PENTAX VIDEO LARYNGOSTROBOSCOPIES

INSTRUCTIONS FOR USE

VLS-1190STK
VLS-1070STK
VLS-1590STi
**Intended Use**

To provide optical visualization (via video monitor) of the laryngeal and pharyngeal area in order to observe glottic action with the use of a stroboscopic light source.

These instruments are introduced via the mouth or the nose, as decided by physician, when indications consistent with the need for the procedure are observed in adult and pediatric patient populations.

Never use these endoscopes for any purpose other than that for which they have been designed. The video endoscopes contained in this manual can only be used with PENTAX Video Processor, Model EPK-i5010, or other compatible PENTAX Video Processors.

**Notes**

Read this manual before operating, and save this book for future reference. Failure to read and thoroughly understand the information presented in this manual, 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 manual may result in damage to, and/or malfunction of, the equipment.

This manual describes the recommended procedures for inspecting and preparing the equipment prior to its use and for the reprocessing and maintenance of the equipment after 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.

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, reprocessing 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.

Current infection control guidelines require that Laryngostroboscopes and other semi-critical medical devices, that normally come into contact with intact mucous membranes, such as in the upper airway tract, must at least be cleaned properly and disinfected before patient use. Only the user can determine if an instrument has undergone appropriate infection control procedures prior to each clinical use. It must be recognized that infection control practices involve many complex and often controversial issues which are constantly evolving. PENTAX strongly recommends that user remain informed of the latest federal and local regulations, and encourages users to follow infection control guidelines developed by various organizations for health care professionals.

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

**Sterility Statement**

These instruments identified in this manual are reusable semi-critical medical devices. Since they are packaged non-sterile, they must be properly cleaned, 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 process.

**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 manual, 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.
Symbols on Marking
Symboles distinctifs

Symbol for “MANUFACTURER”

Symbol for “DATE OF MANUFACTURE”

Symbol for “Authorised Representative in the European Union”

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

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)
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1. NOMENCLATURE AND FUNCTION

1-1. Video Laryngostroboscope

NOTE:
Function of each button depends upon the processor. The function can be changed. For more details, refer to the manual supplied with the processor. The following table shows the factory setting.

<table>
<thead>
<tr>
<th>Button</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Button 1</td>
<td>Freeze</td>
</tr>
<tr>
<td>Button 2</td>
<td>Copy</td>
</tr>
<tr>
<td>Button 3</td>
<td>VCR</td>
</tr>
<tr>
<td>Button 4</td>
<td>Enhance</td>
</tr>
</tbody>
</table>
NOTE:
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.

⚠️ WARNING:
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.

⚠️ CAUTION:
To avoid damaging the endoscope, do NOT twist, rotate or bend any of the rubber strain reliefs. The rubber strain reliefs of endoscopes with split (bifurcated) umbilical cords should never be grasped together or pressed firmly against each other to avoid the potential for endoscope damage in these areas.
1-2. Video Processors/Laryngeal Strobe

NOTE:

• Water bottle and air pump are not used with these endoscopes.
• Please read the manual supplied with the processor.

WARNING:

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

EPK-i5010

WARNING:

The lamp life is 500 hours. Check the lamp life indicator on the operation panel before you use the processor. Replace the lamp cartridge immediately if the bar on the LIFE indicator illuminates orange and the [Please replace the lamp] message appears on the monitor. The lamp life could be affected by frequency of use, in which case, the lamp life might become shorter than 500 hours.

NOTE:

Software update may be required depending on the software version of the EPK-i5010 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.

![Figure 1.1](image-url)
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 endoscopes are only compatible with PENTAX video processor model EPK-i5010, or other compatible 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/Laryngeal Strobe

Please refer to the Owner’s Manual of the PENTAX video processor for complete instructions.

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

![Figure 2.1](image1)

**Figure 2.1**

![Figure 2.2](image2)

**Figure 2.2**
NOTE:

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

4) Attach the light guide adapter, Model 9122, to the light guide plug and insert into the light port on the 9400 Laryngeal Strobe.

5) Turn on the processor to check for proper functioning.

6) Turn off the air pump switch for use with the laryngostroboscope.

7) Make sure that light comes from the distal end of the connected endoscope.

8) Check if the display shown in the diagram appears on the monitor.

9) 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

⚠️ CAUTION:

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

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

Before reprocessing and/or immersion in any fluids, PENTAX endoscopes should be tested for the loss of integrity in their watertight construction by using PENTAX brand leak testers or a leakage tester that is sold by PENTAX. For specific details on PENTAX recommended leak detection procedures, please refer to the instructions supplied with PENTAX leak testers.

⚠️ 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)/Washers-Disinfectors (WDs). It must be recognized that PENTAX does not evaluate non-PENTAX leak tester systems to satisfy their specific product claims, for their effectiveness to accurately detect leaks and/or for their compatibility with PENTAX endoscopes. Insufficient pressures may reduce the likelihood for accurate leak detection, especially if the endoscope’s distal bending section is not flexed during testing. Excessive pressures may adversely affect the endoscope, especially if pressurization occurs during automated reprocessing at elevated temperatures. PENTAX accepts no responsibility for use of non-PENTAX leakage testers.

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

a) Check the entire surface of the insertion tube for abnormal conditions such as dents, crush marks, wrinkles, bumps, buckles, excessive bending, protrusions, 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.

⚠️ CAUTION: In order to avoid damage to an endoscope or the possibility of a device malfunction during a procedure that could result in patient injury (e.g., damage to mucosal membranes due to abrasion or thermal exposure), never use an endoscope that fails to successfully pass all pre-procedure functional tests or displays outward signs of damage (e.g., cracked, severely dented, or peeling surfaces and adhesives; sharp edges due to broken parts; cuts that expose substructure components or materials).

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

![Figure 2.3](Diagram of endoscope with areas A and B)

Figure 2.3

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: All instruments must be reprocessed prior to first time use, after any repairs/service and before every patient use. 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.
NOTE:

- The distal end as well as the electrical contacts/pins on the PVE connector of the endoscope must be protected against damage from impact. Never apply excess force such as twisting, or severe bending to the flexible portion of the endoscope.
- As indicated elsewhere in PENTAX product labelling, endoscopes particularly the quality of the endoscopic image should be checked prior to patient use.
- During pre-use inspection, ensure that the distal objective lens and the illumination cover glass are clean and no residues are present on these distal surfaces. If not, crisp images can NOT be displayed. Wipe them with a gauze or the like moistend with 70-90% medical grade ethyl or isopropyl alcohol.

