

PENTAX™

Only For the Americas

**INSTRUCTIONS FOR USE
(OPERATION)**

PENTAX VIDEO COLONOSCOPES

EC-3890TLK,

EC-2990Li, EC-3490Li

EC-3890Li, EC-3490TLi

EC-3490LK, EC-3890LK

EC-3890LZi, EC34-i10L

EC38-i10L

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 Knobs, air and water is fed from the distal end of the endoscope by operating the Air/Water Feeding Valve, and air or fluids can be suctioned from the distal end of the endoscope by operating the Suction Control Valve.

Indication for Use

These instruments are intended to be used with a PENTAX video processor (including light source), documentation equipment, Monitor, Endotherapy Device such as a Biopsy Forceps, and other ancillary equipment for endoscopy and endoscopic surgery within the lower digestive tract including the anus, rectum, sigmoid colon, colon and ileocecal valve.

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 these instruments.

Intended anatomical area: Lower gastrointestinal tract (rectum, sigmoid colon, colon and ileocecal valve)

User: Medical doctors (experts 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 this model are as follows:

- Angulation capability using control knob
- Remote control operation using remote buttons
- Air/Water feeding function
- Suctioning function

Removable Components

OF-B118	Water jet connector cap
OF-B120	Suction control valve
OF-B161	Suction channel selector(for EC-3890TLK only)
OF-B188	Air/Water feeding valve
OF-B190	Inlet seal
OE-C12	Water jet check valve adapter

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 semi-critical 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 an 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 标志意味着保证该产品遵从欧洲共同体安全法规。

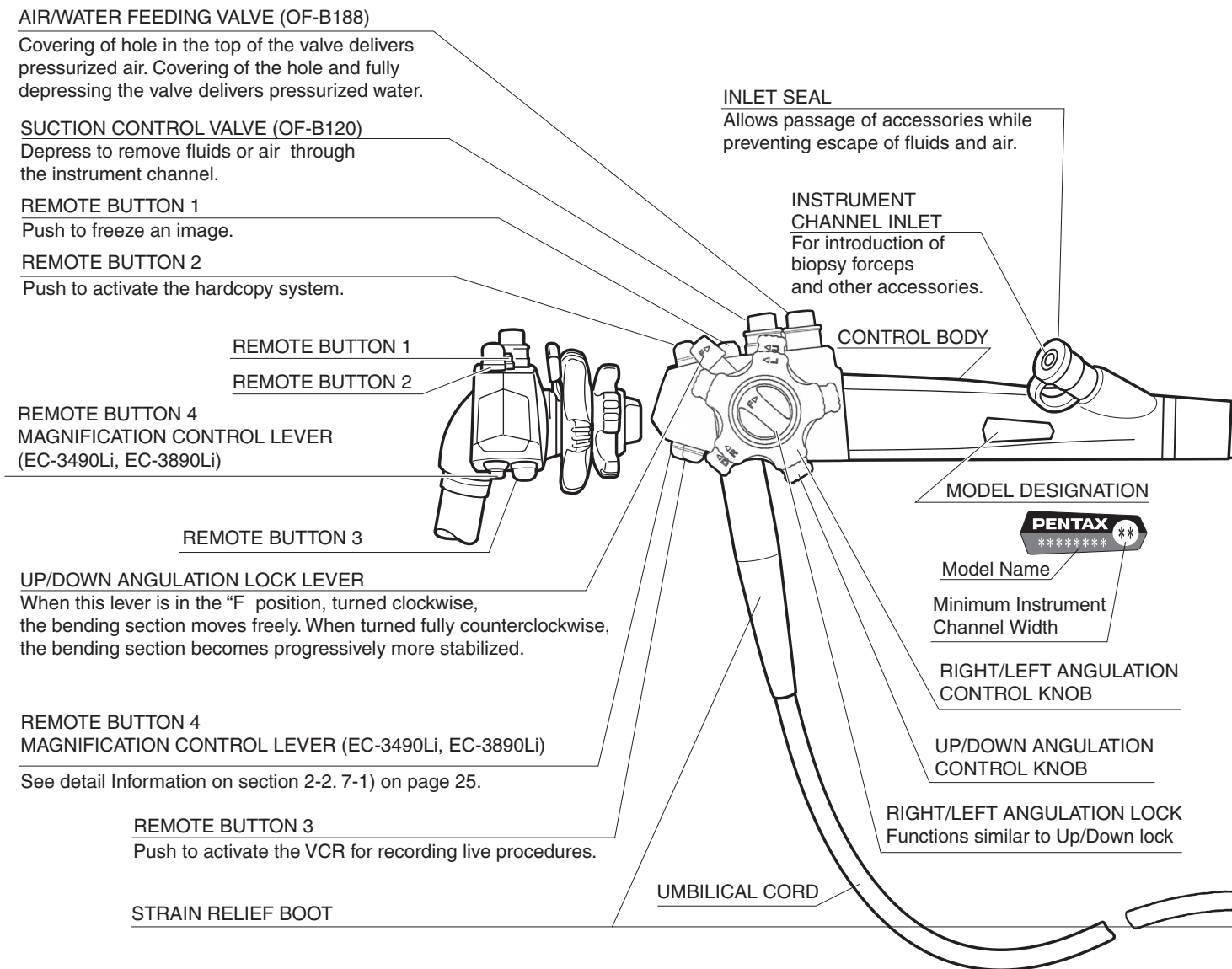
TABLE OF CONTENTS

1. NOMENCLATURE AND FUNCTION	1
1-1. Video Endoscope	1
1-2. Accessories	7
1-3. Video Processor	8
2. PREPARATION AND INSPECTION FOR USE	9
2-1. Inspection of the Video Processor	9
2-2. Inspection of Endoscope	11
2-3. Preparation just before Insertion of Endoscope	32
3. DIRECTIONS FOR USE	34
3-1. Operation	35
3-2. Pretreatment	37
3-3. Insertion and Withdrawal	37
3-4. Magnification Control (EC-3890LZi)	41
3-5. Biopsy	43
3-6. Laser	45
3-7. Electrosurgery	49
4. CARE AFTER USE	53
SPECIFICATIONS	55

1. NOMENCLATURE AND FUNCTION

1-1. Video Endoscope

- **EC-3890TLK, EC-2990Li, EC-3490Li, EC-3890Li, EC-3490TLi, EC-3490LK, EC-3890LK**



NOTE:

Function of each remote button depends upon the video processor. The function can be changed. For more details, refer to the instructions for use supplied with the video processor.

Endoscope Model	EC-3890TLK EC-2990Li, EC-3490TLi EC-3490LK, EC-3890LK	EC-3490Li EC-3890Li
*Remote Button 1	Freeze	Freeze
*Remote Button 2	Copy	Copy
*Remote Button 3	Video	Video
*Remote Button 4	Enhance	-
**Magnification Control Lever	-	Magnification(electronic)

*Setting at factory

**Not applicable to PENTAX Video Processor, model EPK-i5020

EC-3890TLK ONLY

INLET SEAL

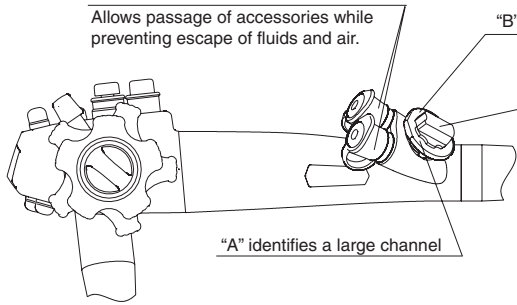
Allows passage of accessories while preventing escape of fluids and air.

"B" identifies a small channel

SUCTION CHANNEL SELECTOR OF-B161

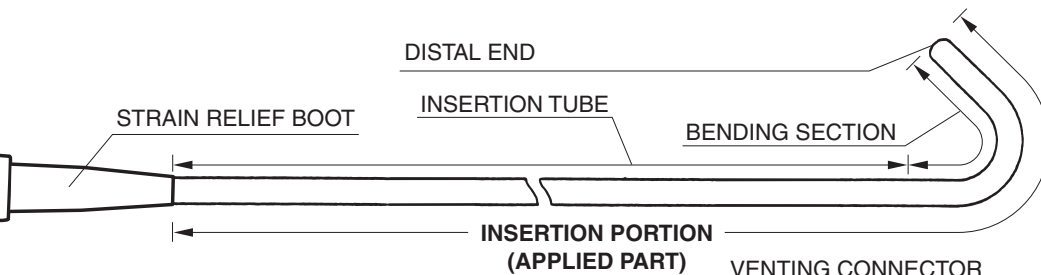
Alignment of the indicator to the prescribed positions allows the user the choice of suction capability through either channel (2.8mm or 3.8mm) or simultaneous suction through both channels

"A" identifies a large channel



CAUTION:

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



WATER JET CONNECTOR

Allows connection of special irrigation tube (OF-B113) for pressurized source of a spray directed at the endoscopically visualized surface.

AIR/WATER PORT

To connect feeding tube from water bottle assembly.

PVE CONNECTOR

Can be rotated within a 180° range.

VENTING CONNECTOR

Accepts "RED" Ventilation cap. Also accepts Leakage Tester.

RED VENTILATION CAP OF-C5

Provides venting of endoscope interior to equalize internal and external pressures. This cap must be removed before immersion.

ELECTRICAL CONTACTS

PVE SOAKING CAP OE-C9

This cap must be securely attached before immersion. Align the black arrow on the soaking cap with the green dot at the base of the silver collar surrounding the electrical contacts on the PENTAX PVE connector. Press the cap down onto the metal collar and turn clockwise to secure.

LIGHT GUIDE PLUG

Transmits light from light source to distal end of endoscope.

FEEDBACK TERMINAL

To connect the OL-Z3 cable From the a compatible PENTAX video processor.

SUCTION NIPPLE

For attachment to external suction source.

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:

Immediately after use, the metal light guide prong 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.

• **EC-3890LZi**

AIR/WATER FEEDING VALVE (OF-B188)

Covering of hole in the top of the valve delivers pressurized air. Covering of the hole and fully depressing the valve delivers pressurized water.

SUCTION CONTROL VALVE (OF-B120)

Depress to remove fluids or air through the instrument channel.

REMOTE BUTTON 1

Push to freeze an image.

REMOTE BUTTON 2

Push to activate the hardcopy system.

REMOTE BUTTON 1

REMOTE BUTTON 2

REMOTE BUTTON 3

MAGNIFICATION CONTROL LEVER

UP/DOWN ANGULATION LOCK LEVER

When this lever is in the "F" position, turned clockwise, the bending section moves freely. When turned fully counterclockwise, the bending section becomes progressively more stabilized.

REMOTE BUTTON 3

Push to activate the video for recording live procedures.

MAGNIFICATION CONTROL LEVER

See detail information on section 2-2. 7-2) on page 26.

INLET SEAL

Allows passage of accessories while preventing escape of fluids and air.

INSTRUMENT CHANNEL INLET

For introduction of biopsy forceps and other accessories.

CONTROL BODY

MODEL DESIGNATION



Model Name

Minimum Instrument Channel Width

RIGHT/LEFT ANGULATION CONTROL KNOB

UP/DOWN ANGULATION CONTROL KNOB

RIGHT/LEFT ANGULATION LOCK KNOB

Functions similar to Up/Down lock lever.

STRAIN RELIEF BOOT

UMBILICAL CORD

NOTE:

Function of each remote button depends upon the video processor. The function can be changed. For more details, refer to the instructions for use supplied with the video processor.

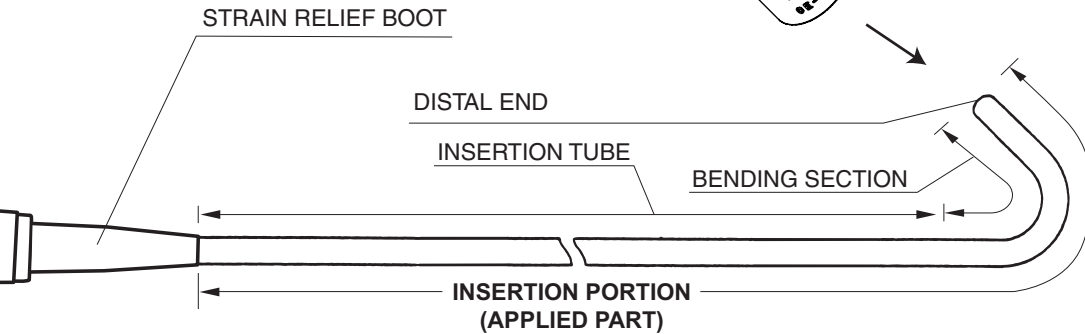
Endoscope Model	EC-3890LZi
*Remote Button 1	Freeze
*Remote Button 2	Copy
*Remote Button 3	Video
Magnification Control Lever	Magnification(optical)

*Setting at factory

DISTAL RUBBER HOOD
OE-A59 for EC-3890LZi

⚠ CAUTION:

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



WATER JET PORT

Allows connection of special irrigation tube (OF-B113) for pressurized source of a spray directed at the endoscopically visualized surface.

