Anexa 2

Specificația Tehnică Completată

Modelul:FB-18V; PN:84178 Nr. Reg: DM000459172;Producătorul: HOYA CORPORATION/ PENTAX Medical; Țara:Japonia

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină ofertată de către autoritatea ofertantă
Fibrobronhoscop Cod 290260 Descriere Fibronhoscop destinat diagnosticului și tratamentul cailor respiratori Parametrul Specificația	Fibrobronhoscop **DA** Cod 290260 Descriere Fibronhoscop destinat diagnosticului și tratamentul cailor respiratori **DA** Parametrul Specificația
Sistem optic Unghiul cîmpului de vedere ≥ 120 grade	Sistem optic Unghiul cîmpului de vedere - 120 grade **DA pag. 2 din Brosura PENTAX Medical High Resolution Fibre Brohoscope**
Înclinarea cîmpului vizual 0 grade	Înclinarea cîmpului vizual 0 grade **DA**
Adîncimea cîmpului vizual 3- 50mm	Adîncimea cîmpului vizual 3- 50mm **DA pag. 2 din Brosura PENTAX Medical High Resolution Fibre Brohoscope**
Capul distal ≤ 6 mm	Capul distal 5,9 mm **pag. 2 din Brosura PENTAX Medical High Resolution Fibre Brohoscope**
Diametrul exterior ≤ 6 mm	Diametrul exterior 6 mm **pag. 2 din Brosura PENTAX Medical High Resolution Fibre Brohoscope**
Înclinarea capului distal sus/jos 180/130 grade	Înclinarea capului distal sus/jos 180/130 grade **pag. 2 din Brosura PENTAX Medical High Resolution Fibre Brohoscope**
Diametrul tubului introdus ≤ 6mm	Diametrul tubului introdus ≤ 6mm **pag. 2 din Brosura PENTAX Medical High Resolution Fibre Brohoscope**
Lungimea de lucru ≥ 600 mm	Lungimea de lucru - 600 mm **pag. 2 din Brosura PENTAX Medical High Resolution Fibre Brohoscope**
Canalul de instrumente ≥ 2,7 mm	Canalul de instrumente - 2,7 mm **pag. 2 din Brosura PENTAX Medical High Resolution Fibre Brohoscope**
Completarea Lampă de halogen de rezervă - 1 unit. Piesă bucală -2 unit. Tester automat (sa se indice modelul) - 1 unit. "Sursa de lumină halogen (minim 150 W) - 1 unit. (sa se indice modelul)" Pensă de biopsie- 2 unit.	Completarea Lampă de halogen de rezervă - 1 unit. **DA Inlcus** Piesă bucală -2 unit. **DA incusl** Tester **manual** (SHA-P5) - 1 unit. **DA** "Sursa de lumină halogen (minim 150 W) - 1 unit. (**LH-150PC**)" **DA** Pensă de biopsie- 2 unit. **DA va fi incluse**

Digitally signed by Chicu Natalia
Date: 2023.10.02 09:56:34 EEST
Reason: MoldSign Signature
Location: Moldova

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Decalaratie de conformitate CE
I.3. Certificatul CE	Certificat CE FQA

Введите текст для поиска...

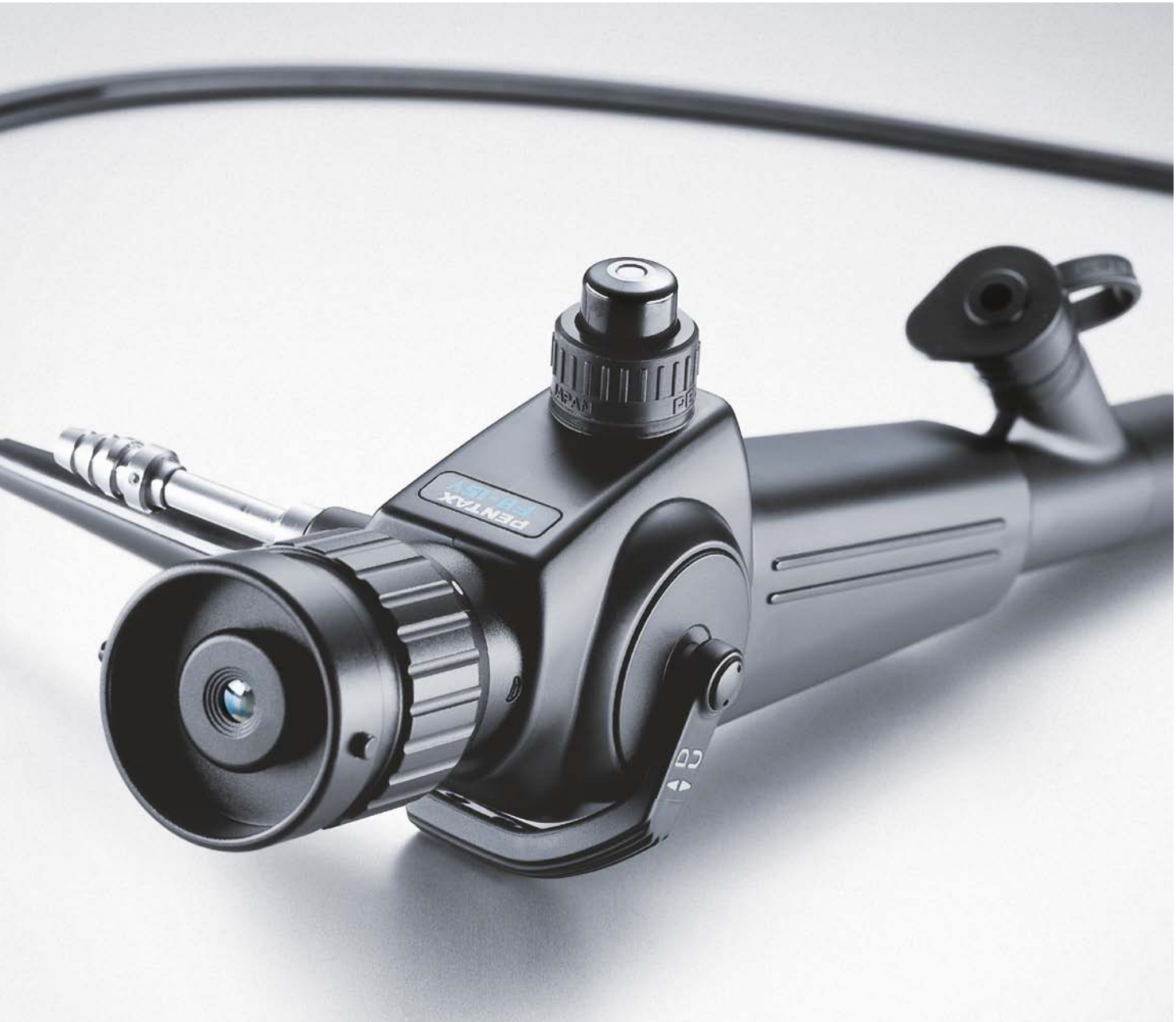
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
				FB-18V						
DM000459172	BRONCHO FIBERSCOP		BRONCHO FIBERSCOPE	FB-18V	Japonia	HOYA CORPORATION	GBG-MLD S.R.L.	Rg04-000059	22-03-2023	

Содержит([Nr. catalog], 'FB-18V')

Очистить

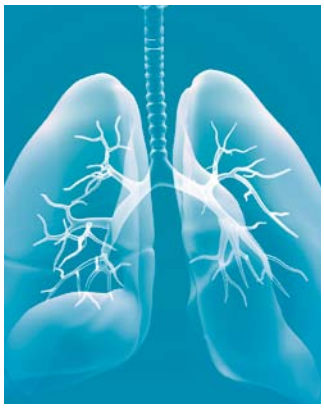
PENTAX Medical
High Resolution Fibre Bronchoscopes

High optical quality in a complete product range.