NOTE:

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

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

1. Venting connector
2. Rubber strain relief along insertion tube and umbilical cable (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.
2) Inspection of the Insertion Tube flexibility

a) Starting at the bending section junction create an approximately 20 cm loop of the insertion tube as shown in the figure below.

![Figure 2.4](image)

b) Gently raise/lower the left/right hands alternatively and confirm equal flexibility for the length of the loop. Do NOT use the endoscope if there are any;
- rigid portions which do not bend as easily as the rest of the loop or
- flexible portions which bend much more than the rest of the loop.

![Figure 2.5](image)

![Figure 2.6](image)
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 local PENTAX service facility.

⚠️ CAUTION:
When performing this inspection, ensure that other components of the endoscope (distal end, control body, etc.) are not damaged by impact to surfaces or objects in the area.
Do NOT adjust the bending section of the endoscope as part of this inspection. Maintain the distal end in a straight orientation.
• Hold the Insertion Tube at the junction of the insertion tube and bending section,
• Do not close your hand around the bending section.

NOTE:
• 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.
• As indicated elsewhere in PENTAX product labeling, endoscopes particularly the quality of the endoscopic image should be checked prior to patient use.
• During pre-use inspection, ensure that the distal objective lens and the illumination cover glass are clean and no residues are present on these distal surfaces. If not, crisp images can NOT be displayed. Wipe them with a gauze or the like moistened with 70-90% medical grade ethyl or isopropyl alcohol.
• 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.

⚠️ CAUTION:
When transporting the endoscope, do NOT grasp or carry it only by its split (bifurcated) umbilical cord or the light guide cable, and take care to protect the distal tip of the insertion tube from damage. Loosely coil both the insertion tube and light guide cable so that the endoscope can be carried by grasping both the control body and distal portion of the insertion tube in one hand and the PVE connector and the light guide plug in the other hand. Failure to do so could result in severe impact damage that will require repair by PENTAX service personnel.
\textbf{CAUTION:}

To avoid damaging the endoscopes, do NOT twist, rotate or excessively bend any of the insertion tube strain reliefs [(1), (2)] during inspection, clinical use, reprocessing, or any handling activity. Be particularly cautious for the insertion tube strain relief [(1)]. When wiping the insertion tube and the umbilical cord, use a slow back and forth motion to wipe them along the tube/cable. Never apply excessive force or torque on these strain reliefs or slim tubes/cables.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{caution.png}
\caption{Do NOT Twist or Rotate Do NOT Bend}
\end{figure}

3) **Inspection of Angulation Control and Lock**

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

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

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{angulation.png}
\caption{UP–DOWN 130–130}
\end{figure}

\textbf{CAUTION:}

\textit{ANY lack of smooth operation of the angulation control may be an early indication of internal damage to and/or part(s) failure within the endoscope’s angulation system. To avoid the possibility of further endoscope damage or the potential for malfunction of the angulation system, do NOT use the endoscope if the angulation mechanism does not operate properly. Prior to use ensure that the angulation control can rotate smoothly, that there is no grinding or excess friction within the angulation system and that the distal bending section bends freely and smoothly. NEVER APPLY EXCESSIVE FORCE TO THE ANGULATION CONTROL!}

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 in any one direction for more than 30 degrees without any corresponding distal tip angulation. The examples above are indications that service is required to avoid more serious problems with the angulation control system, including angle or pulley cable/wire breakage and/or the possibility of a “frozen” distal bending section.

A “frozen” bending section can make instrument extraction from a patient more difficult.
4) **Inspection of magnification control**

Magnification System can be used with PENTAX video processor, EPK-i5010 and be activated with endoscope button. Magnification can be assigned to endoscope button #1, #2, #3, or #4. Currently displayed image should be magnified when the endoscope button is pressed. Pushing the endoscope button again would reduce the image to its original size. For more details, please refer to the owner's manual supplied with the processor.

⚠️ **CAUTION:**

*Software update may be required depending on the software version of the EPK-i5010 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.*

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**NOTE:**

*Magnification provides the magnified image without change of focus and depth of field. Clarity is slightly reduced.*

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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 2.8](image)

**Figure 2.8**

Magnification indicator is displayed as below. When the electrical magnification is activated, this indicator is displayed.

![Figure 2.9](image)

**Figure 2.9**

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**NOTE:**

*Magnification indicator area is displayed while the magnification is activated.*
2-3. Preparation just Before Insertion of Endoscope

⚠️ WARNING:

Every endoscope should be properly disinfected or sterilized before being used for the first time. The endoscope should have been properly cleaned, disinfected, or sterilized after any previous use and after being returned for any repairs/service. Refer to the companion manual describing in detail PENTAX reprocessing instructions.

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 dampened with 70-90% medical grade ethyl or isopropyl alcohol.

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

2) Gently clean the objective lens and the light guides with a cotton-tip applicator moistened with 70-90% medical grade ethyl or isopropyl alcohol. A lens cleaner (anti-fogging agent) may also be applied via gauze or other applicator.

3) Check the endoscopic image and confirm that it is of acceptable quality for clinical use. Refer also to the owner’s manual supplied with the PENTAX video processor for inspection of the image quality.

4) Prior to trans-oral insertion of the endoscope, place a bite-block (mouthpiece) into the patient’s mouth to protect the endoscope from damage during the procedure. Failure to do so can result in scratches, tears and/or crushing of the insertion portion of the endoscope (if the endoscope is to be introduced via the mouth).

5) Apply a medical grade water soluble lubricant to the insertion tube. Do not use petroleum based lubricants.

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

⚠️ WARNING:

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

⚠️ WARNING:
This instrument should only be used by physicians who have thoroughly studied all the characteristics of this instrument and who are familiar with the proper techniques of endoscopy. During the procedure, always wear protective garments such as surgical gloves, gowns, face masks, etc. to minimize the risk of cross contamination.

3-1. Pretreatment

1) The patient should be prepared in your normal endoscopy regimen.