AIR/WATER PORT

To connect feeding tube from water bottle assembly.

PVE CONNECTOR

Can be rotated within a 180° range.

STRAIN RELIEF BOOT

VENTING CONNECTOR

Accepts "RED" Ventilation Cap.
Also accepts Leakage Tester.

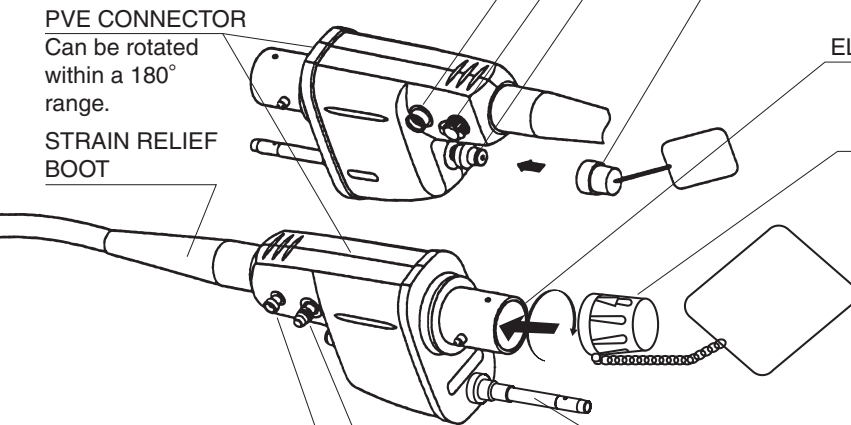
RED VENTILATION CAP OF-C5

Provides venting of endoscope interior to equalize internal and external pressures. This cap must be removed before immersion.

ELECTRICAL CONTACTS

PVE SOAKING CAP OE-C9

This cap must be securely attached before immersion. Align the black arrow on the soaking cap with the green dot at the base of the silver collar surrounding the electrical contacts on the PENTAX PVE connector. Press the cap down onto the metal collar and turn clockwise to secure.



LIGHT GUIDE PLUG

Transmits light from light source to distal end of endoscope.

FEEDBACK TERMINAL

To connect the OL-Z3 cable
From a compatible PENTAX
video processor.

SUCTION NIPPLE

For attachment to
external suction
source.

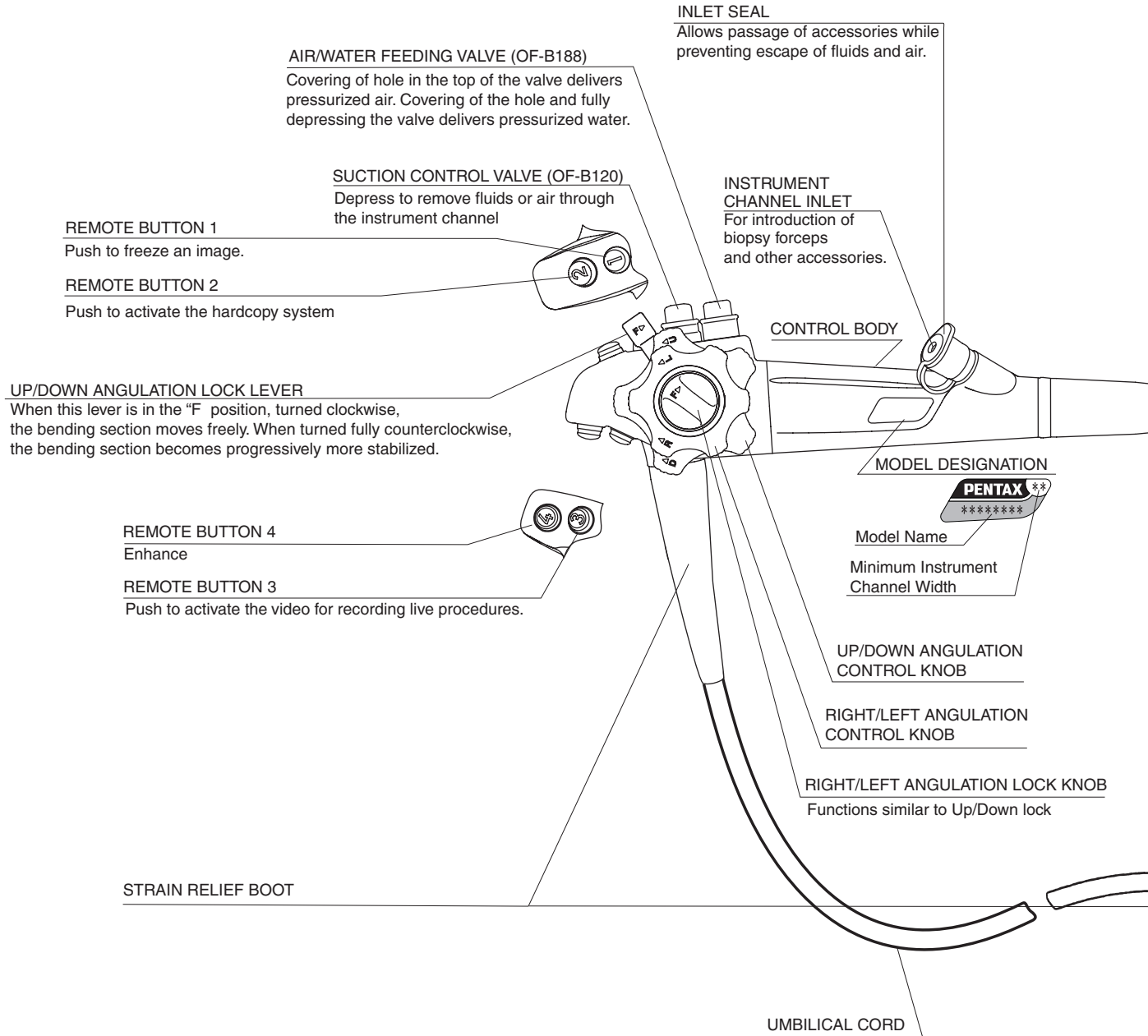
⚠ CAUTION:

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

⚠ 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.

• EC34-i10L/EC38-i10L



NOTE:

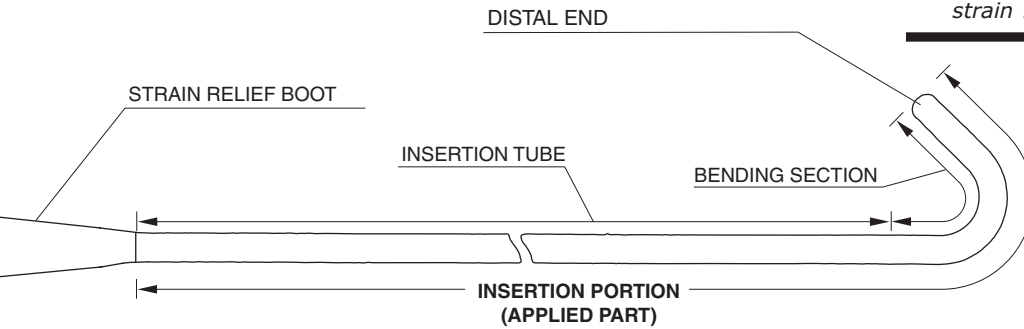
Function of each remote button depends upon the video processor. The function can be changed. For more details, refer to the instructions for use supplied with the video processor.

Endoscope Model	EC34-i10L EC38-i10L
*Remote Button 1	Freeze
*Remote Button 2	Copy
*Remote Button 3	Video
*Remote Button 4	Enhance

*Setting at factory

⚠ CAUTION:

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



WATER JET PORT

Allows connection of special irrigation tube (OF-B113) for pressurized source of a spray directed at the endoscopically visualized surface.

AIR/WATER PORT

To connect feeding tube from water bottle assembly.

PVE CONNECTOR

Can be rotated within a 180° range.

VENTING CONNECTOR

Accepts "RED" Ventilation Cap. Also accepts Leakage Tester.

VENTILATION CAP [RED] OF-C5

Provides venting of endoscope interior to equalize internal and external pressures. This cap must be removed before immersion.

ELECTRICAL CONTACTS

PVE SOAKING CAP OE-C9

This cap must be securely attached before immersion. Align the black arrow on the soaking cap with the base of the silver collar surrounding the electrical contacts on the PENAX PVE connector. Press the cap down onto the metal collar and turn clockwise to secure.

FEEDBACK TERMINAL

To connect the OL-Z3 cable from the PENTAX video processor.

LIGHT GUIDE PLUG

Transmits light from light source to distal end of endoscope.

SUCTION NIPPLE

For attachment to external suction source.

⚠ CAUTION:

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

⚠ 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.

1-2. Accessories

Biopsy Forceps (KW2422R)

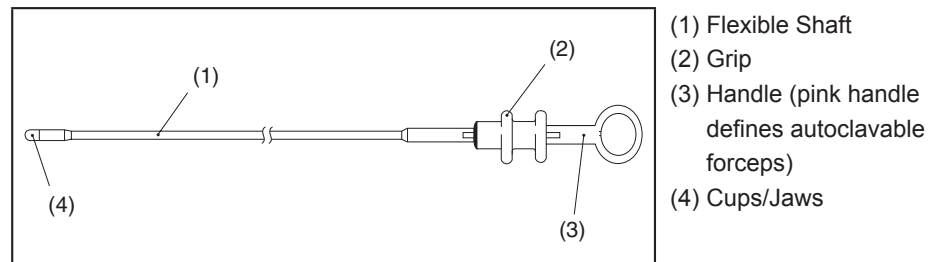


Figure 1.1

⚠ CAUTION:

- *Because of the effect that accessories used through the instrument channel of the endoscope can have on the performance of the endoscope itself, it is strongly recommended that PENTAX accessories be used with PENTAX endoscopes. If a unique or highly specialized accessory is available from another source and its manufacturer claims compatibility with PENTAX instruments, the accessory manufacturer should be consulted to confirm compatibility with PENTAX endoscope before use.*
- *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 may be approximately 30 cm longer than the endoscope working length.*

NOTE:

- *Depending upon country and/or local PENTAX distributor, each PENTAX endoscopic accessory may be an optional accessory.*
 - *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 Processor

NOTE:

Read the instructions for use supplied with the video 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.

NOTE:

Be sure to use compatible bottle and water bottle cap. If incompatible bottle and a water bottle cap are used together, it could cause the air to escape resulting in insufficient pressure and flow of air and water during the endoscopic procedure.

1) PENTAX Video Processor

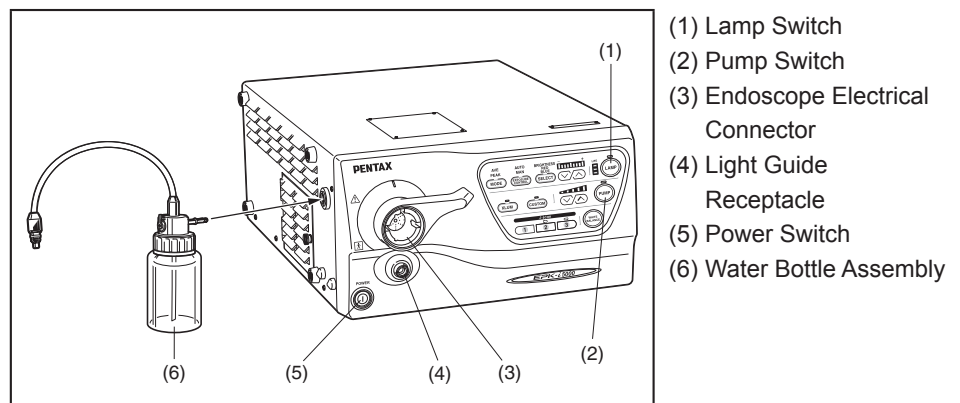


Figure 1.2

⚠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 video 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:

PENTAX video endoscope contained in this instructions for use is only compatible with PENTAX video processors.