Every day, pulmonologists and emergency physicians around the world trust the excellent optical quality and unmatched convenience of PENTAX Medical fibre bronchoscopes. These high quality instruments offer speed and efficiency in diagnostic, therapeutic and emergency medicine.

Outstanding performance characteristics



Maximum Working Comfort

- Up to 180° tip deflection, a tight bending radius and wide angle of view provides easy manoeuvrability and more precise and accurate examinations
- Optimally sized working channels (up to 3.0 mm) accommodate a wide range of instruments and high suction capacity
- PENTAX Medical LSV Solutions (Light Source Versatility). Three light source options; The cordless battery powered LSV module or self contained A/C adapter Light Source module (BS Portable Series only). Finally all models can be connected directly to a conventional light source.
- Ergonomically designed, lightweight control body enhances user performance

Unique Hygiene

- PENTAX Medical CSV (Closed Suction Valve) is a mechanism that facilitates accurate aspiration
- Fully immersible and reprocessible these instruments can be completely and effectively high level disinfected

Excellent Picture Quality

- PENTAX Medical Superfine Technology delivers bright, clear, high resolution images for superior observations

PENTAX Medical Quality & Service Programme

- PENTAX Medical delivers cost effective products of exceptional quality and durability
- Providing industry leading service plans, consultancy, financing, technical services and training

Fibre Bronchoscopes

Type	Slim		Routine	Portable		Therapeutic	
System	FB-8V	FB-10V	FB-15V*	FB-15BS	FB-18BS	FB-18V*	FB-19TV*
Field of view (°)	100	120	120	100		120	
Focal range (mm)	2-50	3-50					
Diopter	+3 ~ – 8						
Tip deflection (°) up/down	180/130				180/90	180/130	
Ø Distal end (mm)	2.7	3.4	4.9	4.8	5.9		6.2
Ø Insertion tube (mm)	2.8	3.5	4.9		6.0		6.2
Ø Instrument channel (mm)	1.15		2.1	1.95	2.55	2.7	3.0
Working length (mm)	600						
Overall length (mm)	900		900	880		900	

Note: Introduction and specifications are subject to change without prior notice and without obligation on the part of the manufacturer.
*HF-compatible

PENTAX Europe GmbH
Julius-Vosseler-Straße 104 . 22527 Hamburg . Germany
Tel.: +49 40 / 5 61 92 - 0 . Fax: +49 40 / 5 60 42 13
E-mail: medical@pentax.de . www.pentaxmedical.com

PENTAX MEDICAL
Excellence in Focus

LCM/04/06/13/17334/02

PENTAX MEDICAL

Instructions for Use

PENTAX Halogen Light Source

LH-150PC

Instructions for use of this device

Please read and fully understand the Instructions for Use (hereinafter referred to as "IFU") of this light source and the endoscope used in combination, and the instruction manuals for the related products before use, and ensure to use properly. Failure to do so may result in damage to the product or any unforeseen injury to the user or the patient.

This IFU describes how to inspect and prepare this device before use, how to operate this device, how to perform maintenance after use, and so on. It does not describe how an actual procedure is to be performed nor does it attempt to teach a beginner the proper techniques or any medical aspects regarding the use of the device.

If you have any questions regarding the information in this IFU, contact your local PENTAX Medical service facility. The content of this IFU is subject to change without notice.

Keep this IFU and the instruction manuals for the related products in a secure place for future reference.

Symbols appearing in this IFU (warning, caution, and note)

The following signal words are used throughout this IFU.

 Warning	Indicates a potentially hazardous situation that could result in death or serious injury if not avoided.
 Caution	Indicates a potentially hazardous situation that could result in minor or moderate injury if not avoided. It may also be used to alert about unsafe practices or potential equipment damage.
 Note	Indicates additional helpful information.

For USA prescription statement:

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

Contents

Important information

Product summary

This device is a light source for endoscopes. This device comes with a halogen lamp and air pump.

The light of the halogen lamp passes through the fibers of the endoscope connected to this device and illuminates the body cavity from the distal end of the endoscope. The quantity of light can be adjusted using the knob on the front of this device.

The air pump feeds compressed air to the water bottle assembly connected to this device. Air and water in the water bottle assembly are expelled from the distal end of the endoscope through the tube connected to the endoscope. Pressing the Air/Water feeding valve on the control body of the endoscope switches the supply between water and air.

The volume of air is adjusted by controlling the output of the pump.

Intended use

This electro-medical device (light source) is intended to be used as a source of illumination for endoscopes.

Together, this light source and endoscope may provide optical visualization of, and/or therapeutic access to, various body cavities, organs and canals. Do NOT use this device for any purpose other than that for which it has been designed.

This device should only be used by physicians who have thoroughly studied all the characteristics of this device and who are familiar with the proper techniques of endoscopy.

Frequently used functions

The air/water pumping function and light quantity adjustment function are frequently used when using this device.

Application

Medical purpose	Observation of body cavities (illumination and Air/Water supply through a connected endoscope.)
Target patients	Patients who are considered suitable for the application of this product by the physician (pediatric to adult)
Intended anatomical areas	Nasal passage, pharynx, larynx, esophagus, stomach, duodenum, small intestine, large intestine, pancreatic and biliary duct, trachea, bronchial tree, oral cavity, kidney, renal cavity, and renal calyces, urethra, endometrial canal (all require endoscope connection. Follow the IFU or manuals of the endoscope to be used because the intended anatomical areas are different by endoscope.)
User qualifications	Physicians (experts who have been approved by the endoscopic medical safety administrator at each medical facility. If the eligibility requirements are defined by an official body such as a government entity and/or an academic society, follow such requirements.) Specific training to use this product is not required.
Place of use	A medical facility

General precautions for handling

Warning

- This device is intended for use in a medical facility. To avoid harm, do NOT use it in any place other than a medical facility.
- While this device is designed for safe use with medical endoscopes, please refrain from applying it directly to the heart to prevent electric shock.
- This device needs to be grounded for safety reasons. Connect it to a hospital-grade receptacle and be sure to ground it. If connecting this device to a non hospital-grade receptacle, use an adapter plug and be sure to connect the earth wire to the earth terminal. Do not ground with a gas pipe.
- Do NOT use this device where explosive or flammable gases are present or in an oxygenrich environment. Failure to observe this precaution may cause the device to catch fire.
- Check the patient's condition before the procedure to ensure that it is appropriate to use this device.
- Do NOT install this device in a place where it could get wet. Failure to observe this precaution may result in electric shock.
- Before turning on this device, ensure that the air vents are not blocked. Blocking ventilation may cause the device to heat up.
- To prevent electric shock, do NOT use this device in combination with devices for which leakage current safety is not verified.
- This device employs a structure with insulated applied parts to prevent electric shock (degree of protection against electric shock: Type BF classification for medical equipment). Do NOT use other electrical devices being used for the patient to ground the endoscope or camera. Insulated gloves should be worn to prevent grounding through the user.
- Turn the brightness control knob to the lowest brightness necessary when inserting the endoscope and performing observations during examinations, to prevent burns and protect your eyes.
- When leaving for long periods of time, turn off the lamp or turn the brightness control knob to the lowest brightness necessary to prevent burns caused by heating of the light guide and the distal end of the endoscope.
- Do not look directly at the light emitted from the light source. Failure to observe this precaution may cause eye injury.
- In case abnormality such as an abnormal heat generation, vibration, and noise during the use of the light source, stop the device operation immediately and contact your local PENTAX Medical service facility.
- Ensure that the power cord is not twisted, damaged, or disconnected.
- This product is intended to be used in the electromagnetic environment specified by the "Electromagnetic disturbances". If the product is used in the unintended environment, the following abnormalities may occur.
  - excessive light is emitted from the distal end of the endoscope
  - excessive high amount of air is fed into the body lumen unintentionally

