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Instructions For Use of

PatCom Distal Chip Endoscope

（RP11A）

"Rx only" Caution: United States Federal law restricts medical devices to sale by or on the order of a licensed healthcare practitioner

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Product Information

- Product Model: RP11A
- Product Name: PatCom Distal Chip Endoscope

Version

The version number of the Instructions for Use is subject to change without prior notice because of change in software or technical specification. Below is the version information of the Instructions for Use:

- Document Number: Instructions For Use of PatCom Distal Chip Endoscope (RP11A)
- Version: eRevision 2
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Statement

Responsibilities of the Manufacturer

The manufacturer is responsible for the safety, reliability and performance of the product when all of the following conditions are satisfied:

Installation, maintenance and upgrading of the product are done by the personnel authorized or certified by the manufacturer.

Overview

◆Main Structure

The product is composed of 3 parts, i.e. grip section, insertion tube and accessories.

◆ Intended Use

The PatCom Distal Chip Endoscope is a video endoscope used for visualization to aid in diagnosis in the regions of mouth, nasal cavity and upper airway. It is to be used by healthcare professionals who have received adequate training in handling nasopharyngoscopes.

◆ Indications for Use

The PatCom Distal Chip Endoscope is indicated when endoscopic visualization in the regions of mouth, nasal cavity, and upper airway is required.

◆ Contraindication

The use of the endoscope is contraindicated if endoscopic applications are contraindicated for any reason.

◆ Essential performance

1. There must be no unexpected image rotation which could alter the visualization of the region studied using the endoscope and affect the procedure done by the Healthcare professional or end user.
2. There must be no image display that could alter the visualization of the region studied using the endoscope and affect the diagnosis performed by a trained operator.
3. There must be obvious markers to distinguish real-time images from non-real-time images.

◆ Cautions, Warnings and Notes

① The PatCom Distal Chip Endoscope must not be repaired by the user. Internal maintenance shall only be conducted by the technical personnel authorized by the manufacturer.

② The PatCom Distal Chip Endoscope is not a treatment device and shall not be used at home.

③ The Endoscope shall be unplugged before cleaning of the product.

④ The product cannot be used with High Frequency Surgical Equipment.

⑤ The product cannot be interconnected with the configuration for endoscopic application to be type SF applied parts or type CF applied parts.

⑥The intended patient population is for adult patients. The use for specific patient population is at the discretion of the medical personnel who have received professional training in endoscopic procedures.

◆ Clinical Benefit

Distal Chip Endoscope provides accurate visualization of internal nose, mouth and throat structures to aid in the evaluation and/ or diagnosis of any impairment or disease present.

About the Instructions for Use

The Instructions for Use gives a detailed account of the usage, functions and operation methods of the product. Please carefully read and understand the contents of the Instructions for Use before using the product, so that the product can be correctly used and the safety of both patients and operators can be ensured.

Please place the Instructions for Use and all related instruction manuals in a safe, accessible location or near the product if necessary.

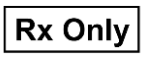
The Instructions for Use is suitable for professional clinical medical personnel. The readers shall have the knowledge of medical procedures, practices, terms and working experience that is necessary for endoscopes.

All the illustrations provided in the Instructions for Use are for reference only. The settings or data in the illustrations are possibly different from what actually displayed on the product.

Table of Contents:

Symbols

The meaning(s) of the symbol(s) shown on the package with the components, the back cover of this Instructions for Use and/or this instrument are as follows:

	Type BF applied part		Keep the device correct upright position of the transport package.
	Serial number		The operation guide must be read.
	Caution: indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.		ENVIRONMENT PROTECTION - Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice.
	Fragile, handle with care		Stacking limit by number
	Manufacturer		Medical device.
	Manufacturing date		Fear rain, keep dry
	CE mark: indicates that the device complies with the EU 2017/745		Authorized representative in the European Union
	Recycle		Federal law restricts this device to sale by or on the order of a physician

Key Points (please read before use)

Purpose of Design

The product has been designed to provide visualization via a computer monitor. And it should not be used for other purposes.

Intended Use

The PatCom Distal Chip Endoscope is a video endoscope used for visualization to aid in diagnosis in the regions of mouth, nasal cavity, and upper airway. It is to be used by healthcare professionals who have received adequate training in handling nasopharyngoscopes.

Applicability

The instrument is indicated for providing endoscopic visualization and diagnosis in the mouth, the nasal cavities and in the upper airway anatomy.

Endoscope Contraindications

The use of the endoscope is contraindicated if endoscopic applications are contraindicated for any reason.

User Qualification

The operator of this instrument must be a Healthcare professional trained in endoscopy.

Instrument Compatibility

Refer to Chapter 1 “Checking the Package Contents”, confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient or operator injury and/or equipment damage.

This product conforms to the EMC standard IEC60601-1-2:2014.

Specifications Table

Model	RP11A	
Input voltage	DC 5V	
Insertion Section	Insertion tube outer diameter	3.2mm
	Working Length	340mm
Optical system	Field of view	110°
	Direction of view	0°
	Depth of field	6-60mm
Bending Section	Angulation range	UP 130°, DOWN 130°
Normal working conditions	Ambient temperature	5℃～+40℃
	Atmospheric pressure	700hPa～1060hPa
	Relative humidity	30%～85%
Transportation and storage conditions	Ambient temperature	-10℃～+55℃
	Atmospheric pressure	500hPa～1060hPa
	Relative humidity	≤93%
FDA classification		Class II
EU classification		Class I
Degree of protection against electric shock		BF
Degree of protection against hazards of explosion		Ordinary equipment, without protection against hazards of explosion
Degree of protection against ingress of liquid		Grip section, IPX7
Equipment type		Handheld
Disinfection method		Equipment of disinfection method recommended by manufacturer
Mode of Operation		Continuous operation equipment
Lifetime		100 times based on disinfection validation

Cleaning, Disinfection Before the First Use / After Use and Storage

This instrument was not cleaned and disinfected before shipment. Before using this instrument for the first time, clean and disinfect it according to the instructions given in Chapter 5 to Chapter 8.

After using this instrument, clean, disinfect and store it according to the instructions given in Chapter 5 to Chapter 8. Improper and/or incomplete reprocessing or storage can present an infection control risk, cause equipment damage or reduce performance.

Maintenance and safety check

Maintenance

The probability of failure of endoscope and ancillary equipment increase as the total operation cause and/or total operating hours increases. In addition to the inspection before each procedure, the person in charge of medical equipment maintenance in each hospital should inspect the items specified in this Instructions for Use periodically. An endoscope with which an irregularity is suspected should not be used, but should be inspected

by following Section 9.1, “Troubleshooting guide”. If the irregularity is still suspected after inspection, contact our company before use.

Preventive maintenance is not necessary. Regular maintenance can, however, contribute to identifying potential problems before they become serious, thus enhancing the instrument’s reliability and extending its useful service life. Maintenance services can be obtained from your local representative or from the manufacturer.

Safety check

Regardless of the accident prevention regulations or testing intervals for medical devices prescribed in different countries, the following checks must be carried out on this device at least once a year by persons who, due to their training, knowledge and practical experience, are able to properly carry out such safety checks and who are not subject to any instructions as far as such checking activities are concerned.

Visual inspection:

- Check the device and accessories for any mechanical damage which may impair functionality.
- Check that the labels relevant to safety are legible.

Electric measurements:

- Touch Current and Patient Leakage currents, measured according to IEC 62353 (current edition), and meets the limits specified in the standard.

Test for proper functioning:

- A functional check must be carried out in accordance with the Instructions for Use (see Chapter 3).
- The safety check must be entered in the unit log-book and the results of the check must be documented.
- If the device does not function reliably and/or safely, it must be repaired.

Servicing and repair

The PatCom Distal Chip Endoscope must not be repaired by the user. Internal maintenance shall only be conducted by the technical personnel authorized by the manufacturer.

Disposal

When disposing of the endoscope, or any of its components (such as cleaning brush), follow all applicable national and local laws and guidelines.

Prohibition of Improper Repair and Modification

The product does not contain any parts that can be repaired by the user. Do not dismantle, repair or restructure the product without authorization; otherwise, personal injury or machine damage will be caused.

The product should be repaired only by person authorized by our company. Instruments that are dismantled, repaired or restructured by persons other than technicians qualified by our company, are out of the scope of our company's warranty, is no longer entitled to any form of warranty provided by our company.

Signal Words

The following signal words are used throughout this Instructions for Use:

Warning — Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

Caution — Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

Note — Indicates additional helpful information.

Warnings and Cautions

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

Warning

- Never install and operate the system in the following locations. An explosion or fire may result because the system is not explosion-proof.
  - The concentration of oxygen is too high.
  - Oxidizing agents (Such as nitrous oxide (N2O)) are present in the atmosphere.
  - Flammable anesthetics are present in the atmosphere.
  - Flammable fluids are near.

- permitted liquid:
  - physiological saline, water-soluble lubricants

- After using this instrument, clean, disinfect and store it according to the instructions given in Chapter 5 to Chapter 8. Using improperly or incompletely reprocessed or stored instruments may cause patient cross-contamination and/or infection.

- Do not perform electrical burn surgery, argon plasma coagulation and laser cauterization with high-frequency electrosurgical knife while using this product, because this product cannot be used together with high-frequency electrosurgical knife, argon plasma coagulation or laser

cauterization.

- Do not strike, hit, or drop the endoscope's distal end, insertion tube, bending section, or control section. Also do not bend, pull, twist the endoscope's distal end, insertion tube, bending section, control section, or monitor with excessive force. The endoscope may be damaged and could cause patient injury, burns, bleeding and/or perforations. It could also cause parts of the endoscope to fall off inside the patient.

- Never insert or withdraw the insertion tube forcefully or suddenly. Never forcefully pull, twist or rotate the angulated bending section. Patient injury can result. It may also become impossible to straighten the bending section during an examination.

Warning

- Never insert or withdraw the endoscope's insertion tube while the bending section is angulated, which could cause patient injury.

- Bending section can be bent upward or downward only, but not to the left or right. The operator should take full account of the bending direction of the endoscope while doing the insertion and withdrawal. Do not insert or withdraw to right or left direction with excessive force. Otherwise, it may lead to patient injury.

- Never operate the bending section, insert or withdraw the endoscope's insertion tube without viewing the clear endoscopic image. Otherwise, it may lead to patient injury.

- Never operate the bending section, insert or withdraw the endoscope's insertion tube or use endo-therapy accessories while the image is frozen. Otherwise, it may lead to patient injury.

- Never insert or withdraw the insertion tube forcefully or suddenly. Otherwise, it may lead to patient injury.

- When it is difficult to insert the endoscope, do not forcefully insert the endoscope but stop the endoscopy. Forcible insertion could result in patient injury.

- Operator shall observe the following precautions with endoscope lighting.
  - Do not continually observe closely, or do not let the distal end contact the living tissue for a long time.
- If liquid has infiltrated into endoscope, do not use the endoscope, because its internal structure may be damaged.

- PatCom Distal Chip Endoscope should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the PatCom Distal Chip Endoscope should be observed to verify normal operation in the configuration in which it will be used.

Note

- The PatCom Distal Chip Endoscope may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances.

- Do not coil the insertion tube into a diameter of less than 12 cm. Equipment damage can result.
- Do not attempt to bend the endoscope's insertion tube with excessive force. Otherwise, the insertion tube may be damaged.
- Do not strike the distal end of insertion tube, especially the surface of the objective lens on the distal end, otherwise it will cause a fault framing.
- Do not twist or bend the bending section with your hands. Equipment damage may result.
- Do not squeeze the bending section forcefully. The covering of the bending section may stretch or break and cause water leaks.
- Electromagnetic interference may occur on this instrument near equipment marked with the following symbol or other portable and mobile RF (Radio Frequency) communications equipment such as cellular phones. If electromagnetic interference occurs, mitigation measures may be necessary, such as reorienting or relocating this instrument, or shielding the location. 
- In order to check the electromagnetic interference from other devices (any devices or equipment components of other system), the system should be observed in the operating environment whether it is working properly.
- PatCom Distal Chip Endoscope meets the requirements of electromagnetic compatibility in IEC60601-1-2:2014.
- The user needs to install and use according to electromagnetism compatibility information which is attached with it.
- Portable and mobile RF communication devices may influence PatCom Distal Chip Endoscope performance, so PatCom Distal Chip Endoscope should be kept away from them during use.
- Guidance and manufacturer's declaration stated in the appendix.

Endoscopic Images Disappear or Freeze Precautions

Warning

- If endoscopic image disappears unexpectedly, or frozen image cannot recover to real-time display working state, immediately stop using the endoscope, and pull out the endoscope insertion tube as specified in Section 9.2 "Withdrawal of the Endoscope with any Abnormality". Continuously operate the endoscope accessories and bending section, withdraw or insert the endoscope may lead to patient injury.
- Please follow these precautions when operating these instruments. Otherwise, the endoscope

image may disappear unexpectedly, or in the inspection process frozen image cannot be restored.

- Do not bend, strike or twist the insertion part and the operation part. It may damage the endoscope, causing leakage and / or damage to internal components, such as CMOS, or circuitry.
- Before the endoscope is inserted through the mouth, if necessary, put an oral pad or guide blade into the mouth of the patient in order to prevent the patient from accidentally biting the insertion part. Chewed insertion part may cause the cable damage and break the insertion tube.
- Ensure that the sealing plug is attached to the endoscope. Otherwise, water will enter into the instrument, and may cause a short circuit. This will cause damage to the CMOS and circuit.
- If there are continuous air bubbles coming from the endoscope during leak test, do not use the endoscope. Otherwise, water may enter the instrument and cause a short circuit. This will cause damage to the CMOS and circuit.

Examples of Inappropriate Handling

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

Warning

- Inserting, withdrawing and using endo-therapy accessories without a clear endoscopic image may cause patient injury.

