

PENTAX™

Only For the Americas

**INSTRUCTIONS FOR USE
(OPERATION)**

PENTAX VIDEO BRONCHOSCOPES

EB-1970TK

EB-1170K, EB-1570K

EB-1970K, EB-1575K

EB-1975K, EB-1990i

This Instructions for Use describes the recommended procedures for inspecting and preparing the equipment prior to its use.

For the cleaning and maintenance of the equipment after its use, please refer to the separate Instructions for Use (reprocessing).

Product Overview

These instruments photograph the subject of observation using a solid-state image sensor located at the endoscope tip under the light transmitted from the processor/light source. The target of the observation is monitored by the physician using the endoscopic image displayed on the video monitor. The endoscopic procedure is performed by inserting biopsy forceps and other endoscopic accessories into the instrument channel inlet on the control body.

The bending section angulates in the intended direction and angle by operating the Angulation Control Lever; and air or fluids can be suctioned from the distal end of the endoscope by operating the Suction Control Valve.

Indication for Use

The PENTAX Video Bronchoscopes (EB Family) have been designed to be used with a PENTAX Video Processor (including Light source), documentation equipment, video monitor, endo-therapy accessories (such as biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the airways and tracheobronchial tree.

Application

Medical purpose: Provide images for optical visualization, recording, and/or diagnostic aid.

Patient populations: Adults and pediatrics who have been determined by the physician to be appropriate candidates for the use of this instrument.

Intended anatomical area: Airways and tracheobronchial tree

User: Medical doctors (expert approved by the medical safety officer to perform endoscopic examinations at each medical facility)

Place of Use: Medical facility

Functions Used Frequently

The frequently used functions in these endoscope models are as follows:

- Angulation capability using control lever
- Remote control operation using remote buttons
- Suctioning function

Removable Components

OF-B179	Suction Control Valve
OF-B190	Inlet Seal

Notes

Read this Instructions for Use (IFU) before operating, and save this book for future reference. Failure to read and thoroughly understand the information presented in this IFU, as well as those developed for ancillary endoscopic equipment and accessories, may result in serious injury, including infection by cross contamination to the patient and/or user. Furthermore, failure to follow the instructions in this IFU or the companion Instructions for Use (Reprocessing) may result in damage to, and/or malfunction of, the equipment.

It is the responsibility of each medical facility to ensure that only well-educated and appropriately trained personnel, who are competent and knowledgeable about the endoscopic equipment, antimicrobial agents/processes, and hospital infection control protocol be involved in the use and the reprocessing of these medical devices. Known risks and/or potential injuries associated with flexible endoscopic procedures include, but are not limited to, the following: perforation, infection, hemorrhage, burns, and electric shock.

This IFU describes the recommended procedures for inspecting and preparing the equipment prior to its use.

It does not describe how an actual procedure is to be performed, nor does it attempt to teach the beginner the proper technique or any medical aspects regarding the use of the equipment. For the cleaning and maintenance after its use, please refer to the separate Instructions for Use (Reprocessing)".

The text contained in this IFU is common for various types/models of PENTAX endoscopes and users must carefully follow only those sections and instructions pertaining to the specific instrument models appearing on the front cover.

If you have any questions regarding any of the information in this IFU or concerns pertaining to the safety and/or use of this equipment, please contact your local PENTAX representative.

Sterility Statement

These endoscopes identified in this IFU are reusable semicritical devices. Since they are packaged non-sterile, they must be high-level disinfected or sterilized BEFORE initial use. Prior to each subsequent procedure, they must be subjected to appropriate cleaning and either high-level disinfection or sterilization processes.

Refer to the companion PENTAX Instruction for Use (Reprocessing) describing in detail the recommended instructions on the care, cleaning, disinfection, and sterilization of these endoscopes.


Contraindication


Please consult regional and national health authority recommendations and requirements regarding protocols to follow in order to reprocess and/or destroy endoscopes that will be used or have been determined to have been used (post procedure) on patients afflicted with Creutzfeldt-Jacob Disease (CJD or vCJD).

Conventions

Throughout this IFU, the following conventions will be used to indicate a potentially hazardous situation which, if not avoided;

 **WARNING** : could result in death or serious injury.

 **CAUTION** : may result in minor or moderate injury or property-damage.

 **NOTE** : may result in property-damage. Also advises owner/operator about important information on the use of this equipment.

Prescription Statement

Federal (U.S.A) law restricts this device to sale by or on the order of a physician or other appropriately licensed medical professional.

Symbols on Marking Symboles distinctifs



Symbol for "MANUFACTURER"



Attention, consult instructions for use
Attention, consulter le manuel d'utilisation



Symbol for "DATE OF MANUFACTURE"



Type BF applied part (Safety degree specified by IEC 60601-1)
Partie appliquée de type BF (niveau de sécurité spécifié par la norme CEI 60601-1)



Symbol for "Authorised Representative in the European Union"



このCEマーキングはEC指令への適合宣言マークです。
The CE marking assures that this product complies with the requirements of the EC directive for safety.
Das CE Zeichen garantiert, daß dieses Produkt die in der EU erforderlichen Sicherheitsbestimmungen erfüllt.
Le logo CE certifie que ce produit est conforme aux normes de sécurité prévues par la Communauté Européenne.
Il marchio CE assicura che questo prodotto è conforme alle direttive CE relative alla sicurezza.
La marca CE asegura que este producto cumple todas las directivas de seguridad de la CE.
CE 标志意味着保证该类产品遵从欧洲共同体安全法规。

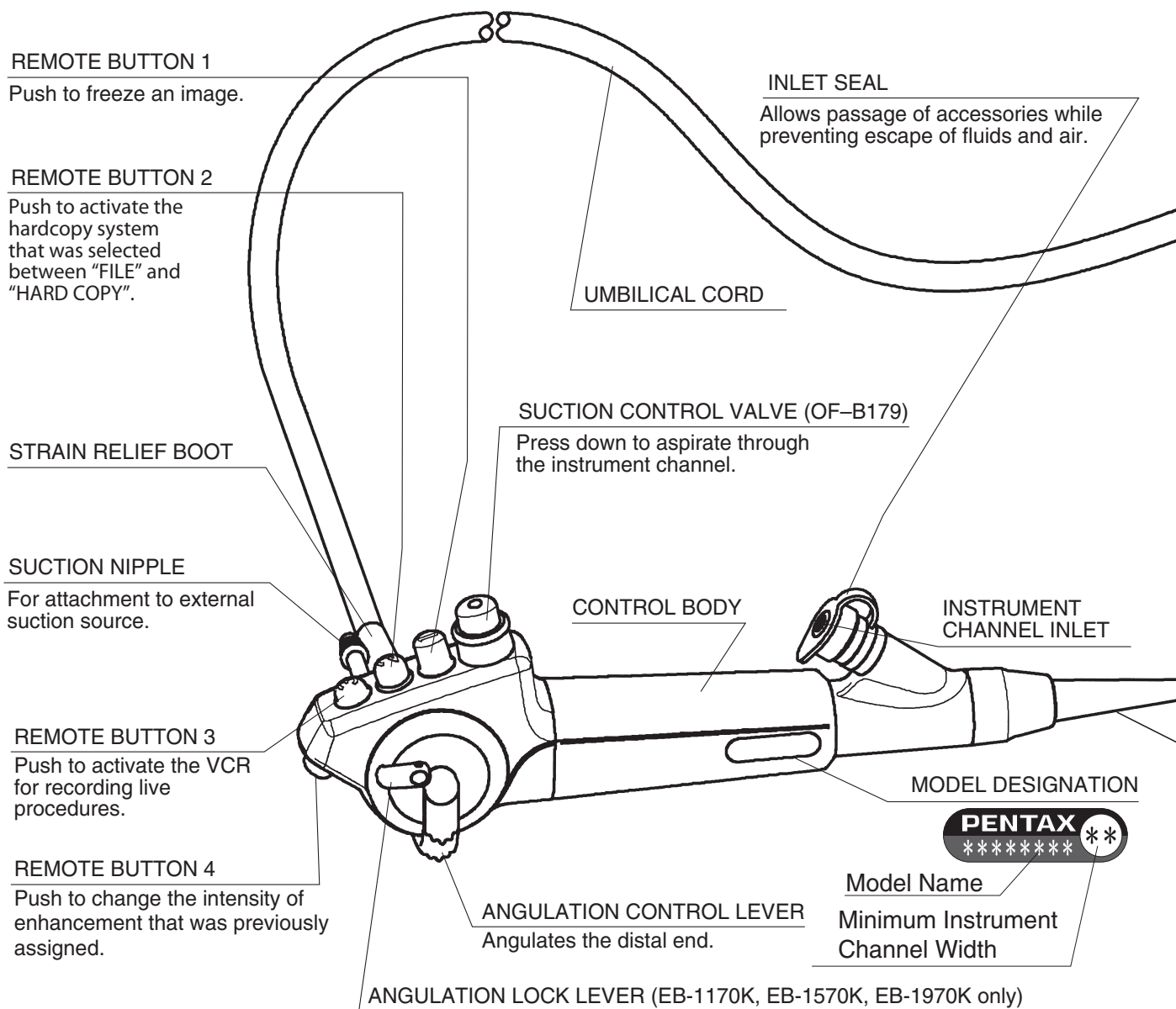
TABLE OF CONTENTS

1. NOMENCLATURE AND FUNCTION	1
1-1. Video Bronchoscope	1
1-2. Accessories	5
1-3. Video Processors	6
2. PREPARATION AND INSPECTION FOR USE	7
2-1. Inspection of the Video Processor	7
2-2. Inspection of Endoscope	8
2-3. Preparation just before Insertion of Endoscope	19
3. DIRECTIONS FOR USE	21
3-1. Operation	21
3-2. Pretreatment	22
3-3. Insertion and Withdrawal	22
3-4. Biopsy	26
3-5. Laser (Except EB-1170K, EB-1990i)	28
3-6. Electrosurgery (Except EB-1170K, EB-1990i)	30
4. CARE AFTER USE	33
SPECIFICATIONS	35