Caution

- Do NOT store this device in a very hot and humid place or where it will be exposed to direct sunlight.
- Place this device on a stable and level surface.
- Do NOT use a sharp object, such as the tip of a pen, to press the switches of this device.
- The approximate lamp life is 50 hours. However, it may not be as long as 50 hours depending on the method of use and the operating environment.
- Do NOT drop this device or apply a strong shock to it. Failure to observe this precaution may cause loss of safety and effectiveness. If the device is subjected to a strong impact, stop use immediately and contact your local PENTAX Medical service facility.
- Ensure that the specifications of the power supply match the electrical ratings displayed on the rear panel.
- Always ensure that there is no problem with the patient and this device during use.
- Repairs should be undertaken only by a person or company authorized by PENTAX Medical. It may adversely affect the operation or safety of this device.
- When disposing this device, dispose it according to the laws and regulations of the relevant country or region.
- Install, configure, and start using this device immediately after purchase. Do NOT store the device for an extended period of time without using it.
- Store this device where it will be protected from dust. If any dust is confirmed, ensure to remove it. Furthermore, when storing the device for a long period, take precautions to reduce dust build-up within the device. Excessive amounts of dust accumulating inside the device may cause it to malfunction, emit smoke, or catch fire or may cause other problems.

Description of label symbols

Symbol	Description
	**Alternating Current**
	**Type BF Applied Part** (Safety degree specified by IEC 60601-1)
	**Power Off**
	Power On
	**Year of Manufacture** This indicates the year that the processor was manufactured.

Symbol	Description
	**Manufacturer** This indicates the manufacturer of the processor.
	**Protective Earth (Ground)** This indicates the protective earth terminal for protecting against electric shock in the event of a failure.
	**Warning** This indicates that you need to be careful regarding handling because there is a potential hazard.
	**Hot Surface Caution** This indicates a surface that could cause a burn injury if touched because it becomes hot.
	**Follow the Instructions for Use** This indicates that you must follow the instructions regarding handling in the IFU.
	**Endoscope** This indicates where to connect the endoscope.
	**Lamp Model/Type Indication**
	**Authorized representative in the European Community**
	**CE Mark** This product complies with the applicable standards harmonised under the Directive 93/42/EEC and Directive 2011/65EU.
	**Fuse** This indicates where the fuses are installed.
	**NRTL Certification Mark** This is the product safety certification mark for North America (US and Canada).
	**WEEE Directive Mark** This indicates this product is falling under the scope of the European Directive 2021/19/EU on Waste Electrical and Electronic Equipment of the European Community applies.
	**Serial Number** This indicates the identification number of the product.
	"ON" for a part of equipment
	"OFF" for a part of equipment
	Warning: Dangerous Voltage

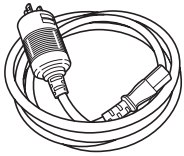
Symbol	Description
	* If this bar code symbol is displayed on the product, see the following explanation. This is a UDI (Unique Device Identification) code required by Unique Device Identification System designed to adequately identify devices through distribution and use. The following information is coded in 2D bar code (GS1 Data Matrix). - (01) GS1 Commodity code (Global Trade Item Number) - (11) Production date - (21) Serial number

1 Contents of the package

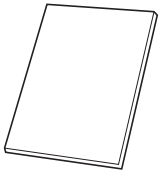
1-1. Contents of the package

The package of this device contains the following items. Check that all the items are included. (The included items differ depending on the sales region.) If any part is missing or the device is damaged, refrain from using the product and contact your local PENTAX Medical service facility.

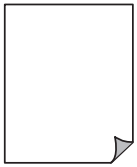
■ Included items



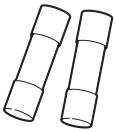
Power Cord



Instructions for Use
(This document)



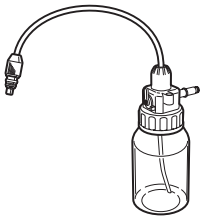
Standard Set List



Fuses
* These are spare parts.
2 sets of Ø5 × 20 mm

Fuse (F1,F2) 220V, 230V	[SOC Corporation] ET2A AC250V T2AL
Fuse (F1, F2) 120V	[SOC Corporation] ULTSC 3.15A AC125V 3.15A