Light-emitting Diode (LED)

The light-emitting diode is built into the endoscope. It is basically safe for the eye. But watching the light emitted from the LED directly for a long time may damage the eyes. Maintenance staff, vendors and others need to read this Instructions for Use in details.

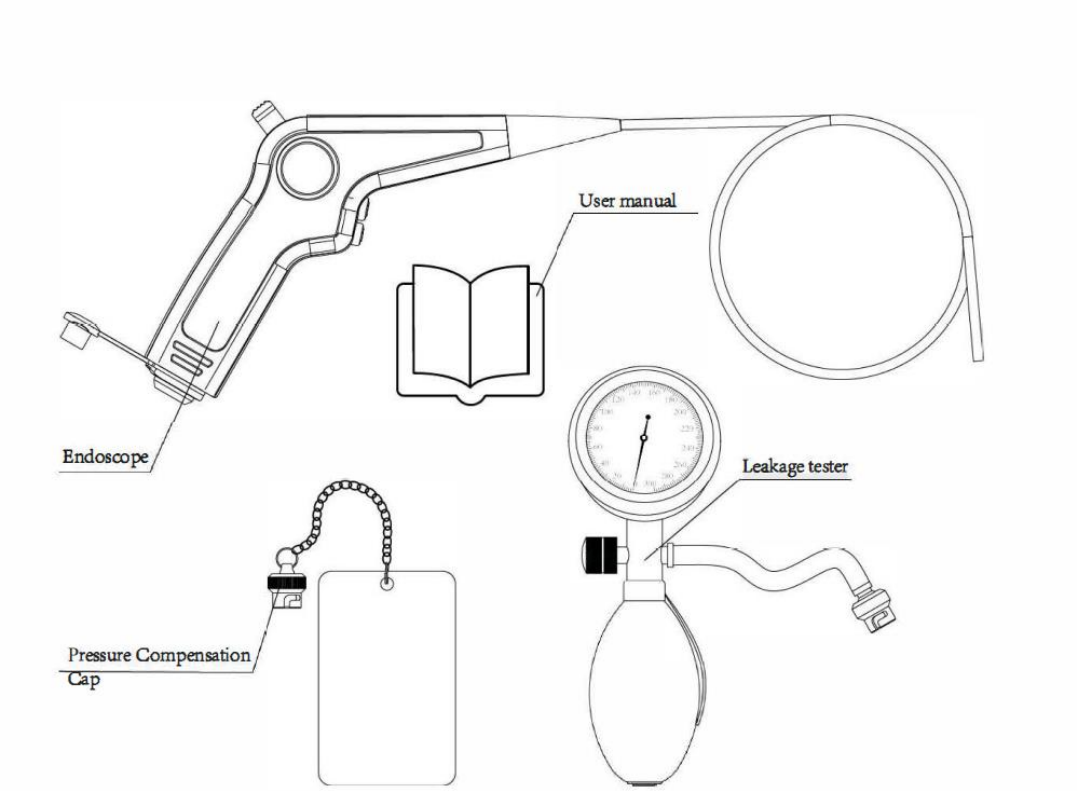
Warning

- Avoid looking directly into the LED.

Chapter 1 Checking the Package Contents

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

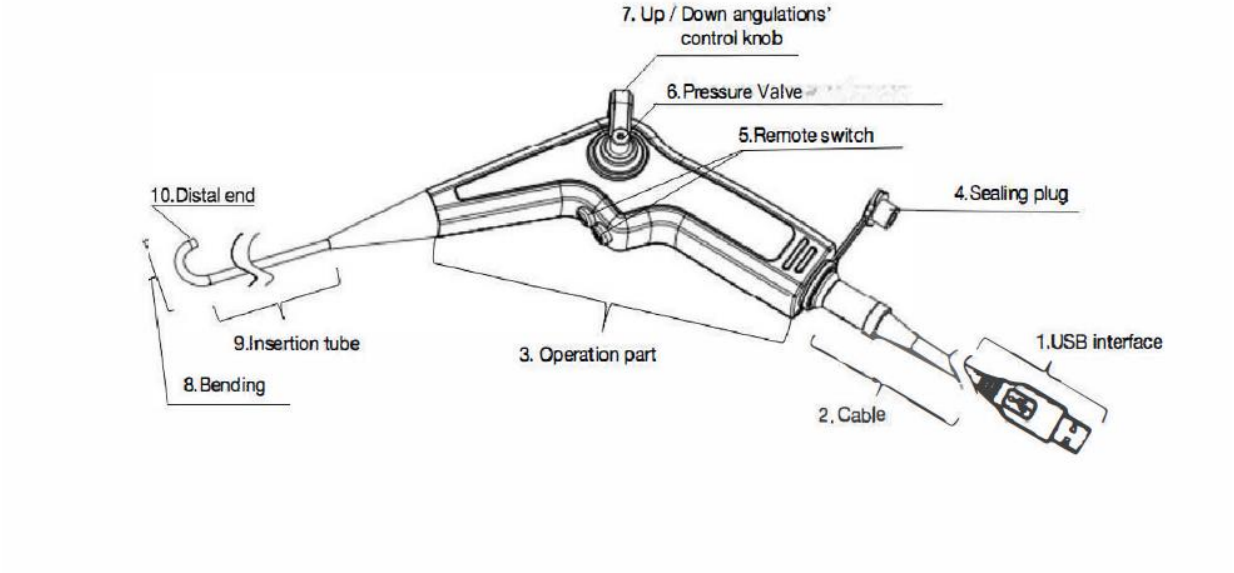
This instrument was not disinfected before shipment. Before using this instrument for the first time, clean and disinfect it according to the instructions given in Chapter 5 “Cleaning and Disinfection: General Policy” to Chapter 7 “Cleaning and Disinfection Procedures”.



Items	Purpose
Endoscope	The PatCom Distal Chip Endoscope is applied in the diagnosis for patients with ENT diseases.
Pressure compensation cap	Prevents large discrepancy between internal endoscope pressure and atmospheric pressure.
Leakage tester	Test the endoscope for leakage.
Instructions for Use in hard version	Provide the guidance for operation and cleaning.

Chapter 2 Instrument Nomenclature and Specifications

2.1 Nomenclature



2.2 Endoscope Functions

1. USB interface - Used to connect the computer.
2. Cable - Used to connect the Endoscope.
3. Operation part - The operator can hold the handle for positioning, the handle is suitable for left and right hand.

4. Sealing plug - Detach the sealing interface before ventilation, transport and operation. Attach the sealing interface before the endoscope is immersed in liquids.

5. Remote switch

- Button 1 is used to adjust brightness.

- Button 2 is used to take photos or video.

6. Pressure valve - The pressure valve is used to keep the internal and external pressure consistent.

7. UP/DOWN angulation control knob - Turn the control knob to ‘U’ direction to make the distal end bend up. Turn the control knob to ‘D’ direction to make the distal end bend down.

8. Bending section - The section moves the distal end of the endoscope when the UP/DOWN angulation control lever is operated.

9. Insertion tube – It is a flexible airway insertion cord.

10. Distal end - The distal end contains the camera, light source.

Note:
There is no guarantee that instruments selected solely using maximum insertion portion width and working length will be compatible in combination.
Installed in the distal end of endoscope, the image sensor is to acquire images, and convert to electrical signals by the cable transmission to video image processing circuit. The real-time image is displayed in the monitor’s screen. This endoscope does not use the optical fiber bundle.

Chapter 3 Preparation and Inspection

Before each case, prepare and inspect this instrument as instructed below. Inspect other equipment to be used with this instrument as instructed in their respective instruction manuals. If the irregularities are suspected after inspection, follow the instructions given in Chapter 9, “Troubleshooting”. If this instrument still malfunctions, do not use it. Return it to our company for repair as described in Section 9.3, “Returning the endoscope for repair”.

Warning

- Using an endoscope that is not functioning properly may compromise patient or operator safety and may result in more severe equipment damage
- This instrument was not cleaned, disinfected before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in Chapter 5, "Cleaning and disinfection: General policy" to Chapter 7, "Cleaning and disinfection procedure” instructions for Cleaning and disinfection.

3.1 Preparation of the Equipment

Prepare the equipment shown below and personal protective equipment, such as eye wear, face mask, moisture-resistant clothing and chemical-resistant gloves, before each use. Personal protective equipment should be the appropriate size, and long enough to avoid skin exposed. Refer to the respective instruction manuals for each piece of equipment.

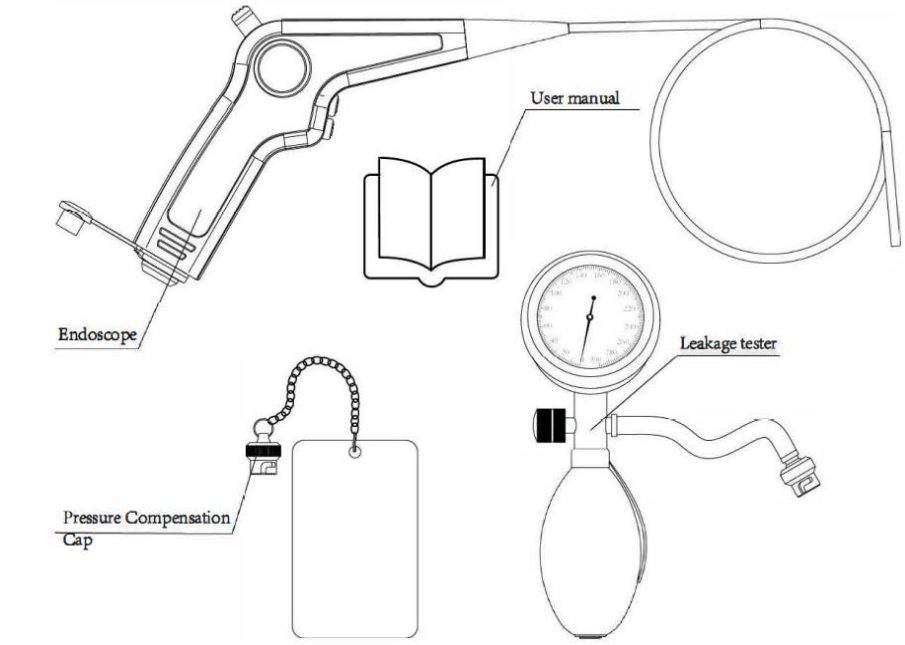


Fig 3.1

3.2 Inspection of Distal End

Warning

- Do not stare directly into the light beam. This may result in eye injury.

1. Connect USB interface of the endoscope to the computer and the endoscope image will appear on the computer monitor.

Caution

- If there is no image on the screen, follow instruction in Chapter 9, "Troubleshooting".

2. Confirm that Examination light is emitted from the distal end of the endoscope. (Fig 3.2)

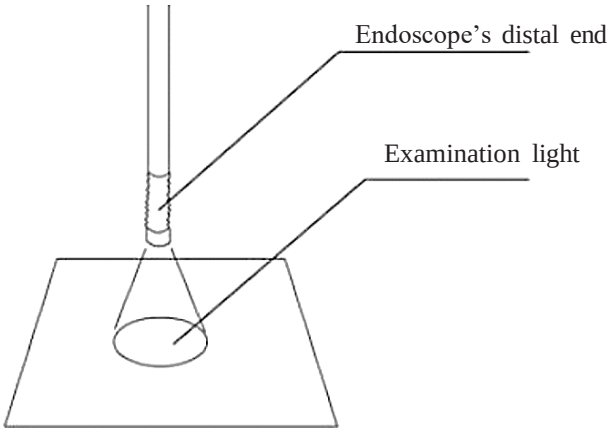


Fig 3.2

3. Point the endoscope's distal end to a suitable object, and move between 1cm and 6 cm away from the object. Confirm that the brightness of the image on the screen remains constant. (Fig 3.3)

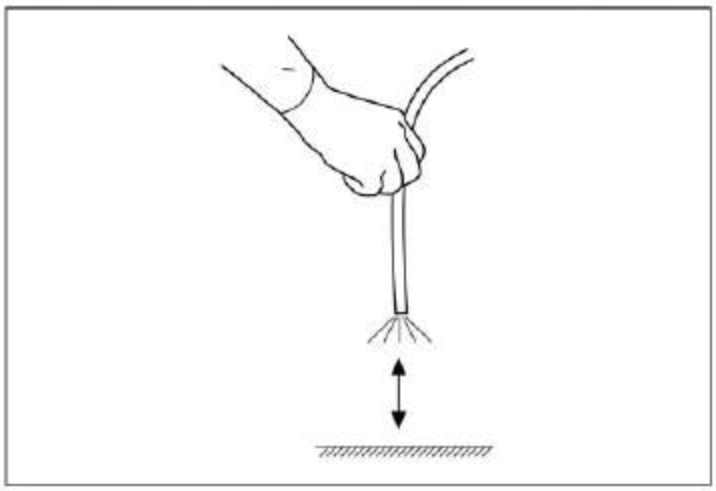


Fig 3.3

4. Point the distal end of endoscope to your palm to observe, confirm that endoscopic image is free from noise, blur, fog or other irregularities such as colour imbalance

Caution

- In case of any device failure or software malfunction, user should turn off the device and remove the device from the patient in a safe manner and try to turn on the device again.
- User must use a back up endoscope for the rest of the procedure if the issue with the software continues and inform PatCom for starting the process of repair.

3.3 Inspection of Endoscope

Clean and disinfect the endoscope as described in Chapter 5 "Cleaning and disinfection: General Policy" to Chapter 7 "Cleaning and disinfection procedure".

1. Inspect the control section for excessive scratching, deformation, loose parts or other irregularities.

2. Inspect the protective boot and the insertion tube near the protective boot for bends, twists or other irregularities.

3. Inspect the external surface of the entire insertion tube including the bending section and the distal end for dents, bulges, swelling, scratching, holes, sagging, transformation, bends, and adhesion of foreign bodies, dropout of parts, any protruding objects or other irregularities.