3-2. Insertion and Withdrawal

⚠️ WARNING:
For safety reasons, always insert and advance the endoscope in the standard, non-magnified mode. Magnified vision reduces the area of the viewing field making it difficult to clearly see wide areas and identify anatomical landmarks. Do not advance the endoscope through the mouth or the nose in the magnified (zoom) mode.

1) Slowly insert the endoscope under direct vision (if endoscope is introduced via the mouth). The patient should be gently biting down on the bite block to maintain the bite block’s position during the procedure.

![Bite Block Diagram](image)

Figure 3.1

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

⚠️ WARNING:
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.
3) The angulation control should be used as needed to position the endoscope. The angulation of the tip should be done under direct vision in a gentle and deliberate manner. Should resistance be encountered, never apply excessive force.

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

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

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. Should the angulation system fail for any reason, stop the procedure, release the lock lever and carefully withdraw the endoscope under direct visualization.
The examples above are indications that service is required to avoid more serious problems with the angulation control system, including the possibility of a "frozen” distal bending section.
A “frozen” bending section can make instrument extraction from a patient more difficult.

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

5) When attempting to withdraw the endoscope, return the angulation lock lever to its free position. Always withdraw the endoscope under direct visualization.

6) Finally, remove the bite block if present.

Figure 3.2

⚠️ WARNING:
If for any reason, the image is lost due to power shortage, lamp or processor failure, etc. the angulation lock lever 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.
4. CARE AFTER USE

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

4-1. General

NOTE:
This Instructions for Use (IFU) has been written in accordance with 21CFR Part801, ISO 17664, and national guidelines on reprocessing of medical products.

4-1-1. Application

⚠️ WARNING:
Reprocessing may affect device functionality. Prior to use, always inspect the endoscope, components, and accessories according to their respective IFU for proper function to determine that they are appropriate for patient use.

Components and Accessories for Video Laryngostroboscope

<table>
<thead>
<tr>
<th>TYPE</th>
<th>MODEL</th>
<th>Video Laryngostroboscope</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Name</td>
<td>Number</td>
</tr>
<tr>
<td>Reprocessing Accessory</td>
<td>PVE Soaking Cap</td>
<td>OE-C9 - Y</td>
</tr>
<tr>
<td></td>
<td>Ventilation Cap</td>
<td>OF-C5 - Y</td>
</tr>
</tbody>
</table>

4-1-2. Important Instructions

⚠️ WARNING:
- Reusable Medical Devices that are initially supplied non-sterile require the end user to clean and disinfect or sterilize them prior to initial use and to subsequently reprocess them after each subsequent use.
- Proper care of the device after each procedure is extremely important. Immediately (within one hour) after the completion of a procedure, the endoscope and its removable components, and accessories should be both pre-cleaned and mechanically cleaned with detergent solution. Generally, if these endoscopes and accessories are not precleaned within 15 minutes and mechanically cleaned within one hour after the conclusion of the procedure, dried blood, mucus, or other patient debris may cause damage to the devices or interfere with the ability of the user to properly reprocess them.
- The use of detergent immediately after each procedure to dissolve and remove organic contaminants and proteinaceous debris is essential to the proper care and maintenance of the endoscope. Prior to disinfection or sterilization, all instruments and components must be meticulously cleaned. Failure to do so can result in incomplete or ineffective disinfection or sterilization.
- Always inspect reprocessed endoscopes and accessories prior to use according to their respective Instructions for Use (IFU).
⚠️ **WARNING:**

Endoscopes are semicritical devices that require cleaning and at least high-level disinfection. Use only legally marketed solutions and/or automated endoscope reprocessors (AERs) for which validation testing with PENTAX products has been performed by their manufacturers. A list of legally marketed solutions/systems that have been determined to be compatible with PENTAX brand products is contained in this manual.

⚠️ **CAUTION:**

- During the reprocessing process, always wear protective equipment (e.g., gloves, gowns, face masks, etc.) to minimize the risk of cross-infection and chemical injuries.
- Contact the manufacturer and follow local regulations regarding safe use, appropriate handling, and disposal of cleaning and disinfection solutions, including alcohol and rinse water. Material Safety Data Sheets available from the cleaning and disinfection solution manufacturer should be consulted to provide guidance to end users about formulation, hazards, chemical and physical properties, first aid, handling and storage, stability, precautions, disposal, etc.
- To avoid damaging the endoscope, do NOT twist, rotate or excessively bend the strain reliefs [(1), (2)] during inspection, clinical use, reprocessing, or any handling activity. Be particularly cautious regarding the insertion tube strain relief [(2)]. When wiping the insertion tube and the umbilical cable, use a slow back and forth motion to wipe them along the tube/cable. Never apply excessive force or torque to the strain reliefs or tubes/cables.

![Figure 4.1](image-url)
NOTE:
This IFU contains detailed recommendations on the manual reprocessing of PENTAX endoscopes using PENTAX supplied cleaning/disinfecting adapters. AERs may also be used to reprocess flexible endoscopes. However, only those AERs should be used whose manufacturers provide device-specific instructions and have validation data to support each AER claim with respect to PENTAX instruments. AER manufacturers should be consulted for their specific claims including, but not necessarily limited to:

A) the ability of the AER to provide a cleaned and high-level disinfected (or sterilized) endoscope and endoscope components (e.g., valves),
B) the identification of any special feature (internal channel) or endoscope component that cannot be reprocessed and therefore requires manual reprocessing,
C) the microbial quality of the rinse water,
D) the inclusion of an “automated” alcohol rinse cycle,
E) the inclusion of a terminal drying cycle that removes the majority of water from within endoscope channels,
F) maintenance procedures for water filter replacement and/or decontamination of the filtration system to ensure water of suitable quality,
G) compliance with local regulations and/or guidelines.

NOTE:
PENTAX flexible endoscopes should not be exposed to temperatures in excess of 140°F (60°C) during either reprocessing or storage. During reprocessing depending upon the detergent used, the endoscope may be damaged even if the temperature does not exceed 140°F (60°C). A list of detergents that are compatible with PENTAX endoscopes is contained in this manual.