■ Optional accessory



PENTAX Medical
Water Bottle Assembly

2-1. **Main unit**

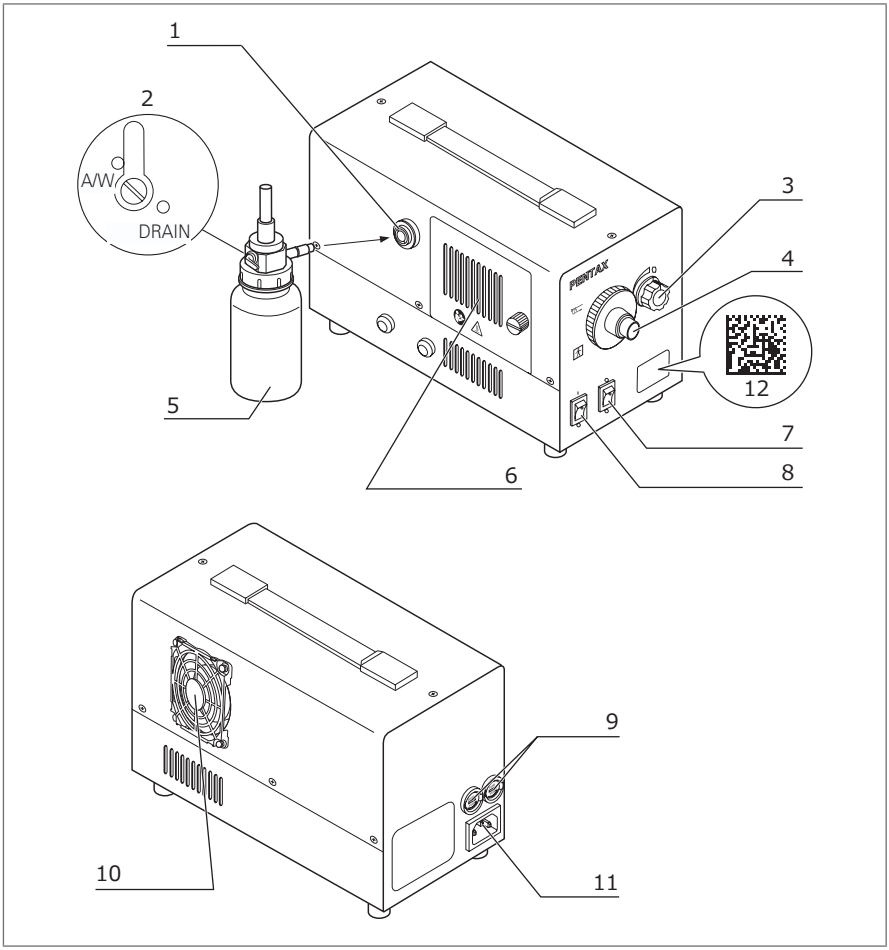


Figure 2.1

1. **Water bottle socket**
   Insert the air pipe stem of the water bottle assembly.
2. **A/W and DRAIN lever**
   Use this to switch between the air/water supply and drain. Align the switch to the [A/W] position before use.
3. **Brightness control knob**
   Brightness of observing field can be adjusted.
4. **Light guide receptacle**
   Insert the light guide plug of a fiberscope. You can also connect endoscopes from other manufacturers by using an adapter.
5. **PENTAX Medical water bottle assembly**
   Fill with sterile water for endoscope lens cleaning. When cleaning and sterilizing the PENTAX water bottle assembly, refer to the IFU of the respective water bottle assembly.
6. **Lamp housing cover**
   Using a flat-blade screwdriver, open the cover to expose lamp housing for lump replacement.
7. **Air pump switch**
   Power switch must be on to activate air pump.
8. **Power switch**
   Press this switch to turn the light source on or off.
9. **Fuse holder**
   The fuse holder contains two fuses.
10. **Air vent**
    This air vent allows for ventilation and cooling of the lamp and unit.
11. **Power input socket**
    Connect the power cord.
12. **UDI**

Note

The lamp of the light source should be turned off at all times, except during pre-use inspections and device operation.

3 Preparation

Caution

Always perform pre-use inspection before each use. NEVER use a device with a suspected
abnormality. Doing so may result in malfunction, device damage, and/or injury to the patient and/or user. Ensure that another device is also prepared to avoid interruption of the procedure due to device failure or unforeseen events.

3-1. System configuration

Below is an example of a system configuration in which this device can be used.

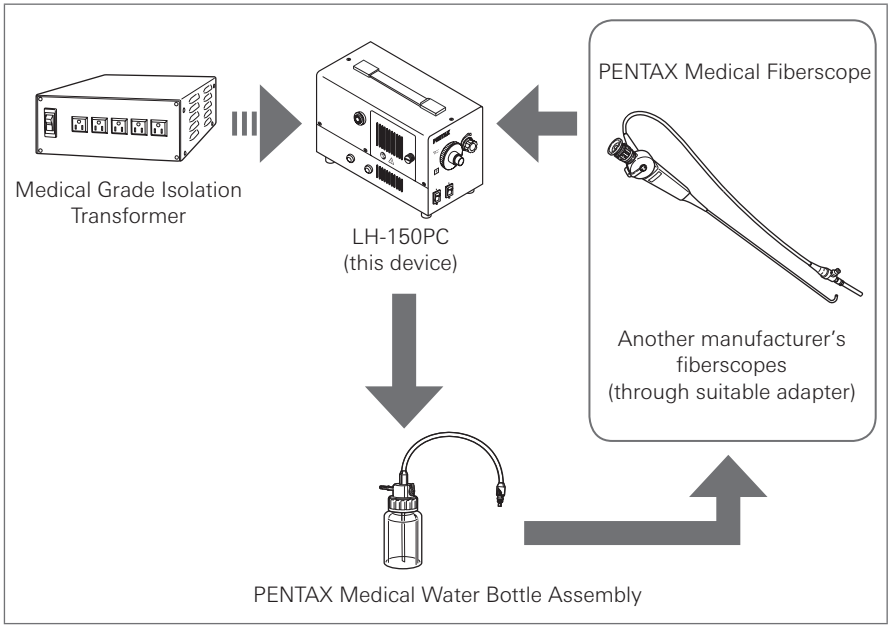


Figure 3.1

3-2. Installation

1. Place the device on a stable and level surface.

Warning

- Do NOT block the air vents of the device. Blocking ventilation may cause the equipment to heat up.
- Ensure that there is a gap of at least 15 cm between the air vents along the sides of this device and the wall. Ensure that there is a gap of at least 15 cm between the rear air vent and the wall.
- Avoid placing the product where it may be exposed to liquids.
- The device and other equipments adversely affect each other and may not operate properly in the case of placing right nearby or stacked on top of the device. If it is necessary to install the equipment close together for unavoidable reasons, ensure that there is no abnormality in each equipment in advance.

Caution

- Do NOT install, operate, or store this product in a dusty environment. Accumulation of dust within the equipment may cause it to malfunction, emit smoke, or catch fire.
- When connecting peripheral devices, ensure that each cable is firmly connected to the specified connector. Incorrect connection may cause certain functions to be unavailable.

Note

When loading the light source on a shelf of the cart, provide sufficient space for attaching or detaching the water bottle assembly easily.

2. Insert the AC power cord into the power input socket of this device.
3. Connect the power cord to a hospital-grade isolation transformer or a three-prong power outlet that complies with the electric rating indicated on the rating plate. Check that the power of this device is turned off before setting it up.

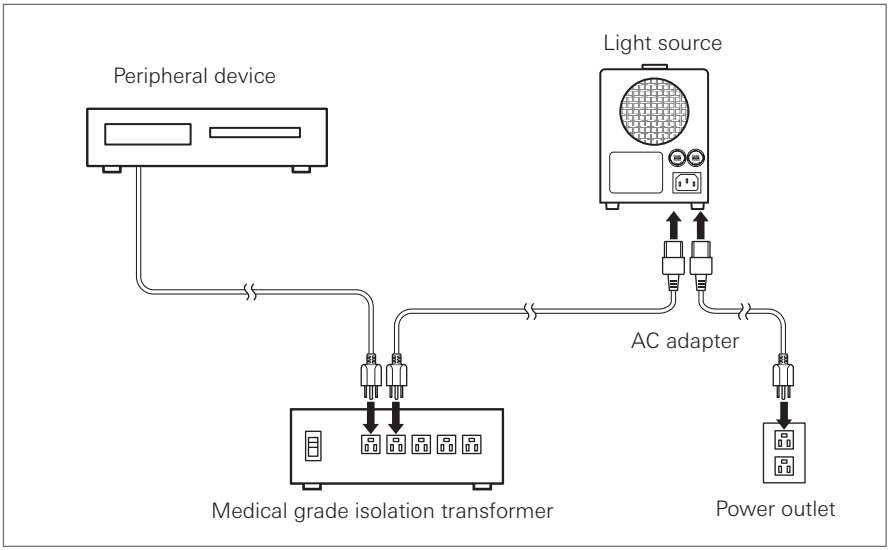


Figure 3.2

Warning

- When connecting peripheral devices to this device, use only the cables specified in these Instructions for Use. Using a different cable may alter this device's resistance tolerance to electromagnetic waves. This may adversely affect other devices, or cause this device to be adversely affected by other devices.
- To avoid the risk of electric shock, this device must be connected only to an appropriate power outlet with a protective earth conductor.
- When using non-medical grade peripheral devices such as a monitor for consumer use, ensure to supply power from a medical grade isolation transformer to reduce the risk of electric shock. Do NOT connect any other the medical-grade devices which are not used to the isolation transformer.