1. NOMENCLATURE AND FUNCTION

1-1. Video Bronchoscope

• EB-1970TK, EB-1170K, EB-1570K, EB-1970K



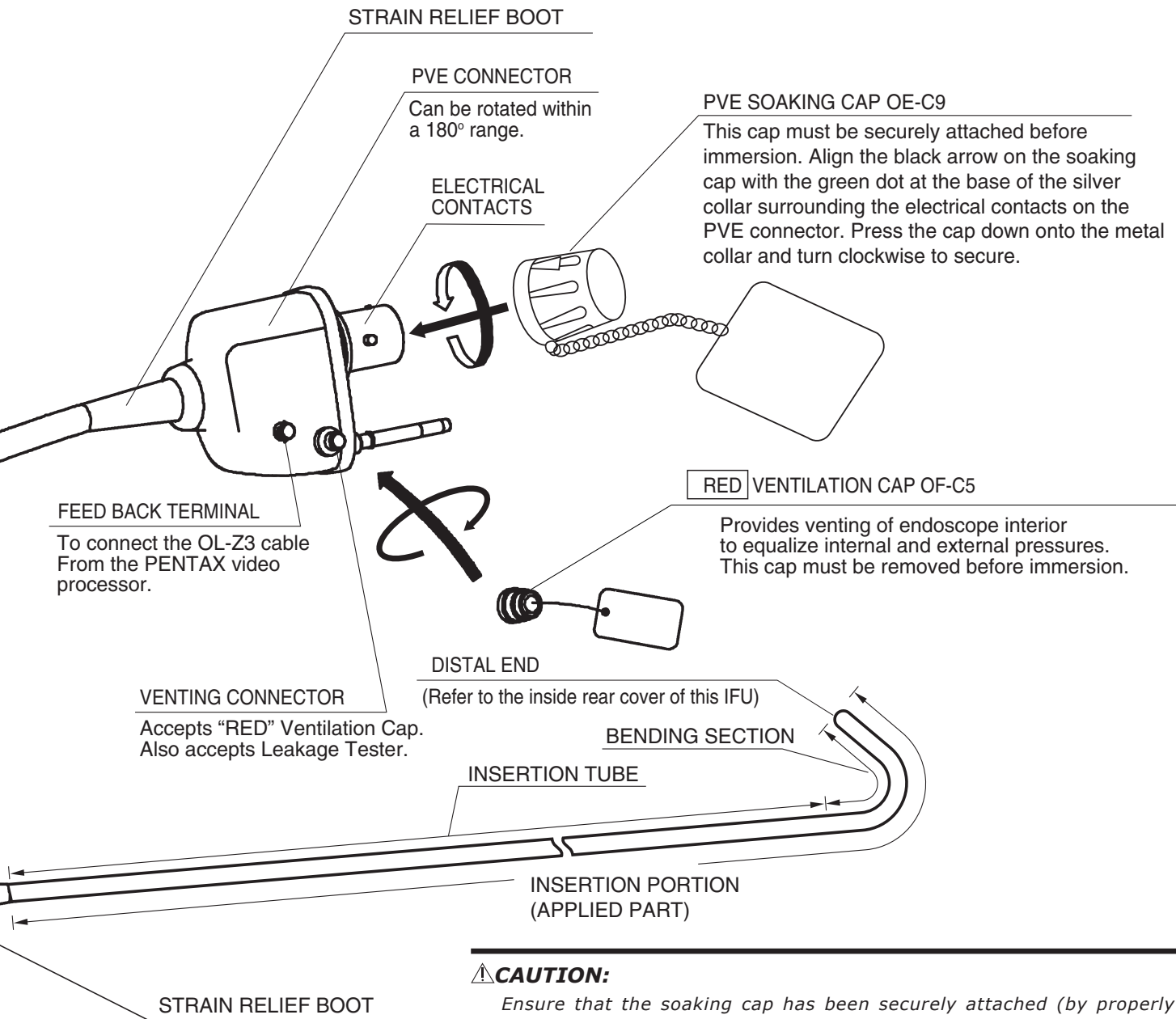
NOTE:

Function of each button depends upon the processor. The function can be changed. For more details, refer to the Instructions for Use supplied with the processor.

The following table shows the factory setting.

*Remote Button 1	Freeze
*Remote Button 2	Copy
*Remote Button 3	VCR
*Remote Button 4	Enhance

*Setting at factory



⚠ CAUTION:

Ensure that the soaking cap has been securely attached (by properly rotating it) to prevent the cap from coming off during reprocessing. Failure to securely attach the soaking cap can result in endoscope damage.

⚠ CAUTION:

To avoid damaging the endoscope, do NOT twist, rotate or bend excessively any of the strain relief boots.

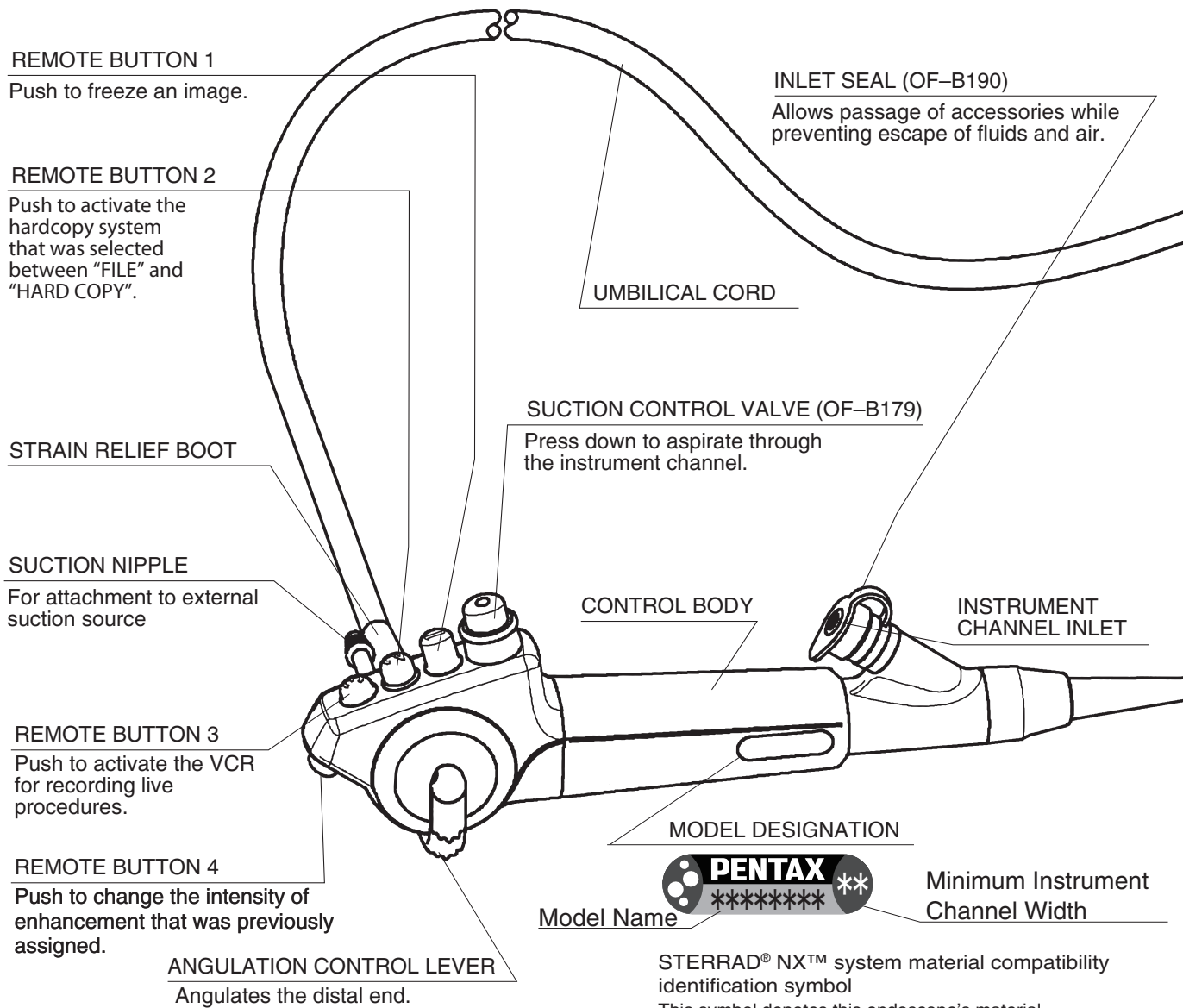
⚠ CAUTION:

Immediately after use, the metal light guide plug and the electrical contacts/pins of the endoscope may be HOT. To avoid burns, do not touch these areas immediately after use. For safer handling after a procedure, grasp the PVE connector housing.

⚠ CAUTION:

EB-1970TK, EB-1170K, EB-1570K and EB-1970K are incompatible to STERRAD® NX™ system. Never try to perform STERRAD® NX™ sterilization to those endoscopes.

• **EB-1575K, EB-1975K, EB-1990i**



STERRAD® NX™ system material compatibility identification symbol
 This symbol denotes this endoscope's material compatibility with the STERRAD® NX™ system. The endoscope that does not have this symbol is incompatible to STERRAD® NX™ system.

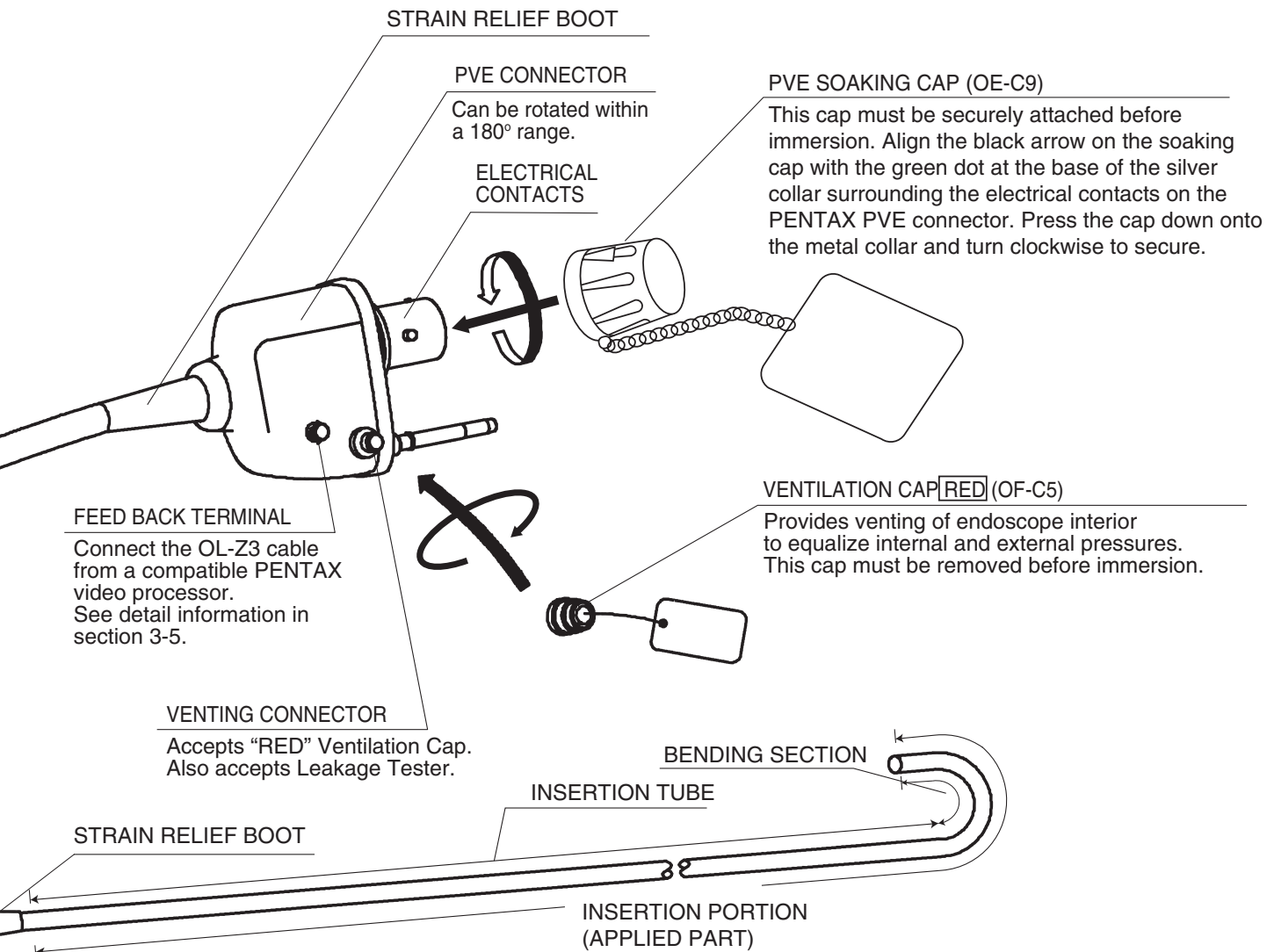
NOTE:

Function of each button depends upon the processor. The function can be changed. For more details, refer to the Instructions for Use supplied with the processor.

The following table shows the factory setting.

