	(cm)	2.0	2.0		-		#
	Focus Depth (B/THE/CH-EUS)	(cm)	1.3	8.5		-		#
	Location of PW cursor / ROI	(cm)	-	-		5.5		#
	Acoustic output	(%)	100	100		100		#
	View Angle	(°)	61	61		-		#
	ROI Angle(Flow)	(°)	-	-		-		#
	V-Range(PRF)	(kHz)	-	-		2.2		#

Acoustic Output Reporting Table (IEC 60601-2-37:2007+A1:2015)

System: **EU-ME2 PREMIER**
EU-ME2 PREMIER PLUS

Operating Mode: **Color Doppler mode**

Transducer Model: **BF-UC190F**

Index Label			MI	TIS		TIB		TIC
				at surface	below surface	at surface	below surface	
Maximum Index Value			1.03	0.58		0.58		#
Index Component Value				0.58	0.58	0.58	0.58	
Associated Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.53					
	P	(mW)		2.15/13.95		2.15/13.95		#
	P_{1x1}	(mW)		1.97/13.95		1.97/13.95		
	z_s	(cm)			#			
	z_b	(cm)					#	
	z_{MI}	(cm)	0.76					
	$z_{pii,\alpha}$	(cm)	0.76					
	f_{awf}	(MHz)	6.07	6.80/7.71		6.80/7.71		#
Other Information	prr	(Hz)	8071					
	srr	(Hz)	123.04					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	319.27					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	47.51					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	64.20					
	p_r at z_{pii}	(MPa)	2.97					
Operating Control Conditions	Mode		B	B/H-FLOW		B/H-FLOW		#
	Frequency		5.0M	6.0M/7.5M		6.0M/7.5M		#
	Display Range	(cm)	2.0	2.0		2.0		#
	Focus Depth (B/THE/CH-EUS)	(cm)	1.3	8.5		8.5		#
	Location of PW cursor / ROI	(cm)	-	4.5		4.5		#
	Acoustic output	(%)	100	100		100		#
	View Angle	(°)	61	61		61		#
	ROI Angle(Flow)	(°)	-	61		61		#
	V-Range(PRF)	(kHz)	-	20.0		20.0		#

Acoustic Output Reporting Table (IEC 60601-2-37:2007+A1:2015)

System: **EU-ME2 PREMIER**
EU-ME2 PREMIER PLUS

Operating Mode: **Combined mode**

Transducer Model: **BF-UC190F**

Index Label			MI	TIS		TIB		TIC
				at surface	below surface	at surface	below surface	
Maximum Index Value			1.03	0.58		1.27		#
Index Component Value				0.58	0.58	0.44	1.27	
Associated Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.53					
	P	(mW)		2.15/13.95		17.48		#
	P_{1x1}	(mW)		1.97/13.95		17.48		
	z_s	(cm)			#			
	z_b	(cm)					0.76	
	z_{MI}	(cm)	0.76					
	$z_{pii,\alpha}$	(cm)	0.76					
	f_{awf}	(MHz)	6.07	6.80/7.71		5.32		#
Other Information	prr	(Hz)	8071					
	srr	(Hz)	123.04					
	n_{pps}		1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	319.27					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	47.51					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	64.20					
	p_r at z_{pii}	(MPa)	2.97					
Operating Control Conditions	Mode		B	B/H-FLOW		PW		#
	Frequency		5.0M	6.0M/7.5M		5.0M		#
	Display Range	(cm)	2.0	2.0		-		#
	Focus Depth (B/THE/CH-EUS)	(cm)	1.3	8.5		-		#
	Location of PW cursor / ROI	(cm)	-	4.5		5.5		#
	Acoustic output	(%)	100	100		100		#
	View Angle	(°)	61	61		-		#
	ROI Angle(Flow)	(°)	-	61		-		#
	V-Range(PRF)	(kHz)	-	20.0		2.2		#

Acoustic Output Reporting Table (IEC 60601-2-37:2007+A1:2015)

System: **EU-ME2 PREMIER**
EU-ME2 PREMIER PLUS

Operating Mode: **Other mode**

Transducer Model: **BF-UC190F**

Index Label			MI	TIS		TIB		TIC
				at surface	below surface	at surface	below surface	
Maximum Index Value			0.97	0.32		0.32		#
Index Component Value				0.32	0.32	0.32	0.32	
Associated Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	2.07					
	P	(mW)		14.64		14.64		#
	P_{1x1}	(mW)		13.46		13.46		
	z_s	(cm)			#			
	z_b	(cm)					#	
	z_{MI}	(cm)	0.76					
	$z_{pii,\alpha}$	(cm)	0.76					
	f_{awf}	(MHz)	4.51	4.92		4.92		#
Other Information	prr	(Hz)	5919					
	srr	(Hz)	29.74					
	n_{pps}		2					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	135.15					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	14.92					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	18.88					
	p_r at z_{pii}	(MPa)	2.33					
Operating Control Conditions	Mode		CH-B	THE		THE		#
	Frequency		CH-R	THE-P		THE-P		#
	Display Range	(cm)	2.0	2.0		2.0		#
	Focus Depth (B/THE/CH-EUS)	(cm)	0.9	5.4		5.4		#
	Location of PW cursor / ROI	(cm)	-	-		-		#
	Acoustic output	(%)	100	100		100		#
	View Angle	(°)	61	61		61		#
	ROI Angle(Flow)	(°)	-	-		-		#
	V-Range(PRF)	(kHz)	-	-		-		#

Measurement uncertainties for acoustic quantities

Measurement uncertainties for power, pressure, intensity, frequency are shown in the table below. The measurement uncertainty values are determined by repeating measurements and stating the uncertainty values as a percentage.

Acoustic quantity	Uncertainty (%)
W_o	28.9
p_r	13.7
P_{II}	26.7
f_c	3.8

Acoustic output information in accordance with IEC 60601-2-37

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Date of Issue 2021-07-29
RC8193 02

Printed in Japan 20210730 *0000