4. Holding the insertion tube gently with a hand, carefully run the fingertips over the entire length of the insertion tube in both directions (Fig 3.4). Confirm that there is no object stopping the hand or protrusion of metallic wire from the inside on and around the insertion tube and that the insertion tube is not abnormally rigid

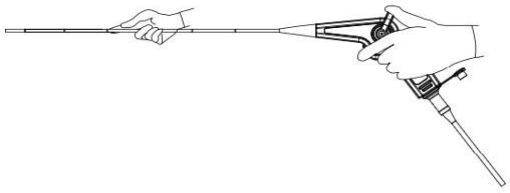


Fig 3.4

5. Inspect the covering of the bending section for sagging, swelling, cutting, holes, or other irregularities.

6. Using both hands, bend the insertion tube of the endoscope into a semicircle. Then, moving your hands as shown by the arrows, confirm that the entire insertion tube can be smoothly bent to form a semicircle and that the insertion tube is pliable enough (Fig 3.5).

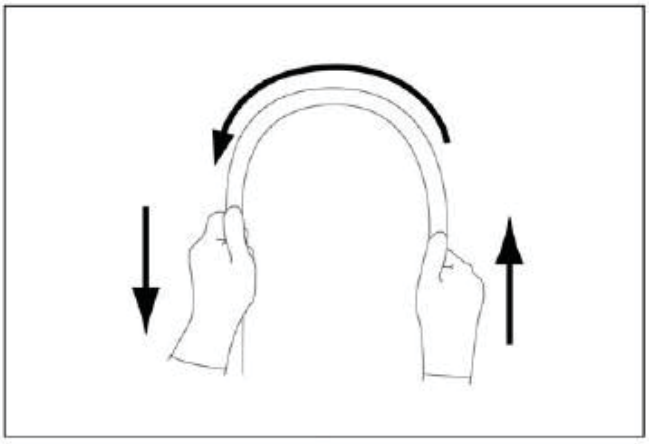


Fig 3.5

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

8. Inspect the distal end of the endoscope's insertion tube for scratching, cracks, stains, and gaps around the lens or other irregularities.

Inspection of the bending mechanisms

Perform the following inspections while the bending section is straight.

Warning

- Gently hold the midpoint of the bending section and a point 10 cm from the distal end. Push and pull gently to confirm that the border between the bending section and the insertion tube is not loose. Inspect the distal end of the endoscope's insertion tube for scratching, cracks, stains, and gaps around the lens or other irregularities.

1. Turn the angulation control knob slowly in each direction until they stop, and return to respective neutral positions. Confirm that the bending section will angulate smoothly and correctly, and confirm that maximum angulation can be achieved and return to respective neutral positions.

2. As shown below in Fig 3.6, turn the UP/DOWN angulation control knob slowly to its neutral position, confirm that the bending section returns smoothly to an approximately straight condition.

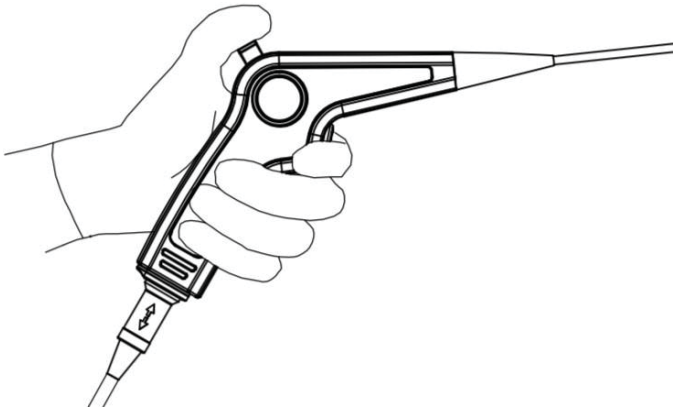


Fig 3.6

Chapter 4 Operation

The operator of this instrument must be a trained healthcare professional and must have received sufficient training in clinical endoscopic technique. This Instructions for Use, therefore, does not explain or discuss clinical endoscopic procedures. It only describes basic operation and precautions related to the operation of this instrument.

Warning

- Surface temperatures over 41°C (106°F) may cause mucosal burns. Always use the minimum time and suitable distance necessarily for adequate viewing. Whenever possible, avoid close stationary viewing and do not leave the distal end of the endoscope close to the mucous membrane for a long time.
- Never insert or withdraw the endoscope under any of the following conditions. Otherwise, the patient injury can result.
  - Insertion or withdrawal while the bending section is in an angle shape.
  - Insertion or withdrawal with an excessive force, or forcible insertion or withdrawal.
- The bending section has up/down angulation only, but has no right/left angulation. Take full account of the bending direction when doing insertion or withdrawal .Do not insert or withdraw with an excessive force to the right/left. Otherwise, the patient injury can result.
- If any of the following phenomena occurs during an examination, immediately stop the examination and withdraw the endoscope from the patient as described in Section 9.2 “Withdrawal of the Endoscope with any Abnormality”.
  - If any abnormality is suspected with the functionality of the endoscope.
  - If the endoscopic image on the computer monitor disappears or freezes unexpectedly.

- If the angulation control mechanisms are not functioning properly. Continuous use of endoscope under the situation stated above may cause the patient injury.

- If an abnormal endoscopic image/function occurs and returns to normal condition by itself, the endoscope may have malfunctioned. Continuous use of such an endoscope may cause repetition of the abnormality, which may not return to normal. In this case, stop the procedure immediately and slowly withdraw the endoscope while viewing the endoscopic image. Otherwise, patient injury can result.

4.1 Connect the equipment with the Computer

1. Connect USB interface of the endoscope to the computer. Please consider the following minimum specifications:
   - CPU: Intel ® Core™ i5-10300H CPU @ 2.50 GHz or equivalent/better
   - Memory: 8GB RAM or equivalent/better
   - GPU: Intel ® UHD Graphics 630 or equivalent/better
   - OS: Windows 10 or later
   - Display Resolution: 1920x1080 or higher
   - Display brightness: 220 nits or equivalent/better
   - A display color calibration prior to initial use with the PatCom Distal Chip Endoscope is recommended.

   On a Windows computer navigate to Control Panel → Color Management → Select the "Advanced" tab → click on "Calibrate Display" → Follow the prompts of the calibration wizzard. The calibration may be repeated at a later time if accuracy of colors seems incorrect.
   For more details refer to Appendix B: Color Calibration User Instructions

2. Real time endoscopic image will show on the computer monitor, and the illumination light is emitted from the distal end of the endoscope. (Fig 4.1)

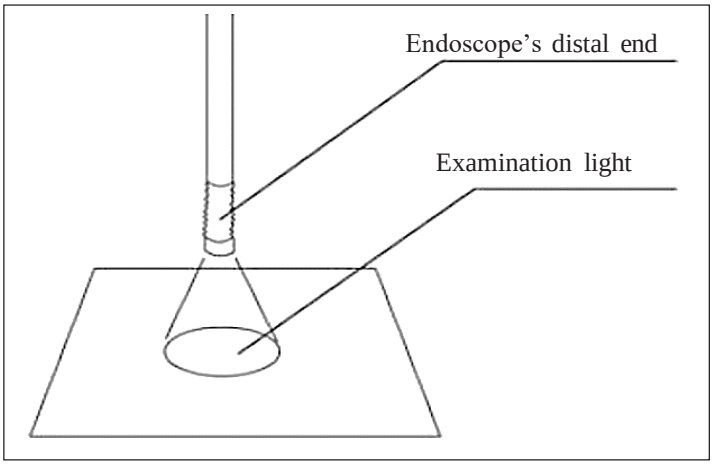


Fig4.1

4.2 Insertion

Holding and manipulating the endoscope

The control section (handle) of the endoscope has a symmetrical pistol shaped design and can be held comfortably in either the right hand or the left hand. The UP/DOWN angulation control knob can be operated using the thumb. The other hand is free to hold the insertion tube. (Fig. 4.2)

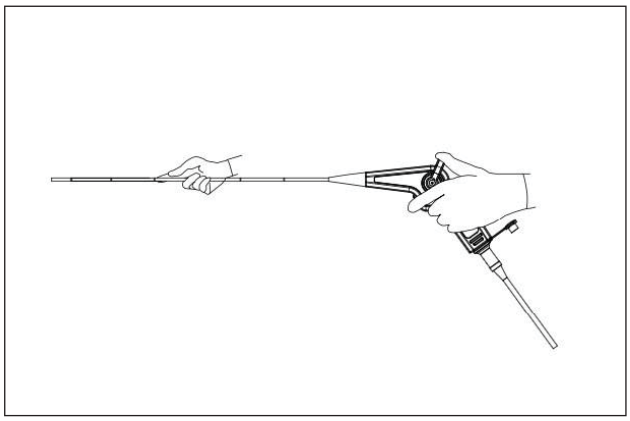


Fig 4.2

Insertion of the endoscope

Caution

- To prevent the patient from accidentally biting the insertion tube during an examination, if necessary, it is recommended to place a guide blade or oral pad in the patient's mouth before inserting the endoscope.
- Do not apply olive oil or products containing petroleum-based lubricants (e.g. Vaseline). These products may cause stretching and deterioration of the bending section's covering.
- Do not allow the insertion tube to be bent within a distance of 10 cm or less from the junction of the protective boot. Insertion tube damage can occur (Fig 4.3).

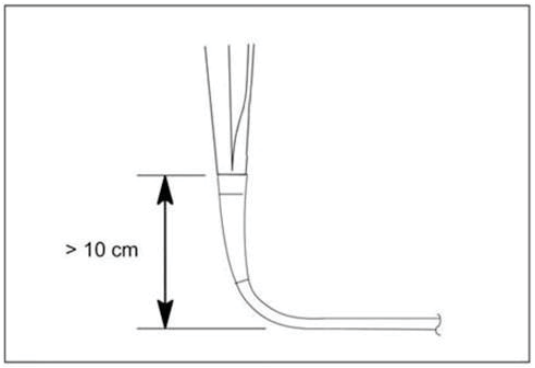


Fig 4.3

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

2. Place the guide blade or oral pad between the patient's teeth, with the outer flange on the outside of the patient's mouth.

3. Always view the endoscopic image when passing the distal end of the endoscope from the mouth or nose to the pharynx.

Angulation of the distal end

Caution

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

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

Observation of the endoscopic image

Warning

- Check before the endoscopic procedures confirming it is a live image instead of recorded image.
- Please confirm orientation of the image before use to prevent unexpected image orientation during operation.

Keep eyes on endoscopic image all the time when operating the angulation control knob.

4.3 Withdrawal of the Endoscope

Warning

- If blood unexpectedly adheres to the surface of the insertion tube of the withdrawn endoscope, check the conditions of the patient carefully.
- If the endoscope cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Forcibly withdrawing the endoscope may cause patient injury.

1. Carefully withdraw the endoscope while observing the endoscopic image.
2. Unplug the endoscope

Chapter 5 Cleaning and Disinfection: General Policy

5.1 Key Points of Cleaning and disinfection

The medical literature reports incidents of patient cross contamination resulting from improper cleaning, disinfection. It is strongly recommended that all individuals responsible for cleaning, disinfection should thoroughly understand and follow the instructions in this Instructions for Use and all manual instructions for auxiliary equipment.

－Occupational health and safety regulations in local hospital

－Cleaning, disinfecting procedures for each individual equipment

－The structure and operation method of endoscopic equipment

Please make judgments from a professional point of view on the type and conditions of methods of Cleaning and disinfection.

For appropriate reprocessing methods, refer to the recommendations of your infection control committee and national and local hospital guidelines and policies.

5.2 Precaution

Warning

- Failures to properly clean and high-level disinfect endoscopic equipment after each examination can compromise patient safety. To minimize the risk of transmitting diseases from one patient to another, the endoscope must undergo thorough manual cleaning followed by high-level disinfection according to Chapter 7 “Cleaning and disinfection Procedures” after each examination.
- If the endoscope is not cleaned meticulously, effective disinfection may not be possible. Clean the endoscope and accessories thoroughly before disinfection to remove microorganisms or organic material that could reduce the efficacy of disinfection.
- Incorrect cleaning and disinfection of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope.
- The Instructions for Use specifies fitting/usable and unfitting/unusable detergent, disinfectant and other chemical agent and washer/ disinfector for the endoscope. As for the detergent, disinfectant, and other chemical agent and washer/disinfector that are not shown in this Instructions for Use, please contact our company, service center qualified by our company or Sales Representatives of our company. Improper use of chemical agent or washer/disinfector may cause deterioration of endoscope, parts of the endoscope fall off and cause danger to patient’s health. Please refer to the respective operation manual for the detailed operation

when using these chemical agent and washer/disinfector. Our company cannot guarantee the cleaning, disinfecting effect of these chemical agent or washer/disinfector. Please confirm with their manufacturers.

- Patient debris and reprocessing chemicals are hazardous. Wear personal protective equipment to guard against dangerous chemicals and potentially infectious material. During cleaning and disinfection. Wear appropriate protective equipment, such as eye wear, face mask, moisture-resistant clothing and chemical- resistant gloves that fit properly and are long enough so that your skin is not exposed.
- Thoroughly rinse off the disinfectant solution. Rinse the outer surface of the endoscope and cleaning equipment thoroughly with potable water to remove the disinfectant solution residue.
- Be sure to perform the water leakage test before the manual cleaning. If a leak is tested, stop using the endoscope. Just before each procedure, check if the endoscope needs Cleaning and disinfection. If necessary, clean and disinfect it by following the instructions given in this Instructions for Use.
- With the Cleaning and disinfection methods stated in this Instructions for Use, prions, which are considered to be the pathogenic substance of the Creutzfeldt-Jakob disease (CJD) cannot be destroyed or inactivated. When using this instrument on a patient with CJD or variant Creutzfeldt-Jakob disease (vCJD), be sure to use this product for such patient only and/or immediately dispose of this product after use in an appropriate manner. For methods to handle CJD, please follow the respective guidelines in your country.