*Remote Button 1	Freeze
*Remote Button 2	Copy
*Remote Button 3	VCR
*Remote Button 4	Enhance

**Setting at factory*



⚠ CAUTION:

Ensure that the soaking cap has been securely attached (by properly rotating it) to prevent the cap from coming off during reprocessing. Failure to securely attach the soaking cap can result in endoscope damage.

⚠ CAUTION:

To avoid damaging the endoscope, do NOT twist, rotate or bend excessively any of the strain relief boots.

⚠ CAUTION:

Immediately after use, the metal light guide plug and the electrical contacts/pins of the endoscope may be HOT. To avoid burns, do not touch these areas immediately after use. For safer handling after a procedure, grasp the PVE connector housing.

⚠ CAUTION:

EB-1575K, EB-1975K, EB-1990i can be sterilized using STERRAD® NX™ systems.

For more detail of sterilization using STERRAD® NX™ systems, refer to the sections 1-2-5-1 of the separate Instructions for Use(reprocessing).

- After every 100 cycles of STERRAD® NX™ exposure the endoscopes should be returned to an authorized PENTAX service facility for repair. Replacement of at least insertion tube and bending section is necessary.
- Although the endoscopes are capable of withstanding the STERRAD® NX™ sterilization up to 100 cycles, repair/parts replacement might be necessary before reaching 100 cycles depending on the condition of the endoscope.
- Prior to use, the endoscope must be carefully inspected for absence of any abnormality. For more detail, refer to the section 2-2 of this Instructions for Use. If there is any doubt as to the suitability of the endoscope for use STERRAD® NX™ sterilization, contact your local PENTAX service facility.
- Be sure to attach the Ventilation cap to the Venting connector before performing STERRAD® NX™ sterilization.

1-2. Accessories

1) Biopsy Forceps - GENERAL DESIGN

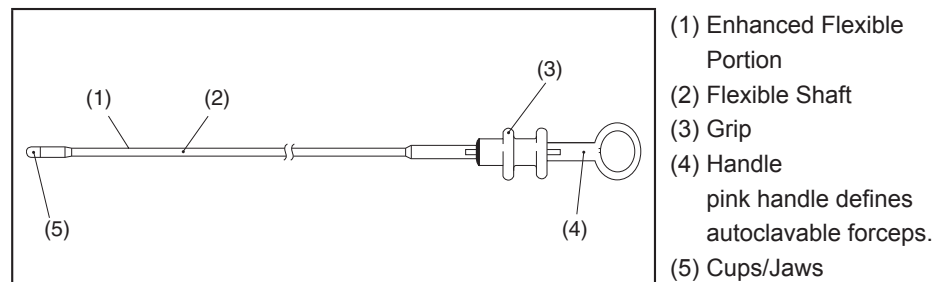


Figure 1.1

⚠ CAUTION:

- *Maximum outer diameter of an endoscopic accessory instrument must be at least 0.2 mm less than the specified instrument channel diameter in PENTAX endoscopes. Working length of an endoscopic accessory instrument should be approximately 30 cm longer than the endoscope working length.*

NOTE:

- *For patient contact endoscopic accessories, follow the specific and detailed instructions on use, care and maintenance supplied with each product.*
 - *To confirm the exact condition of any new accessory device, check the labeling/packaging accompanying the product. Each label/package should clearly identify the contents as either sterile or non-sterile.*
-

1-3. Video Processors

NOTE:

- Water bottle and air pump are not used with these endoscopes.
 - Please read the Instructions for Use supplied with the processor.
-

⚠ WARNING:

Do not install, operate or store electro-medical equipment in a dusty environment. Accumulation of dust within these units may cause malfunction, smoke, or ignition.

(1) PENTAX Video Processor

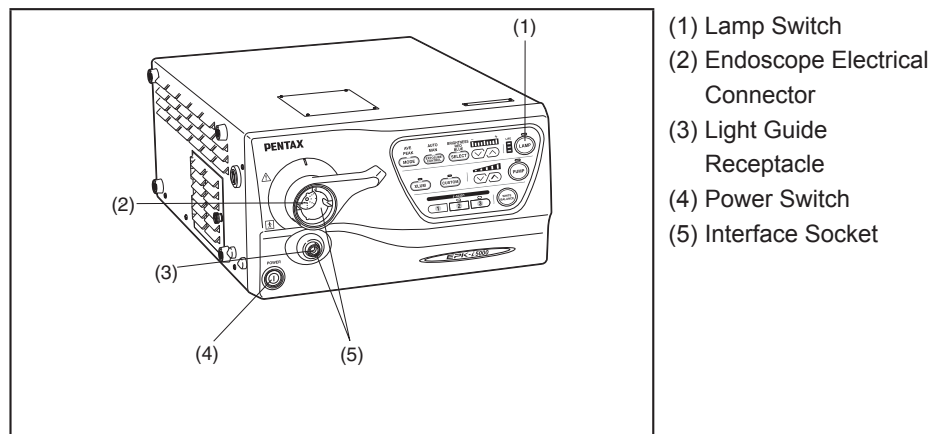


Figure 1.2

⚠ CAUTION:

Replace the lamp before the lamp life expires. Prior to use, check the lamp life indicator. Excessive use of the lamp beyond the lamp life could cause the lamp to explode resulting in damage to the video processor. Refer to the processor's Instructions for Use regarding the lamp life.

NOTE:

Software update may be required depending on the software version of the PENTAX Video Processor. If the software is not updated, the image will not be displayed. If the images are not displayed correctly, please contact your local PENTAX service facility.

2. PREPARATION AND INSPECTION FOR USE

Prior to use, the endoscope, video processor and endoscopic accessory instruments must be carefully inspected for cleanliness and proper function to determine that they are appropriate for patient use:

NOTE:

These video endoscopes are only compatible with PENTAX video processor.

⚠CAUTION:

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

2-1. Inspection of the Video Processor

Please refer to the Instructions for Use for the PENTAX video processor for complete instructions.

⚠WARNING:

To avoid the risk of an electric shock, check that the video processor is properly grounded, or that it is connected to an appropriate isolation transformer (PENTAX SAT-1300 or other medical purpose isolation transformers). Also, be sure to use a video processor specified by PENTAX.

- 1) Plug the processor into a properly grounded receptacle with the power switch in the OFF position.
- 2) Make sure that the PVE connector is aligned with the interface socket on the front panel of the processor.
- 3) Connect the endoscope to the interface socket on the processor as illustrated.

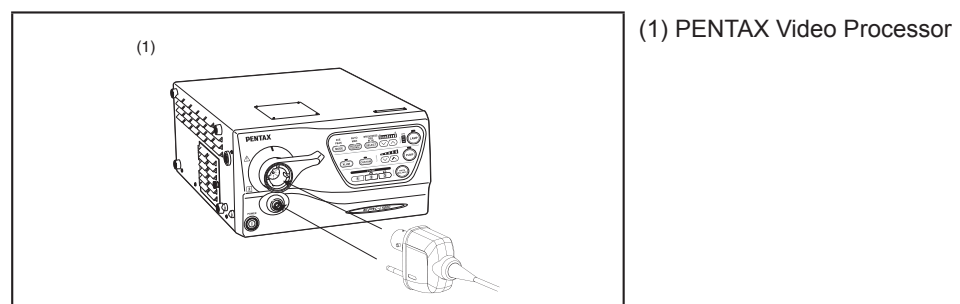


Figure 2.1

- 4) Rotate the locking lever clockwise after insertion.

⚠CAUTION:

After connecting the endoscope to the video processor, always make sure that the endoscope is firmly secured to the Endoscope Electrical Connector by turning the locking lever to the "lock" position.

- 5) Turn on the processor to check for proper functioning.
- 6) Turn off the air pump switch for use with the bronchoscope.
- 7) Press the lamp switch of the processor to ignite the lamp.

⚠CAUTION:

Do not look directly at the light emitted from the endoscope distal tip or the processor unit. The intense light might hurt your eyes. Turn off the lamp when looking directly at the endoscope distal tip.

- 8) Make sure that light comes from the distal end of the connected endoscope. The lamp will light several seconds after the lamp button is pressed.
- 9) Check if the display appears on the monitor.
- 10) Prior to each procedure, check the endoscope image quality displayed on the monitor. Confirm that the image quality, color, automatic brightness (iris) functions are acceptable as per the instructions provided with the PENTAX video processor.

2-2. Inspection of Endoscope

⚠WARNING:

Disassembling or modifying a PENTAX endoscope may impair its original functionality and possibly result in a serious injury. Never disassemble or modify the endoscope.

⚠WARNING:

If the endoscope is intended to be clinically used after testing of individual endoscope functions without further reprocessing, the following precaution should be exercised.

Use sterile or bacterial free water during individual endoscope function tests to avoid recontamination of the previously reprocessed instrument by waterborne microorganisms. Tap water, especially that which may be left idle and uncovered for a prolonged period of time, should not be used during any inspection/testing of the endoscope.

Before proceeding with inspection of individual functions, PENTAX endoscopes should be tested for the integrity of their water-tight design (example: tear in the instrument channel).

⚠CAUTION:

PENTAX endoscopes should be tested for the integrity of their water-tight design using a leakage tester. If the endoscope is used in a condition where the integrity of its water-tight design is compromised, it could result in endoscope damage due to permeated water.

⚠CAUTION:

Various types of endoscope leakage testers exist including manual, electro-mechanical and "automated" versions, some of which are stand alone units and others which may be integrated into Automated Endoscope Reprocessors (AERs). It must be recognized that PENTAX does not evaluate non-PENTAX leak tester systems to satisfy their specific product claims, for their effectiveness to accurately detect leaks and/or for their compatibility with PENTAX endoscopes. Insufficient pressures may reduce the likelihood for accurate leak detection, especially if the endoscope's distal bending section is not flexed during testing. Excessive pressures may adversely affect the endoscope, especially if pressurization occurs during automated reprocessing at elevated temperatures. PENTAX accepts no responsibility for use of non-PENTAX leakage testers.

Users should check with the leak tester manufacturer and confirm their specific product claims, including compatibility with PENTAX endoscopes at various temperatures and their ability to detect leaks with/without fluid immersion and with/without flexing of the endoscope's distal bending section.

- 1) Inspection of the Insertion Tube
 - a) Check the entire surface of the insertion tube for abnormal conditions such as sharp edges, dents, crush marks, wrinkles, bumps, buckles, excessive bending, protrusions, bite marks, peeling of outer sheath, cuts/holes or other irregularities. Any crush or indentation of the flexible shaft of the endoscopes can cause damage to the internal mechanisms of the endoscopes.
 - b) Similarly, check the condition of the umbilical cord for outward signs of damage such as buckling, crush marks, etc.

⚠WARNING:

To avoid serious damage to the patient or possibility of malfunction during a procedure, do not use any endoscope if you find any abnormalities or outward signs of damage.

- c) These areas [A], [B] should be checked for ANY abnormalities or irregularities. If anything unusual is found including but not limited to rough textured surfaces, cracks, brittleness, sharp-edges, holes, peeling, tackiness, etc., the endoscope should NOT BE USED. During this inspection process check the surface/condition of the adhesive by applying slight pressure with one's gloved fingers and by slightly wiping this area with dry gauze. Make sure the glue is not peeling, nor does it have roughened texture or any sharp-edges.