NOTE:
All of the steps in the validated reprocessing protocol described in this manual are intended to be performed in rapid succession and as a single, continual procedure. There should be no breaks in between steps of the protocol that are of sufficient duration to permit the endoscope to dry to such an extent that dislodged debris and/or microbial contaminants would be permitted to dry onto any endoscope surface. In the event that drying of the endoscope occurs due to an excessive break in the reprocessing procedure, the procedure should be completely repeated, beginning with the first pre-cleaning step.
4-1-3. Endoscope Reprocessing Procedure Flow

Pre-Cleaning
- Preparation
- Wiping of insertion section
- Transport to cleaning room

Leak Testing

Cleaning
- Preparation
- Cleaning the all external surfaces
- Soaking entire scope in detergent solution
- Rinsing with clean potable water
- Drying by wiping with a new lint-free gauze
- Visual inspection

High-Level Disinfection
- Preparation
- Immersing the endoscope in disinfectant
- Soaking in disinfectant
- Rinsing
- Drying

Sterilization
4-1-4. Inspection of Reprocessing Accessories

Before use, inspect reprocessing accessories according to the following procedure.

⚠️ **WARNING:**
Replace reprocessing accessory with a new one when inspection of the device indicates that it is damaged or unable to function properly.

4-1-4-1. Inspection of PVE Soaking Cap (OE-C9)

1) Check that there is no cracking on the outer surface of the PVE Soaking Cap.
2) Check that there are no scratches, cracking, or chipping of the sealing surfaces inside the PVE Soaking Cap.

![Seal Portion](Figure 4.2)

4-1-4-2. Inspection of Ventilation Cap (OF-C5)

1) Make sure that of the Locking Groove Potion of the Ventilation Cap is not deformed.
2) Check that there are no scratches, cracking, or chipping of the O ring inside the Ventilation Cap.

![O Ring Locking Groove](Figure 4.3)
4-2. Video Laryngostroboscope

Video Laryngostroboscope can be subjected to the following cleaning, disinfection, and sterilization process.

<table>
<thead>
<tr>
<th>Video Laryngostroboscope</th>
<th>Cleaning</th>
<th>High-Level Disinfection</th>
<th>Sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Manual</td>
<td>Ultrasonic</td>
<td>STERIS System 1E&lt;sup&gt;®&lt;/sup&gt;</td>
</tr>
<tr>
<td>VLS-1070STK</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>VLS-1190STK</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>VLS-1590STi</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
</tbody>
</table>

Y: YES  
N: NO

4-2-1. Pre-Cleaning

⚠️ **WARNING:**
- During reprocessing, always wear protective equipment (e.g., gloves, gowns, face masks, etc.) to minimize the risk of cross-infection and chemical injuries.
- Pre-cleaning is intended to remove visible debris from the endoscope immediately after its withdrawal from the patient, in order to withdrawal subsequent cleaning procedure. Endoscopes that are from the patient are soiled with debris such as blood, tissues, and mucus. When such debris dries, it cannot be adequately removed in the subsequent cleaning procedure. It should be noted that pre-cleaning cannot substitute for the mechanical cleaning process. **Always mechanically clean the endoscope after precleaning.**
- During pre-cleaning, never wipe the insertion tube with alcohol or disinfectant. These solutions may fix organic contaminants and proteinaceous debris to the instrument and have an adverse effect on endoscope functionality and proper reprocessing.
- When using detergent, use only legally marketed brands that have been tested and found to be materially compatible by PENTAX (see APPENDIX).

⚠️ **CAUTION:**
- Immediately after use, the metal light guide plug and 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.
- Prior to pre-cleaning the endoscope, leave the PVE connector attached to the video processor.

**NOTE:**
If the use of detergent solution is not permitted in the procedure room, remove the endoscope from the procedure room and perform pre-cleaning immediately in the reprocessing area.
4-2-1-1. Items Required
- Protective equipment such as gloves, gowns, face masks, etc., to minimize the risk of crossinfection and chemical injuries.
- Detergent solution, Endozime® (Ruhof Corporation)
- 500 mL basin
- Lint-free gauze

4-2-1-2. Preparation
1) Wear personal protective equipment.
2) Prepare a 500 mL basin with 400 mL - 450 mL of detergent solution per manufacturer’s instructions (temperature, concentration). In the case of Endozime®, add 30 mL of Endozime® concentrate to 3.8 L (1 gallon) of clean potable water at 20 °C~30 °C (68 °F~86 °F).

4-2-1-3. Wiping of the Insertion Section
1) Turn off the 9400 Laryngeal Strobe lamp.
2) Immediately after removing the endoscope from the patient, gently wipe the entire length of the insertion section from control body to distal end three times using lint-free gauze soaked with detergent solution.

4-2-1-4. Transport to Cleaning Room
1) Turn off the power to the video processor, and detach the PVE connector from the video processor and the light guide connector from the laryngeal strobe.
2) Transport the pre-cleaned endoscope to the cleaning room in a closed container.

4-2-2. Leak Testing
Before reprocessing and/or immersion in any fluids, PENTAX endoscopes should be tested for the loss of integrity in their watertight construction by using either PENTAX brand leakage testers (SHA-P2 or SHA-P5) or a leakage tester that is sold by PENTAX. For specific details on PENTAX leak detection procedures, please refer to the instructions supplied with PENTAX leakage testers or a leakage tester that is sold by PENTAX.
⚠️ CAUTION:
Various types of manual and automated endoscope leakage testers exist. Some are standalone units, and others may be integrated into an AER. PENTAX does not evaluate leakage testers that are not sold by PENTAX to verify their specific product claims with respect to their effectiveness to accurately detect leaks and/or their compatibility with PENTAX endoscopes. Insufficient pressures may reduce the likelihood for accurate leak detection, especially if the endoscope’s distal bending section is not flexed during testing. Also, excessive pressures may adversely affect the endoscope, especially if pressurization occurs during automated reprocessing at elevated temperatures. PENTAX accepts no responsibility for use of leakage testers that it does not sell. 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.