Chapter 6 Compatible Reprocessing Methods and Chemical Agents

6.1 Compatibility Summary

Certain materials and structure of our endoscope may not compatible with some cleaning, disinfection methods.

To justify whether the method is effective, the following were considered:

— Microbiological effectiveness

— Material durability

Microbiological effectiveness

Mui Scientific only validated the method with chemical disinfectants that was described in this Instructions for Use. Mui Scientific cannot guaranty the microbial effectiveness from other validation methods or Chemical disinfectants that are not included on this Instructions for Use unless they have a validation record from a certified third party lab.

Material durability

If the method has been declared to get the "confirmation" of material durability, it explains that this method can be used to repeat the Cleaning and disinfection. Only the material durability certification does not indicate the level of microbiological effectiveness is confirmed.

Cleaning and disinfection methods

Refer to section 7.2 for the Cleaning and Disinfection Procedures.

Choose appropriate Cleaning and disinfection methods in compliance with the recommendations of your infection control committee and all national and local hospital guidelines and policies.

Please contact the local infection control institutions to determine suitable cleaning methods specified by the institutions.

Monitoring

In accordance with national and local regulations or requirements, inspect and confirm Cleaning and disinfection methods for reusable instruments, record the regular interval and cleaning and disinfection results.

Although there are no biological indicators available to confirm the disinfection process, you can use test strips to monitor the concentration of disinfectant. Monitor the concentration for daily use to ensure that the solution will not be lower than the effective concentration.

Compatible methods and chemical agents list

Cleaning and disinfection methods and chemical agents listed below have been tested on endoscope:

- 0,1 % Prolystica 2X concentrate enzymatic presoak and cleaner, Steris
- Revital-Ox™ Resert® High Level Disinfectant (US/Australia/New Zealand/Europe/ Middle East) (8-min cycle)
- Revital-Ox™ Resert® High Level Disinfectant - Chemosterilant (Canadian use only) (5-min cycle)
- Resert XL HLD High Level Disinfectant (Rest of World-Latin America/Asia Pacific) (8-min cycle)

* These products may not be available in certain areas. Recommended soak times for chemicals can vary from country to country. Follow the chemical manufacturer's instructions for use valid for your country.

* Only duct and connector of the leakage tester can be immersed.

Further validated reprocessing methods are listed in Appendix C of this Instructions for Use.

Warning

- Do not perform steam sterilization (high temperature and autoclave sterilization) on the endoscope. Otherwise, it may be damaged.

6.2 Detergent Solution

Use a medical-grade, low-foaming, neutral pH detergent or enzymatic detergent and follow the

manufacturer's dilution and temperature recommendations.

Warning

- The detergent solution must comply with national and local regulations or requirements and has been certified. Inadequate cleaning agents will bring the risk of infection.
- Do not reuse detergent solutions.

Caution

- The detergent solution must be confirmed by our company for compatibility with the endoscope and certified by an authority organization in your country. Incompatible detergent solution may pose great damage to the endoscope and accessories.

6.3 Disinfection Solution

In general, disinfection solutions mentioned in 6.1 are compatible with the endoscope when used according to the manufacturer's instructions. If the disinfectant solution is reused, routinely check its efficacy with a test strip recommended by the manufacturer. Do not use solutions beyond their expiration date.

Warning

- Do not use endoscopes only disinfected by alcohol.
- Only use approved disinfectant solutions.

Caution

- Refer to the manufacturer's instructions for the concentration, temperature and immersion time. Do not exceed the level specified by the manufacturer.

Warning

- Do not reuse rinsing water.

Chapter 7 Cleaning and Disinfection Procedures

Caution

- The endoscope MUST be cleaned and high-level disinfected during EVERY reprocessing cycle. Otherwise, insufficient cleaning and disinfection of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope.
- Do not coil the endoscope's insertion tube with a diameter of less than 12 cm. The endoscope can be damaged if coiled too tightly.
- Before the endoscope immersed in detergent or disinfectant, confirm the pressure compensation cap is removed from the endoscope. Otherwise, the water will seep inside endoscope, causing damage.

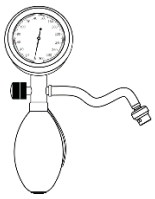
This chapter includes patient safety and health-related cleaning and disinfection procedures to endoscopic equipment. About the cleaning and disinfection equipment maintenance procedures, please refer to Section 7.10, "Maintenance procedures for Cleaning and disinfection equipment"

7.1 Required Cleaning and Disinfection Equipment

Preparation of the equipment

Prior to cleaning and disinfection, prepare the equipment shown in Table 7.1.

Table 7.1

Items		Pictures
Leakage tester		
Sealing plug		
Personal protective equipment		
75% ethyl or isopropyl alcohol		
Potable Water/Tap water/flowing water (20 ± 2°C) (minimum drinking water quality)		
Sterile lint-free cloths		
Cleaning	Detergent: enzymatic detergent (e.g. 0,1 % Prolystica 2X concentrate enzymatic presoak and cleaner, Steris or other compatible products)	
	Lint-free wipes e.g. Braun Wipes Eco #19726 or equivalent	
	Three tanks/ basins (40cm x 40cm x 5cm or bigger)	
High-Level Disinfection	Disinfectant Solution- Revital-Ox Resert High Level Disinfectant For High Level Disinfection	
	Revital-Ox Resert R60 Solution Test Strip For High Level Disinfection	
	A basin with seal cover, approximately 40 cm × 40 cm (16” × 16”) in size and deep enough to completely immerse the entire endoscope, made from polypropylene, acrylonitrilebutandienestyrene(ABS), polyethylene, polycarbonate plastics, 304 stainless steel or 316 stainless steel. For High Level Disinfection	

Cleaning and Disinfection Equipment Parts and Functions

For inspection of other equipment than that mentioned below, refer to the instruction manual for the equipment being used.

Leakage tester

Attach leak test pressure connector to the gas valve on the control handle and press the gasbag of the leakage tester to test if there is any leakage of the endoscope (Fig 7.1).

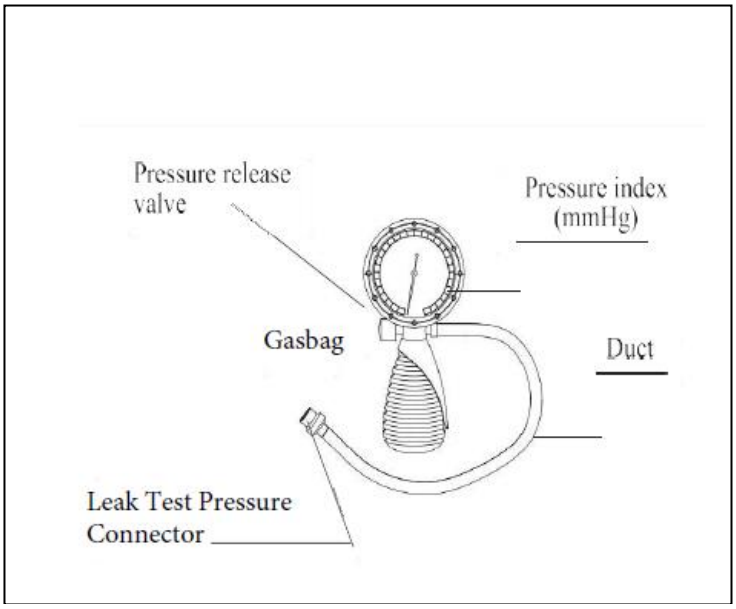


Fig 7.1

Inspection of the reusable equipment

For inspection of other equipment than that mentioned below, refer to the instruction manual for the equipment being used.

Warning

- All equipment mentioned below is consumable items. Whenever the slightest irregularity is suspected, use a spare instead. Using defective equipment may make it difficult to effectively reprocess the endoscope, and cause endoscope and/or equipment damage.

Inspection of the leakage tester

1. Confirm that the leakage tester is free from cracks, scratches, flaws, debris and/or other damage. (See Fig 7.2)
2. Press the gasbag, confirmed that the leakage tester exhausts the air from the connector (see Fig 7.2).

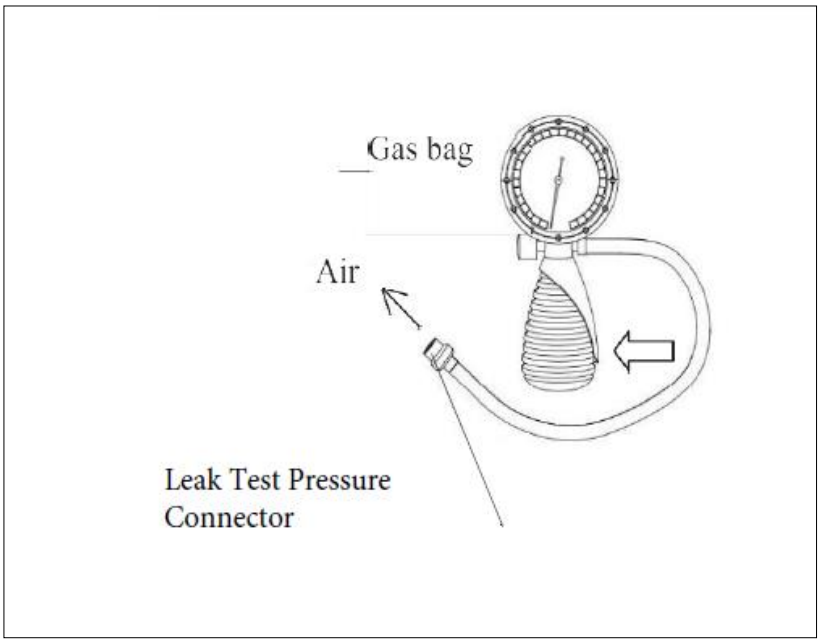


Fig 7.2 Leakage tester

7.2 Cleaning and Disinfection Procedures

After the procedure, clean and disinfect the endoscope according to the procedure described below.

Endoscope reprocessing summary chart

Endoscope extraction from patient
↓
Point of Use Cleaning (Section 7.3)
↓
Leakage Test (Section 7.5)
↓
Cleaning (Section 7.6)
↓
High Level Disinfection (Section 7.7) (alternate methods listed in Appendix C)
↓
Rinsing and Drying after High Level Disinfection (Section 7.8), (if required; dependent on method used)

↓
Storage, Transport and Disposal (Section 8)

Fig 7.3

Warning

- The endoscope MUST be cleaned and high-level disinfected during EVERY reprocessing cycle. Otherwise, insufficient cleaning and disinfection of the endoscope may pose an infection control risk to the patient and/or operators performing the next procedure with the endoscope.
- Do not skip any of the steps described below. Otherwise, it may lead to infection.
- If you want to use storage devices, refer to local regulations and guidelines.

7.3 Point of Use Cleaning

Warning

- If the endoscope is not immediately cleaned after each procedure, residual organic debris will begin to solidify, and it may be difficult to effectively clean and disinfect the endoscope.

Pre-clean the endoscope at the bedside in the procedure room immediately after the procedure.

Equipment needed

Prepare the following equipment

- personal protective equipment
- clean, lint-free cloths
- tap water (drinking quality)

Instructions

1. Wear personal protective equipment.
2. Turn off the device and detach the cable.
3. Wipe the entire insertion tube at least one time with a lint- free wipe (single use) moistened with cold water (minimum drinking quality). The wipe should be conducted from the top of the protective sleeve to the distal end.
4. Put on the disinfection cap on electrical connector of the endoscope.

7.4 Transportation of the Endoscope

Warning

- Do not spill out debris or pre-cleaning liquid during transportation.

Transporting within the hospital

1. When carrying the endoscope by hand, hold the control section in one hand and hold the distal end of the insertion tube securely, but gently without squeezing, in the other hand (see Fig 7.4).

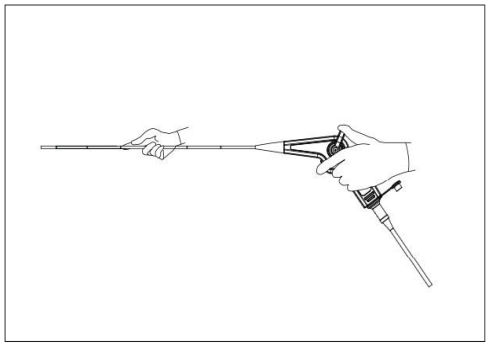


Fig 7.4

2. Transport the endoscope and reusable components from the site of use to the cleaning and disinfection area.
3. It is recommended to transport the contaminated instruments in a closed container.
4. Use of PatCom Scope Mate is strongly recommended to avoid coiling and any possible damage as well as to prevent cross contamination while transporting the endoscope to the cleaning and disinfection site. (see Fig 7.5)

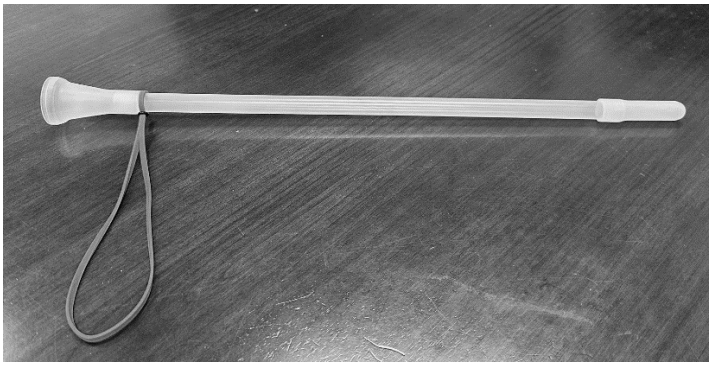


Fig 7.5

Caution

- The equipment should be cleaned and disinfected immediately after use. Do not let the instruments without cleaning, disinfection overnight. If you keep the instrument for a long time without cleaning and disinfection processing, debris will become hard and difficult to remove.
- Do not hit the distal end of endoscope during transport. Otherwise, it will damage the distal end.
- Do not only hold the endoscope insertion section to take up the whole endoscope. Otherwise, it will damage the endoscope.