⚠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

NOTE:

For details of operations such as starting and stopping, please refer to the PENTAX video Processor Instructions for Use.

⚠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.

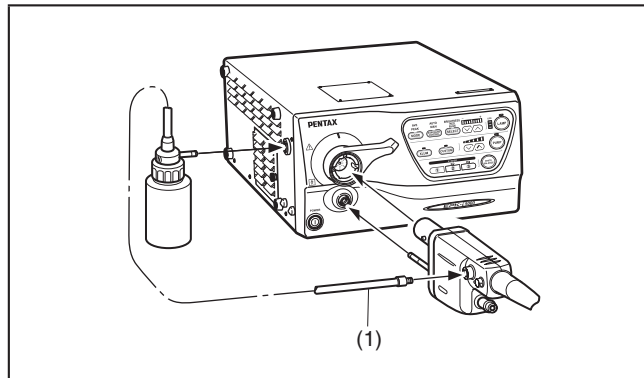
- 1) Attach water bottle assembly, 2/3 filled with sterile water to the appropriate location on the left side of the video processor.
-

⚠WARNING:

The addition of defoaming agents to the water supply is NOT recommended. Due to their nature, these silicone based agents cling tenaciously to surfaces. Unless they are rinsed very thoroughly, a "barrier" could be created which could reduce the effectiveness of the disinfection/sterilization process. Additionally, repeated use of such defoamers could eventually lead to residual silicone build up resulting in equipment malfunction such as clogged air and/or water channels.

- 2) Set the drain lever on the water bottle assembly to the upright position labeled A/W (air/water).
- 3) Plug the video processor into a properly grounded receptacle with the power switch in the OFF position.

- 4) Make sure that the PENTAX PVE connector is aligned with the interface socket on the front panel of the video processor.
- 5) Connect the endoscope to the Endoscope Electrical Connector and Light Guide Receptacle on the video processor as illustrated.



(1) Air/Water Feeding Tube

Figure 2.1

- 6) Rotate the locking lever clockwise after insertion.

⚠ CAUTION:

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

- 7) Connect the air/water feeding tube from the water bottle assembly to the air/water port on the side of the PVE connector.
- 8) Turn the video processor and air pump to the "ON" position and check for proper functioning.
- 9) Press the lamp switch of the video processor to turn ON the lamp.

⚠ CAUTION:

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

- 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 (suction, air/water delivery, water jet, etc.) without further reprocessing, the following precaution should be exercised.

Use sterile water during individual endoscope function tests to avoid recontamination of the previously reprocessed instrument by waterborne microorganisms. Sterile water should be used during endoscopic examination also. 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 PENTAX 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)/Washer-Disinfectors (WDs). It must be recognized that PENTAX does not evaluate non-PENTAX leak tester systems to satisfy their specific products claims, for their effectiveness to accurately detect leaks and/or for their compatibility with PENTAX endoscopes. Insufficient 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 leakage 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 Portion
 - 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 adhesive band is not peeling, nor does it have roughened texture or any sharp-edges.

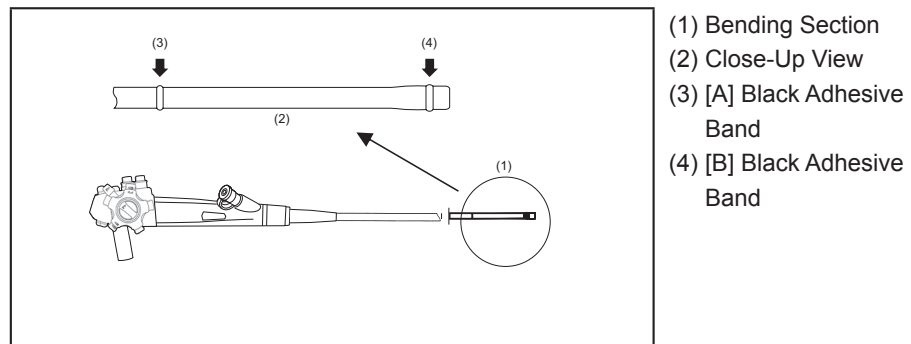


Figure 2.2

- 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 first time 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.

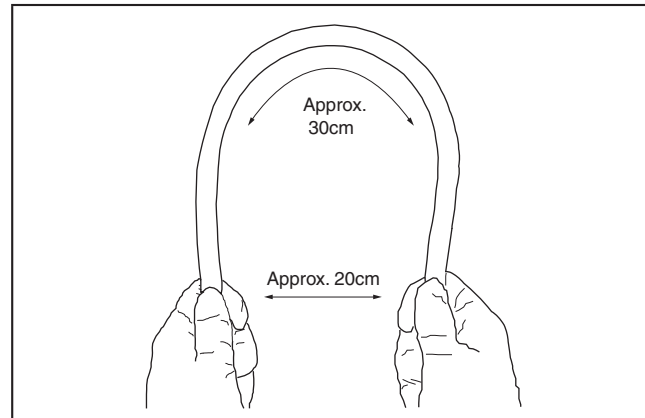


Figure 2.3

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.

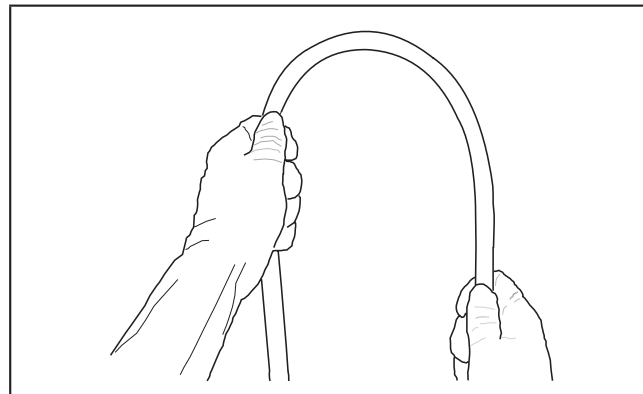


Figure 2.4

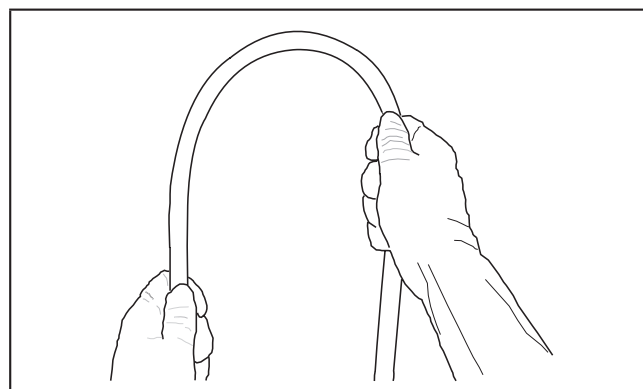


Figure 2.5

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 exercise 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. It could cause the bending section to be damaged.

⚠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.

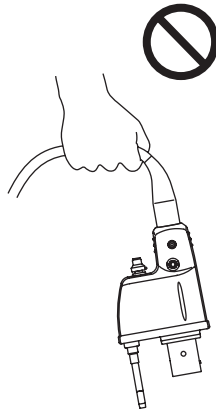


Figure 2.6

⚠CAUTION:

Flexible endoscopes and other sophisticated medical devices 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)*
- *the air/water port (3)*
- *the water jet port (4)*
- *any valve cylinder (5)*
- *basically, any inlet or outlet port associated with an internal channel, an indirect patient contact portion of the endoscope*
- *strain relief boot along insertion tube and umbilical cord (rotate clockwise only to tighten)*

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.

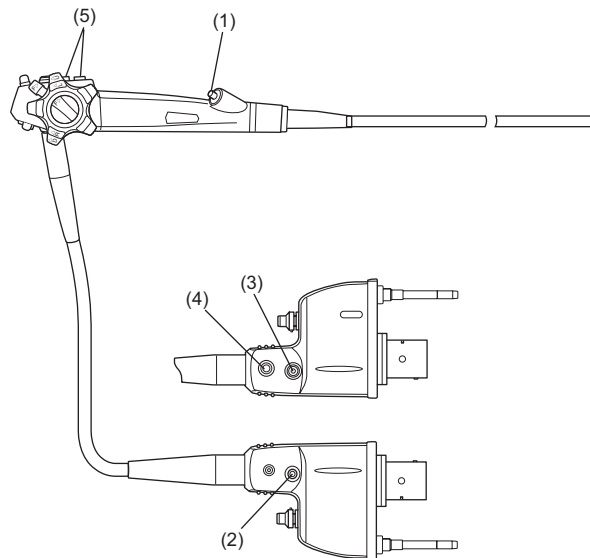


Figure 2.7

⚠ CAUTION:

To avoid damaging the endoscopes, do NOT twist, rotate or bend excessively any of the strain relief boots (1), (2) during inspection, clinical use, reprocessing or any handling activity. Be particularly cautious for the insertion tube strain relief boot (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 relief boots 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.

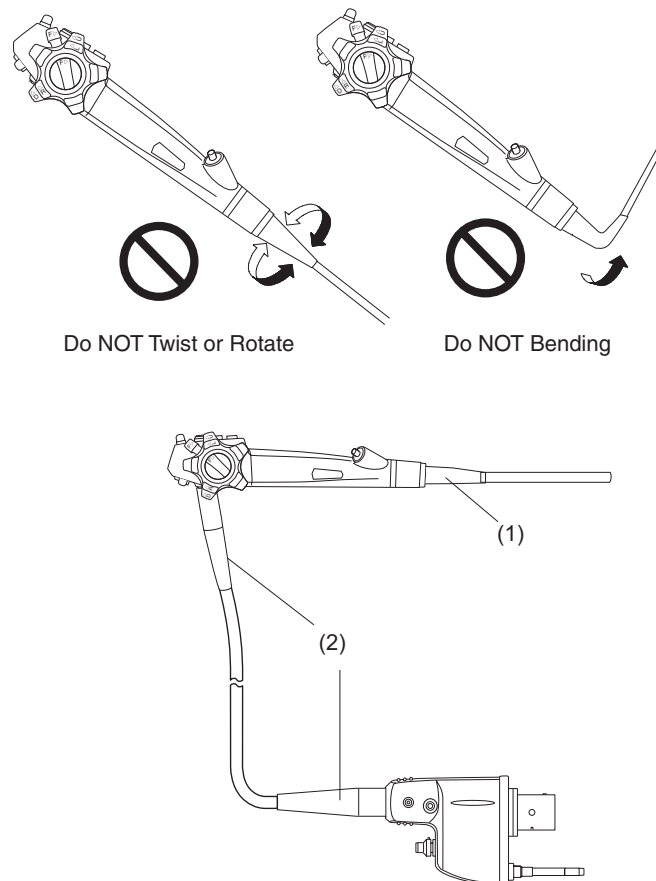


Figure 2.8

- 3) Inspection of Angulation Controls and Locks
 - a) Slowly manipulate the Up/Down and the Right/Left control knobs to see that they function smoothly. Be certain that a full and appropriate range of angulation is possible.
 - b) Check that the observed image turns in the intended direction when the control knob is operated to move the angulation up/down and left/right.

- c) Engage fully the angulation locks to be certain that the position of the angulated tip can be stabilized.

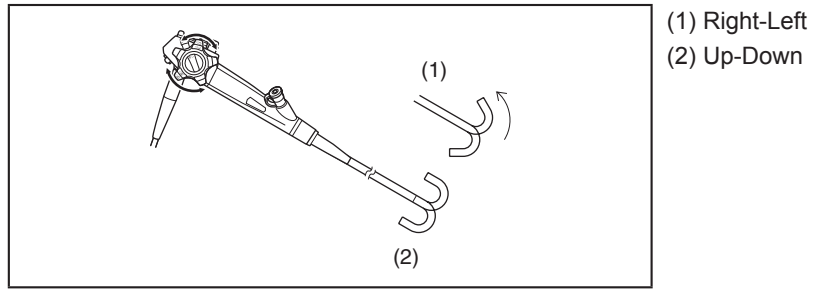


Figure 2.9

⚠WARNING:

Prior to use 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 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. Use of endoscope with suspect angulation mechanism could lead to angulated distal tip to not being able to be released and end up damaging patient tissue/membrane or perforation.

⚠CAUTION:

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

Excessive "knob play" can be defined as rotating of the angulation control knob(s) 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.