NOTE:
- The leak sensitively and performance of PENTAX Leakage Tester (SHA-P5) for PENTAX Medical Endoscopes has been tested under the following condition;
  - Air pressure: 16 - 20kPa (2.3 - 2.9psi) (GREEN zone)
  - Time: 1 minute

4-2-3. Cleaning

⚠️ WARNING:
- During reprocessing, always wear protective equipment (e.g., gloves, gowns, face masks, etc.) to minimize the risk of cross-infection and chemical injuries.
- In order to ensure thorough cleaning, be sure to perform all cleaning steps. The effectiveness of each cleaning step will influence the effectiveness of subsequent steps. **Failure to properly follow the cleaning steps described may result in incomplete or ineffective cleaning, disinfection, and/or sterilization of endoscope, and may pose a cross-infection risk.**
- Immediately (within one hour) after the completion of a procedure, the endoscope and its components should be thoroughly and carefully cleaned with detergent solution. If the endoscope and its components are left uncleaned for an excessive time after use, dried blood, mucus, or other patient debris may cause damage or interfere with the ability of the user to properly reprocess the device.
- For cleaning, use only legally marketed detergents that have been tested according to the instructions of the manufacturer and found to be compatible by PENTAX (see APPENDIX).
- Fresh detergent solution must be used for each endoscope that is reprocessed.
CAUTION:
• **PVE soaking cap (OE-C9) must be properly secured over the electrical contacts.** Failure to do so could result in water invasion and damage to the endoscope. If an endoscope is cleaned **without** the soaking cap attached, do not use the endoscope, and contact your local PENTAX Medical service facility or sales representative.
• **Ventilation cap (OF-C5) must be taken OFF during reprocessing.** Failure to do so can result in damage to the endoscope. If an endoscope is cleaned **with** the ventilation cap attached, do not use the endoscope, and contact your local PENTAX Medical service facility or sales representative.
• **During cleaning, never twist, rotate, or bend the insertion portion and umbilical cable excessively.**
• **Never subject the endoscope to ultrasonic cleaning methods.**
• **In order to prevent damage to the endoscope, do not place any objects other than the reprocessing accessories listed in section 4-2-3-1 of this instruction for use with the endoscope when immersing it in a cleaning basin.**

4-2-3-1. Items Required
Reprocessing accessory
• PVE soaking cap (OE-C9)
Other Equipment
• Protective equipment such as gloves, gowns, face masks, etc., to minimize the risk of crossinfection and chemical injuries.
• Detergent solution, Endozime® (Ruhof Corporation)
• Clean potable water
• Basin sufficient in size to immerse the entire endoscope (at least 50 cm in length x 40 cm in width x 15 cm in depth, or 19.7 inches in length x 15.8 inches in width x 5.9 inches in depth)
• Lint-free gauze
• 30 mL luer slip syringe

4-2-3-2. Preparation
1) Wear personal protective equipment.
2) Ensure that PVE soaking cap (OE-C9) is attached to the endoscope, and ventilation cap (OF-C5) is detached from the endoscope.

![Figure 4.5](image)

3) Fill a basin with a sufficient volume of detergent solution to completely immerse the endoscope. Prepare the detergent in accordance with the manufacturer’s instructions (temperature, concentration). In the case of Endozime®, add 30 mL of Endozime® concentrate to 3.8 L (1 gallon) of clean potable water at 20 °C~30 °C (68 °F~86 °F).
4-2-3-3. Cleaning of all External Surfaces

⚠️ CAUTION:  
- Do not squeeze or severely bend the insertion tube.  
- Do not use any abrasive materials.  
- Be careful to avoid damage to the distal lenses.

1) Fully immerse the endoscope in detergent solution.  
2) While still immersed in detergent solution, wipe the entire surfaces of endoscope one time in one direction with a lint-free gauze.  
3) Visually inspect the entire surface of the endoscope to insure that no soil is present, paying special attention to areas such as the distal end, and control body, which are the most likely regions to retain visible soil.

4) If any soil is still present on the endoscope, use lint-free gauze to gently wipe until it has been completely removed.

4-2-3-4. Soaking in Detergent Solution

⚠️ WARNING:  
- The detergent solution must remain in contact with ALL external endoscope surfaces for the time period recommended by the manufacturer of the detergent.  
- Adhere to the conditions (temperature, concentration, time) specified by the detergent manufacturer to accomplish effective and complete cleaning. Use of the detergent solution under conditions that fall outside the manufacturer’s directions might damage the endoscope. Use of a timer or audible alarm is recommended in order not to exceed the recommended soaking time.

⚠️ CAUTION:  
Never subject the endoscope to ultrasonic cleaning methods.
1) While fully immersing the endoscope ensure that there are no air bubbles on all external surfaces. If any air bubbles are detected, flush them away with detergent solution using a 30 mL syringe.

2) Soak the endoscope under conditions (temperature, concentration, time) specified by the detergent manufacturer. In the case of Endozime®, the soaking time is 3 minutes.

3) After soaking, remove the endoscope from the detergent solution.

**4-2-3-5. Rinsing**

⚠️ **WARNING:**

*It is important that all external endoscope surfaces be thoroughly rinsed with clean potable water to remove residual detergent solution. Failure to do so can result in ineffective or incomplete disinfection and sterilization.*

**First rinse**

1) Place the endoscope in a basin of clean potable water that is of sufficient volume to completely immerse the endoscope.

2) Wipe the all external surfaces of the endoscope one time with a lint-free gauze in order to remove residual detergent solution.

3) While still completely immersed in clean potable water, grasp the distal end, control body, PVE connector, and Light guide connector with two hands, and agitate it under the clean potable water by moving it from side to side repeatedly for 20 seconds.
4) Remove the endoscope from the clean potable water.

Second rinse
5) * Fill a basin with clean potable water and repeat steps 1-4 to perform a second rinse.
   * This step can be skipped, when using an AER with a washing cycle following the manual cleaning.

4-2-3-6. Drying

1) Gently wipe and dry all external surfaces of the endoscope with a new lint-free gauze.

4-2-3-7. Visual Inspection

NOTE:
Ideally, work surfaces used for inspection require 1,000 - 2,000 lux illumination (ANSI/AMMI ST79).

1) Under adequate lighting, visually inspect the entire surface of the endoscope to insure that no debris is present. If any soil is still present on the endoscope, remove it by wiping and/or brushing the area(s) in question in detergent solution with lint-free cloths until it has been completely removed. After complete removal of residual soil has been attained, perform all rinsing steps that normally follow cleaning.

4-2-4. High-Level Disinfection

Prior to high-level disinfection, the end user should confirm that the high level disinfectant concentration is greater than the minimum effective concentration (MEC) of reused disinfectant as specified in the manufacturer’s instructions.