7.5 Leakage Testing

After pre-cleaning, perform leakage testing on the endoscope to ensure that it is waterproof.

Equipment needed

Please prepare the following equipment:

- personal protective equipment
- basin, 40 cm × 40 cm (16” × 16”) minimum size and deep enough to immerse the endoscope completely
- potable water
- leakage tester

Caution

- Attach the Leak test pressure connector to the endoscope before immersion. Otherwise it could allow water to enter the endoscope and may damage the endoscope.
- Attach the Leak test pressure connector to the endoscope and make sure it is in place. If it is not fully and properly attached, the endoscope's interior will not be pressurized. Leakage Test will fail.
- During leakage testing, a continuous series of bubbles emerging from a location on the endoscope indicates a leak at that location. This means that water will be able to penetrate the endoscope. If you locate a leak, remove the endoscope from the water and contact our company.
- When connecting the Leak test pressure connector, make sure that the inside of the Leak test pressure connector and the outside of pressure valve are thoroughly wipe and dry. Water remaining on either component may penetrate the inside and could cause endoscope malfunction.

Note

- With the leak tester attached, the covering of the bending section will expand as the air pressure inside the endoscope increases. This is normal.

Leakage Testing

Caution

- Always keep the leakage tester dry. Any water remaining on the leakage tester may cause damage to the endoscope.
- Open the pressure release valve before taking the leak test pressure connector off the Leakage Tester. Discharge air in the endoscope until the indicator on the screen points to 0 MMHG. Otherwise, it may lead to endoscope damage.
- Only the leak test pressure connector can be immersed. (as shown in Fig7.6). Immersion of other components of the leakage tester may lead to its damage.
- The pressure shall not exceed 200 mmHg. If the pressure increases too much, it might damage the endoscope. Press the pressure release valve to discharge the air (as shown in Fig 7.6).

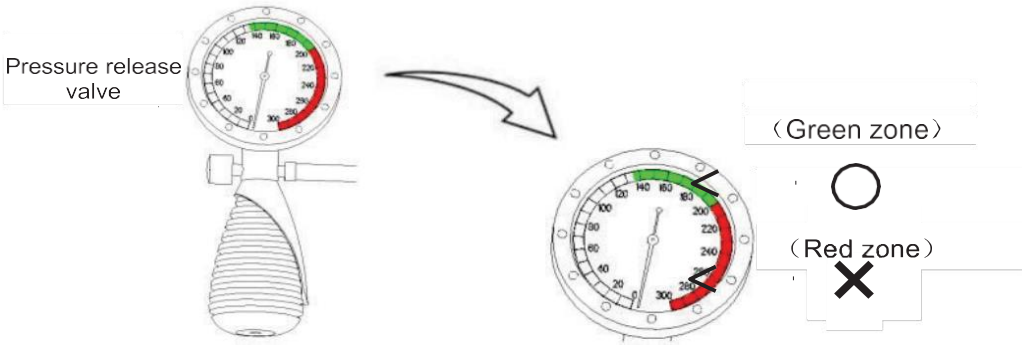


Fig 7.6

The leakage test described below is a wet leakage test, meaning it is performed under water. A dry leakage test may also be performed. For a dry leakage test skip steps 2, 6, 7 and 8.

1. Wear appropriate personal protective equipment.

2. Fill a basin with potable water. The basin is at least 40 cm × 40 cm (16” × 16”) in size and deep enough to completely immerse the entire endoscope.

3. Attach the leak test pressure connector to the pressure valve of the endoscope, and make sure it is in place (as shown in Fig 7.7).

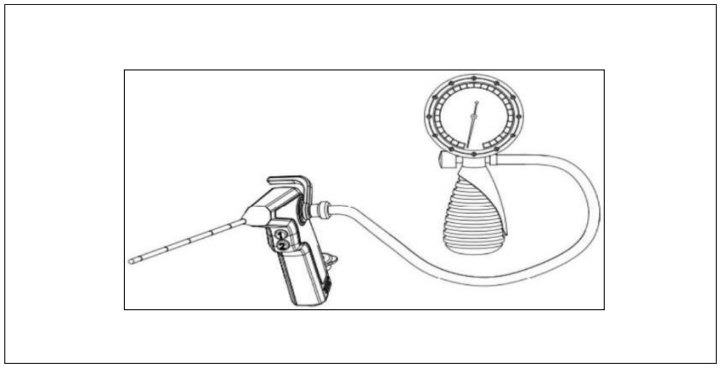


Fig 7.7

4. Confirm the pressure release valve is closed.

5. Press gasbag of leakage tester till the pressure is between 140-200mmHg in the green zone. Read the pressure data while the indicator is stable for a few seconds.

Caution

- If the indicator continues to decrease to 0 mmHg, it indicates there is a potential serious leakage, or damage on leakage tester. Stop leak test immediately. If the endoscope is still soaked in water, the absence of pressure within the endoscope will cause water to enter the inside of the endoscope. This can damage the endoscope severely.

- During leakage testing, a continuous series of bubbles emerging from the leak test pressure connector indicates damage of the leak tester or pressure valve. Please replace the leak test pressure connector or contact our company for repair.

6. Confirm that the indicator is stable. With the leakage tester connected, immerse the entire endoscope into water and angulate the bending section to observe if there are bubbles coming out continuously, and then observe the operation part and other connected parts to see if bubbles occur. Observe for about 50 seconds to confirm that there is no location on the endoscope from which a continuous series of bubbles emerge.

7. Remove the endoscope from the basin with the leakage tester attached.

8. Loosen the pressure release valve on the left side of the air bag anticlockwise, to release the internal pressure of the endoscope. Detach the leak test pressure connector from the endoscope.

9. Thoroughly dry the leakage tester.

7.6 Cleaning

Warning

- If the endoscope is not cleaned meticulously, effective disinfection may not be possible. Clean the endoscope and accessories thoroughly before disinfection to remove microorganisms or organic material that could reduce the efficacy of disinfection. If the endoscope is not immediately cleaned after each procedure, residual organic debris will begin to solidify, and it may be difficult to effectively clean and disinfect the endoscope.

Caution

- In order to avoid damage, do not wash the endoscope with too much force.
- Attach the Sealing Plug to the endoscope.

After completing the leakage test, perform cleaning according to the procedures described below.

Manual Pre-Cleaning:

Equipment needed

Please prepare the following equipment:

- Detergent: enzymatic detergent (e.g. 0,1 % Prolystica 2X concentrate enzymatic presoak and cleaner, Steris or other compatible products)
- Potable Water/Tap water/flowing water (20 ± 2°C) (minimum drinking water quality),
- Lint-free wipes e.g. Braun Wipes Eco #19726 or equivalent
- three tanks/ basins (40cm x 40cm x 5cm or bigger)

Instructions

1. Attach the sealing plug to the endoscope.
2. Prepare the detergent solution in accordance with the detergent manufacturer's instructions for use. For example, dilute 0.1% Prolystica 2x concentrate 1 to 4 ml per liter of warm water in one tank/basin.
3. Fill one tank/basin with potable water and rinse the endoscope completely under water for a minimum of 1 minute and wipe the outer surfaces with a lint free wipe (single use) while the endoscope is submerged.
4. Place the endoscope completely in the tank/basin filled with detergent for the duration specified in the detergent manufacturer's instructions for use. For example, fully submerge the endoscope in a tank/basin with 0.1% Prolystica 2X concentrate and wipe the outer surfaces with a lint free wipe (single use) while the endoscope is submerged.
5. Make sure that all surfaces are completely covered with cleaning solution.
6. Remove the endoscope from the cleaning solution.
7. Fill one tank/basin with potable water and rinse the endoscope completely under water for a minimum of 1 minute and wipe the outer surfaces with a lint free wipe (single use) while the endoscope is submerged.
8. Perform a visual inspection on cleanliness, if residue is visible, repeat the cleaning steps above.
9. Tap dry the endoscope with a lint free wipe or cloth.

7.7 High-level Disinfection

Caution

- If possible, all disinfection steps should be performed with the endoscope and all equipment completely immersed in disinfectant solution. If the equipment is connected to the endoscope while immersed or any part of them is not immersed completely, disinfectant solution may not adequately contact all surfaces of the equipment. As a result, the effectiveness of disinfection may be reduced.

Note

- Refer to "Disinfectant solution" in Section 6.3 for details of disinfectant solution.

After cleaning, disinfect the endoscope according to the procedures described below (alternate methods listed in Appendix C).

Equipment needed

Please prepare the following equipment:

- Personal protective equipment
- A Basin with seal cover, approximately 40 cm × 40 cm (16" × 16") in size and deep enough to completely immerse the entire endoscope, made from polypropylene, acrylonitrilebutandienestyrene(ABS), polyethylene, polycarbonate plastics, 304 stainless steelor 316 stainless steel.
- Disinfectant Solution- Revital-Ox Resert High Level Disinfectant (or other approved disinfectant)
- Revital-Ox Resert R60 Test Solution Test Strips.
- Potable Water
- Clean, lint-free cloths
- Timer
- Environmentally Controlled Room

Preparation

1. Wear appropriate personal protective equipment and in an environmentally controlled room.
2. Ensure the endoscope is thoroughly cleaned using detergent such as Prolystica 2x Enzymatic Cleaner, rinsed and dried prior to disinfection.
3. No activation or dilution is required for Revital-Ox Resert High Level Disinfectant. Ensure the disinfectant is within the expiration date. After opening, the solution remaining in the original container may be stored for up to 90 days, not extending past the expiration date. Always store remaining solution in its original, closed container.
4. Fill a basin with Revital-Ox Resert High Level Disinfectant solution and ensure the temperature is above 20.0°C. The basin with seal cover should be approximately 40 cm × 40 cm (16" × 16") in size and deep enough to completely immerse the entire endoscope.
5. Confirm the concentration of hydrogen peroxide in disinfectant prior to the start of testing to be above the Minimal Recommended Concentration (MRC) of 1.5% using Revital-Ox Resert R60 Test Solution Test Strips.

Test Disinfectant using Revital-Ox Resert R60 Test Solution Test Strips

1. Ensure the Revital-Ox Resert R60 Test strips are stored in temperature of 6-300C (43-860F) and is within the expiration date or 180 days after opening the bottle whichever comes first.
2. Ensure the test strip is at room temperature before testing.
3. Ensure that the high-level disinfectant solution is above 20C (68F). The test strip may not perform properly in solution temperature below 20C.
4. Take one test strip holding it in a way such that the front side having the viewing 'window' for the indicator pad is facing you, directed by the text on the handle.
5. Dip the indicator pad at the end of the strip into the disinfectant for two seconds and remove. Do not leave in disinfectant for longer than two seconds or stir the strip in solution.
6. Remove excess solution by touching the short edge of the indicator pad with a paper towel and start a 60 second timer. Do not shake the strip.
7. Read the colour developed on the indicator pad in the viewing window at 60 seconds. The yellow pad will become blue/purple.
8. A complete uniform blue/purple indicates it is above the Minimal Recommended Concentration (MRC) of 1.5%. If the pad turns pink or not completely blue/purple, it is at or below the Minimal Recommended Concentration (MRC) of 1.5% and should be discarded.
9. Revital-Ox Resert R60 Test strips is to be used exclusively with Revital-Ox Resert High Level Disinfectant, Revital-Ox Resert High Level Disinfectant -Chemosterilant and Resert XL HLD High Level Disinfectant.
10. Discard used or expired strips in accordance with national, federal, state and local laws.

Instructions

Warning

a. If possible, all disinfection steps should be performed with the endoscope and all equipment completely immersed. If the equipment is not immersed, disinfectant solution may not

adequately contact all surfaces of the equipment. As a result, the effectiveness of disinfection may be reduced.

1. Confirm that the disinfectant solution meets the concentration requirement, for example confirm the Minimal Recommended Concentration (MRC) 1.5% of hydrogen peroxide using the Revital-Ox Resert R60 Test strips. If test results show the concentration is not acceptable, do not use the solution and discard.
2. Immerse the endoscope completely into a basin of high level disinfectant for the duration recommended by the disinfectant manufacturer's instructions for use, for example submerge the endoscope in Revital-Ox Resert high level disinfectant solution and set a timer for eight minutes or the time validated relevant to the specific disinfectant at is used.
3. Immerse the endoscope and ensure full exposure of the immersed surfaces to the chemistry and that no air bubbles are present on the surface.
4. Cover the basin with a sealing cover to minimize evaporation of disinfectant, prevent spillage and extraneous contamination.
5. Upon completion of standard cycle (e.g. 8 minutes for Revital OX Resert) or the time validated relevant to the specific disinfectant at use, remove the endoscope from disinfectant solution.
6. The disinfectant solution in the basin can be reused. The life time of the disinfectant inside a secondary container is defined by the disinfectant manufacturer's instructions for use. For example, Revital Ox Resert can be used for a period up to 21 days inside a secondary container. The solution must be discarded after 21 days or sooner confirmed by testing with Revital-Ox Resert R60 Test strips. The expiration date cannot be extended due to a test strip indicating a passing result.

7.8 Rinsing and Drying after High-level Disinfection

Warning

- Thoroughly rinse and dry the endoscope after Cleaning and disinfection. Otherwise, bacteria developing may pose an infection risk to the patient and/or operators performing the next procedure with the endoscope.
- Rinse the external surface of the endoscope to remove the residual detergent solution. Otherwise, the residual detergent solution may cause mucosal inflammation.

Caution

- In order to remove all residues, use deionized water if available, washing equipment thoroughly. Use potable water if deionized water is not available. Note that potable water might be less effective removing disinfectant.
- Alcohol is flammable. Handle it with care.

After high-level disinfection, rinse and dry the endoscope and all equipment according to the procedures described below (if required, dependent on disinfection method used).