Caution

- Ensure that the total power consumption of the peripheral devices that are supplied with power via the isolation transformer does not exceed the maximum rating displayed on the isolation transformer.
- Make sure that the power cord is connected to an outlet for a plug with earth terminal.

3-3. Connecting a fiberscope

Connect a fiberscope to the light source. Connect the water bottle assembly and suction source to the fiberscope before use. For details on the fiberscope to be used, refer to the IFU of the fiberscope.

1. Check that a suitable light guide adapter is connected to the light guide receptacle of this device.
   - If using a PENTAX Medical endoscope, attach the PENTAX OL-H3 Adapter to the light guide receptacle. This enables a PENTAX Medical endoscope to be connected.

Note

This device comes with the OL-H3 attached.

   - If using another manufacturer's fiberscope, attach a suitable adapter to the light guide receptacle. If the adapter has attachment pins, attach the pin in the holes of the light guide receptacle. Contact your local PENTAX Medical service facility for details.

Note

Connecting an fiberscope without the proper adapter may damage the fiberscope or this device.

2. Gently push the light guide of the endoscope into the light guide receptacle of this device until it clicks.
3. Fill approximately two-thirds (up to 200) of the bottle with sterile water. Then place the water bottle cap onto the bottle and tighten it securely.

Caution

- Before connecting the water bottle assembly to this device, check for abnormalities such as cracks on the exterior of the water bottle assembly and refrain from using it if abnormalities are found.
- Ensure that the water bottle cap is tightened securely. If the cap is loose, the air/water supply may be inadequate.
- The cap of the PENTAX Medical water bottle assembly must not be used with a water bottle other than the PENTAX Medical water bottle assembly. Air may leak during use, resulting in a failure to obtain the necessary pressure or flow volume for feeding air or water. Model names are written on the water bottle and water bottle cap. Check that the PENTAX Medical water bottle cap is combined with the PENTAX Medical water bottle before use.

4. Align the A/W and DRAIN lever with the [A/W] (air/water supply) position (Figure 3.3).

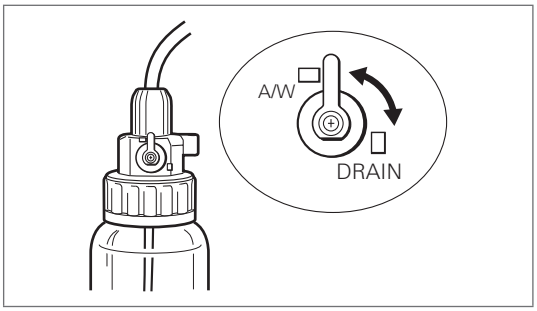


Figure 3.3

Caution

The air/water connector should be inserted into the holder on the water bottle cap when the water bottle assembly is not connected to the fiberscope (Figure 3.4). Water may leak out of the air/water connector if it is not kept in the holder.

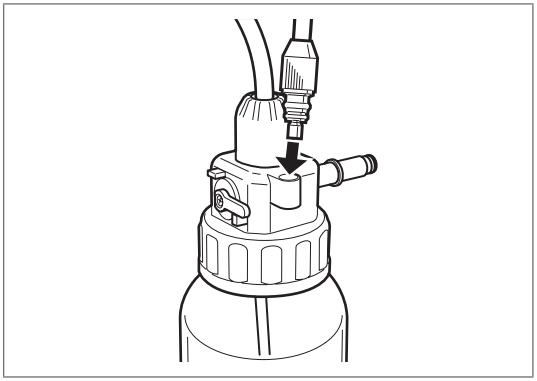
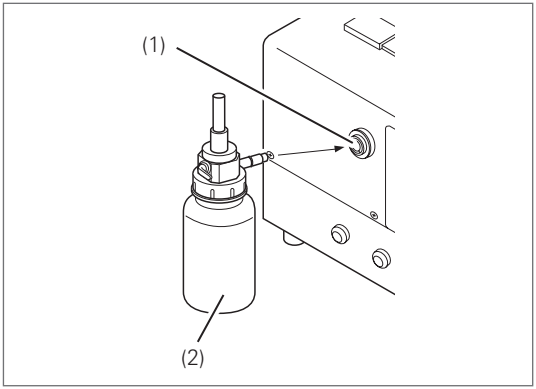


Figure 3.4

Caution

- Remove the water bottle assembly before packing this device for transportation. Failure to do so may result in damage to this device and the water bottle assembly.
- Remove the water bottle assembly before moving this device. Failure to do so may result in displacement and damage to the water bottle assembly.

5. Ensure that the O-ring is attached to the tip of the air pipe stem of the water bottle assembly and then insert the air pipe stem into the water bottle socket of the fiberscope until it clicks into position (Figure 3.5).

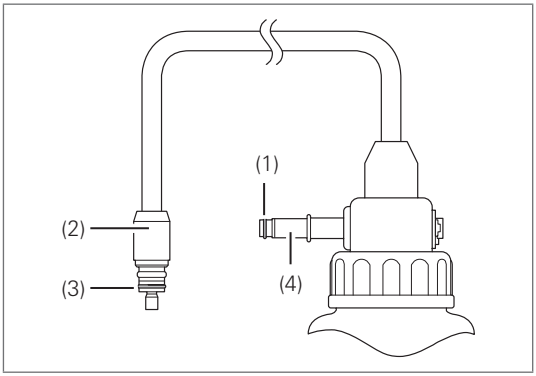


(1) Water Bottle Socket
(2) Water bottle assembly

Figure 3.5

Caution

- Ensure that the O-ring is attached to the tip of the air pipe stem of the water bottle assembly. If the O-ring is missing or damaged, the Air/Water supply may be inadequate (Figure 3.6).
- Do NOT use excessive force when pushing the water bottle assembly toward the light source. Rough handling may cause water to leak from the water bottle assembly.



(1) O-ring (small)
(2) Air pipe stem
(3) O-ring (large)
(4) Air/Water connector

Figure 3.6

6. Insert the air/water connector of the water bottle assembly into the air/water connector of the fiberscope until it clicks.
7. Connect the suction tube of the suction source to the suction nipple of the fiberscope.

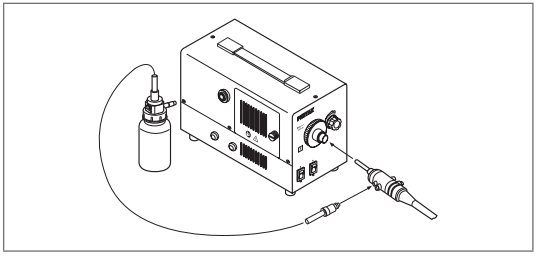


Figure 3.7

3-4. Pre-use inspections

To ensure that the light source is in good working condition for use with patients, check that the fiberscope, this device, and accessories are clean and functioning properly before use and also the IFU or manuals provided with the fiberscope or other accessories.

Warning

Ensure that the inspections described in this section are performed before use. In the event that any function or device in the light source system does not work properly, do NOT perform endoscopic examination. Contact your local PENTAX Medical service facility before using this device for a procedure.