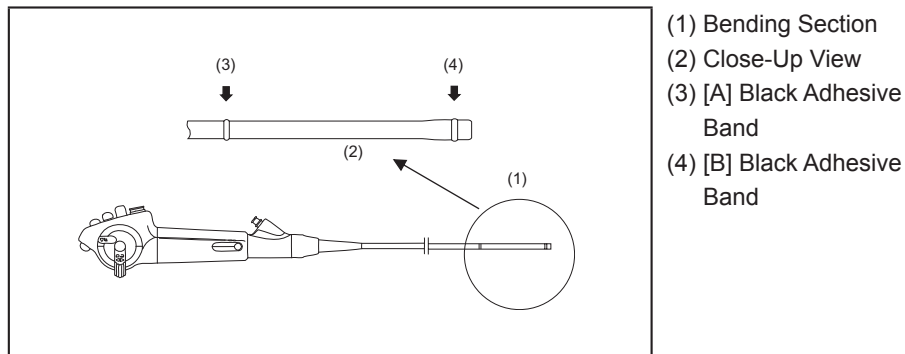


Figure 2.2

- d) Make sure that the entire endoscope is clean and has been subjected to either a high-level disinfection or sterilization process before each patient use.

⚠WARNING:

From the standpoint of infection control, all instruments must be reprocessed prior to initial use, after any repairs/service and before every patient use.

⚠CAUTION:

In order to obtain crisp endoscopic images, when utilizing chemo-thermal processes for reprocessing PENTAX endoscopes, the instruments should be allowed to return to room temperature prior to use and/or further handling.

2) Inspection of insertion tube flexibility

a) Form an arch with the Insertion Tube as shown in the figure below.

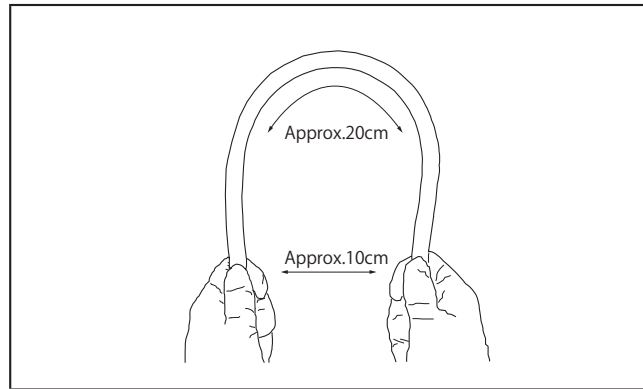


Figure 2.3

b) Gently raise/lower the left/right hands alternately and confirm equal flexibility for the length of the arch. Do NOT use the endoscope if there are any:

- extraordinarily rigid portion which do not bend as easily as the rest of the arch or
- extraordinarily flexible portions which bend much more than the rest of the arch.

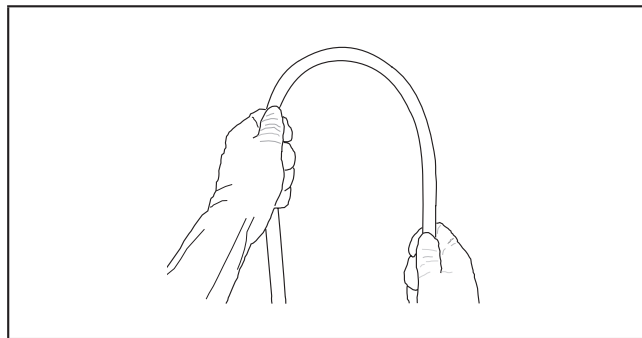


Figure 2.4

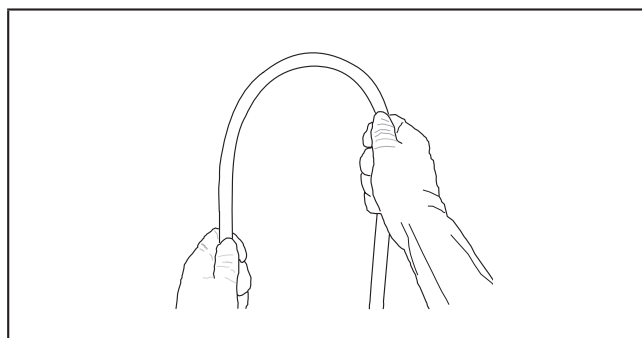


Figure 2.5

c) Repeat steps a) and b) above until the inspection of the entire insertion tube is complete. If the endoscope fails the inspection above;

- Do NOT use the endoscope and
- Contact your PENTAX representative.

⚠CAUTION:

When performing this inspection, ensure that other components of the endoscope (distal end, control body, etc.) are not damaged by impact to surface or objects in the area.

Do NOT adjust the bending section of the endoscope as part of this inspection. Maintain the distal end in a straight orientation.

- Hold the Insertion Tube at the junction of the insertion tube and bending section,
 - Do not close your hand around the bending section.
-

⚠CAUTION:

The distal end of the endoscope as well as the electrical contacts/pins on the PVE connector must be protected against damage from impact. Never apply excess force such as twisting, or severe bending to the flexible portion of the endoscope. These actions could result in endoscope damage or membrane/tissue damage to the patient. Therefore, do not use the endoscope if there is any sign of abnormalities in the distal end of the endoscope.

⚠CAUTION:

During pre-use inspection, ensure that the distal objective lens and the illumination (LCB) cover glass are clean. If not, crisp images can NOT be displayed.

NOTE:

As indicated elsewhere in PENTAX product labeling, endoscopes particularly the quality of the endoscope image should be checked prior to patient use.

⚠CAUTION:

When transporting the endoscope, do NOT grasp or carry it only by its umbilical cord or insertion tube, and take care to protect the distal tip of the insertion portion from damage. Loosely coil both the umbilical cord and insertion tube so that the endoscope can be carried by grasping both the control body and distal portion of the insertion portion in one hand and the PVE connector in the other hand. Failure to do so could result in severe impact damage that will require repair by PENTAX service personnel.

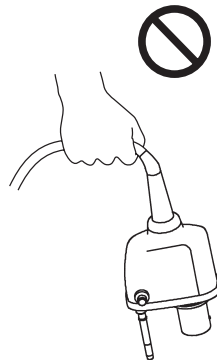


Figure 2.6

⚠ CAUTION:

Flexible endoscopes and other sophisticated medical instruments are constructed of special materials, unique parts and intricate components with strict dimensional tolerances. Specialized assembly techniques and application of specific sealants and/or adhesives are required to ensure the watertight integrity and maintain the functionality of these devices. It is therefore imperative that endoscopes be routinely checked to ensure that parts used in their construction are not loose, missing or compromised that could otherwise negatively affect the functionality of these devices. Compromised or loose components could result in device failure, endoscope damage (via fluid invasion) and/or in incomplete decontamination of used instruments.

PENTAX recommends that prior to use endoscopes should be carefully inspected for their integrity and checked for any "looseness" in the mating or joining of components including the following parts/areas:

- the instrument channel inlet (biopsy inlet port) (1)
- the suction nipple (2)
- suction cylinder (3)
- venting connector (4)
- basically, any inlet or outlet port associated with an internal channel, an indirect patient contact portion of the endoscope

One method to check for looseness is to lightly grip the exposed part, and while grasping the component carefully attempt to move it in various directions.

Use of a lint-free gauze while grasping metal parts is recommended as a protection for one's fingers.

If any part/component remains loose (after attempting to tighten) and/or if there is any indication or suspicion of an abnormality or outward signs of damage, do NOT use the endoscope. Contact your local PENTAX service facility.

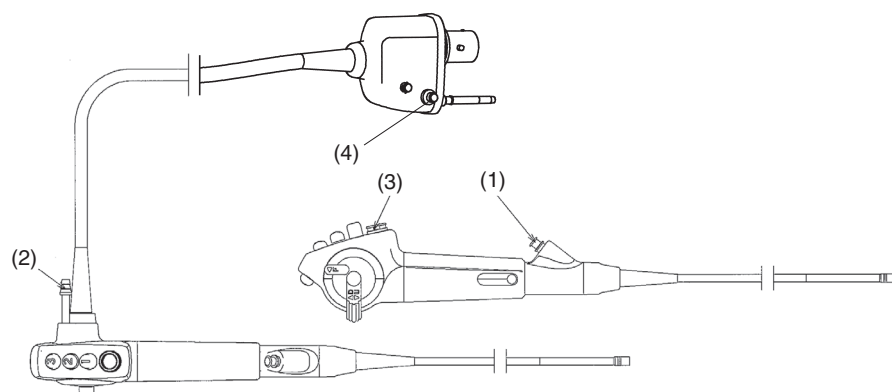


Figure 2.7

⚠CAUTION:

To avoid damaging the endoscopes, do NOT twist, rotate or excessively bend any of the insertion tube strain reliefs (1), (2) during inspection, clinical use, reprocessing, or any handling activity. Be particularly cautious for the insertion tube strain relief (1). When wiping the insertion tube and the umbilical cord, use a slow back and forth motion to wipe them along the tube/cable. Never apply excessive force or torque on these strain reliefs or slim tubes/cables. During ANY handling of the instrument avoid excess force, twisting, rotation and/or bending of the actual insertion tubes and umbilical cord to prevent inadvertent damage (crush, compression, deformity, etc.) to these parts as well as to internal components contained within the endoscope.

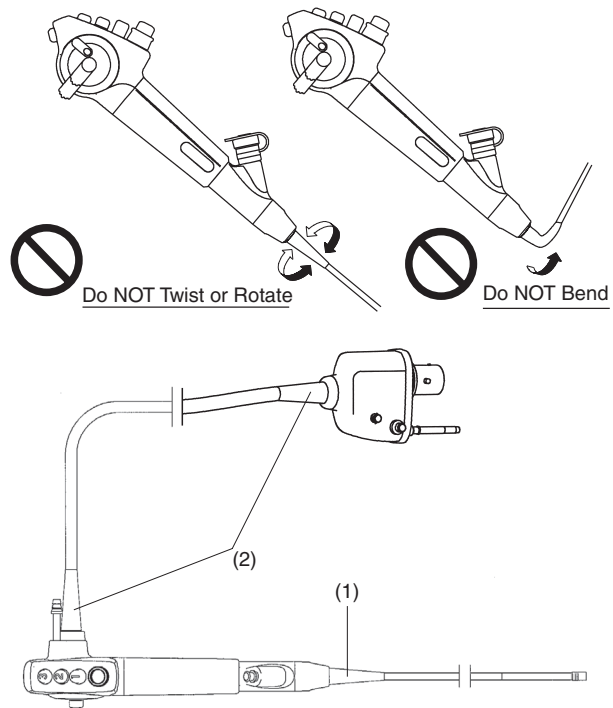


Figure 2.8

3) Inspection of Angulation Control and Lock

- a) Slowly manipulate the angulation control lever to see that it functions smoothly. Be certain that a full and appropriate range of angulation is possible.

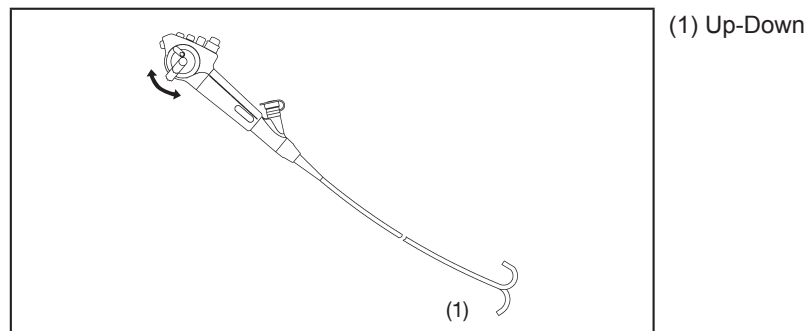


Figure 2.9

- b) Check that the observed image turns in the intended direction when the control lever is operated to move the angulation up/down.

- c) (EB-1170K, EB-1570K, EB-1970K) Engage fully the angulation locks to be certain that the position of the angulated tip can be stabilized.