Equipment needed

Please prepare the following equipment:

- personal protective equipment
- Basins, 40 cm × 40 cm (16" × 16") minimum size and deep enough to immerse the endoscope completely

- Deionized water if available, potable water
- Lint-free wipes

Instructions

1. Wear appropriate personal protective equipment.
2. Fill a basin with potable water. The basin is at least 40 cm × 40 cm (16” × 16”) in size and deep enough to completely immerse the entire endoscope.
3. Immerse the endoscope completely in potable water for a minimum of one minute soak.
4. Following the one minute soak, perform simulated cleaning consisting of wiping of the surfaces.
5. Immerse in fresh potable water without a cleaning agent for a five minute soak.
6. Perform simulated cleaning and immerse in deionized water for an additional one minute rinse.
7. Remove the endoscope and let it air dry.

7.9 Maintenance Procedures for Cleaning and Disinfection Equipment

The following Cleaning and disinfection equipment should be cleaned and disinfected separately from endoscope.

Caution

- leakage tester
- For the applicable Cleaning and disinfection methods, refer to Section 6.1 "Compatibility Summary".

Maintenance of leakage tester

Caution

- Only the tube and connectors of the leakage tester are immersible. Immersion of other parts of the leakage tester may cause damage.

1. Wipe the surface of the leakage tester with a clean lint-free cloth soaked with detergent solution.
2. Wipe the detergent solution on the surface of leakage tester with a clean lint-free cloth soaked with potable water.
3. Clean and disinfect the tube and connectors of the leakage tester.
4. Thoroughly dry leakage tester.

Chapter 8 Storage and Disposal

Keep the clean endoscope and accessories after cleaning and disinfection away from the contaminated equipment. If the clean endoscope and accessories are contaminated, their use may pose an infection control

Caution

risk to the patient and/or operators performing the next procedure with the endoscope.

- To prevent contamination of clean endoscopes and accessories, be sure to keep the storage cabinet also clean.
- The storage cabinet must be clean, dry, well ventilated and maintained at ambient temperature. Do not store the endoscope in direct sunlight, at high temperature, in high humidity or exposed to X-rays and ultraviolet-rays. Otherwise, it may damage the endoscope or present an infection control risk.
- Do not store the endoscope in the carrying case. Use the carrying case only for shipping the endoscope. Routinely storing the endoscope in a humid, non-ventilated environment such as the carrying case may present an infection control risk.

8.1 Storage of the Endoscope

1. Detach all equipment (**pressure compensation cap**).
2. Confirm that the outer surfaces of the endoscope (especially distal end, lens and electrical contacts) are dry.
3. Carefully wipe the objective lens of the distal end with lint free cloth moistened with 70% alcohol.
4. Hang the endoscope in the storage cabinet with the distal end hanging freely or lay the endoscope flat. Make sure that the insertion tube hangs vertically or lies flat and as straight as possible.
5. Store the endoscope in a clean and dry place at room temperature (10-40 ° C, humidity of 30-85%).

8.2 Storage of Reusable Parts, Reprocessing Equipment and Leakage Tester

1. Confirm that all the reusable parts and reprocessing equipment are thoroughly dry.
2. Store all reusable parts loosely in the storage cabinet.
3. Store all reprocessing equipment in a container, then store the container in the storage cabinet.

8.3 Transporting Outside the Hospital

Transport the endoscope in the carrying case.

Warning

- Always clean and disinfect the endoscope after removing it from the carrying case. If the endoscope is not cleaned, disinfected, the patient might be infected.

Caution

- The carrying case cannot be cleaned, disinfected. Clean and disinfect the endoscope before placing it in the carrying case.
- Attach the Sealing Plug when transporting the endoscope, to avoid damage to the endoscope caused by changes in air pressure.

8.4 Disposal

When disposing of the endoscope, or any of its components (such as cleaning brush), follow all applicable national and local laws and guidelines.

Chapter 9 Troubleshooting

If the endoscope is visibly damaged, does not function as expected or is found to have irregularities during the inspection described in Chapter 3, “Preparation and Inspection”, do not use the endoscope. Contact our company.

Some problems that appear to have irregularities may be correctable by referring to Section 9.1, “Troubleshooting guide”. If the problem cannot be resolved by the described remedial action, stop using the endoscope and send it to us for repair.

Our company does not repair accessory parts. If an accessory part becomes damaged, contact us to purchase a new one.

Warning

- Never use the endoscope on a patient if an abnormality is suspected. Damage or irregularity in the instrument may compromise patient or user safety and may result in more severe equipment damage.
- If any parts of the endoscope fall off inside the patient body due to equipment damage or failure, stop using the endoscope immediately and retrieve the parts in an appropriate way.

If any abnormality in the function of the endoscope and/or endoscopic image is suspected during use, stop the examination immediately and carefully withdraw the endoscope from the patient as described in Section 9.2,

"Withdrawal of the Endoscope with any Abnormality".

9.1 Troubleshooting Guide

The following Fig shows the possible causes of and countermeasures against troubles that may occur due to equipment setting errors or deterioration of consumables.

Troubles or failures due to other causes than those listed below should be serviced. As repair performed by persons who are not qualified by our company could cause patient or user injury and/or equipment damage, be sure to contact us for repair according to Section 9.3, "Returning the endoscope for repair".

Image quality

Irregularity description	Possible cause	Solution
There is no video image.	Poor connection between endoscope and the computer.	Reconnect the endoscope and computer.
An image is not clear.	The objective lens is dirty.	Wipe with lint free cloth moistened with 70% ethyl or isopropyl alcohol; If the image cannot be observed, return the endoscope to our company for repair.

Form 9.1

9.2 Withdrawal of the Endoscope with Any Abnormality

If an abnormality occurs while the endoscope is in use, take a proper measure as described in either "When the endoscopic image appears on the monitor" or "When the endoscopic image does not appear on the monitor or the frozen image cannot be restored" below. After withdrawal, return the endoscope for repair as described in Section 9.3, "Returning the endoscope for repair".

Warning

- If the endoscope cannot be withdrawn from the patient smoothly, do not attempt to forcibly

withdraw it. If any irregularities are suspected, immediately contact us. Forcibly withdrawing the endoscope may cause patient injury.

When the endoscopic image appears on the computer monitor

1. Turn OFF all equipment except the computer monitor.
2. Carefully withdraw the endoscope while observing the endoscopic image.

When the endoscopic image does not appear on the monitor or the frozen image cannot be restored

1. Turn OFF all equipment except the computer monitor.
2. Turn the computer OFF and then ON again. If the endoscopic image appears or the frozen image is restored, follow the procedure of step 2 and steps below in "When the endoscopic image appears on the monitor". When the endoscopic image still does not appear or the frozen image cannot be restored, perform the following steps.
3. Turn OFF the computer.
4. Turn the UP/DOWN angulation control knob to neutral positions.
5. Release the angulation control knobs and carefully withdraw the endoscope.

9.3 Returning the Endoscope for Repair

Warning

- Thoroughly clean and high-level disinfect the endoscope before returning it for repair. Improperly reprocessed equipment presents an infection control risk to each person who handles the endoscope within the hospital or in our company.

Caution

- Our company is not responsible for the equipment damage and/or person injury which are not caused by our company personnel trying to repair the equipment.

Before returning the endoscope for repair, contact PatCom Medical Inc, with the endoscope, include a description of the malfunction or damage and the name and telephone number of the individual at your location who is most familiar with the problem.

When returning the endoscope for repair, follow the instructions given in Section 8.3 "Transporting outside the hospital".

Appendix A: EMC

Warning

- If the essential performance is lost or degraded due to EM disturbances, there must be obvious markers to distinguish real-time images from non-real-time images, no unexpected image rotation which could alter the visualization of the region studied using the endoscope and affect the procedure done by the Healthcare professional or end user., no image display that could alter the visualization of the region studied using the endoscope and affect the diagnosis performed by a trained operator.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the PatCom Distal Chip Endoscope, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The product can’t be used with HF EQUIPMENT, such as, high frequency electric knife, high frequency cauterization, laser cauterization treatment, or argon plasma coagulation therapy with this device. This product is not available for these treatments. Otherwise, it will cause patient injury, and equipment damage.

Guidance and manufacturer´s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer´s declaration – electromagnetic emission		
The PatCom Distal Chip Endoscope is intended for use in the electromagnetic environment specified below. The customer or the user of PatCom Distal Chip Endoscope should assure that it is used in such an environment.		
Immunity test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The PatCom Distal Chip Endoscope uses RF energy only for its internal function. There for, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The PatCom Distal Chip Endoscope is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning**: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the PatCom Distal Chip Endoscope (RP11A) or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer´s declaration – electromagnetic immunity			
The PatCom Distal Chip Endoscope is intended for use in the electromagnetic environment specified below. The customer or the user of the PatCom Distal Chip Endoscope should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50/60 Hz	30 A/m 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer´s declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM

Guidance and manufacturer´s declaration – electromagnetic immunity

The PatCom Distal Chip Endoscope is intended for use in the electromagnetic environment specified below. The customer or the user of the PatCom Distal Chip Endoscope should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the PatCom Distal Chip Endoscope, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{p}$ $d = 1.2\sqrt{p}$ 80 MHz to 800 MHz $d = 2.3\sqrt{p}$ 80 MHz to 800 MHz where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
	6 Vrms ISM bands inside 150 KHz and to 80MHz	6 Vrms ISM bands inside 150 KHz and to 80MHz	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz RF communication equipment inside 80 MHz to 6 GHz	3 V/m 80 MHz to 2.7 GHz RF communication equipment inside 80 MHz to 6 GHz	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures,

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PatCom Distal Chip Endoscope (RP11A) is used exceeds the applicable RF compliance level above, the PatCom Distal Chip Endoscope (RP11A) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PatCom Distal Chip Endoscope (RP11A).

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

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM -for EQUIPMENT and SYSTEMS

Recommended separation distances between portable and mobile RF communications equipment and the PatCom Distal Chip Endoscope

The PatCom Distal Chip Endoscope is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PatCom Distal Chip Endoscope can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PatCom Distal Chip Endoscope as recommended below, according to the maximum output power of the communications equipment

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{p}$	80 MHz to 800 MHz $d = 1.2\sqrt{p}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{p}$
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Product Cable

NO.	Cables	Max. cable length（m）	Shielded	Remark
1	PatCom Distal Chip Endoscope cable	2.0 m	Yes	/
2	Insertion tube	0.3 m	No	/

Color Calibration User Instructions

Introduction

In order to obtain optimal imaging results when capturing and displaying the Distal Chip endoscope video using a Windows or macOS computer, it is suggested that color calibration be performed in the clinical setting regularly every month or as needed as calibration is relatively fast and interface is user friendly. The calibration will ensure that the captured endoscope video displays the colors as close as possible to the true color of the scenes and areas being imaged.

Computer devices that run under the Windows OS come with a built-in color calibration software within the “Color Management” application. This tool comes with all windows computers. The calibration method is recommended directly by Windows OS and calibrates essential parameters such as gamma, brightness, contrast, and color balance.

In Apple computers, the macOS offers its own built-in display calibration tool called "Display Calibrator Assistant." This tool allows you to adjust and calibrate the color settings of your Mac's display to achieve more accurate and consistent colors.

Calibration Steps

Color Calibration Tool for Windows 10 OS and up

The Windows operating system offers a built-in feature called "Color Calibration" that allows users to adjust and calibrate their display settings to ensure accurate and consistent colors on the screen. This feature is essential for tasks such as photo and video editing, graphic design, and any other activity where color accuracy is crucial.

To access the Color Calibration tool, follow these steps:

- Open the "Start" menu and type "Color Calibration" in the search bar. Click on the "Color Calibration" option that appears in the search results.
- The "Display Color Calibration" wizard will open, guiding you through the calibration process step by step.
- The first step usually involves setting the gamma. Gamma represents the relationship between the brightness levels of the red, green, and blue components of your monitor. Adjusting gamma helps achieve the appropriate balance and contrast.
- Next, you'll be asked to adjust the brightness and contrast settings. These settings can vary depending on the monitor's model and the ambient lighting conditions of your workspace.
- The next step focuses on adjusting the color balance. You'll be presented with a series of grayscale images, and you need to ensure that each shade of gray appears neutral without any color tint.
- After the grayscale adjustment, you will be asked to adjust the individual color channels: red, green, and blue. The goal is to achieve a balanced and accurate representation of each color.
- Once you've completed all the adjustments, the wizard will prompt you to save the calibrated color profile with a descriptive name.
- Finally, Windows will apply the new color profile to your display.

It's worth noting that the effectiveness of color calibration can vary depending on the quality and capabilities of your monitor. For precise color-critical work, professional color calibration tools and hardware are often used to achieve the most accurate results. However, Windows' built-in Color Calibration tool can still significantly improve color accuracy for everyday use.

Keep in mind that the process may slightly differ based on the Windows version you are using, but the overall steps and purpose of color calibration remain consistent across various Windows operating systems.

Color Calibration in macOS
The Windows Color Calibration is a feature specifically designed for Windows operating systems and is not available directly on macOS. Therefore, you cannot use the native Windows Color Calibration tool on a Mac computer.

To access the Display Calibrator Assistant on macOS, follow these steps:

- Click on the Apple menu ( ) in the top-left corner of the screen.
- Select "System Preferences" from the dropdown menu.
- In the System Preferences window, click on "Displays."
- In the Displays preferences, go to the "Color" tab.
- Click on the "Calibrate..." button. This will open the Display Calibrator Assistant.
- The Display Calibrator Assistant will guide you through the calibration process step by step. It will display a series of images and instructions to help you adjust various display settings like gamma, white point, and brightness.
- Follow the on-screen instructions and adjust the settings accordingly until you are satisfied with the display's color accuracy.
- Once you've completed the calibration process, macOS will apply the new color profile to your display.