4) Inspection of Air/Water Feeding System

- a) Prior to use, the air/water feeding valve (OF-B188) should be inspected. Remove the air/water valve from the control body and ensure that O-rings in good condition are properly attached.

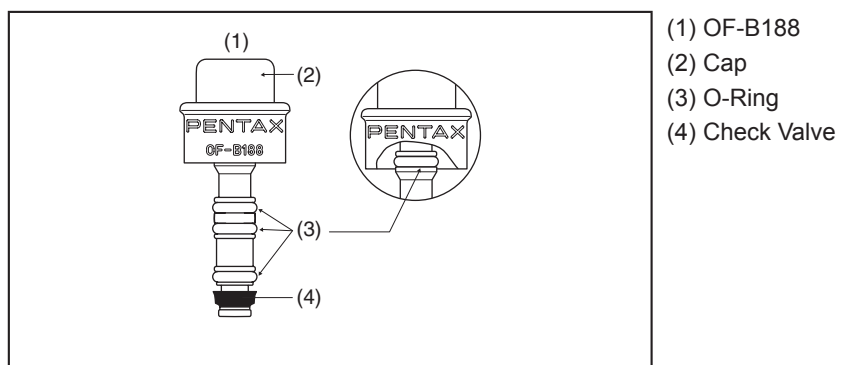


Figure 2.10

⚠ WARNING:




If air bubbles discharge continuously from the distal end of the endoscope during inspection, it is possible that the O-ring may be damaged, installed incorrectly, or the air/water feeding valve may be damaged or installed incorrectly.

If the instrument is used in this condition, it could cause infection by cross contamination to the patient as result of reflux or spit-back of patient fluids from the valve or damage the patient's body cavity. Also, the air could be delivered to the patient's body excessively as well as continuously and expose the patient to pain and suffering and/or cause damage as result of gas embolism, etc.

Therefore, if the aforementioned characteristic was observed, make sure to replace the O-ring or the air/water feeding valve with fully reprocessed new ones which have already been subjected to a high-level disinfection or sterilization procedure (O-ring set, model OF-B192, and the air/water feeding valve, model OF-B188 can be used) and perform the inspection again.

Since the check-valve can NOT be replaced by the end user, replace the entire A/W valve with a new one if the check valve is damaged/missing.

- b) Install the valve into the A/W cylinder by gently pushing the valve into the cylinder. Never apply excessive force to push the valve into the A/W cylinder.
- c) Connect the endoscope to the video processor. Turn air pump "ON" to desired pressure setting. Place the endoscope distal tip into sterile water and confirm that no air bubbles exit the distal air nozzle.
- d) To inspect air delivery, cover the hole at the top of the air/water valve and confirm that air flows freely from the air/water nozzle at the endoscope distal tip.
- e) By depressing the air/water feeding valve, the water delivery system is activated. Water should flow in a steady stream from the air/water nozzle at the distal tip of the endoscope. (This may take several seconds on the initial attempt.) **USE STERILE WATER ONLY.**

Action			
Result	–	Air Feeding	Water Feeding

- f) Release the air/water feeding valve to determine if the valve freely returns to its OFF (neutral) position and delivery of water (and air) ceases.

⚠CAUTION:

Before use, make sure that the air/water feeding valve is not clogged or does not have any other problem that could cause the uninterrupted flow of air/water. If the endoscope is used in such condition, it will hinder its capability to clear the debris off the objective lens and the endoscopic examination might be interrupted.

- g) If air and/or water do not flow properly, the following steps should be followed.
- [1] Disconnect the endoscope from the video processor.
 - [2] Remove the suction control valve and the air/water feeding valve.
 - [3] Using a cotton tipped applicator and alcohol, clean the valve recess (receptacle) in the control body thoroughly to remove any debris. Do NOT attempt to insert the applicator into the small openings within the valve receptacle as the cotton or applicator could become lodged within these openings and cause channel blockage.
 - [4] • Following the companion Instructions for Use (reprocessing) for chemical cleaning of the air and water channel with detergent, flush detergent through both the air and water channels.
Rinse the air and water channel(s) with sterile water.
Then flush the air several times to force any residual solution out of the channel.
• If the cleaning adapter is being attached, remove the adapters and install the air/water feeding valve.
(Alternate) By leaving the air/water feeding valve in the cylinder instead of the OF-B153 adapter, one may direct pressured fluid (or air) independently to either channel to expel debris from and/or more forcefully flush solution into either the air or water channel. This should not be attempted on a completely clogged/blocked air or water channel/nozzle.
 - [5] Test for normal delivery of air and water. It may be necessary to repeat the above procedure if normal air and water delivery is still not available.

⚠CAUTION:

Do NOT apply excessive force or use a sharp object in an attempt to unblock a clogged channel as the endoscope channel could become damaged. Whenever channel damage is suspected, the endoscope should be leak tested.

If repeated attempts to flush the air/water system are unsuccessful, do not attempt to use the endoscope on a patient.

Contact the PENTAX service facility.

- h) If the air/water feeding valve does not function properly, does not move smoothly or feels “sticky”, remove the valve and apply a very small amount of silicone oil lubricant (OF-Z11) onto all the O-rings. Do NOT use excess oil, avoid “blobs”, large drops and/or squirts of oil directly onto the metal valve stems - instead, simply place a small droplet of oil on one’s sterile gloved forefinger and gently swirl between thumb and forefinger. Next place the valve with O-ring in-between thumb and finger and gently rotate the valve so that the oil is evenly applied to the outer edges of each O-ring. Make sure the oil is applied to all O-rings and wipe off all excess.

Do NOT apply excess oil. Doing so can allow for inadvertent migration of the oil inside channels or other areas not intended to be lubricated.

NOTE:

Prior to clinical use, it is important that the entire air channel system be dry. Failure to thoroughly dry the air system could result in an unclear or blurry image caused by very fine droplets of moisture being swept over and/or onto the objective lens at the distal end of the endoscope.

5) Inspection of Water Jet

- a) Prior to use, the water jet check valve adapter (OE-C12) should be inspected. Open the water jet connector cap (OF-B118). Turn the water jet adapter counterclockwise and remove it from its cylinder. Make sure that the black check-valve (OE-C14) is properly attached to the bottom of the water jet check valve adapter.

If the check-valve is missing or not attached properly, correctly reposition the check-valve by turning it several times on the water jet adapter unit.

For proper positioning, there should be no clearance (gap) between the check-valve and the water jet check valve adapter stem.

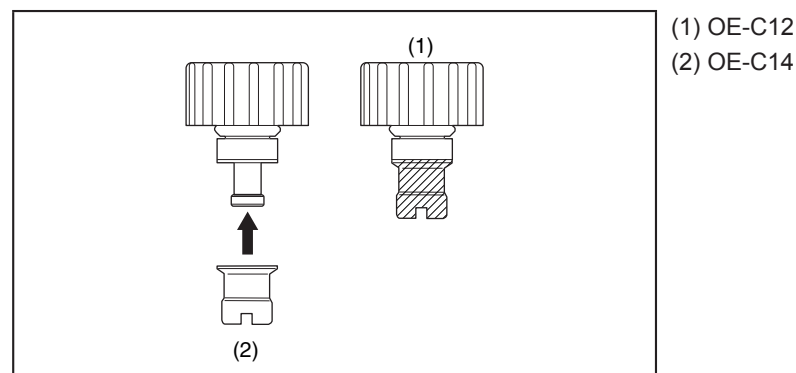


Figure 2.11

⚠WARNING:

The check-valve OE-C14 is a reusable component and it as well as the OE-C12 check-valve adapter, water jet cylinder, irrigation tube and water jet channel should be reprocessed after each use.

Make sure that the check-valve OE-C14 is securely attached to the check-valve adapter OE-C12.

A worn or damaged check-valve should be replaced with a new one which has already been subjected to a high level disinfection or sterilization procedure (Check valve set, model OE-C15 which contains 10 pieces of OE-C14 is optionally available).

For repeated use, always ensure that the valve has already been reprocessed. A damaged, worn or missing check-valve could create a risk of cross-contamination to the end user due to the potential for reflux (spit-back) of patient fluids through an unsealed path if the check-valve is not attached properly.

- b) Attach the water jet check-valve adapter (OE-C12) and water jet connector cap (OF-B118) opened and then irrigation tube (OF-B113) to the water jet port on the (PVE) connector.
- c) Attach a syringe filled with sterile water to this tube and flush water through the tube. Water should flow in a steady and forceful stream from the water jet nozzle at the distal end of the endoscope (this may take several seconds on the initial attempt).

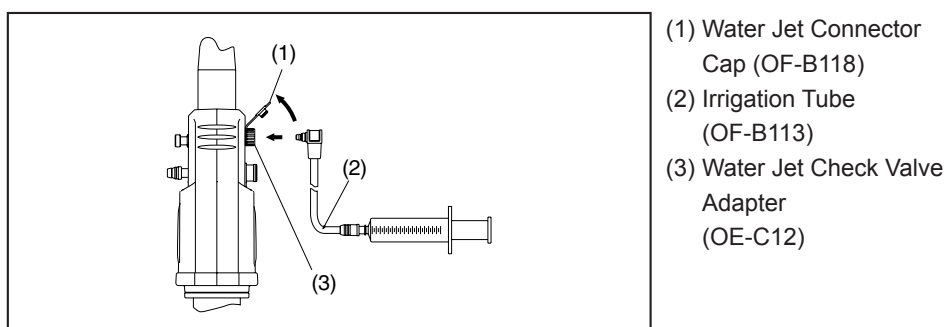


Figure 2.12

- d) Use only sterile water in the water jet system.
- e) If water does not flow properly, the following steps should be followed:
 - [1] Attach a syringe filled with a compatible cleaning detergent solution to the irrigation tube.
 - [2] Flush solution through the tube and nozzle. Soaking of the water jet channel with detergent solution should help dissolve and dislodge whatever is restricting the normal forceful stream from the water jet nozzle.
 - [3] Remove the syringe containing detergent solution and attach a syringe with air. Purge the channels with air and then rinse the air and water channel(s) with sterile water. Then, flush air through the irrigation tube and nozzle several times to remove any residual solution from the tubing and nozzle.

⚠ CAUTION:

It may be necessary to repeat the steps above several times to obtain proper water jet function.

If water still does not flow properly after several attempts, contact your local PENTAX service facility.

Do NOT apply excessive force or use a sharp object in an attempt to unblock a clogged channel as it could result in endoscope damage.

- f) In place of manual flushing via syringe, specially designed irrigator pumps intended for endoscopic irrigation may be used via the PENTAX water jet system. PENTAX check-valve mechanisms should always be connected and positioned within the water jet channel pathway. Always use the lowest irrigator pump setting as the procedure requires and increase water flow rates as patient conditions allow.
-

⚠ WARNING:

Although the water jet system may not be clinically used during each procedure, because the water jet channel of the endoscope enters the body cavity, it can be contaminated the same way as the insertion portion of the endoscope. Therefore, it still MUST be properly cleaned and subjected to the same disinfection/sterilization processes as other internal channels of the endoscope.

NOTE:

The water jet system featured in PENTAX endoscopes should not be confused with "auxiliary" or manual water feed systems whose function is simply to clean the distal objective lens. A true forward water jet allows the endoscopist to direct a forceful stream of water to clear blood, debris, etc. from a particular area of interest to improve visualization.