⚠ WARNING:

Prior to use ensure that the angulation control can rotate smoothly, that there is no grinding or excess friction within the angulation system and that the bending section bends freely and smoothly. NEVER APPLY EXCESSIVE FORCE TO THE ANGULATION CONTROL!

ANY lack of smooth operation of the angulation control may be an early indication of internal damage to and/or part(s) failure within the endoscope's angulation system. To avoid the possibility of further endoscope damage or the potential for malfunction of the angulation system, do NOT use the endoscope if the angulation mechanism does not operate properly.

A "frozen" bending section can make instrument extraction from a patient more difficult.

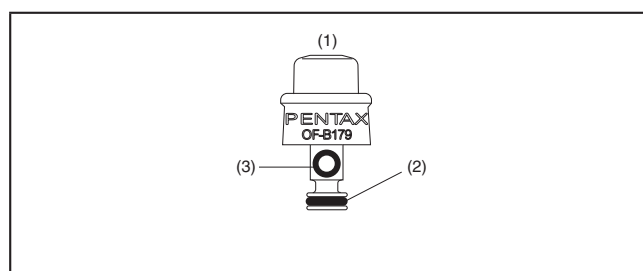
⚠ CAUTION:

When an endoscope exhibits excessive "lever play" or if angulation is lost in any direction, do NOT use the instrument.

Excessive "lever play" can be defined as rotating of the angulation control lever in any one direction for more than 30 degrees without any corresponding distal tip angulation. The examples above are indications that service is required to avoid more serious problems with the angulation control system, including angle or pulley cable/wire breakage and/or the possibility of a "frozen" distal bending section. Do not apply excessive force to the angulation control lever if any problem or strangeness is recognized during angulation operation.

4) Inspection of Suction Mechanism

- a) Prior to use, the suction control valve (OF-B179) should be inspected. Remove the suction valve from the control body and make sure that the O-ring and rubber part are not damaged or worn.



- (1) OF-B179
(2) O-Ring
OF-B181
(3) Rubber part

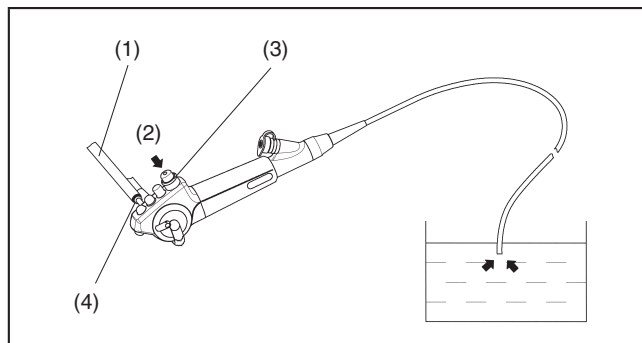
Figure 2.10

⚠ WARNING:

Make sure that the correct suction valve (OF-B179) is being used. Worn or damaged suction valve and/or O-ring should be replaced with new ones which have already been subjected to a high-level disinfection or sterilization procedure prior to use (O-ring set, model OF-B181, is optionally available). Failure to do so could result in continuous aspiration which in certain clinical situations can suction tissue into the distal channel opening at the distal end and/or create a loss of insufflated air via the suction system. A compromised valve could also result in the potential for reflux or dispersal of patient fluids that may present infection control risks.

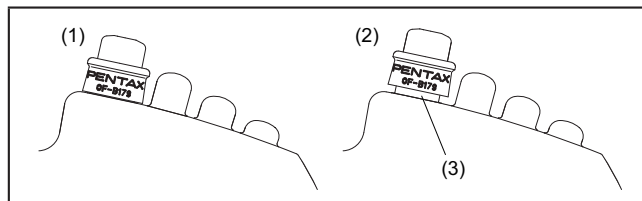
- b) Connect suction source tube from an external suction source to the suction nipple located on the control body.

Place the distal end of the endoscope in a basin of sterile water and depress the suction control valve. Water should be rapidly aspirated into the suction system collection container.



- (1) Suction Source Tube
(2) Depress
(3) Suction Control Valve
(4) Suction Nipple

Figure 2.11



- (1) Correct
(2) Incorrect
(3) Metal

Figure 2.12

⚠ WARNING:

Make sure suction control valve OF-B179 is correctly attached (see figure 2.12).

Improperly installed suction valves may not function as originally intended. Such valves may not return to their neutral (released) positions and/or they may provide continuous suction.

Continuous aspiration can cause loss of air/fluid, difficulty in maintaining proper insufflation and/or inadvertent suctioning of tissue into the distal instrument channel opening. Also it could possibly result in the potential for reflux or dispersal of patient fluids.

- c) Release the suction valve to determine if the suction valve freely returns to its OFF position and the aspiration of water ceases.
- d) If the suction valve does not function properly, does not move smoothly or feels “sticky”, remove it from the suction cylinder. Apply a very small amount of silicone oil (OF-Z11) to the O-ring and rubber part. Do NOT use excess oil, avoid “blobs”, large drops and/or squirts of oil directly onto the metal valve stem – instead, simply place a small droplet of oil on one’s sterile gloved forefinger and gently swirl between thumb and forefinger. Next place the suction valve with O-ring in-between thumb and finger and gently rotate the suction valves so that the oil is evenly applied to the outer edges of the O-ring. Make sure the oil is applied to the O-ring and wipe off all excess.

⚠ WARNING:

If the instrument is to be used immediately after the inspection, use only sterile or bacteria-free water. To avoid recontamination of a previously reprocessed endoscope, avoid use of tap water.

⚠ WARNING:

An inlet seal in good condition must be attached to the instrument channel inlet to prevent loss of suction and a risk of cross contamination to the end user due to the potential for reflux (spit-back) of patient fluids. Worn inlet seals will result in leakage and should be replaced. To ensure maximum performance of these sealing mechanisms, consider replacing the inlet seal with a new fully reprocessed one for each procedure.

5) Inspection of Biopsy Forceps and Instrument Channel

- a) Make sure there are no kinks in the flexible shaft of the biopsy forceps.
- b) The cups/jaws of the forceps must be free of any residual debris. Any debris must be cleaned from the forceps before they are used. **Use only sterile forceps.**
- c) The handle mechanism on the forceps should be operated to open and close the cups/jaws. This mechanism should operate freely.

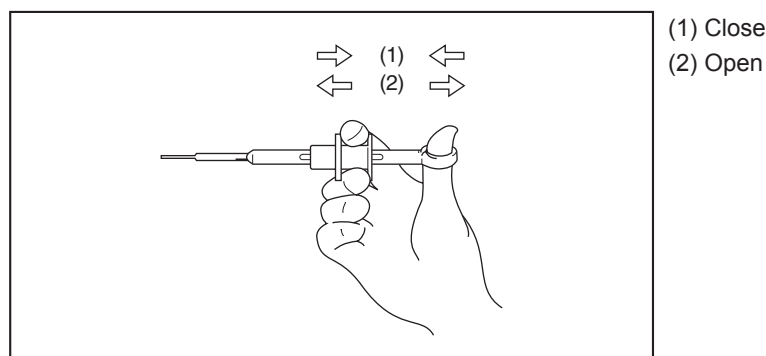


Figure 2.13

- d) Close and inspect the cups/jaws of the forceps to make sure the cups/jaws are in proper alignment. If the forceps has a spike, the spike must be completely straight and fully within the cups/jaws.

⚠ WARNING:

The use of any forceps or accessory that shows any sign of damage or difficulty of operation must be avoided. Any malfunction of a forceps or accessory during a patient procedure could result in serious injury to the patient. Also, the use of damaged forceps or accessories may result in serious and costly damage to the endoscope.

- e) Any accessory should be slowly inserted through the instrument channel inlet with the endoscope in a straight position. There should be no resistance encountered. If resistance is encountered, do not attempt to introduce the accessory further. The instrument channel may be damaged and the endoscope should not be used. Contact the PENTAX service facility.

⚠CAUTION:

Endoscopic accessory instruments (EAI) may be used with PENTAX flexible endoscopes. It should be understood that special care and caution must be exercised when using accessories, particularly non-PENTAX products through the instrument/suction channel of an endoscope. This is especially true when attempting to pass accessories through narrow channels when curved in a tight bending radius.

Please note that damage to the endoscope and/or accessory instrument is possible if excessive force is applied during insertion (or withdrawal) of the EAI. Also, using excessive force during insertion causes the withdrawal of the EAI to be more difficult. To prevent equipment damage, device failure, or patient injury, please adhere to the following precautions:

- *Never apply too much pressure or excessive force during insertion through the instrument channel.*
- *Never attempt to force endoscopic accessories, such as biopsy forceps through a fully angulated distal bending section.*
- *Prior to using accessories from another source (non-PENTAX products), contact PENTAX to confirm if the device has been checked for compatibility.*

Failure to follow these recommendations can result in endoscope and/or accessory damage/failure, including but not limited to:

- *Channel puncture/leakage*
- *Fluid invasion*
- *Fiber breakage*
- *Other internal component failure*

Should resistance be encountered when inserting an accessory, STOP! If resistance is at the endoscope tip, slightly withdraw the accessory, reduce the angulation (within the bending section), then slowly and carefully advance the accessory under direct vision.

Several factors can affect the ease/difficulty of accessory passage through the endoscope channel:

- *Outside diameter of accessory compared to inside channel diameter*
- *Non-flexible (rigid) portions of an accessory*
- *The curve or bend (bending radius) within a channel through which the accessory will pass*
- *Damaged accessory*

Due to the variables above, prior to each procedure, it is important to check the particular accessory intended to be used to satisfy the clinical procedure to be performed. Such pre-use inspections will allow for uninterrupted and more expeditious examinations.

To confirm the absence of severe channel damage affecting the watertight integrity of the endoscope, perform appropriate leak testing of the endoscope per PENTAX instructions.

⚠ WARNING:

From the standpoint of infection control, all patient contact accessories must be thoroughly cleaned and subjected to an appropriate high-level disinfection or sterilization process before being used for the first time and subsequently after each clinical use.

⚠ CAUTION:

The instrument channel is made of stainless steel, noryl and fluorine-contained polymers.

When any fluids are used with these endoscopes, please read carefully and follow all instructions in the instruction for use supplied with the fluids for use and pay special attention to any reactions with the materials identified in the intended fluid path. Only the user can determine if the fluids are appropriate for patient use.

NOTE:

Bronchoscope instrument channels are composed of both stainless steel and polymers containing fluorine. PENTAX is not aware of any reports of material incompatibility between these materials and fluids that are commonly used during endoscopic procedures. As relates to reprocessing, PENTAX publishes a list of compatible detergents and disinfectants. In the event that the healthcare team intends to infuse a less commonly or rarely used fluid through the instrument channel in conjunction with a procedure, it is strongly advised that the manufacturer of the fluid be consulted for material compatibility information with stainless steel and polymers containing fluorine. Also, please consult the PENTAX list of compatible reprocessing agents for guidance regarding compatible detergents and disinfectants.

NOTE:

Accessories should always be inspected and checked with the particular endoscope prior to each procedure.

⚠ CAUTION:

Do NOT clinically use the endoscope if any irregularity or abnormality is suspected. If there is any doubt as to the suitability of use for any endoscope component, replace it with a new fully reprocessed one. An instrument irregularity may cause endoscope damage and/or compromise patient or user safety.

2-3. Preparation just before Insertion of Endoscope

⚠ WARNING:

From the standpoint of infection control, every endoscope should be properly disinfected or sterilized before being used for the first time. The endoscope should have been properly cleaned and disinfected or sterilized after any previous use and after being returned for any repairs/service.