Caution

- Check the following before you begin inspection.
  - The device is turned off (p. 25).
  - The device is installed on a stable and level surface (p. 15).
  - The water bottle assembly is appropriately prepared and properly connected (p. 18).
  - The fiberscope is properly connected (p. 18).
  - The power cord is properly connected (p. 15).
- Wear insulated gloves when performing inspection.

1. Ensure that the power cord is connected to the power inlet socket properly.

> **Caution**
>
> Do not pull hard on the cord. The cord may come out of the outlet.

2. Check that the fiberscope is correctly connected to the light guide receptacle.
3. Turn on the power of any peripheral devices such as a monitor before turning on the power switch of this device (turning it to |). Check that light is emitted from the distal end of the fiberscope and that the sound of the cooling fan can be heard.

> **Caution**
>
> As a precaution, always have an extra (spare) lamp available as a standby lamp.

Note

- If the power does not turn on, replace the fuses on the back. “5-6. Inspection/ replacement of the fuses” (p. 30)
- If the lamp does not turn on, replace the lamp immediately. “5-5. Replacement of the lamp” (p. 28)

4. Turn on the pump switch of this device (turn it to |). Check that the operating sound of the pump can be heard.
5. Insert the distal end of the fiberscope into sterile water and gently cover the air hole on the Air/Water feeding valve of the fiberscope. Check whether air comes out of the distal end of the fiberscope and air bubbles are generated (Figure 3.8).

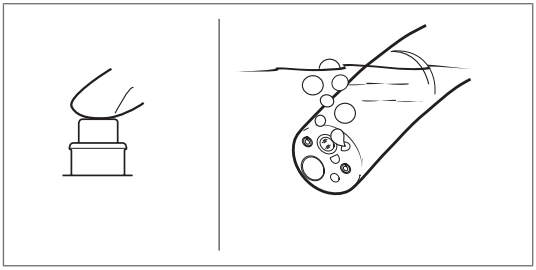


Figure 3.8

Warning

Ensure that freshly sterilized water is used. Using old sterile water may cause infection.

- Remove the distal end of the fiberscope from the water and press down the Air/Water feeding valve. Check whether water comes out of the distal end of fiberscope (Figure 3.9).

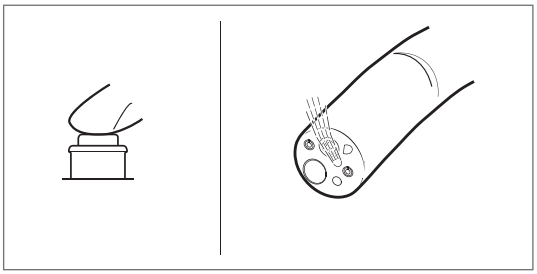


Figure 3.9

6. Turn the brightness control knob to adjust the brightness of your field of view. Look through the fiberscope while adjusting.

Warning

To protect your eyes, avoid looking directly at the light emitted from the fiberscope and/or light source.

Caution

All inspected items should be functioning properly to perform endoscopic examination. If there is a problem with any of the functions, do NOT perform endoscopic examination and contact your local PENTAX Medical service facility.

4 Directions for use

Before using this device, be sure to read these Instructions for Use, those of the endoscope you will be using with this device and those of any other manufacturers' products to ensure proper understanding of the characteristics and safety precautions of this device and use it according to its intended purpose as a specialist examination device.

4-1. **Power**

1. Turn on the power switch on the front of this device (turn it to |).
   - Perform endoscopic examinations in a darkened room to obtain a clearer observation image.
   - Turn on the pump switch on the front of this device (turn it to |) if feeding air or water.

Warning

- Use the lowest quantity of light necessary, to prevent burns to the patient and protect your eyes.
- When feeding water, use sterile water to prevent infection.
- Do not block the air vent while using this device. This device may become hot if the ventilation is blocked.
- Do NOT drop this device or apply a strong shock to it. Failure to observe this precaution may cause loss of safety and effectiveness. If the device is subjected to a strong impact, stop use immediately and contact your local PENTAX Medical service facility.
- If the endoscopic image unexpectedly disappears during the examination due to causes such as a power outage or breaking of equipment such as the lamp, light source or fiberscope, immediately stop using this device and gently remove the fiberscope from the patient according to the instructions for removal in the event of an anomaly in the Instructions for Use of the endoscope. Continued use may injure the patient.

Caution

Do NOT storage this device in a place where it could get wet. Failure to observe this precaution may result in electric shock.

4-2. Turning the power off

Caution

Do NOT turn off the light source before turning off the connected peripheral devices. Failure to observe this precaution can cause failure of the peripheral device(s).

1. Turn off the pump switch on the front of this device (turn it to O).
2. Turn off the power switch on the front of this device (turn it to O).
3. Remove the air/water connector of the water bottle assembly from the endoscope.
   - Insert the air/water connector into the holder of the water bottle cap.
4. Remove the suction tube of the suction source from the endoscope.

5 Maintenance

5-1. After use

1. Turn off the light source.
2. Disconnect the fiberscope, water bottle assembly, and power code from the light source.

> ⚠ Caution
>
> - Do NOT touch the light guide plug immediately after disconnecting the fiberscope as the heat from the lamp may cause burn injury.
> - Pull the fiberscope straight out to prevent excessive force from being applied to the connector.
> - Always turn off the light source before disconnecting the fiberscope. Failure to observe this precaution may cause the fiberscope to malfunction.

3. Wipe the surfaces of the light source with gauze dampened with ethanol (70%-90% concentration) or isopropyl alcohol for disinfection.
   - Follow the below-mentioned procedure to remove body fluids or blood stains that are difficult to remove.
     (1) Wipe the stains using gauze dampened with an enzymatic cleaning solution.
     (2) Remove the cleaning solution with gauze dampened with clean water.
     (3) Wipe off any moisture with dry gauze.
     (4) Wipe all surfaces of the product with gauze dampened with ethanol (70%–90% concentration) or isopropyl alcohol for disinfection.

> ⚠ Caution
>
> - Ensure that no chemical solution or water enters this device during the cleaning and disinfection procedure. In particular, make absolutely sure that no water enters through the connectors and air vents. Entry of a chemical solution or water into the device may cause it to malfunction.
> - Do NOT use a spray-type chemical (e.g., rubbing alcohol) directly on this product as it may enter the device through small openings, for example, the air vents, resulting in device malfunction.

5-2. Storage

Observe the following points with regard to storage.

Caution

- Turn off the device and disconnect the power cord before storage. If the device is connected to the medical isolated transformer of the cart, turn off the cart power and disconnect the power cord from the power outlet.
- Do NOT store the device in a very hot and humid location or where it will be exposed to water or direct sunlight.
- Store the device where it will be protected from dust. If any dust is confirmed, ensure to remove it. Furthermore, when storing the product for a long period, take precautions to reduce dust build-up within the product. Excessive amounts of dust accumulating inside this device may cause it to malfunction, emit smoke, or catch fire or may cause other problems.

5-3. Cleaning and storage of the endoscope

For cleaning and storage of the PENTAX Medical endoscope, follow the instructions given in the IFU of the endoscope.

5-4. Cleaning and storage of the water bottle assembly

For cleaning and storage of the PENTAX Medical water bottle assembly, refer to the IFU of the respective water bottle assembly.

5-5. Replacement of the lamp

The lamp for this device is consumable. If the lamp goes out, follow the steps below to replace the PENTAX OL-H4 Halogen Lamp.