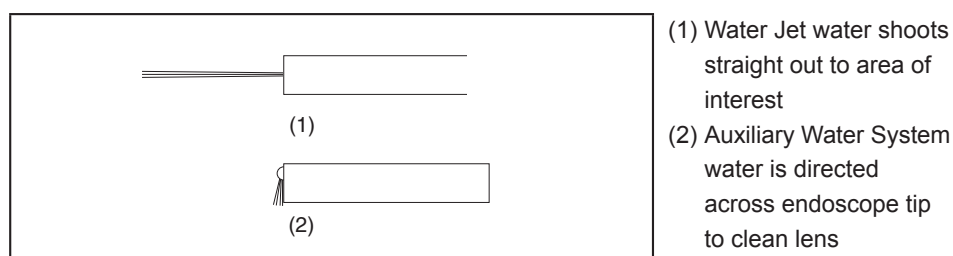


Figure 2.13

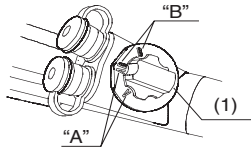
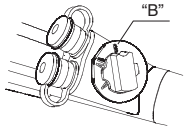
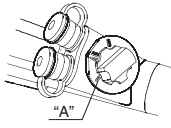
- 6) Inspection of Instrument Channel Selector (EC-3890TLK ONLY)
- a) Check the condition of the instrument channel selector (OF-B161). The selector knob should move smoothly when rotated and click into position at the prescribed indicators. The instrument channel selector allows the user the choice of suction capability through either channel, or simultaneous suction through both channels.
-

NOTE:

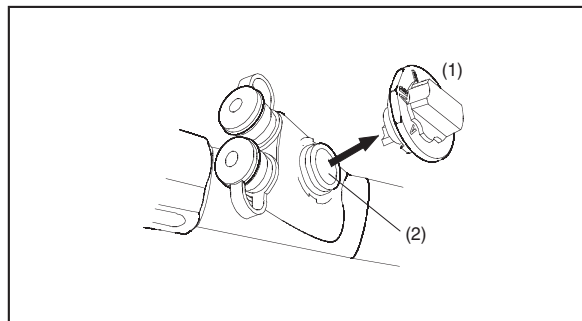
The suction channel selector knob can be rotated either clockwise or counterclockwise.

⚠ warning

NEVER use the OF-B161 with any outward signs of damage or any abnormal conditions. Using a compromised selector or failure to attach the selector appropriately to the suction selector cylinder could result in decreased suction capability, air/fluid leakage and/or the potential for cross contamination due to the possible reflux or spit-back of patient fluids.

	HANDLING	OPERATION
Simultaneous suction through both channels. (1) Suction Channel Selector		Align the instrument channel selector knob to the combined "A B" indicator and depress the suction valve to start/stop activation of suction.
Suction through the small channel only.		Align the instrument channel selector knob to the single "B" indicator and depress the suction valve to start/stop activation of suction.
Suction through the large channel only.		Align the instrument channel selector knob to the single "A" indicator and depress the suction valve to start/stop activation of suction.

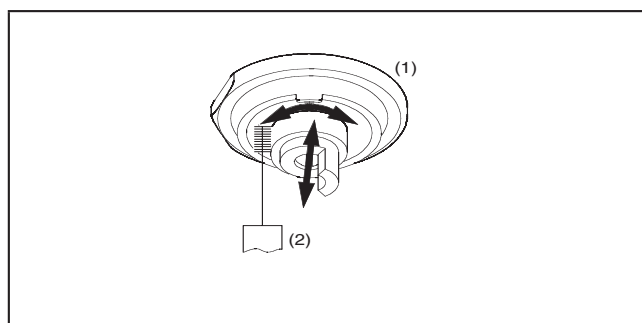
b) Should the instrument channel selector not rotate smoothly, it might require further cleaning.



- (1) Suction Channel Selector
- (2) Suction Cylinder

Figure 2.14

- [1] Remove the entire instrument channel selector mechanism from the endoscope.
- [2] Scrub all internal and external surfaces of the selector using the smaller side of the cleaning brush (CS-C9S).



- (1) Suction Channel Selector
- (2) CS-C9S

Figure 2.15

- [3] Using the large bristle of the specially designed cleaning brush, CS-C9S, insert the brush into the opening of the instrument channel selector cylinder. Thoroughly clean the surface areas.
- [4] Next, thoroughly clean the instrument channel selector and rinse well.

7-1) Inspection of Remote Buttons and Magnification Control (except EC-3890LZi)

a) Remote Buttons

Check to ensure that the function that you assigned to each remote button works properly.

NOTE

The function can be assigned to remote buttons #1, #2, #3, or #4. For more details, refer to the instructions for use supplied with the video processor.

b) Magnification control

NOTE

PENTAX Video Processor, model EPK-i5020 is not compatible.

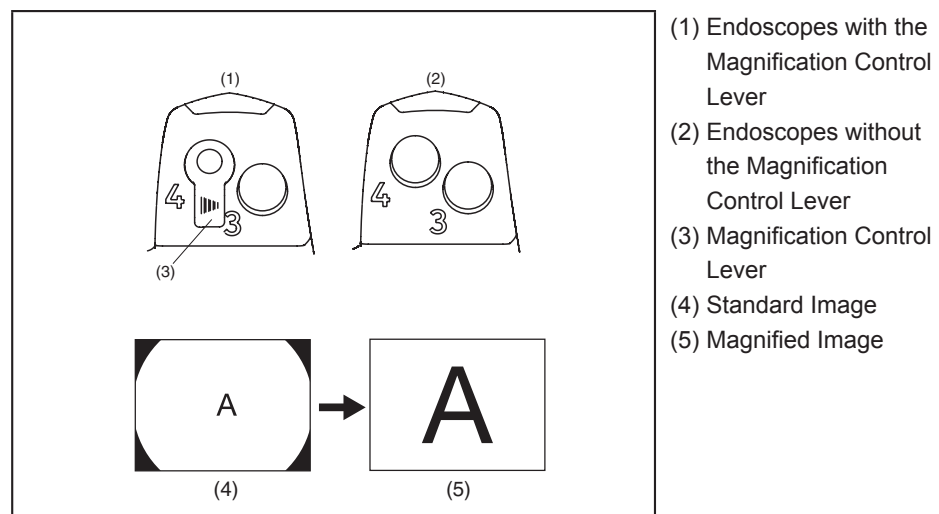


Figure 2.16

[1] Endoscopes with the Magnification Control Lever

Turn the magnification control lever clockwise to magnify the image up to two times. Turn counterclockwise to return to the original size.

[2] Endoscopes without the Magnification Control Lever

Press the remote button which the magnification function is assigned to magnify the image. Pressing the same remote button again will make the image return to the original size.

NOTE:

As this magnification function is performed electronically, focus and depth of field do not change. Clarity is slightly reduced.

7-2) Inspection of Remote Buttons and Magnification Control (EC-3890LZi)

a) Remote Buttons

Check to ensure that the function that you assigned to each remote button works properly.

NOTE:

The function can be assigned to remote buttons #1, #2, or #3.

For more details, refer to the instructions for use supplied with the video processor.

b) Electronic Magnifying System

NOTE

PENTAX Video Processor, model EPK-i5020 is not compatible.

Press the remote button which the magnification function is assigned to magnify the image. Pressing the same remote button again will make the image return to the original size.

NOTE:

As this magnification function is performed electronically, focus and depth of field do not change. Clarity is slightly reduced.

c) Optical Magnifying System

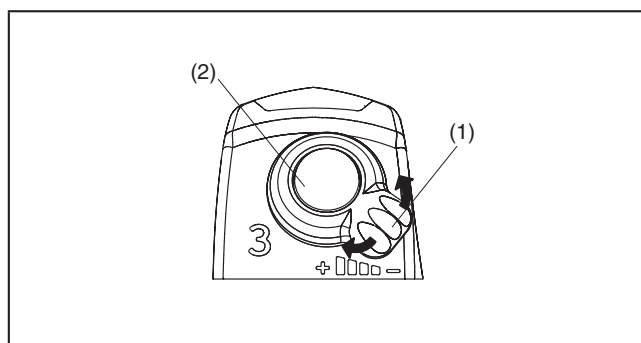


Figure 2.17

To inspect the optical magnification, check that the observed image on the monitor changes when the magnification control lever is operated to turn to clockwise/counterclockwise.

Turn the lever clockwise to magnify the image, counterclockwise to return to the standard size image.

NOTE:

PENTAX 90Zi endoscope can use Optical Magnification System and Electrical Magnification System at the same time.

However, the magnification control lever is designed to control ONLY the Optical Magnification System. It cannot control the electrical magnification system.

8) Inspection of Suction Mechanism

- a) Prior to use, the suction control valve (OF-B120) should be inspected. For easier identification, an orange colored indicator is placed on top of the OF-B120 valve mechanism. Remove the valve from the control body and make sure that rubber portions of the valve are not damaged or worn.

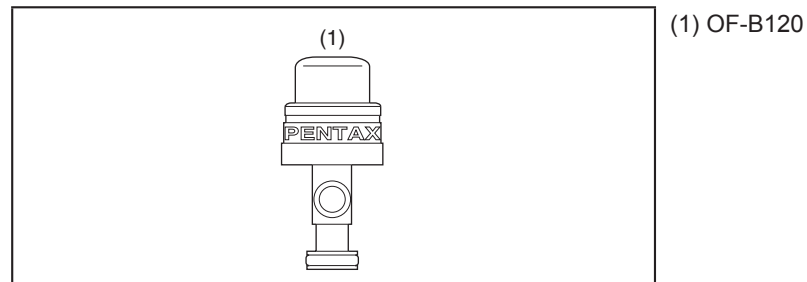


Figure 2.18

⚠WARNING:

Make sure that the correct suction control valve (OF-B120) is being used. A worn or damaged valve and/or O-ring should be replaced with a new one. The entire valve mechanism should be subjected to a high-level disinfection or sterilization procedure prior to use (O-ring set, model OF-B127, 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 endoscope tip and/or create a loss of insufflated air via the suction system.

A compromised valve could also result in the potential for reflux or spit-back of patient fluids that may present infection risks.

- b) Position the valve OF-B120 so that the small metal tab near the base on the valve stem aligns with the notched suction valve cylinder, also color coded in orange. Install the valve into the suction cylinder by gently pushing the valve into the cylinder. Never apply excessive force to push the valve into the suction cylinder.

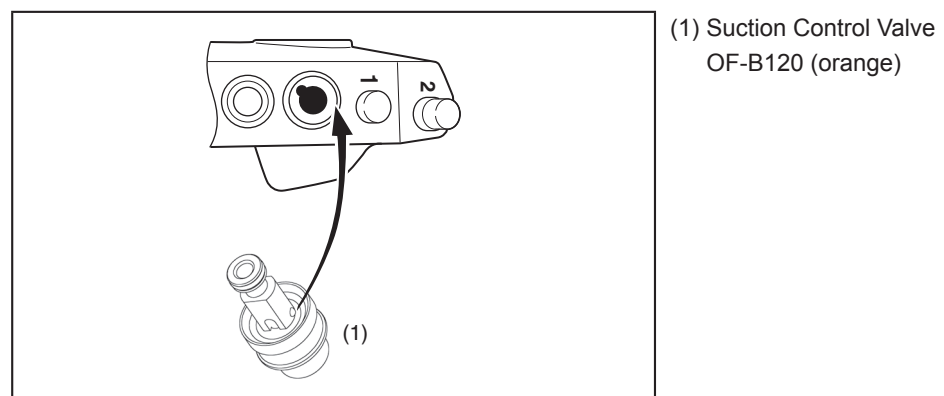
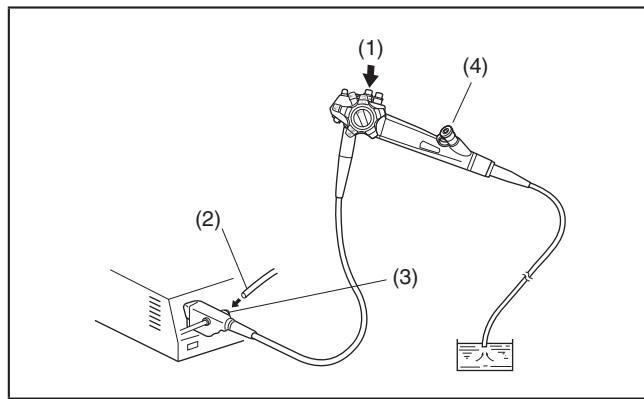
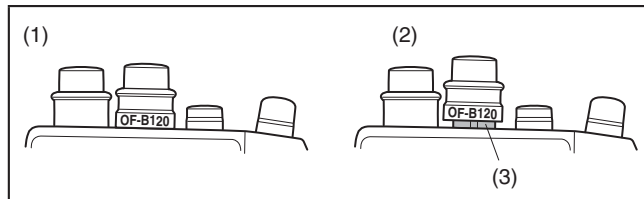


Figure 2.19



- (1) Depress
- (2) Suction Source Tube
- (3) Suction Nipple
- (4) Inlet Seal

Figure 2.20



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

Figure 2.21

⚠ WARNING:

Make sure suction control valve OF-B120 is correctly attached (see figure 2.21).

Improperly installed 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 spitback of patient fluids.

- c) Connect suction tubing from an external suction source to the suction nipple located on the PVE Connector at the end of the umbilical cord. Make sure that the inlet seal is attached to the instrument channel inlet. Place the distal tip 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.