⚠️ WARNING:
• During the reprocessing process, always wear protective equipment (e.g., gloves, gowns, face masks, etc.) to minimize the risk of cross-infection and chemical injuries.
• Prior to disinfection, it is imperative that any solutions previously used in the cleaning process be thoroughly rinsed and dried. Failure to do so can result in ineffective or incomplete disinfection.
• For high-level disinfection, use an appropriate disinfectant according to the instructions of the disinfectant manufacturer (temperature, concentration, time). Adhere to the instructions to accomplish effective and complete disinfection. The endoscope may be damaged if exposed to a disinfectant under conditions other than those specified by the disinfectant manufacturer.
• Use only a legally marketed disinfectant that has been tested according to the instructions provided by the manufacturer and found to be materially compatible by PENTAX (see APPENDIX).
• Ideally, all final rinses should be performed with sterile water, clean potable water, or water that meets the requirements of the health care facility.
• Prior to disinfection, the endoscope must be meticulously cleaned. Failure to do so can result in incomplete or ineffective disinfection.
CAUTION:

- Prior to high level disinfection, attach PVE soaking cap (OE-C9). Failure to do so can result in water invasion and damage to the endoscope. If the endoscope is disinfected without the soaking cap attached, do not use the endoscope, and contact your local PENTAX Medical service facility or sales representative.
- Prior to disinfection, detach the ventilation cap (OF-C5). Failure to do so can result in damage to the endoscope. If the endoscope is disinfected with the ventilation cap attached, do not use the endoscope, and contact your local PENTAX Medical service facility or sales representative.
- During disinfection, never twist, rotate, or bend the insertion tube and umbilical cable excessively.
- In order to damaging the endoscope, do not place any objects with the endoscope when immersing the endoscope in the disinfection basin.

4-2-4-1. Items Required

Reprocessing accessory
- PVE soaking cap (OE-C9)

Other equipment
- Protective equipment such as gloves, gowns, face masks, etc., to minimize the risk of crossinfection and chemical injuries.
- Disinfectant, CIDEX® Activated Dialdehyde Solution (Johnson & Johnson).
- Sterile water (preferred) or clean potable water.
- Basin sufficient in size to immerse the entire endoscope (at least 50 cm in length x 40 cm in width x 15 cm in depth, or 19.7 inches in length x 15.8 inches in width x 5.9 inches in depth)
- Sterile gauze
- 30 mL luer slip plastic syringe

4-2-4-2. Preparation

1) Wear personal protective equipment.
2) Attach the PVE soaking cap (OE-C9) to the endoscope.
3) Ensure that the ventilation cap (OF-C5) is detached from the endoscope.

4) Prepare a basin of sufficient volume capacity to fully immerse the endoscope with CIDEX® Activated Dialdehyde Solution in accordance with the disinfectant manufacturer’s instructions for concentration and temperature.
4-2-4-3. Soaking in Disinfectant

⚠️ WARNING:

• The disinfectant must remain in contact with external endoscope surfaces for the time period recommended by the disinfectant manufacturer.
• Adhere to the conditions (temperature, concentration, time) specified by the disinfectant manufacturer to accomplish effective and complete disinfection. Disinfectant solution use under conditions that fall outside the manufacturer’s directions might damage the endoscope. Use of a timer or audible alarm is recommended in order not to exceed the recommended soaking time.

1) While fully immersed, ensure that the endoscope do not have air bubbles on the endoscope surfaces. If any air bubbles are detected, flush them away with disinfectant using a syringe.

2) Soak the endoscope under the conditions (temperature, concentration, time) specified by the disinfectant manufacturer. In the case of CIDEX® Activated Dialdehyde Solution, the soaking time is 45 minutes at 25°C (77°F).

![Figure 4.10](image)

3) After soaking, remove the endoscope from the disinfectant.
4-2-4-4. Rinsing

⚠️ WARNING:

- Ideally, all final rinses should be performed with sterile water. However, if sterile water is not used, use potable water or the water that meets the requirements of the health care facility.

First rinse

1) Place the endoscope in a basin of sterile water that is of sufficient volume to completely immerse the endoscope.

2) Wipe all exterior surfaces of the endoscope two times with sterile gauze in order to remove residual disinfectant.

3) While still completely immersed in water, grasp the distal end, control body, PVE connector, and Light guide connector with two hands, and agitate the scope under the water by moving it from side to side repeatedly for 20 seconds.

4) Remove the endoscope from the water.

Second rinse

5) Fill a basin with sterile water and repeat steps 1-4 in order to perform a second rinse.

Third rinse

6) Fill a basin with sterile water and repeat steps 1-4 in order to perform a third rinse.

4-2-4-5. Drying

Drying of all external surfaces

1) Gently dry all external surfaces of the endoscope with a sterile gauze.
4-2-5. Sterilization

⚠️ WARNING:
- Please note that PENTAX Medical has not validated any steam sterilization methods for flexible endoscopes.
- During the reprocessing process, always wear protective equipment (e.g., gloves, gowns, face masks, etc.) to minimize the risk of cross-infection and chemical injuries.
- After sterilization, ensure that the package is intact. If there are any signs of abnormalities such as stains, tears, or any other indications that the packaging has been damaged or opened, repeat sterilization of the device with new packaging.
- Sterilization efficacy and material compatibility depend on the following factors:
  - thorough cleaning of the device
  - load of the devices to be sterilized
  - wrapping of the devices to be sterilized
  - sterilizer cycle parameters
  - quality of rinse water
- Prior to sterilization, clean and dry the endoscope thoroughly. Failure to do so can result in ineffective or incomplete sterilization.
- Use a chemical indicator (CI) and/or biological indicator (BI) to control the sterilization process and ensure sterilization efficacy.
- The manufacturer of the sterilizer should be consulted to confirm that test data exists to substantiate that no harmful levels of any residues (active/inert ingredients, their byproducts or derivatives of the processed devices) remain on any instrument that may pose a risk to patients and users.
- Prior to sterilization, the endoscope and accessories must be meticulously cleaned. Failure to do so can result in incomplete or ineffective sterilization.