Refer to the companion Instructions for Use describing in detail PENTAX reprocessing instructions.

⚠WARNING:

Current infection control guidelines require that endoscopes and their patient contact accessories either be sterilized or at the least be subjected to high-level disinfection. Accessories which ENTER STERILE TISSUE or THE VASCULAR SYSTEM must be sterilized before patient use. Only the user can determine if any instruments and accessories have undergone appropriate infection control procedures prior to each clinical use.

- 1) If the endoscope has just recently been reprocessed, has been prepared or stored properly and passed all pre-procedure inspections, the instrument should be ready to use. If necessary, the endoscope's insertion tube may be wiped down with gauze moistened with 70-90% medical grade ethyl or isopropyl alcohol.

⚠WARNING:

Contact the manufacturer and follow local regulations regarding safe use, appropriate handling and disposal of cleaning and disinfection solution including alcohol. Material Safety Data Sheets (Health and Safety Data Sheets or similar documents depending upon country) available from the cleaning and disinfection solution (including alcohol) manufacturer should provide guidance to end users about composition, hazards, chemical and physical properties, first aid, handling and storage, stability, precautions, disposal, etc. associated with cleaning and disinfection solution including alcohol.

- 2) Gently clean the objective lens and the light guides with a cotton-tip applicator moistened with 70-90% medical grade ethyl or isopropyl alcohol. A lens cleaner (anti-fogging agent) may also be applied via gauze or other applicator.
- 3) Check the endoscopic image and confirm that it is of acceptable quality for clinical use. Refer also to the Instructions for Use supplied with the PENTAX video processor for inspection of the image quality.
- 4) Prior to trans-oral insertion of the endoscope, place a bite-block (mouthpiece) into the patient's mouth to protect the endoscope from damage during the procedure. Failure to do so can result in scratches, tears and/or crushing of the insertion portion of the endoscope. **(if the endoscope is to be introduced trans-orally).**
- 5) Apply a medical grade water soluble lubricant to the insertion tube. Do not use petroleum based lubricants.

NOTE:

The objective lens and the light guides must be kept free of the lubricant and excess lens cleaner.

⚠CAUTION:

Never drop this equipment or subject it to severe impact as it could compromise the functionality and/or safety of the unit. Should this equipment to be mishandled or dropped, do not use it. Return it to an authorized PENTAX service facility for inspection or repair.

3. DIRECTIONS FOR USE

⚠ WARNING:

This instrument should only be used by physicians who have thoroughly studied all the characteristics of this instrument and who are familiar with the proper techniques of endoscopy. There is a possibility of backflow and/or spit-back of patient fluids, chemicals, etc. from the Instrument Channel Inlet or the Suction Control Valve. During the procedure, always wear protective garments such as surgical gloves, gowns, face masks, etc. to minimize the risk of cross contamination.

⚠ WARNING:

When using this instrument on a patient with invasive medical device such as pacemaker, consult a physician specialized in the field to determine whether the use of this instrument is safe by taking all factors into consideration.

⚠ WARNING:

Because of the leakage current from the endoscope, there is a possibility of electric shock if any part of the skin comes in contact with exposed metallic surfaces of an endoscope while using an electrosurgical device. Be sure to wear protective rubber gloves during endoscopic examinations to prevent the skin from contacting the metallic surfaces of an endoscope.

3-1. Operation

- 1) Angulation function
 - a) Manipulate the Angulation Control Lever in the “U” direction in order to angulate the distal end in the UP direction.
 - b) Manipulate the Angulation Control Lever in the “D” direction in order to angulate the distal end in the DOWN direction.

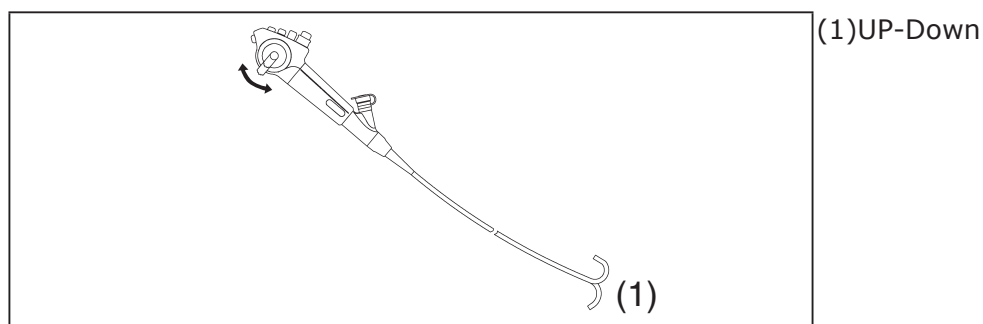
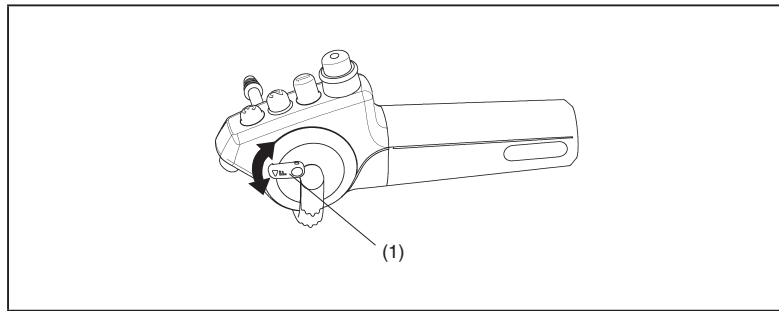


Figure 3.1

- 2) Angulation Lock function (EB-1170K, EB-1570K, EB-1970K)
 - a) Turn the angulation Lock Lever clockwise to lock the angulation position.
 - b) Turn the angulation Lock Lever counter-clockwise to unlock the angulation position.

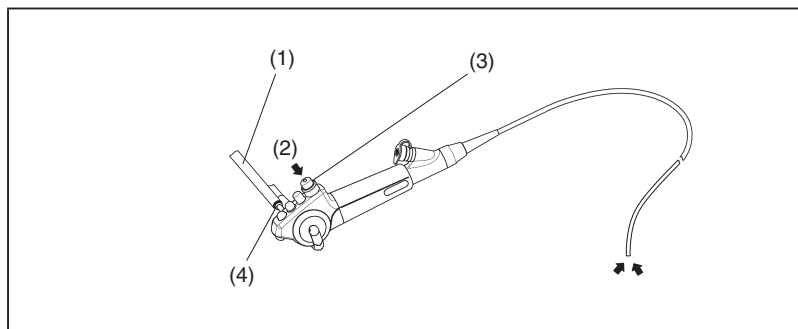


(1) Angulation Lock Lever
(EB-1170K, EB-1570K,
EB-1970K)

Figure 3.2

3) Suction function

- a) Connect the suction source tube from an external suction source to the suction nipple located on the control body.
- b) Depress the Suction Valve to suction fluid and/or gas, debris.
- c) Release the Suction Valve to stop suctioning.



(1) Suction Source Tube
(2) Depress
(3) Suction Control Valve
(4) Suction Nipple

Figure 3.3

4) Remote Button function

Function assigned to each Remote Button is activated by pressing the corresponding Remote Button.

Refer to the Instructions for Use supplied with the processor for assignment of function to each Remote Button.

The following table shows the factory setting.

Remote Button 1	Freeze
Remote Button 2	Copy
Remote Button 3	VCR
Remote Button 4	Enhance

3-2. Pretreatment

The patient should be prepared appropriately based on your expertise as an endoscopic specialist.

3-3. Insertion and Withdrawal

⚠CAUTION:

For safety reasons, always insert and advance the endoscope in the standard, non-magnified mode. Magnified vision reduces the area of the viewing field. Do not advance the endoscope in the magnified (zoom) mode.

⚠ CAUTION

Patient material and secretions should be removed from the area of observation to eliminate the potential to blur the endoscopic image and/or obscure the illumination system.

Continuing use of the light guide with sticky debris might cause steam because debris is deprived of moisture by heat. As a result, endoscopic images become blurry. If steam is found on the light guide during a procedure, stop it immediately and withdraw the endoscope carefully from a patient.

⚠ CAUTION:

Do not assume that the endoscope can be used trans-nasally on all patients. Individual differences in the shapes and sizes of patients' nasal lumens, as well as their receptivity to trans-nasal insertion must be considered prior to trans-nasal insertion. There is a potential for nasal lumen injury if trans-nasal insertion is forced.

Whether to insert trans-nasally should be confirmed and carefully judged by the doctor. The patient should be appropriately prepared prior to the endoscopic examination as relates to the intended point of entry into the patient.

- 1) Slowly insert the endoscope under direct vision.

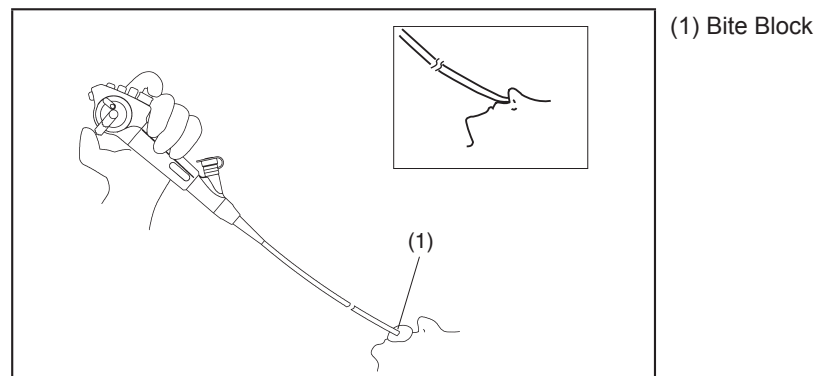


Figure 3.4

- 2) **(ENDOSCOPES TO BE INTRODUCED TRANSORALLY)**

When the distal end of the endoscope is passed through the pharynx, the patient should be gently biting down on the bite block to maintain the bite block's position during the procedure.

- 3) Adjust the intensity of the video processor to obtain a brightness level suitable for observation.

⚠ CAUTION:

The light emission from the endoscope could cause thermal injury. To minimize the risk, use only the minimum amount of brightness and avoid close stationary viewing and unnecessary prolonged use.

- 4) The angulation control should be used as needed to position the endoscope. Angulation of the tip should be performed under direct vision in a gentle and deliberate manner.

⚠WARNING:

Ensure that the angulation controls can rotate smoothly, that there is no grinding or excess friction within the angulation system and that the bending section bends freely and smoothly.

NEVER APPLY EXCESSIVE FORCE TO THE ANGULATION CONTROLS!

ANY lack of smooth operation of the angulation controls may be an early indication of internal damage to and/or part(s) failure within the endoscope's angulation system. To avoid the potential for malfunction of the angulation system, do NOT use the endoscope if the angulation mechanism does not operate properly. Use of endoscope with suspect angulation mechanism could lead to angulated distal end to not being able to be released and could cause possibly perforation.

If during a procedure angulation is lost in any direction such as when "cables snap" (broken pulley wire, broken angle wire, etc.), do NOT continue to use the instrument and do NOT rotate the angulation controls. Should the angulation system fail for any reason, stop the procedure and carefully withdraw the endoscope under direct visualization.

The examples above are indications that service is required to avoid more serious problems with the angulation control system, including the possibility of a "frozen" bending section.

A "frozen" bending section can make instrument extraction from a patient more difficult.

- 5) If bronchial secretions or other debris are present in the lungs, making observation difficult, suctioning should be performed.