⚠ WARNING:

An inlet seal in good condition (that is not worn or damaged) must be attached to the instrument channel inlet to prevent the 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 seals will result in leakage and should be replaced. To ensure maximum performance of these sealing mechanisms, consider replacing the inlet seal with a fully reprocessed new one for each procedure.

- d) Release the suction control valve to determine if the valve freely returns to its OFF position and the aspiration of water ceases.

- e) If the suction control valve does not move smoothly or feels “sticky”, remove the valve from the suction cylinder on the control body of the endoscope. Apply a small amount of silicone oil lubricant (OF-Z11) onto rubber part and the O-ring. Place a small droplet of oil (OF-Z11) on one’s sterile gloved forefinger and gently swirl between thumb and forefinger. Next place the valve with O-ring in-between thumb and finger and gently rotate the valve so that the oil is evenly applied to the outer edges of the O-ring. Remove/wipe off excess lubricant with a soft gauze. Do not use excessive silicone oil.

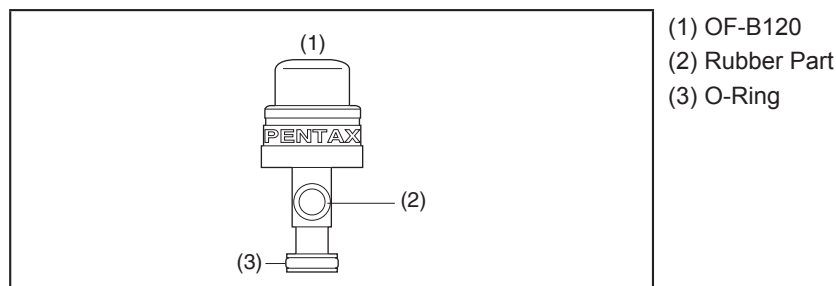


Figure 2.22

9) Inspection of Biopsy Forceps and Instrument Channel

- Make sure there are no kinks in the flexible shaft of the biopsy forceps.
- The 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.**
- The handle mechanism on the forceps should be operated to open and close the jaws. This mechanism should operate freely.

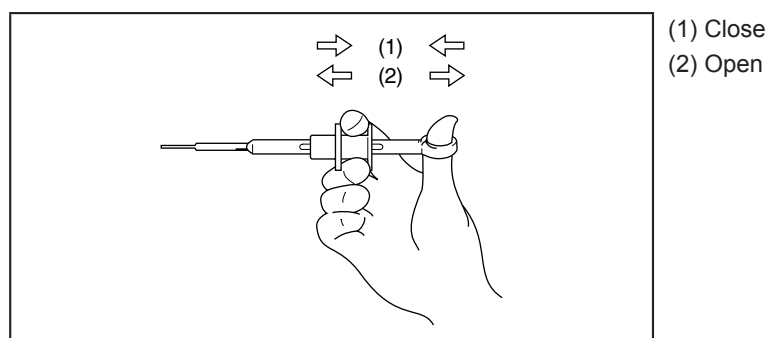


Figure 2.23

- Close and inspect the 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. Subsequently it contributes to the cause of injury to patient tissue/membrane. To prevent instrument 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 bending section.*
- *Prior to using accessories from another source (non-PENTAX products), contact the manufacturers of the accessories 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, A/W and the water jet channel systems are made of stainless steel, Noryl and fluorine-contained polymers. When any fluids are used with this endoscope, please read carefully and follow all instructions in the instructions for use supplied with the fluids for use and pay special attention to any reactions with the materials identified in the intended fluid path.

NOTE:

Endoscope instrument, A/W and the water jet channels are composed of stainless steel, Noryl and fluorine contained polymers. 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 a 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 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) Apply a medical grade water soluble lubricant to the insertion portion. Do not use petroleum based lubricants.
-
-

NOTE:

The objective lens must be kept free of the lubricant. Try avoid using 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 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 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.

⚠WARNING:

Do not use a water supply device that can exert 30kPa or greater of water pressure to the suction channel (suction valve) during endoscopic examination. Failure to do so could result in the potential for reflux (spit-back) of patient fluids through an unsealed path due to any looseness/missing in the installed valve.

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.
 - c) Manipulate the Angulation Control Lever in the “R” direction in order to angulate the distal end in the Right direction.
 - d) Manipulate the Angulation Control Lever in the “L” direction in order to angulate the distal end in the Left direction.

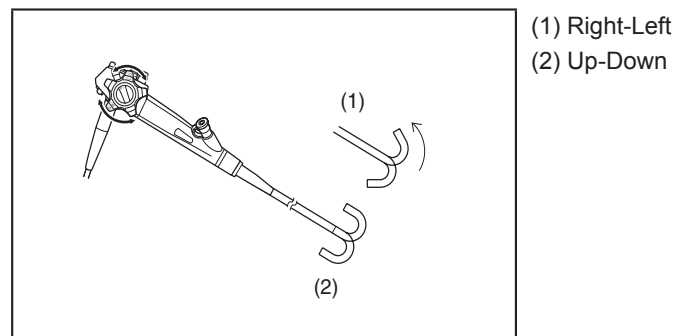


Figure 3.1

- 2) Angulation Lock function
 - a) Turn the Up/Down Angulation Lock Lever counterclockwise to lock the Up/Down angulation position.
 - b) Turn the Up/Down Angulation Lock Lever clockwise to unlock the Up/Down angulation position.
 - c) Turn the Right/Left Angulation Lock Knob counterclockwise to lock the Right/Left angulation position.
 - d) Turn the Right/Left Angulation Lock Lever clockwise to lock the Right/Left angulation position.

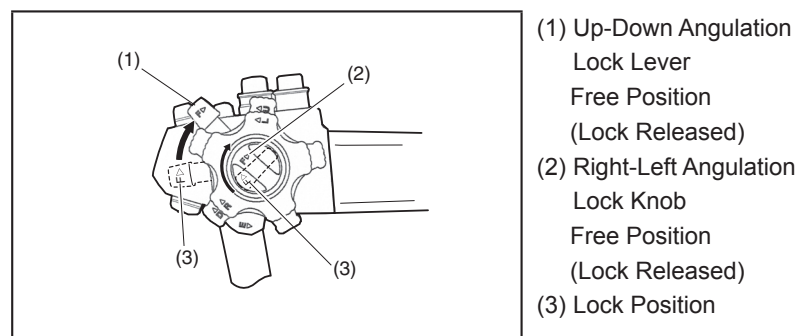





Figure 3.2

3) Air/ Water Feeding function

- a) Connect the air/water feeding tube from the water bottle assembly to the air/water port located on the PVE connector.
- b) Cover the hole on top of the Air/Water Feeding Valve to feed air.
- c) Depress the Air/Water Feeding Valve to feed water.
- d) Release the Air/Water Feeding Valve to stop feeding air/water.

Action			
Result	-	Air Feeding	Water Feeding

4) 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 Control Valve to suction fluid and/or gas, debris.
- c) Release the Suction Control Valve to stop suctioning.

5) 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.

Endoscope	EC-3890TLK 2990Li/3490TLi 3490LK/3890LK	EC-3490Li/3890Li EC-3890LZi	EC34-i10L EC38-i10L
Remote Button 1	Freeze	Freeze	Freeze
Remote Button 2	Copy	Copy	Copy
Remote Button 3	Video	Video	Video
Remote Button 4	Enhance	-	Enhance

6-1) Electronic Magnification Control function

NOTE

PENTAX Video Processor, model EPK-i5020 is not compatible.

a) EC-3490Li EC-3890Li

- [1] The image is electronically magnified by turning the Magnification Control Lever clockwise.
- [2] The image returns to normal by turning the Magnification Control Lever counter-clockwise.

- b) Except EC-3490Li, EC-3890Li
 - [1] The image is electronically magnified by pressing the Remote Button to which the magnification function is assigned.
 - [2] The image returns to normal by pressing the Remote Button again.

6-2) Optical Magnification Control function (EC-3890LZi)

- a) The image is optically magnified by turning the Magnification Control Lever clockwise.
- b) The image returns to normal by turning the Magnification Control Lever counterclockwise.

3-2. Pretreatment

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

3-3. Insertion and Withdrawal

⚠WARNING:

Never operate the endoscope with excessive force. Insertion or bending with excessive force may cause a mucosal injury or perforation to the patients.

NOTE:

For details of operations such as starting and stopping, please refer to the PENTAX video Processor Instructions for Use.

- 1) (Endoscopes with Magnification Control Lever)
 - Turn the magnification control lever counterclockwise to return to the standard non-magnified viewing.

⚠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 mode.

- 2) Slowly insert the endoscope under direct vision.
- 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 controls 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. Should resistance be encountered, never apply excessive force.

⚠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 tip 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 control knob. Should the angulation system fail for any reason, stop the procedure, release the lock lever and carefully withdraw the endoscope under direct visualization. If the endoscope is withdrawn without releasing the angulation lock lever, it may cause an injury such as perforation to the patient.

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" distal bending section.

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

- 5) Insufflation should be controlled by the combined use of the air/water feeding valve to increase the amount of insufflation and the suction control to decrease the level of insufflation.

⚠WARNING:

Be careful not to deliver too much air.

It must be recognized that variations in air flow (pressure and volume) for patient insufflation may exist from one manufacturer's equipment (light source, video processor and/or endoscope type) to another. It is, therefore, important to closely monitor the patient at all times to prevent the pain and/or gas embolism that is caused by excessive air aspiration.

- 6) Procedures involving poorly prepped patients should be avoided as excessive patient material can negatively affect certain endoscope channel functions as well as the ability to maintain a clear endoscopic view.
- 7) Mucous, fluids and/or other patient material should be aspirated via the instrument/suction channel and suction control valve to improve visualization. Maintain a clear view during aspiration, avoid prolonged suction time and use the minimum level of negative pressure required to perform the clinical procedure.

⚠ CAUTION:

Do not apply excessively 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.

⚠ CAUTION:

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.

- 8) The objective lens may be cleaned during the procedure by alternately using the air/water and suction control valves.
-

⚠ 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:

Use of the distal rubber hood might result in decreased visibility during a procedure due to the accumulation of debris on the distal objective lens. When using the distal rubber hood, please pay particular attention to maintaining adequate visibility by suctioning and then delivering water and air to remove debris from the distal objective lens. Depending upon the particular procedure being performed, consideration should be given to removing the distal rubber hood completely if it is found excessively hinder adequate visibility.

NOTE:

*Should debris on the objective lens be difficult to clean, one can **temporarily** use the HIGH air pressure setting on the video processor and simultaneously press the air/water and suction control valves. Return air pressure setting to original selection before proceeding.*

- 9) A Water Jet may be directed at the target area during the procedure as necessary.
USE STERILE WATER ONLY.
- 10) Image capture, hard copy, video recording, etc. may be carried out as necessary.

NOTE:

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

- 11) Before withdrawing the endoscope, trapped air should be suctioned to reduce patient discomfort.
- 12) When attempting to withdraw the endoscope, return the angulation lock levers to their free position. Always withdraw the endoscope under direct visualization.

⚠WARNING:

*If for any reason, the image is lost due to power shortage, lamp or video 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.*

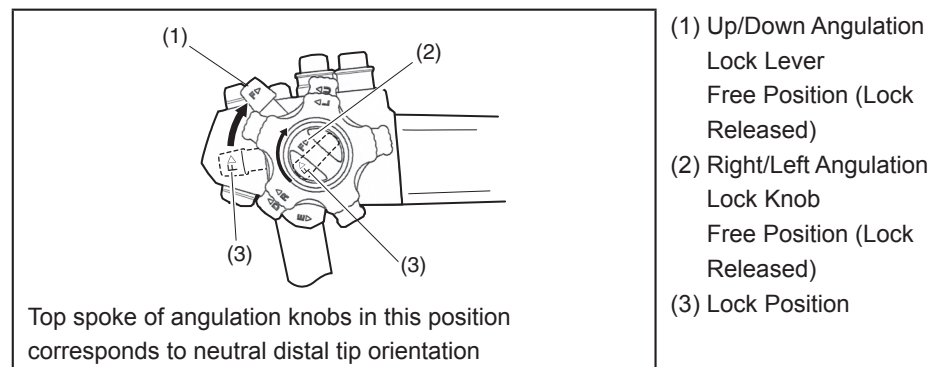


Figure 3.3

3-4. Magnification Control (EC-3890LZi)

1) Optical Magnifying System

- Optical magnification System is controlled with lever on the control body.
- Turn the control lever clockwise to activate Optical Magnification System, counterclockwise to return to the standard image size. While turning the control lever, image size changes continuously. Release the lever to stop Optical Magnification System.