⚠️ CAUTION:
- Due to the heat sensitive nature and/or the specific biocompatible materials used in the construction of flexible endoscopes, some sterilization systems/processes/solutions may have detrimental effects on flexible endoscopes. To avoid the potential for instrument damage and/or endoscope failure, confirm the compatibility of such systems/solutions with your local PENTAX Medical facility prior to use with any PENTAX products. Also, before using any sterilization method/process described in this IFU, confirm with PENTAX that the specific method/process not in this IFU is acceptable for the PENTAX endoscope used in your healthcare facility.
- NEVER place the endoscope in a steam sterilizer!
**4-2-5-1. Liquid Chemical Sterilization of VLS scope using the STERIS System 1E**

*Liquid Chemical Sterilant Processing System*

**Items required for STERIS System 1E Liquid Chemical Sterilization**

- Personal Protective Equipment (e.g., gloves, gowns, face masks) to minimize the risk of crossinfection and chemical injuries
- S40® Sterilant Concentrate (STERIS Corporation)
- C1160E Universal Flexible Processing Tray
- No Quick Connector required

PENTAX VLS scopes mentioned in this IFU may undergo liquid chemical sterilization using the STERIS System 1E® Liquid Chemical Sterilant Processing System. Please consult the following documents for specific instructions:

- STERIS System 1E Liquid Chemical Sterilant Processing System Operator Manual – provides instructions for operation of the processor and the use of S40 Sterilant Concentrate
- C1160E Universal Flexible Processing Tray Processing Instructions – provides instructions for preparation of the universal flexible processing tray and tray placement into the STERIS System 1E Liquid Chemical Sterilant Processing System

Additional information about the STERIS System 1E Sterilant Processing System may be obtained at www.steris.com or by contacting STERIS Customer Service at 1-800-548-4873.

### 4-3. Endoscope Components and Accessories

Endoscope components and accessories can be subjected to the following cleaning, disinfection, and sterilization processes.

<table>
<thead>
<tr>
<th>Reprocessing Accessory</th>
<th>Model Name</th>
<th>Number</th>
<th>Cleaning (Manual, Ultrasonic)</th>
<th>High-Level Disinfection</th>
<th>Sterilization (Steam)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVE Soaking Cap</td>
<td>OE-C9</td>
<td></td>
<td>Y*</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Ventilation Cap</td>
<td>OF-C5</td>
<td></td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
</tbody>
</table>

*Y*: YES  
*N*: NO

* : The PVE Soaking Cap (OE-C9) should be attached to the endoscope during cleaning and disinfection procedures.

**NOTE:**

Automated Endoscope Reprocessor (AER) manufacturers may not make specific claims or provide special instructions for reprocessing all of endoscope components and accessories that are integral to the safe and effective operation of endoscopes. Therefore, should the AER manufacturer’s instructions not specifically address reprocessing of any particular endoscope components and accessories (suction valve, inlet seal, etc.) reprocess those components and accessories manually as described in this IFU. Prior to use, check with the AER manufacturer regarding their specific claims with respect to reprocessing individual endoscope components and accessories.
5. POST REPROCESSING AND STORAGE

⚠️ WARNING:

- Never store the endoscope, its components, or accessories in the carrying case, as this type of dark, humid, and unventilated environment is conducive to bacterial colonization and increases the risk of cross contamination. These cases are intended only for transportation of the instrument, not storage.

⚠️ CAUTION:

- Never store the endoscope in areas of high humidity, high temperature, or in direct exposure to sunlight or X-rays.
- Avoid storage of the endoscope in cabinets that have sharp edges, exposed nails/screws, etc. Contact with sharp objects can puncture, scratch, or otherwise damage the endoscope.
- When utilizing heated disinfectants for reprocessing PENTAX endoscopes, the instruments should be allowed to return to room temperature prior to use and/or further handling.

1) Following reprocessing, the endoscope may either be reused or placed into storage.

2) Prior to storage, ensure that all endoscope accessories and instrument surfaces are thoroughly dry.

3) The endoscope should be hung vertically in a clean, dry, well-ventilated storage cabinet at room temperature. The insertion tube and light guide cable should be hung and kept as straight as possible during storage.

4) Prior to reuse, ensure that instrument has been properly inspected and fully prepared for the next clinical procedure.
6. SERVICING

⚠️ WARNING:

- Instrument repairs should only be performed by an authorized PENTAX Medical 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.

- A list of “compatible” reprocessing agents with PENTAX endoscopes based upon material compatibility and functionality studies performed by PENTAX, Japan is contained in this manual. These tests 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.

- Please note that PENTAX does not evaluate non-PENTAX parts, components, materials, and/or servicing methods. Therefore, questions regarding material compatibility and/or functionality of PENTAX instruments repaired 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.

- Independent Service Organizations should confirm the ability of these serviced/remanufactured devices to be reprocessed safely and effectively with reprocessing agents/systems recognized as compatible by PENTAX for standard PENTAX products. These companies and/or remanufacturers should be consulted to confirm whether they have performed reprocessing validation studies on instrument models which they have serviced (or remanufactured) that support their cleaning, high-level disinfection, and/or sterilization via the 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 will render an instrument equivalent to the 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 can 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 Medical service facility for inspection or repair.
Prior to returning any instrument for repair to PENTAX, the instrument should first undergo appropriate reprocessing/decontamination procedures for the purpose of infection control. Check with your local PENTAX Medical service facility for more details.

1) All instruments requiring repair should be shipped in the original carrying case with appropriate packing along with comments describing the instrument damage and complaint.

2) A repair purchase order number, contact name, and phone number of the individual responsible for authorizing repairs, as well as shipping address should be included.

3) The ventilation cap (OF-C5) should be attached to the instrument if it will be shipped by air freight.

4) Any accessories and/or endoscope components potentially related to the endoscope damage or complaint should also be returned with the endoscope.

5) PVE soaking cap (OE-C9) should also be returned with the endoscope to check/confirm the integrity of its watertight seals.

6) After servicing, all endoscopes must be reprocessed prior to patient use.

7) For disposal of instruments, follow local or country regulations.
7. APPENDIX

7-1. PENTAX Medical Compatible Reprocessing Agents/Systems

The information below for the endoscope(s) identified in this IFU is based upon material compatibility studies performed by HOYA Corporation PENTAX Lifecare Division, Japan. Reference to specific brand name products is not an endorsement of their efficacy.