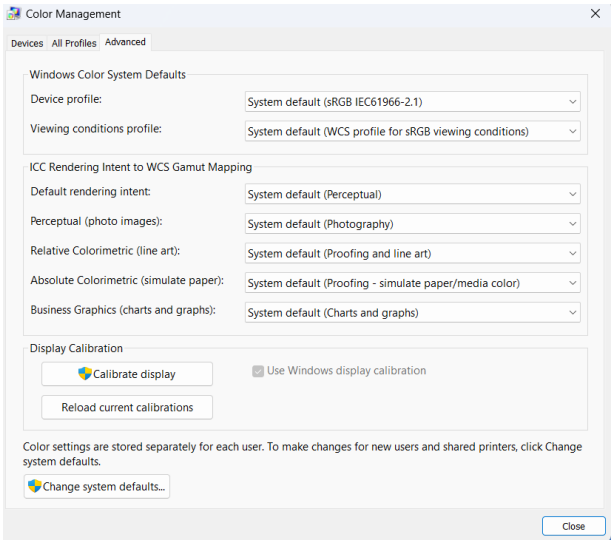
Please note that the effectiveness of the macOS Display Calibrator Assistant can vary depending on the quality and capabilities of your Mac's display. For precise color-critical work, professional color calibration tools and hardware are often used to achieve the most accurate results.

If you need to use the Windows Color Calibration tool on a Mac, you may consider running a virtual machine with Windows installed or using Boot Camp to set up a dual-boot system with Windows on your Mac computer. However, keep in mind that using a virtual machine or Boot Camp may introduce additional complexities and performance considerations.

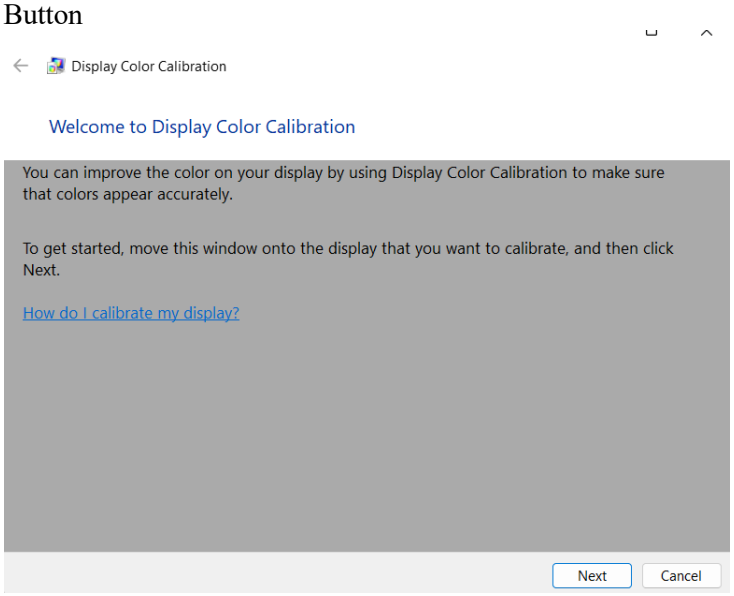
Windows Operating System Color Calibration – Graphic Instructions

Calibration Process

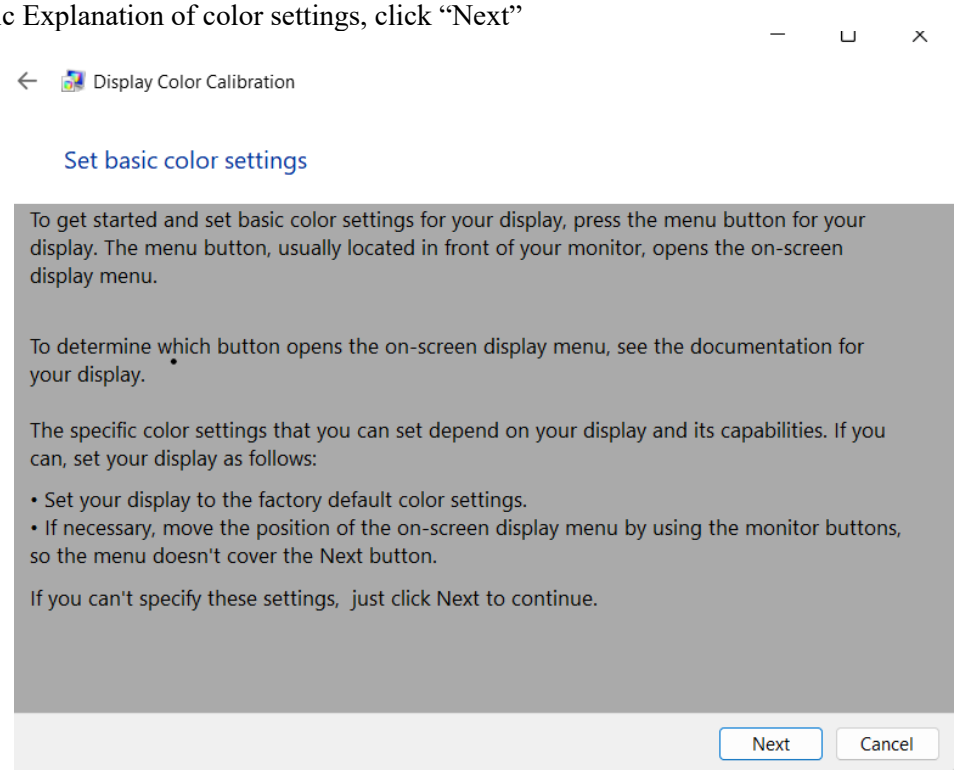
Step 1: Open Windows Color Management Application and Select “Calibrate Display” under the advanced tab.



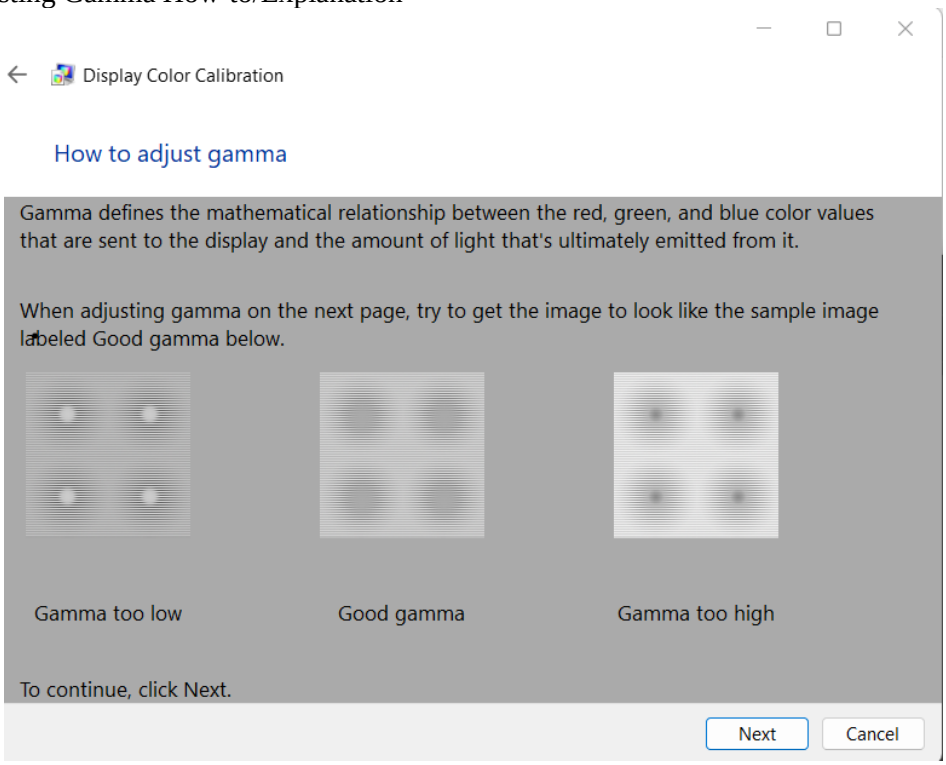
Step 2: Select “Next” Button



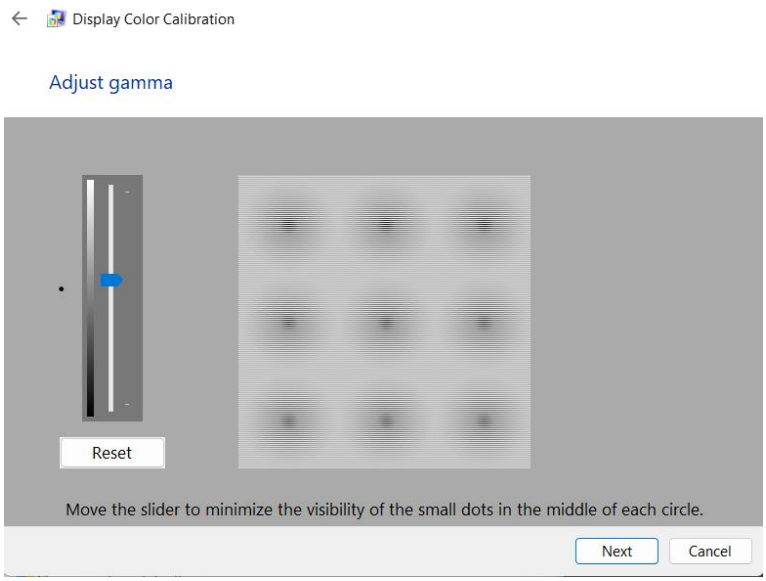
Step 3: Basic Explanation of color settings, click “Next”



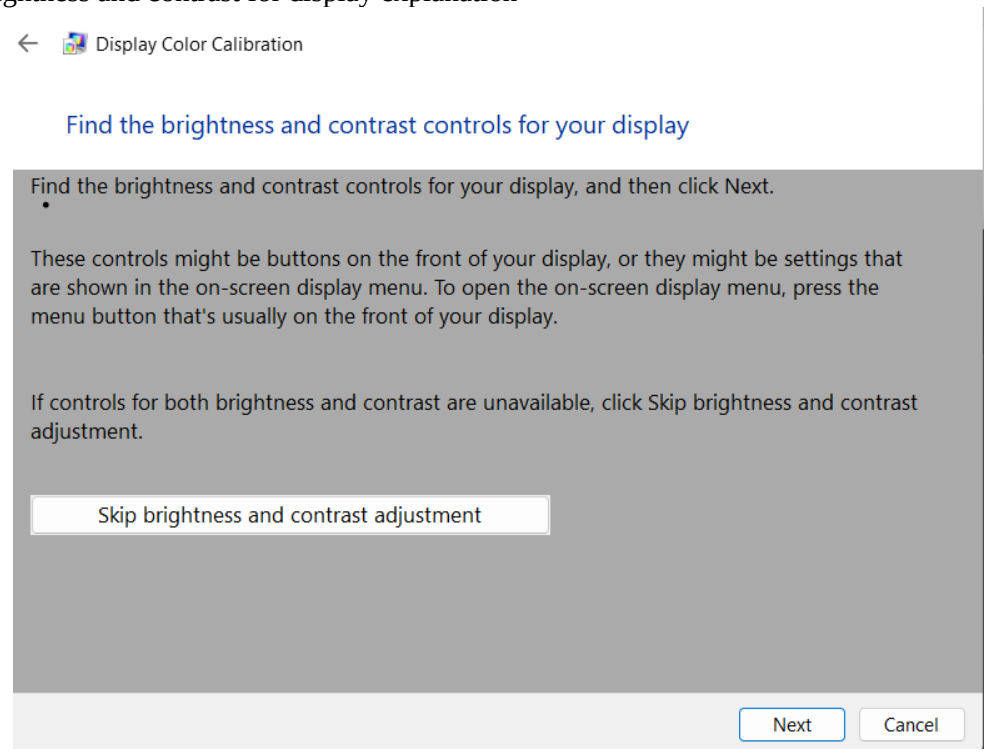
Step 4: Adjusting Gamma How-to/Explanation



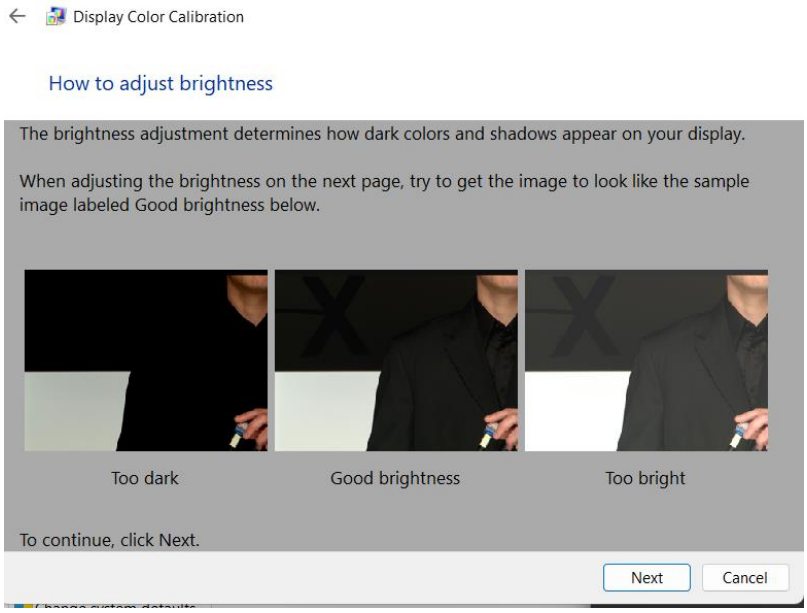
Step 5: Gamma Adjustment



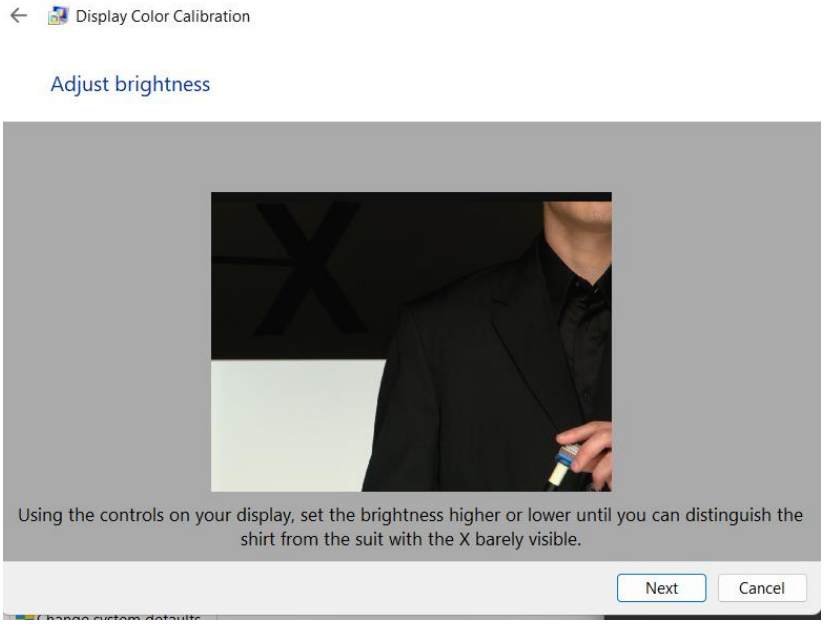
Step 6: Brightness and contrast for display explanation