NOTE:

While optical magnification is activated, focus and depth of field are changed. To achieve optimum view, please adjust the distance from objective lens to observation object. When the magnification is maximum, optimum working distance is about 2~3 mm. Magnified image can be achieved without losing clarity.

- Optical magnified image is shown as below.
As the image is magnified, Magnification Indicator changes. Magnification Indicator is displayed in the lower right portion of the screen.

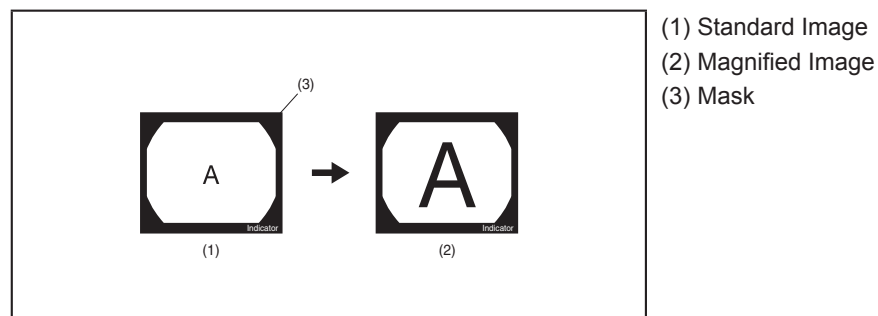


Figure 3.4

2) Electrical Magnifying System

NOTE

PENTAX Video Processor, model EPK-i5020 is not compatible.

- Electrical Magnification System can be activated with video processor, keyboard, foot switch, or remote button.
- Electrical magnified image is shown as below.
As the image is magnified, magnification indicator changes, and mask is swept away to outside of the screen.

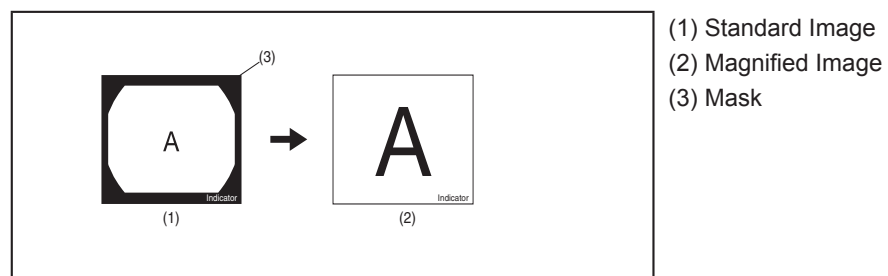


Figure 3.5

3) Magnification Indicator

- Magnification indicator is shown as below. Optical magnification and Electrical magnification are indicated separately.

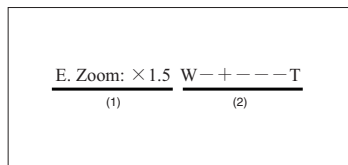


Figure 3.6

(1) Electrical magnification indicator

When the electrical magnification is activated, this item is displayed.

(2) Optical magnification indicator

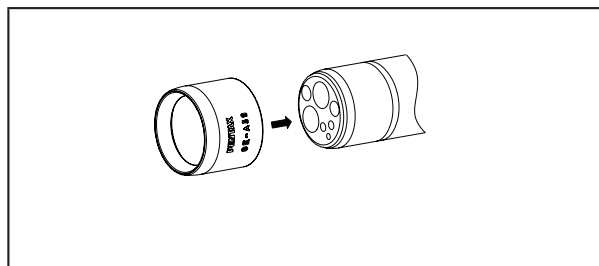
“+” indicates the magnification. When the magnification is not activated (standard image), position of “+” is far left (next to W). As the image is magnified, “+” moves to right. When the magnification is maximum, position of “+” is far right (next to T).

NOTE:

Magnification indicator area acts as both message area and magnification indicator. Magnification indicator is cleared briefly when the message is displayed (Ex: "Capture OK"). After the message is displayed, magnification indicator will be redisplayed.

4) Distal Rubber Hood

- The Distal Rubber Hood can be attached (OE-A59 for EC-3890LZi) to maintain the optimum distance from the distal objective lens to the observed area (mucosal surface). It makes observing the target easier especially under the magnified image.
- To attach or detach a Distal Rubber Hood, gently press the Distal Rubber Hood onto the endoscope tip until the Distal Rubber Hood completely covers the endoscope tip. Make sure that there is no space between the Distal Rubber Hood end and the plastic endoscope tip.



(1) OE-A59 for EC-3890LZi

Figure 3.7

CAUTION:

In standard image mode, the tip of the Distal Rubber Hood may appear on the screen depending on how it is attached.

Do not hold the endoscope or grab the bending section too firmly when attaching or detaching the Distal Rubber Hood. Applying excessive force to the bending section causes damages to the endoscope.

3-5. Biopsy

⚠ WARNING:

From the standpoints of infection control, accessories which ENTER STERILE TISSUE, THE VASCULAR SYSTEM, BLOOD VESSELS, or MUCOUS 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:

Because of the effect accessories used in the instrument channel of the endoscope can have on the performance of the endoscope itself, it is strongly recommended that only PENTAX accessories be used with PENTAX endoscopes. If a unique or highly specialized accessory is available from another source, the accessory manufacturer should be consulted to confirm compatibility with PENTAX endoscope 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.

(Not applicable to PENTAX Video Processor, model EPK-i5020)

- 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.

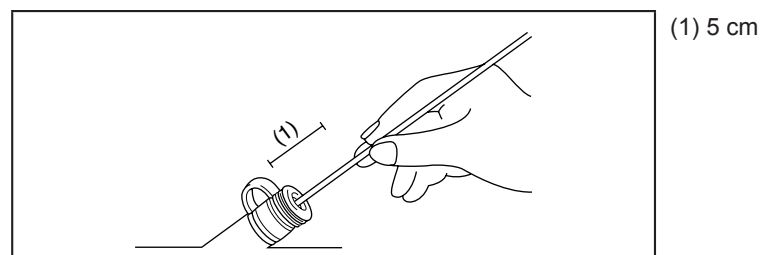


Figure 3.8

⚠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.

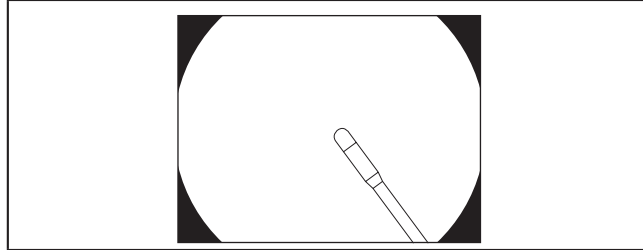


Figure 3.9

- 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.

3-6. Laser

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.

⚠WARNING:

The PENTAX endoscopes identified in this instructions for use are compatible with Nd: YAG laser (wavelength 1064nm) 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 explosion. If there is a possibility of flammable gas being present within a body cavity, use nonflammable gas (such as CO₂ or air) instead.*
 - *When using nonflammable gas, there is a possibility of gas embolism if excessive gas is flushed. When using nonflammable gas, be careful not to flush excessive gas. Use suction capability of an endoscope to remove gas if necessary.*
-
-

⚠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 user has the option of using a nonflammable gas for insufflation. Nonflammable gas from a pressure-regulated and flow-rate controlled source can be connected to the provided or optionally available gas adapter, model OF-G11, as illustrated.

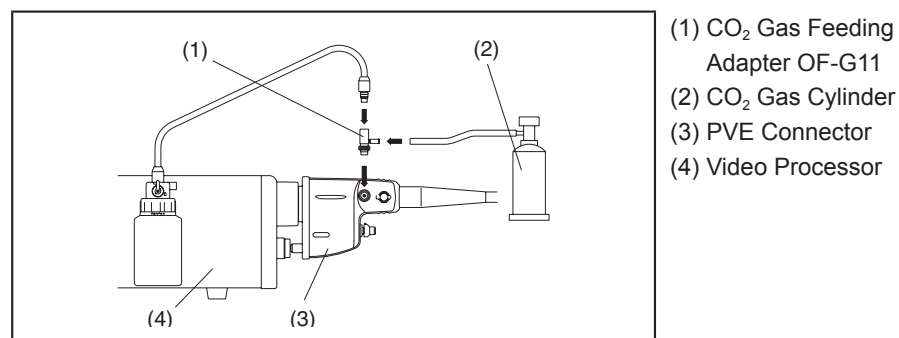


Figure 3.10

NOTE:

When connecting to the PENTAX endoscope, connect only the medical grade regulated source of gas which pressure can be controlled.

- 2) The gas adapter, which can be secured to the air/water port on the PVE connector, has a luer receptacle to accept tubing from an external source of nonflammable gas. As long as the air/water feeding tube from a PENTAX water bottle assembly is connected to the gas adapter and the air pump in the video processor is turned OFF, nonflammable gas can be delivered.

NOTE:

Set the pressure below 49kPa (7.1psi) and the flow rate at about 4 liters/min.

⚠CAUTION:

Open the valve of the CO₂ gas cylinder only AFTER turning off the pump switch of the video processor. Failure to do so will apply excessive pressure to the video processor and can cause damage to the air pump.

- 3) Flow of gas from the nozzle at the distal end of the endoscope can be checked by placing the tip of the endoscope under water and covering the hole on the top of the air/water feeding valve. The flow rate of gas should be no greater than the rate of air delivery when the air/water feeding valve on the control head of the endoscope is covered.
- 4) The water delivery system is activated by pressing the air/water feeding valve.
- 5) The operator and assistant(s) should wear surgical gloves to avoid burns during use of laser equipment.

⚠CAUTION:

It should be noted that as long as the valve of the CO₂ gas cylinder is OPEN and the hole at the top of the A/W feeding valve is NOT covered, CO₂ gas will constantly be vented through the A/W valve into the room. To reduce excessive CO₂ concentrations, it is, therefore, recommended to close the CO₂ gas cylinder valve, work in a well ventilated room, and use air delivery whenever possible during examinations which are lengthy or in very confined quarters.

As an alternative, the optionally available gas/water feeding valve, model OF-B194, may be used in place of the standard air/water feeding valve. OF-B194 is a closed two-stage valve mechanism. Pressing the first stage delivers CO₂ gas and depressing the second stage activates water delivery.

NOTE:

When using the OF-B194 valve, there will be no venting of CO₂ gas into the room. Place OF-B194 with the air/water feeding valve OF-B188 after using the CO₂ gas.

NOTE:

One may choose to leave the OF-G11 adapter attached to the endoscope during conventional air insufflation using the air/water feeding valve. However, the luer sideport of the OF-G11 must be capped.

Similarly, for normal water delivery, the air pump must be turned ON and the plastic luer lock cap must be secured to the OF-G11 adapter.

- 6) The laser probe should be introduced through the endoscope in the same manner as described for biopsy forceps in section 3-5.
- 7) The position of the active portion of the laser probe should always be clearly visualized before laser equipment is activated.
- 8) 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.
- 9) 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.

- 10) Should the distal tip 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 in figure 3.11. If this smear affect becomes too severe and distorts the visual field, the intensity of the aiming light should be decreased.

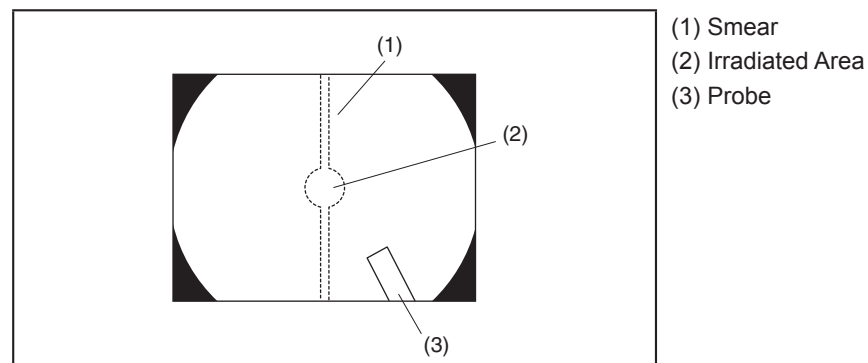


Figure 3.11

- 11) When activating the laser at high power (about 100W for Yag 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 in Figure 3.12.