⚠WARNING:

Avoid suctioning foreign objects and solid particles that are large enough to potentially clog the Suction Channel and Suction Control Valve. If such objects and/or particles have been suctioned into the endoscope, insure that they have been completely removed from the endoscope before continuing to use it. If the Suction Control Valve has been clogged to the extent that it is not possible to stop the suctioning operation, detach the Suction Source Tube that is attached to the endoscope from the suction source, detach the Suction Control Valve from the endoscope, and remove any trapped debris that might be preventing the Suction Control Valve from operating properly. If it is impossible to confirm that all foreign objects and solid particles have been removed from the Suction Channel, do not use the endoscope and contact your local PENTAX service facility.

⚠CAUTION:

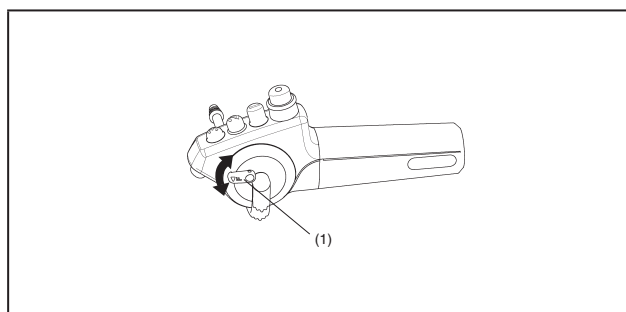
Do not apply excessive negative pressures (high suction settings) and/or prolonged contact of the distal instrument channel opening (endoscope tip) against mucosal surfaces to avoid "suction polyps", bleeding and/or other trauma to the patient. During aspiration keep an endoscopic view of patient anatomy as clear as possible and maintain some distance from endoscope tip to tissue to avoid suctioning of mucosa onto/into the distal channel opening.

- 6) Image capture, hard copy documentation, video recording, etc. may be carried out as necessary.

NOTE:

Leaving the finger on the remote button could cause the function (hard copy or recording, etc.) to be activated inadvertently.

- 7) When attempting to withdraw the endoscope, always withdraw the endoscope under direct visualization.



(1) Angulation Lock Lever
(EB-1170K, EB-1570K,
EB-1970K)

The angulation lock lever
should be released.

Figure 3.5

- 8) Finally, remove the bite block if present.

⚠ WARNING:

*If for any reason, the image is lost due to power shortage, lamp or processor failure, etc. The angulation lock levers should be released, the endoscope tip should be **straightened** to its neutral position, and the insertion tube should be carefully and slowly withdrawn from the patient. If the endoscope is withdrawn without releasing the angulation lock lever, it may cause an injury such as perforation to the patient.*

3-4. Biopsy

⚠WARNING:

From the standpoints of infection control, accessories which ENTER STERILE TISSUE, THE VASCULAR SYSTEM, BLOOD VESSELS, or MUCUS MEMBRANE must be sterile.

⚠WARNING:

For ALL types of endoscopic accessory instruments, always maintain a view of the accessory during advancement, use, and withdrawal of the device.

Incautious use of EAI devices could end up damaging patient tissue/membrane or perforation.

⚠CAUTION:

If the use of a unique or highly specialized accessory is planned, the accessory manufacturer should be consulted to confirm compatibility with PENTAX endoscopes before use.

⚠CAUTION:

For safety reasons, always insert and advance the accessory in the standard, non-magnified mode.

Magnified vision reduces the depth of the viewing field making it difficult to maintain a clear view of the accessory.

- 1) Insert the forceps through the slit in the inlet seal. Be certain to hold the forceps handle in such a way to ensure that the cups/jaws of the forceps are in a fully closed position during insertion.
-

NOTE:

When the cups/jaws are first passed through the inlet seal, a temporary resistance will be encountered.

Hold the shaft tightly at about 5cm from the cups/jaws and push it through. During insertion, if the forceps are found hard to advance further due to resistance, decrease the angulation of the bending section to a level suitable for smooth insertion and insert the forceps again.

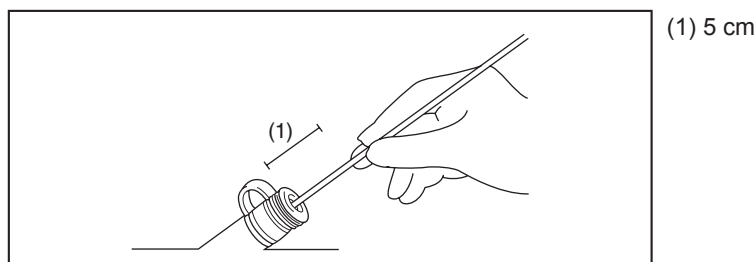


Figure 3.6

⚠CAUTION:

Never apply excessive pressure when introducing any accessory since the instrument channel may be damaged. Malfunction of the endoscope as well as costly repairs may result.

- 2) When a portion of the cups/jaws of the forceps becomes visible in the viewing field, carefully advance the forceps onto the target area.

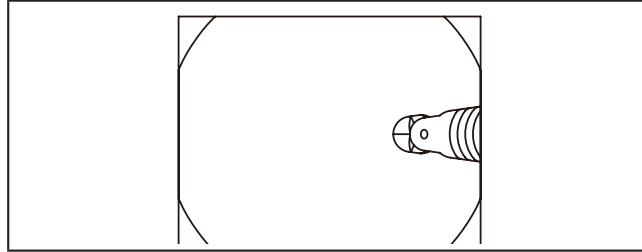


Figure 3.7

- 3) Open the forceps cups/jaws and advance the forceps against the target area. Carefully squeeze the forceps handle to close the cups/jaws and obtain a specimen within the cups/jaws. Always maintain a view of accessory during advancement.
- 4) Withdraw the forceps slowly with the cups/jaws closed.

⚠WARNING:

Withdraw the forceps carefully and gently. Never withdraw the forceps rapidly.

It could cause reflux of patient debris left in the endoscope channel.

3-5. Laser (Except EB-1170K, EB-1990i)

Laser equipment should only be used by physicians who have thoroughly studied all the characteristics of the equipment and who are familiar with the proper techniques of endoscopic laser therapy. The user must carefully read and follow all instructions in the Instructions for Use supplied with the Laser equipment. The Laser equipment should be carefully and thoroughly inspected and calibrated. Only the user can determine if the condition of the Laser equipment is suitable. Follow standard hospital protocol regarding safe-use of lasers, including the wearing of safety eyewear.

⚠WARNING:

The PENTAX endoscopes identified in this instruction for use are compatible with Nd:YAG laser (wavelength 1064nm) and Diode Laser (wavelength 800nm ~ 1000nm) only. Do not use these endoscopes with other types of laser such as KTP, He-Cd, or Excimer Laser Systems. It could result in serious injury to the patient.

⚠WARNING:

Using laser devices in a flammable surroundings, such as an environment with a high oxygen concentration, may cause combustion. If there is a possibility of flammable gas being present within a body cavity, use non-explosive gas (such as air) instead.

⚠WARNING:

- *When using a laser equipment, the physicians as well as the assisting personnel should wear goggles.*
 - *Do not look directly at the light emitted from the laser equipment. The intense light may cause damage to your retinas.*
-
-

- 1) The operator and assistant(s) should wear surgical gloves to avoid burns during use of Laser equipment.
 - 2) The laser probe should be introduced through the endoscope in the same manner as described for biopsy forceps in section 3-3.
 - 3) The position of the active portion of the laser probe should always be clearly visualized before Laser equipment is activated.
 - 4) It should be recognized that a variety of factors can affect the quality of the video endoscope image during laser use. Intensity of the aiming beam, high power setting of the laser, close distance of laser fiber to endoscope tip, excessive tissue burning, can each adversely influence image quality. To obtain optimum results, it is recommended that the power settings of the aiming beam and laser be adjusted to minimal levels capable of achieving the desired clinical effect.
 - 5) Follow standard hospital protocol regarding safe-use of lasers, including the wearing of safety eyewear.
-
-

⚠CAUTION:

Prior to activation of the laser, make sure that the laser fiber exits the distal channel opening of the endoscope. Failure to confirm activation and deactivation of the laser could result in endoscope damage.

⚠ WARNING:

Never deliver oxygen with any endoscopic laser therapy.

NOTE:

It is normal for the aiming light to appear white in the video endoscope image.

- 6) Should the distal end of the endoscope be moved closer than 20mm from the irradiated tissue surface, the aiming beam may create a “smear” in the image as shown at left. If this smear affect becomes too severe and distorts the visual field, the intensity of the aiming light should be decreased.

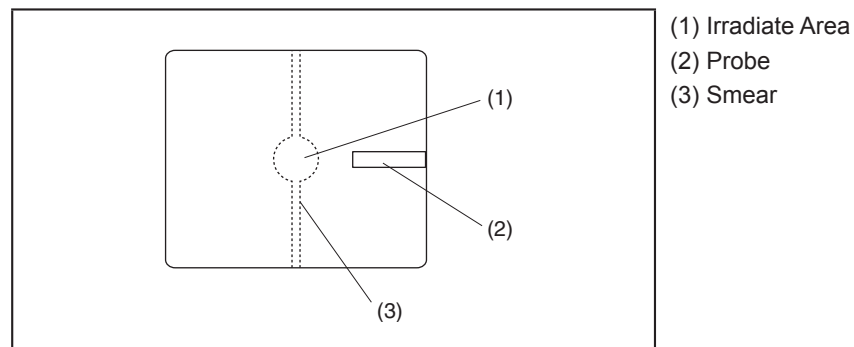


Figure 3.8

- 7) When activating the laser at high power (about 100W for YAG Laser and 60W for Diode Laser) and/or if the endoscope tip comes to within 10mm of the irradiated tissue, flare may appear at the corners of the image as shown below.

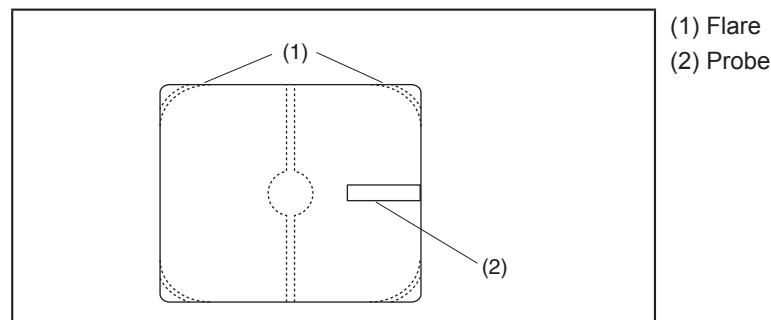


Figure 3.9

NOTE:

The reference of 100W or 60W is NOT intended to be a recommended power setting for pulmonary applications. Only a medical professional can determine the appropriate laser settings necessary to achieve the desired clinical effect.

⚠ WARNING:

Activation of the laser at high power settings may cause patient injury or thermal damage of the endoscopes tip. Avoid use of high power.

3-6. Electrosurgery (Except EB-1170K, EB-1990i)

Traditionally, electrosurgical devices have been recognized as an important and effective treatment modality via flexible endoscopes. Recent advances in bronchoscope design including the use of insulating materials likely to be in contact with a patient now allow the use of bronchoscopic electrosurgical devices.

⚠WARNING:

Please refer to the Instructions for Use provided with the electrosurgical unit. Electrosurgical systems may be of the floating type (Type BF, Type CF) or non-floating (Type B). To avoid patient and user burn, use only the floating type ESU/accessory systems. Do not use the non-floating (Type B) electrosurgical systems. The electrosurgical generator and any electrosurgical accessory should be carefully and thoroughly inspected. Only the user can determine if the condition of the electrosurgical generator and the electrosurgical accessory are suitable.