Warning

- Ensure that insulated gloves are worn when replacing the lamp. Failure to observe this precaution may result in electric shock.
- Ensure that the device is turned off and the power cord is disconnected before replacing the lamp. Replacing it while power is being supplied may result in electric shock.
- When replacing the lamp, do NOT touch the light source and the patient simultaneously. Failure to observe this precaution may result in electric shock.
- Do NOT use a lamp not specified by PENTAX Medical as this may generate excessive brightness and/or heat, which could adversely affect the safety of the patients and users.

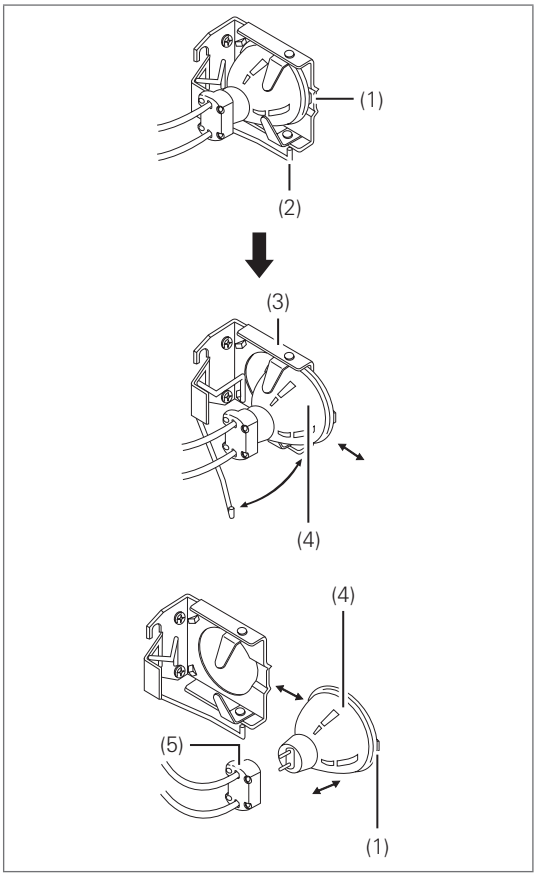
Caution

- Do NOT touch the lamp protective cover or lamp immediately after use. There is a risk of burn injury because these parts are hot immediately after use. Turn off the device and allow sufficient time for these parts to cool down before undertaking lamp replacement.
- Ensure that there is no foreign material inside at the time of lamp replacement as it could result in damage to the device if a foreign material is used when connecting the lamp.
- Attach in the correct position. The ledge should be at the front as shown in the Figure 5.1.
- Do NOT directly touch the glass surface of the new lamp with your fingers. Skin oil from your hands may be transferred onto the glass surface, resulting in insufficient brightness or damage to the lamp. If skin oil or dirt from your hands gets on the glass surface of the lamp, wipe it off with lint-free paper dampened with methanol to avoid the napped paper. Dry the lamp completely before use.
- Do NOT look directly at light emitted from the distal end of the fiberscope and/or light source when checking that the lamp is working after replacing the lamp. Failure to observe this precaution may cause eye injury.

Note

- The approximate lamp life is 50 hours.
- The lamp life may not be as long as 50 hours depending on the method of use and the operating environment.
- If this device still does not work after changing the lamp, check that the lamp housing cover is attached properly. If the lamp housing cover is not straight, or is loose, the safety stop function activates and the power is automatically shut off.

1. Turn OFF the main power by depressing the power switch and disconnect the plug from the power outlet.
2. Loosen the screws of the lamp housing cover using a flat-blade screwdriver, then remove the cover.
   - This exposes the halogen lamp, lamp base and lamp socket.
3. Slide the lamp lever to the left
   - This moves the lamp base forward.
4. Remove the lamp base from the lamp holder.
5. Remove the lamp base from the lamp socket.
6. Attach the new lamp base terminal into the holes in the lamp socket.



(1) Ledge
(2) Lamp lever
(3) Lamp holder
(4) Lamp base
(5) Lamp socket

Figure 5.1

7. Push the lamp base into the lamp holder.
8. Secure the cover by tightening the screws of the lamp housing cover using a flat-blade screwdriver.

5-6. Inspection/replacement of the fuses

If the power does not turn on when the power switch is turned on, turn the power switch off and check that the power cord is properly inserted. If the power still does not turn on when the power switch is turned on, follow the steps below to change the fuses.

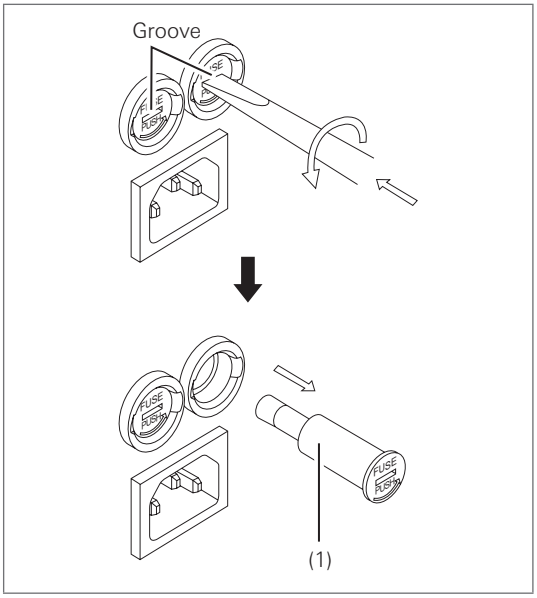
Warning

- Always replace the fuses using the supplied spare fuses (Ø5×20mm, 2 pieces, see the fuse models in "1-1. Contents of the package" (p. 11). If fuses other than the supplied spare fuses are used, the power to the device may be interrupted suddenly during use.
- Connect the fuses such that proper conduction is facilitated between the fuse terminals. Do NOT attempt to use the device when the fuses are not installed.
- When replacing the fuses, do NOT touch parts of the device and the patient simultaneously. Failure to observe this precaution may result in electric shock.

Caution

A flat-blade screwdriver is required to replace the fuses. Take protective measures, such as wearing insulated gloves, to avoid injury.

1. Unplug the power cord.
2. Insert a flathead screwdriver into the groove of the fuse holder and turn it to the left.
3. Remove the fuse holder by hand and inspect it.
4. If a fuse is broken, replace it with a new rated fuse.



(1) Fuse holder

Figure 5.2

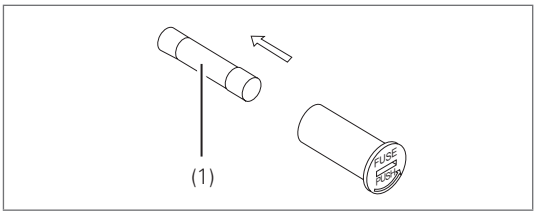
Caution

- Do NOT bypass the fuse.
- Be sure to replace the fuse with the rated fuse indicated on the rating plate.

Note

The rating of the fuse is indicated on a rating plate on the fuse holder.

5. After replacing the fuse, reinsert the fuse holder and tighten it by turning it to the right with a flathead screwdriver.



(1) Fuse

Figure 5.3

Note

If the device cannot be turned on even after the fuses have been replaced with new ones, immediately turn off the power switch, disconnect the power cord, and contact your local PENTAX Medical service facility.

5-7. Returning the light source for repairs

When returning the light source for repairs to PENTAX Medical, be aware of the following points. For further details, contact your local PENTAX Medical service facility.