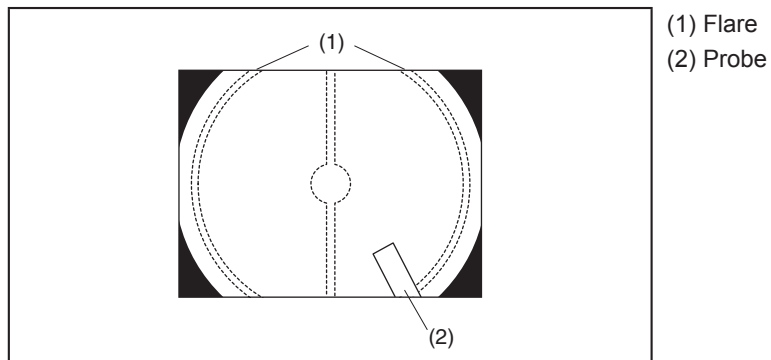


Figure 3.12

⚠ WARNING:

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

Do not use the laser at high power setting.

3-7. Electrosurgery

⚠ 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 electrosurgical 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 atmosphere, such as an environment with a high oxygen concentration, may cause explosion. If there is a possibility of flammable gas being present within a body cavity, use nonflammable gas (such as CO₂ or air) instead.
 - When using nonflammable gas, there is a possibility of gas embolism if excessive gas is flushed. When using nonflammable gas, be careful not to flush excessive gas. Use suction capability of an endoscope to remove gas if necessary.
-
-

- 1) The user has the option of using a nonflammable gas for insufflation. Nonflammable gas from a pressure-regulated and flow-rate controlled source can be connected to the provided or optionally available gas adapter, model OF-G11, as described for Laser in section 3-6.

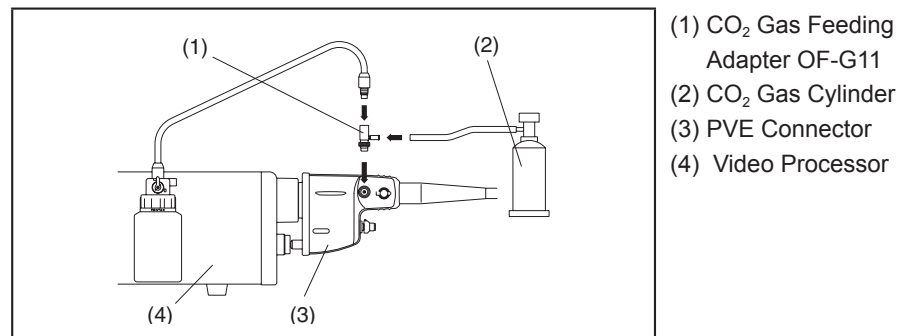


Figure 3.13

⚠CAUTION:

It should be noted that as long as the valve of the CO₂ gas cylinder is OPEN and the hole at the top of the Air/Water feeding valve is NOT covered, CO₂ gas will constantly be vented through the Air/Water feeding valve into the room. To reduce excessive CO₂ concentrations, it is, therefore, recommended to close the CO₂ gas cylinder valve, work in a well ventilated room, and use air delivery whenever possible during examinations which are lengthy or in very confined quarters.

As an alternative, the optionally available gas/water feeding valve, model OF-B194, may be used in place of the standard air/water feeding valve. OF-B194 is a closed two-stage valve mechanism.

Pressing the first stage delivers CO₂ gas and depressing the second stage activates water delivery.

⚠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.

- 2) The electrosurgical devices should be introduced through the endoscope in the same manner as described for biopsy forceps in section 3-5.

⚠WARNING:

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

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

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

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

For Floating Ground Electrosurgical 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 video 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. Otherwise, it will result 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:

Before start using electrosurgical device, the noise level should be checked to make sure that problems that interfere with endoscopic examination such as loss of image will not be caused by the existing noise.

It should be recognized that the use of electro-surgical 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 a condenser earth cable, model OL-Z3 intended to reduce potential RF interference and electronic noise that may appear in the endoscope image when using electrosurgical device. 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.

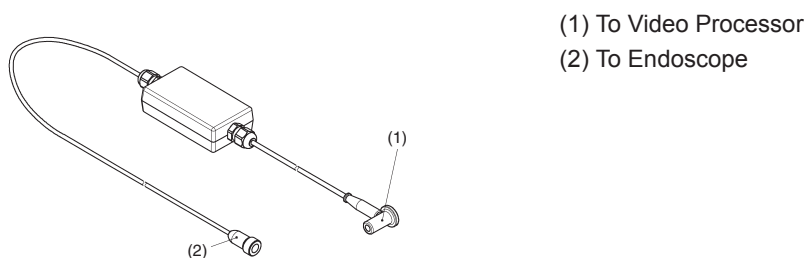


Figure 3.14

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 this product 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

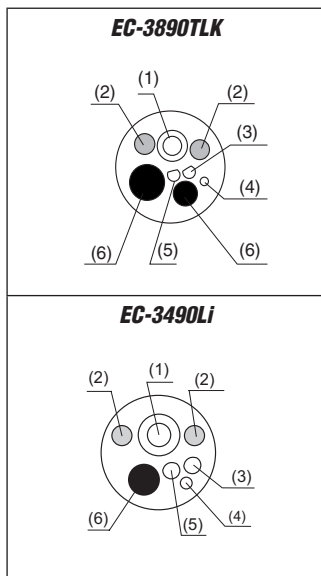
Endoscope Model		EC-3890TLK	EC-2990Li	EC-3490Li	EC-3490TLi	EC-3890Li
Direction of View		Forward				
Field of View		140°				
Depth of Field (mm)		3 - 100		4 - 100	3 - 100	4-100
Tip Angulation	Up-Down	180° - 180°			210° - 180°	180° - 180°
	Right-Left	160° - 160°				
Rigid Distal Width (O. D. φmm)		ø13.2	ø10.2	ø11.5	ø10.5	ø13.2
Distal End Width (O. D. φmm)		ø13.2	ø10.2	ø11.5	ø10.5	ø13.2
Insertion Tube Width (O. D. φmm)		ø13.2	ø9.8	ø11.6	ø11.6	ø13.2
Maximum Insertion Portion Width (O. D. φmm)		ø14.65	ø11.35	ø12.85	ø12.85	ø14.65
*Minimum Instrument Channel Width (I. D. φmm)		ø2.8, ø3.8	ø2.8	ø3.2	ø3.2	ø3.8
Insertion Tube Working Length(mm)		1,700				
Total Length(mm)		2,023				
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				
Function Y: Yes N: No	Magnification (Optical)	N	N	N	N	N
	Selection of Suction Channel	Y	N	N	N	N

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

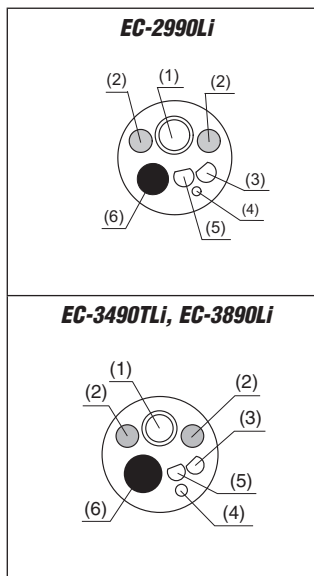
**PENTAX flexible endoscopes should not be exposed to temperatures in excess of 140°F (60°C) during either reprocessing or storage. In reprocessing, depending on detergents, even if the temperature does not exceed 60°C, the scopes may be damaged. For specific brands of compatible detergents, please contact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

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

DISTAL END



- (1) Objective Lens
- (2) Light Guide
- (3) Water Nozzle
- (4) Water Jet Nozzle
- (5) Air Nozzle
- (6) Instrument Channel



- (1) Objective Lens
- (2) Light Guide
- (3) Water Nozzle
- (4) Water Jet Nozzle
- (5) Air Nozzle
- (6) Instrument Channel

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

- (1) Objective Lens
- (2) Light Guide
- (3) Water Nozzle
- (4) Water Jet Nozzle
- (5) Air Nozzle
- (6) Instrument Channel

Endoscope Model		EC-3490LK	EC-3890LK	EC-3890LZi
Direction of View		Forward		
Field of View		140°		140° (Wide) / 50° (Tele)
Depth of Field (Magnifying) (mm)		3 - 100		4 - 100 (Wide) / ***2-3 (Tele)
Tip Angulation	Up-Down	180° - 180°		
	Right-Left	160° - 160°		
Rigid Distal Width (O. D. φmm)		φ11.5	φ13.2	φ13.0
Distal End Width (O. D. φmm)		φ11.5	φ13.2	φ12.0
Insertion Tube Width (O. D. φmm)		φ11.6	φ13.2	φ13.2
Maximum Insertion Portion Width (O. D. φmm)		φ12.85	φ14.65	φ14.65
*Minimum Instrument Channel Width (I. D. φmm)		φ3.8	φ4.2	φ3.8
Insertion Tube Working Length (mm)		1,700		
Total Length (mm)		2,023		2,025
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		
Function	Magnification (Optical)	N	N	Y
	Y: Yes N: No	Selection of Suction Channel		N

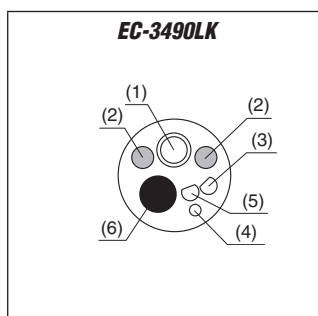
*There is no guarantee that instruments selected solely using this minimum instrument channel width will be compatible in combination.

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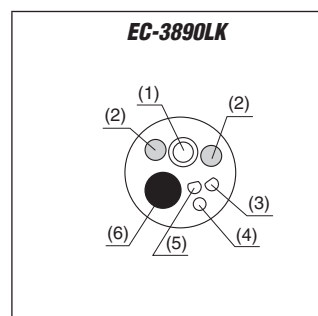
***Reference value.

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

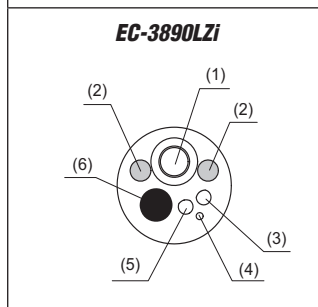
DISTAL END



- (1) Objective Lens
- (2) Light Guide
- (3) Water Nozzle
- (4) Water Jet Nozzle
- (5) Air Nozzle
- (6) Instrument Channel



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

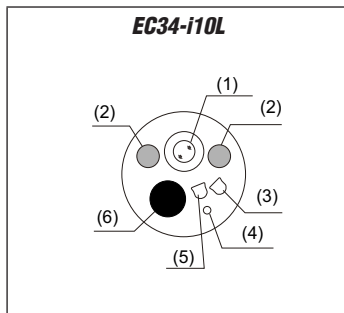
Endoscope Model		EC34-i10L	EC38-i10L
Direction of View		Forward	
Field of View		140°	
Depth of Field (mm)		2 - 100	4 - 100
Tip Angulation	Up-Down	180° - 180°	
	Right-Left	160° - 160°	
Rigid Distal Width (O. D. φmm)		ø11.5	ø13.2
Distal End Width (O. D. φmm)		ø11.5	ø13.2
Insertion Tube Width (O. D. φmm)		ø11.6	ø13.2
Maximum Insertion Portion Width (O. D. φmm)		ø12.85	ø14.8
*Minimum Instrument Channel Width (I. D. φmm)		ø3.8	ø3.8
Insertion Tube Working Length (mm)		1,700	
Total Length (mm)		2,016	
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	
Function	Magnification (Optical)	N	N
	Selection of Suction Channel	N	N

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

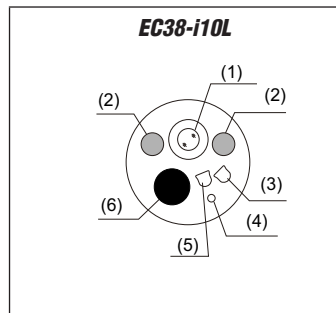
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- (1) Objective Lens
- (2) Light Guide
- (3) Water Nozzle
- (4) Water Jet Nozzle
- (5) Air Nozzle
- (6) Instrument Channel

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 radio frequency energy equipment.

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

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