⚠WARNING:

Using electrosurgical devices in a flammable surroundings, such as an environment with a high oxygen concentration, may cause combustion. If there is a possibility of flammable gas being present within a body cavity, use non-explosive gas (such as air) instead.

- 1) The operator and assistant(s) should wear surgical gloves to avoid burns during use of electrosurgical devices.
- 2) The electrosurgical accessories should be introduced through the endoscope in the same manner as described for biopsy forceps in section 3-3.

⚠CAUTION:

Prior to performing electrosurgery, make sure that the electrosurgical device exits the distal channel opening of the endoscope. Failure to confirm activation and deactivation of the electrosurgical device could result in endoscope damage.

⚠WARNING:

To avoid patient and user burn, follow the instructions below before electro-surgical energy is delivered.

- 1) Use only the electro-surgical generator with the floating grounding type (Type BF or Type CF). Do not use the non-floating (Type B) electro-surgical systems.*
- 2) There are two types of Floating Ground Electro-surgical Generators. The operator should confirm if the Floating Ground Electro-surgical Generator requires an endoscope feedback cord (s-cord).*

For Floating Ground Electro-surgical Generators which require an s-cord, connect the s-cord between;

- the endoscopes feedback terminal and*
- the Electro-surgical Generator patient ground connecting socket.*

For Floating Ground Electro-surgical Generators which do not require an s-cord;

- DO NOT use the s-cord, to avoid potential patient injury.*
- use the Condenser Earth Cable, OL-Z3 to reduce interferences or noise that may appear in the video image.*

If the processor does not have an equipotential terminal, do not connect any functional ground cord.

- 3) High frequency energy should be delivered for as short a time period as necessary to accomplish the desired clinical effect.*
 - 4) Select a high frequency output power setting suitable for the particular intended procedure in order to avoid thermal invasion of the tissue, or insufficient coagulation, resulting in excessive bleeding.*
-
-

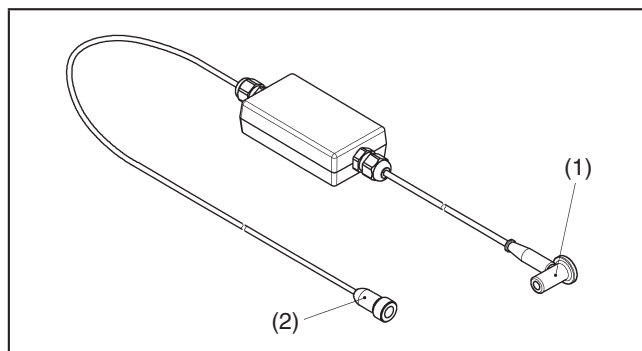
⚠CAUTION:

To avoid user burn and/or unexpected burn to the patient, follow the instructions below before high frequency energy is delivered.

- 1) Do not touch the exposed metal parts of the endoscope with unprotected skin to avoid burns while using an electrosurgical device. Be sure to wear protective gear such as rubber gloves and goggles.
- 2) The position of the target area, the insulated distal portion of the electrosurgical device and the active portion of the electrosurgical device, should be visible.
- 3) The active portion of the electrosurgical device should not touch the metallic distal portion of the endoscope directly or via fluids.
- 4) The metallic portion of the endoscope should not touch the surrounding tissue directly or via fluids.
- 5) The active portion of the electrosurgical device should not touch the surrounding tissue directly or via fluids.
- 6) The head of any lesion such as polyp should not touch the surrounding tissue directly or via fluids.
- 7) Physicians and assisting personnel should avoid contact with the patient while high frequency energy is delivered.
- 8) To avoid the risk of thermal injury, use only insulated devices. Never use non-insulated devices while performing endoscopic electrosurgical procedures.

⚠CAUTION:

It should be recognized that the use of electrosurgical devices employing high frequency current may interfere with the normal endoscopic image and this interference is not indicative of a malfunction of the video endoscope system. PENTAX has developed an earth cable, model OL-Z3 intended to reduce potential RF interference and electronic noise that may appear in the endoscope image when using electrosurgical devices. Ensure that cable OL-Z3 is correctly connected between the endoscope and video processor as described in the instructions provided with the OL-Z3. If electronic noise appears in the endoscope image when using the OL-Z3, select a high frequency setting to minimum levels capable of achieving the desired clinical effect.



- (1) To Video Processor
(2) To Endoscope

Figure 3.10

4. CARE AFTER USE

For the cleaning and maintenance of the equipment after its use, please refer to the separate Instructions for Use (reprocessing).

⚠WARNING:

*Instrument repairs should only be performed by an authorized PENTAX service facility. PENTAX assumes no liability for any patient/user injury, instrument damage or malfunction, or **REPROCESSING FAILURE** due to repairs made by unauthorized personnel.*

Your local PENTAX distributor can provide a list of "compatible" reprocessing agents with PENTAX endoscopes based upon material compatibility and functionality studies performed by PENTAX, Japan. These tests of course apply only to genuine PENTAX parts, components and materials including proprietary adhesives, sealants, lubricants, etc. specifically selected for use in PENTAX endoscopes to satisfy their original design criteria. PENTAX manual reprocessing instructions supplied with each product have been validated for PENTAX endoscopes utilizing exclusive PENTAX parts/materials and assembled based upon proprietary PENTAX manufacturing technologies and/or servicing techniques.

It must be recognized that PENTAX does not evaluate non-PENTAX parts, components, materials and/or servicing methods and therefore questions regarding material compatibility and/or functionality of PENTAX instruments built with these unauthorized, untested and unapproved items, materials, repair/assembly methods must be referred to the third party service organization and/or device remanufacturer. It is unknown to PENTAX if serviced or remanufactured instruments (performed by unauthorized PENTAX entities) which still bear a PENTAX label are within PENTAX device specifications and/or if unauthorized activities have significantly changed the instrument's performance, intended use, safety and/or effectiveness.

These companies should confirm the ability for these serviced/remanufactured devices to be reprocessed safely and effectively with reprocessing agents/systems recognized as compatible by PENTAX for standard PENTAX products. These third party companies and/or remanufacturers should be consulted to confirm if they have performed reprocessing validation studies on instrument models which they have serviced (or remanufactured) that support the cleaning, high-level disinfection and/or sterilization of these endoscopes via the normal endoscope OEM reprocessing recommendations, standard AER device-specific instructions and/or their own unique reprocessing recommendations.

Ultimately, owners of these medical devices are responsible for selecting an appropriate service facility or vendor whose activities render an instrument to the same expectations and quality of a finished device supplied by the endoscope OEM.

⚠CAUTION:

Never drop this equipment or subject it to severe impact as it could compromise the functionality and/or safety of the unit. Should this equipment be mishandled or dropped, do not use it. Return it to an authorized PENTAX service facility for inspection or repair.

⚠CAUTION:

- *The service life of the endoscopes addressed in this IFU is 6 years from the date of manufacture.*
 - *Follow the instructions in the Instructions for Use for appropriate pre-use inspections, proper usage, care after use, storage, and replacement of consumables.*
 - *Have the vendor/specialist specified by PENTAX to perform repairs and annual periodic inspections.*
-

⚠WARNING:

Follow the national or local laws/guidelines to appropriately dispose of the consumables. Ask the manufacturer or PENTAX representative about the disposal of the instrument.

SPECIFICATIONS

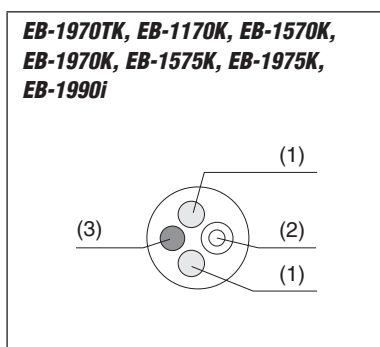
Endoscope Model		EB-1970TK	EB-1170K	EB-1570K	EB-1970K	EB-1575K	EB-1975K	EB-1990i
Direction of View		Forward						
Field of View		120°						
Depth of Field (mm)		3 - 50						
Tip Angulation	Up	180°	210°		180°	210°	180°	
	Down	130°						
Rigid Distal Width (O. D. φmm)		φ6.2	φ3.8	φ5.5	φ6.3	φ5.5	φ6.3	φ6.6
Distal End Width (O. D. φmm)		φ6.2	φ3.8	φ5.5	φ6.3	φ5.5	φ6.3	φ6.6
Insertion Tube Width (O. D. φmm)		φ6.3	φ3.7	φ5.1	φ6.2	φ5.2	φ6.4	φ6.4
Maximum Insertion Portion Width (O. D. φmm)		φ7.75	φ4.95	φ6.35	φ7.55	φ6.65	φ7.55	φ7.75
*Minimum Instrument Channel Width (I. D. φmm)		φ3.2	φ1.2	φ2.0	φ2.8	φ2.0	φ2.8	φ1.2
Insertion Tube Working Length (mm)		600						
Total Length (mm)		860						
Operating environment	Ambient temperature	10 - 40°C						
	Relative humidity	30 - 85%RH						
	Air pressure	700 - 1060 hPa						
Storage environment	Ambient temperature	-20 - 60°C						
	Relative humidity	0 - 85%RH						
	Air pressure	700 - 1060 hPa						
**Maximum reprocessing temperature		60°C						
Degree of protection against electric shock		Type BF (Use on heart is prohibited)						
Mode of Operation		Continuous Operation						
Compatibility Y:Yes N:No	Laser	Y	N	Y	Y	Y	Y	N
	Electrosurgery	Y	N	Y	Y	Y	Y	N
	STERRAD® NX™ systems	N	N	N	N	Y	Y	Y

*There is no guarantee that instruments selected solely using this minimum instrument channel width will be compatible in combination.

**PENTAX flexible endoscopes should not be exposed to temperatures in excess of 140°F (60°C) during either reprocessing or storage. In reprocessing, depending on detergents, even if the temperature does not exceed 60°C, the scopes may be damaged. For specific brands of compatible detergents, please contact your local PENTAX service facility or sales representative.

Note: Specifications are subject to change without prior notice and without any obligation on the part of the manufacturer.

DISTAL END



- (1) Light Guide
- (2) Objective Lens
- (3) Instrument Channel

MEMO

MEMO

NOTICE

These instruments are used with Class B Medical Equipment (specified CISPR11) and are intended for Hospitals, Ambulatory Surgery Centers, and Medical Clinics.

Together, these endoscopes and the compatible processor comply with EN 60601-1-2 for EU, IEC 60601-1-2 for other countries.

When used in clinical or residential areas near radio and TV receiver units, these instruments may cause radio interference.

To avoid and resolve adverse electromagnetic effects, do NOT operate these instruments near the RF energy equipment.

HOYA Corporation

2-7-5 Naka-Ochiai, Shinjuku-ku, Tokyo 161-8525 Japan



PENTAX Medical Company

A Division of PENTAX of America, inc.

3 Paragon Drive Montvale, New Jersey 07645-1782 USA

Tel: +1-201-571-2300 Toll Free: +1-800-431-5880

Fax: +1-201-391-4189

PENTAX Canada Inc.

1770 Argentia Road Mississauga, Ontario L5N 3S7 Canada

Tel: +1-905-286-5585

Fax: +1-905-286-5571

PENTAX Europe GmbH

Julius Vosseler Strasse 104, 22527 Hamburg, Germany

Tel: +49-40-561-920

Fax: +49-40-560-4213



Manufacturing Site

HOYA Corporation, PENTAX Miyagi Factory

30-2 Okada, Aza-Shimomiyano, Tsukidate, Kurihara-shi, Miyagi 987-2203 Japan

- Specifications are subject to change without notice and without any obligation on the part of the manufacturer.

88895

2014.06

6217001

S015 R04

printed in JAPAN