Tests have shown these solutions to be compatible with materials used in the construction of PENTAX Medical endoscopes, provided that the manufacturers’ instructions for use are followed.

Users must strictly follow the manufacturers’ instructions for these agents with respect to concentration, temperature, and soaking time.

In the event that the manufacturer changes the formulation or concentration of its product(s), this declaration of conformity will no longer be valid as relates to the affected products.

The latest list of compatible cleaning and disinfection agents with PENTAX Medical endoscopes can be obtained from your local PENTAX Medical service facility.

⚠️ WARNING:

PENTAX Medical does not warrant chemical damage to PENTAX endoscopes that is attributable to the use of unlisted cleaning and disinfection agents.

<table>
<thead>
<tr>
<th>Enzymatic Detergents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Brand Name</strong></td>
</tr>
<tr>
<td>Cidezyme® XTRA (used exclusively in EvoTech ECR)</td>
</tr>
<tr>
<td>Enzol®</td>
</tr>
<tr>
<td>Endozime® AW</td>
</tr>
<tr>
<td>Endozime®</td>
</tr>
<tr>
<td>Endozime® Plus</td>
</tr>
<tr>
<td>Enzy-Clean</td>
</tr>
<tr>
<td>Metrizyme®</td>
</tr>
<tr>
<td>Tergal 800</td>
</tr>
<tr>
<td>ZymeX™ Enzymatic Cleaner Concentrate</td>
</tr>
</tbody>
</table>

**NOTE:**

Cleaning process of the endoscopes and accessories described in this IFU has been validated with Endozime® AW (Ruhof Corporation).
**High Level Disinfectants**

The following liquid chemical germicides have received FDA 510(k) clearance for claims of high level disinfection (HLD). Some HLD products may have multiple label claims and/or may be FDA-cleared only for use in a legally marketed AER machine that can attain specific use parameters (e.g., temperature).

<table>
<thead>
<tr>
<th>Product Brand Name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>CIDEX® Activated Dialdehyde Solution</td>
<td>Advanced Sterilization Products</td>
</tr>
<tr>
<td>CIDEX® OPA</td>
<td></td>
</tr>
<tr>
<td>CIDEX® OPA - C (used exclusively in EvoTech ECR)</td>
<td></td>
</tr>
<tr>
<td>MetriCide® (Glutaraldehyde - may also be marketed as Omnicide NS or MaxiCide® NS)</td>
<td>Metrex Research Corporation</td>
</tr>
<tr>
<td>Sporicidin® (Glutaraldehyde)</td>
<td>Contec Incorporated</td>
</tr>
<tr>
<td>Rapicide® (Glutaraldehyde)</td>
<td>Medivators Inc.</td>
</tr>
<tr>
<td>Wavicide® - 01 (Glutaraldehyde)</td>
<td>Medical Chemical Corporation</td>
</tr>
</tbody>
</table>

**NOTE:**

Disinfection process of the endoscopes and accessories described in this IFU has been validated with CIDEX® Activated Dialdehyde Solution (Advanced Sterilization Products).
### SPECIFICATIONS

<table>
<thead>
<tr>
<th></th>
<th>VLS-1590STi</th>
<th>VLS-1190STK</th>
<th>VLS-1070STK</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Direction of View</strong></td>
<td>Forward</td>
<td>Forward</td>
<td>Forward</td>
</tr>
<tr>
<td><strong>Field of View</strong></td>
<td>100°</td>
<td>80°</td>
<td>85°</td>
</tr>
<tr>
<td><strong>Depth of Field</strong></td>
<td>3 ~ 50 mm</td>
<td>3 ~ 50 mm</td>
<td>3 ~ 50 mm</td>
</tr>
<tr>
<td><strong>Tip Angulation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Up</td>
<td>130°</td>
<td>130°</td>
<td>130°</td>
</tr>
<tr>
<td>Down</td>
<td>130°</td>
<td>130°</td>
<td>130°</td>
</tr>
<tr>
<td><strong>Rigid Distal Width</strong></td>
<td>φ 5.6 mm</td>
<td>φ 4.1 mm</td>
<td>φ 3.1 mm</td>
</tr>
<tr>
<td><strong>Distal End Width</strong></td>
<td>φ 5.6 mm</td>
<td>φ 4.1 mm</td>
<td>φ 2.9 mm</td>
</tr>
<tr>
<td><strong>Insertion Tube Width</strong></td>
<td>φ 5.1 mm</td>
<td>φ 3.7 mm</td>
<td>φ 3.3 mm</td>
</tr>
<tr>
<td><strong>Maximum Insertion Portion Width</strong></td>
<td>φ 6.15 mm</td>
<td>φ 4.90 mm</td>
<td>φ 3.95 mm</td>
</tr>
<tr>
<td><strong>Insertion Tube Working Length</strong></td>
<td>300 mm</td>
<td>300 mm</td>
<td>300 mm</td>
</tr>
<tr>
<td><strong>Total Length</strong></td>
<td>500 mm</td>
<td>500 mm</td>
<td>500 mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Operating environment</strong></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambient temperature</td>
<td>10 ~ 40°C</td>
<td>10 ~ 40°C</td>
<td>10 ~ 40°C</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>30 ~ 85%</td>
<td>30 ~ 85%</td>
<td>30 ~ 85%</td>
</tr>
<tr>
<td>Air pressure</td>
<td>700 ~ 1060 hPa</td>
<td>700 ~ 1060 hPa</td>
<td>700 ~ 1060 hPa</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Storage environment</strong></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambient temperature</td>
<td>-20 ~ 60°C</td>
<td>-20 ~ 60°C</td>
<td>-20 ~ 60°C</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>0 ~ 85%</td>
<td>0 ~ 85%</td>
<td>0 ~ 85%</td>
</tr>
<tr>
<td>Air pressure</td>
<td>700 ~ 1060 hPa</td>
<td>700 ~ 1060 hPa</td>
<td>700 ~ 1060 hPa</td>
</tr>
</tbody>
</table>

| **Degree of protection against electric shock** | BF type | BF type | BF type |

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

### DISTAL END

![Diagram of VLS-1190STK / 1070STK / 1590STi](attachment://diagram.png)
NOTICE

These instruments are used with Class B Medical Equipment (specified CISPR11) and are intended for hospitals or ambulatory surgery centers, and medical clinics.

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

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

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