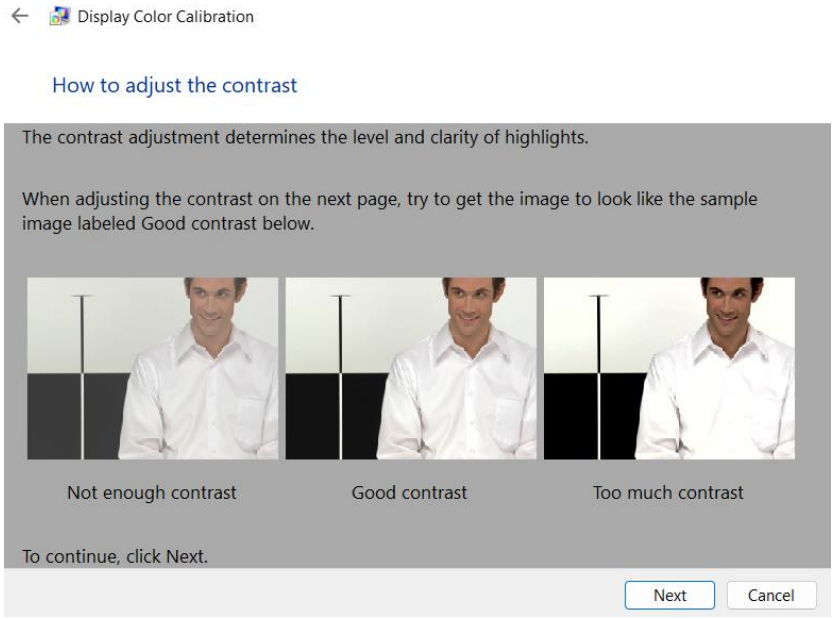
Step 7: Further Brightness and Contrast explanation



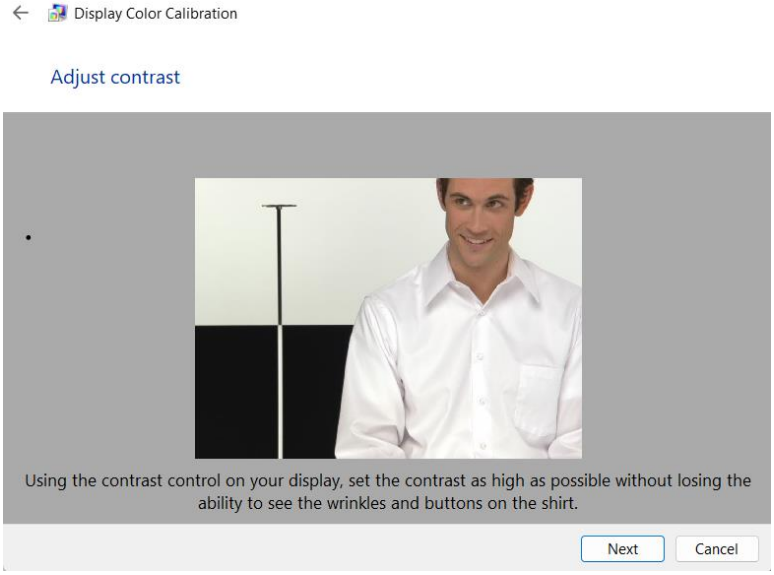
Step 8: Brightness Adjustment



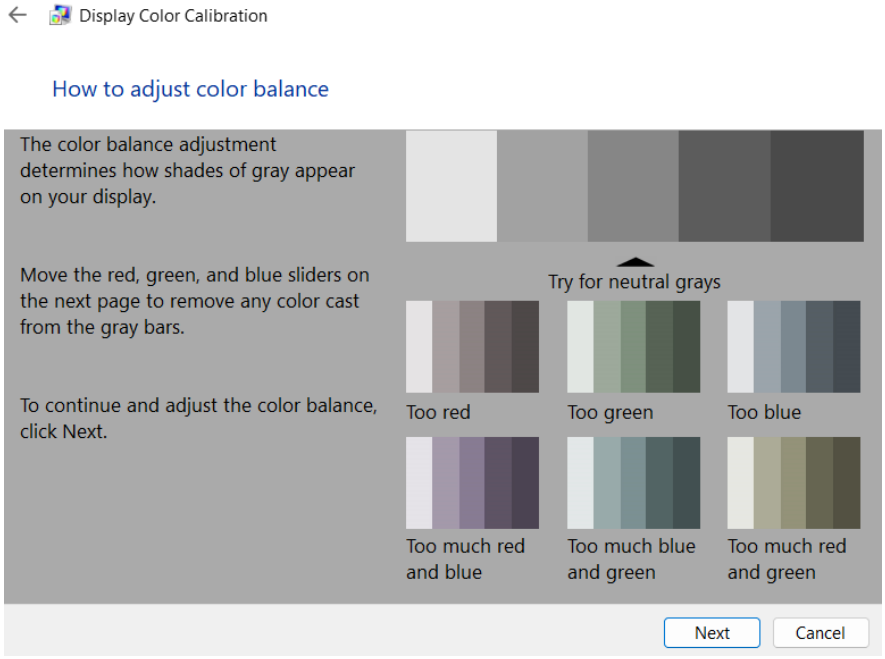
Step 9: Contrast adjustment explanation



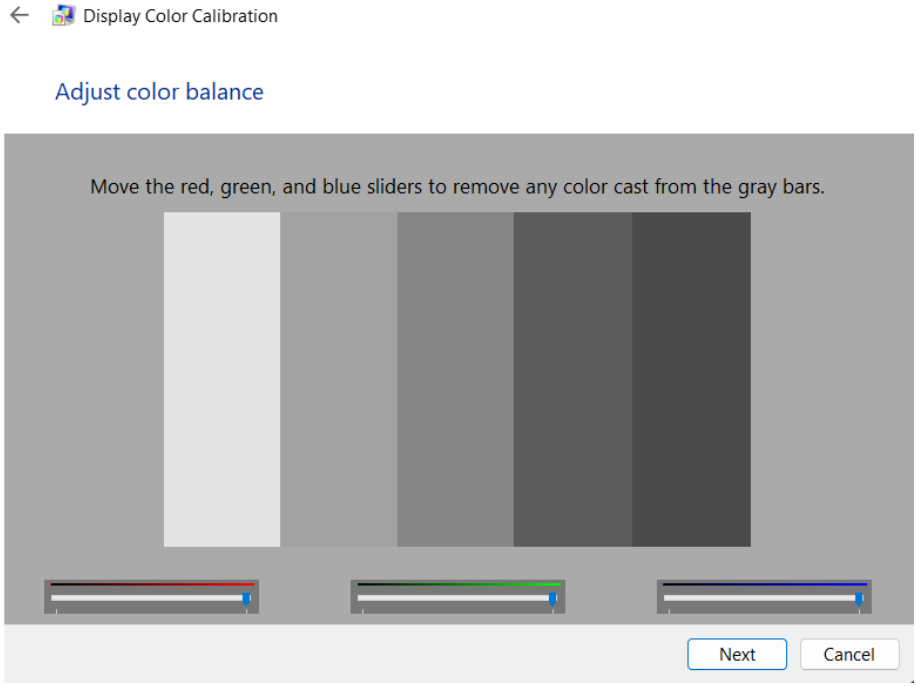
Step 10: Contrast adjustment



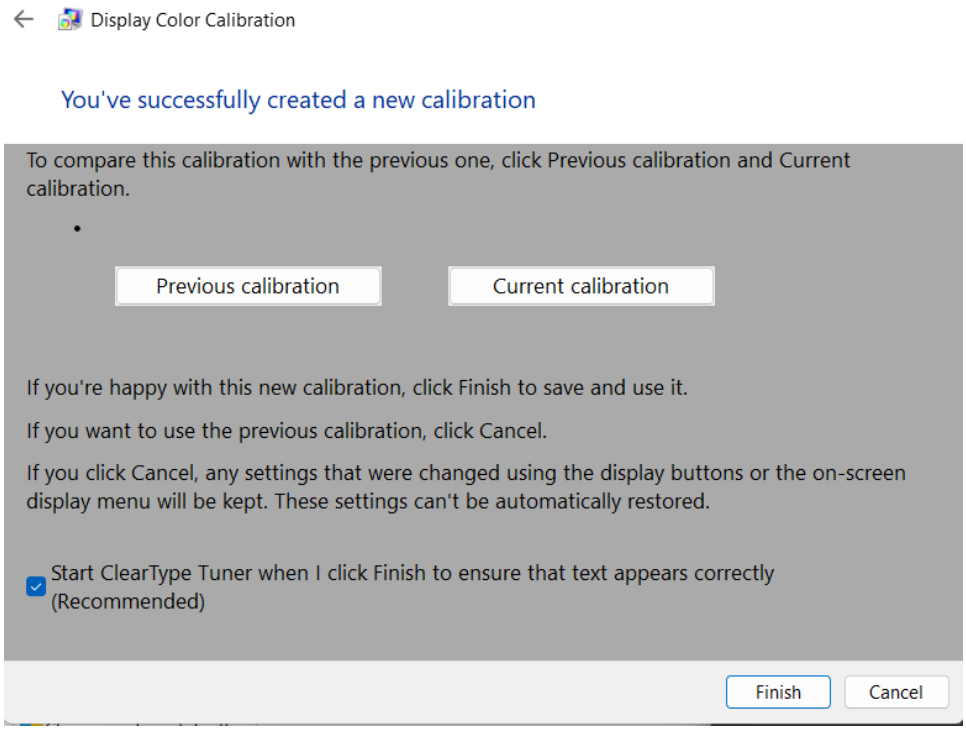
Step 11: Color Balance Adjustment Explanation



Step 12: Color Balance Adjustment



Step 13: Calibration Complete


Display Color Calibration
You've successfully created a new calibration
To compare this calibration with the previous one, click Previous calibration and Current calibration.
Previous calibration
Current calibration
If you're happy with this new calibration, click Finish to save and use it.
If you want to use the previous calibration, click Cancel.
If you click Cancel, any settings that were changed using the display buttons or the on-screen display menu will be kept. These settings can't be automatically restored.
Start ClearType Tuner when I click Finish to ensure that text appears correctly (Recommended)
Finish
Cancel

Appendix C: List of Additional Validated Reprocessing Methods

The following methods have been validated for efficacy and/or material compatibility. Please refer to the instructions for use provided by the manufacturer of the respective disinfection or sterilization method listed below.

Manufacturer	Method	Accessories	Cleaning/Disinfection/Sterilization	Material Compatibility	Efficacy
Steris	SYSTEM 1E® Liquid Chemical Sterilant Processing System	C1140E Flexible Tray C1160E Universal Flexible Tray C1200E General Processing Tray C1220E Directed Flow Tray	Liquid Sterilization	Yes	Yes
Steris	SYSTEM 1® endo Liquid Chemical Sterilant Processing System	C1140E Flexible Tray C1160E Universal Flexible Tray C1200E General Processing Tray C1220E Directed Flow Tray	Liquid Sterilization	Yes	Yes
Steris	V-PRO® maX Low Temperature Sterilization System	Steris Sterilization Tray VP004 Steris Sterilization Mat VP0033 H600 OneStep Sterilization Wrap	Low Temperature Sterilization	Yes	Yes
Steris	V-PRO® maX 2 Low Temperature Sterilization System	Steris Sterilization Tray VP004 Steris Sterilization Mat VP0033 H600 OneStep Sterilization Wrap	Low Temperature Sterilization	Yes	Yes
Steris	V-PRO® 60 Low Temperature Sterilization System	Steris Sterilization Tray VP004 Steris Sterilization Mat VP0033 H600 OneStep Sterilization Wrap	Low Temperature Sterilization	Yes	Yes
Steris	V-PRO® s2 Low Temperature Sterilization System	Steris Sterilization Tray VP004 Steris Sterilization Mat VP0033 H600 OneStep Sterilization Wrap	Low Temperature Sterilization	Yes	Yes
Advanced Sterilization Products (ASP)	STERRAD 100NX Sterilization System	APTIMAX® Instrument Tray, PC: 13837 STERRAD Instrument Tray Mat, PC: 99213 H400 48” x 48” Halyard Health, Inc. Sterilization Wrap, PC: 68248	Low Temperature Sterilization	Yes	Yes
Advanced Sterilization Products (ASP)	STERRAD NX Sterilization System	APTIMAX® Instrument Tray, PC: 13837 STERRAD Instrument Tray Mat, PC: 99213 H400 48” x 48” Halyard Health, Inc. Sterilization Wrap, PC: 68248	Low Temperature Sterilization	Yes	Yes
Tristel Solutions Ltd.	Tristel ™ Trio Wipes System		High Level Disinfection	Yes	No
UV Smart Technologies B.V.	D60 UV-C		Sterilization	Yes	No