(1) All equipment requiring repairs should be disinfected by wiping the surface with gauze dampened with a disinfection solution, packed in a shipment box, and shipped with details of the damage or problem.

(2) Write down the repair order number and your contact name, phone number, and shipping address on a piece of paper and include it in the package.

(3) Together with the device, ship all accessories that you think may be, in any way, related to the device damage or problem.

Warning

Ensure to return the device to PENTAX Medical for repairs. Note that PENTAX Medical is in no way liable for any injuries to patients or users, damage or malfunction of the device, and inadequate disinfection or sterilization as a result of repairs being undertaken by an unauthorized person or company.

It must be recognized that PENTAX Medical does not evaluate non-PENTAX Medical parts, components, materials and/or servicing methods. The questions regarding material compatibility and/or functionality of PENTAX Medical instruments built with these unauthorized, untested and unapproved items, materials, repair/assembly methods must be referred to the third party service organization and/or device remanufacturer.

Disposal

Warning

When disposing of the light source, lamp, or other consumables, dispose of them according to the laws and regulations of the relevant country or region. Disposing of them in an inappropriate way may have an adverse effect on the environment.

If you are unsure of the proper disposal method, contact your local PENTAX Medical service facility.

Device specifications

Item		Specifications		
Power	Voltage	120 VAC	220 VAC	230 VAC
	Frequency	50 – 60 Hz		
	Rated input	2 A	1 A	
	Voltage fluctuation	±10%		
Mode of operation	–	Continuous operation		
Operating Environment	Ambient temperature	10 – 40 °C		
	Relative humidity	30 – 85%		
	Air pressure	700 – 1060hPa		
Storage and Transportation Environment	Ambient temperature	-20 – 60 °C		
	Relative humidity	10 – 85%		
	Air pressure	700 – 1060 hPa		
Illumination	Lamp	EFR 15 V 150 W Halogen Model: OL-H4		
	Lamp's average life span	50 hours, continuous use		
Scope compatibility	–	All models of PENTAX Medical fiberscopes		
	–	Other manufacturer's fiberscope (All models with use of appropriate adapters)		
Air supply function	Air pump system	Electro-magnetic vibrator system		
	Air supply pressure (at a flow rate of 0), reference value)	41 – 62 kPa		
	Air supply rate (at the inlet of the water bottle assembly, reference value)	3.2 – 8.0 l/min		

Item		Specifications
Water feed system	Water compression	Pressurized by pumped air
	Water bottle capacity	200 ml
	Water in normal use	2/3 full, sterile water
Brightness Control System	–	Manual adjustment
Cooling	–	Forced air cooling
Classification as Electro-medical Equipment	Type of protection against electric shock	Class I equipment
	Degree of protection against electric shock	Type BF (Body Floating), using insulated endoscope. Use on the heart is prohibited
	Degree of explosion proofing	Do not use in potentially flammable surroundings.*1
Compliance	Designed in accordance with	IEC 60601-1: 2005+A1: 2012 IEC 60601-2-18: 2009
Dimensions	–	135 mm (W) × 165 mm (H) × 270 mm (D)
Weight	–	6kg
Electromagnetic Compatibility	–	IEC 60601-1-2: 2007
IP Classification	–	IPX0
Power Cable	–	2.5 m (120 V), 2 m (220 V), 2.515 m (230 V)

*1: The light source is not suitable for use in a mixture of air and a flammable anesthetic gas or a mixture of oxygen/ nitrous oxide and a flammable anesthetic gas.

Electromagnetic compatibility (EMC)

This product as the endoscope system, the endoscope with the video processor or the light source conforms to IEC60601-1-2: 2007: Medical electrical equipment, IEC standard.

Guidance and manufacturer's declaration-electromagnetic emissions

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	This product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This product is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	100 V or 120 V model Not applicable	
	230 V/50 Hz or 60 Hz model Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	100 V or 120 V model Not applicable	
	230 V/50 Hz model Complies	

Guidance and manufacturer's declaration-electromagnetic immunity

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product 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	± 6 kV contact ± 8 kV air	Same as left	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Same as left	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Same as left	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Same as left	Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during power mains interruptions, it is recommended that this product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Same as left	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.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of this model 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 $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Note

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a)] should be less than the compliance level in each frequency range.[b)]

a) Field 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 this product is used exceeds the applicable RF compliance level above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this product.

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 this product

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

Rated maximum output power of transmitter (W)	Recommended 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 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
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 metres (m) can be estimated using 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

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Electromagnetic disturbances

This product as the endoscope system, the endoscope with the video processor or the light source conforms to IEC60601-1-2: 2014: Medical electrical equipment, IEC standard.

Guidance and manufacturer's declaration-electromagnetic emissions

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Table 1

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	This product uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This product is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	100 V or 120 V model Not applicable	
	230 V/50 Hz or 60 Hz model Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	100 V or 120 V model Not applicable	
	230 V/50 Hz model Complies	

Guidance and manufacturer's declaration-electromagnetic immunity

This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should assure that it is used in such an environment.

Table 2: Enclosure Port

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to Table5
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Table 3: Input AC Power Port

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS
Electrical fast transients/bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Surges Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips	IEC 61000-4-11	0 % U_T; 0,5 cycle At 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 ° and 315 °
		0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0 °
Voltage interruptions	IEC 61000-4-11	0 % U_T; 250/300 cycles

Note: If this product has the single rated voltage, U_T is the rated voltage.
If the rated voltage has the range, U_T is the lowest voltage and the highest voltage in the voltage range.

Table 4: PATIENT coupling PORT

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz

Immunity to proximity fields from wireless communications equipment

Table 5: Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Modulation[a)]	Maximum power(W)	Distance (m)	Immunity test level (V/m)
385	380 to 390	Pulse modulation[a)] 18 Hz	1.8	0.3	27
450	430 to 470	FM[b)] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 to 787	Pulse modulation[a)] 217 Hz	0.2	0.3	9
745					
780					
810	800 to 960	Pulse modulation[a)] 18 Hz	2	0.3	28
870					
930					
1720	1700 to 1990	Pulse modulation[a)] 217 Hz	2	0.3	28
1845					
1970					
2450	2400 to 2570	Pulse modulation[a)] 217 Hz	2	0.3	28
5240	5100 to 5800	Pulse modulation[a)] 217 Hz	0.2	0.3	9
5500					
5785					

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

b) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Note

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

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

a) Field 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 this product is used exceeds the applicable RF compliance level above, this product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this product.

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 this product

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

Warning

Portable RF communications equipment should be used no closer than 30 cm to any part of this product or the peripheral equipment connected to this product, including cables specified by this IFU. Otherwise, degradation of the performance of this product could result.

Note

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Contacts

Manufacturer

HOYA Corporation
6-10-1 Nishi-shinjuku,
Shinjuku-ku, Tokyo
160-0023 Japan

Distributors

PENTAX Europe GmbH EC REP
Julius-Vosseler-Straße 104
22527 Hamburg, Germany
Tel: +49 40 561 92-0
Fax: +49 40 560 42 13

PENTAX Medical
A Division of PENTAX of America, Inc.
3 Paragon Drive
Montvale, NJ 07645-1782
USA
Tel: +1 201 571 2300
Toll Free: +1 800 431 5880
Fax: +1 201 391 4189

PENTAX Medical Shanghai Co., Ltd.
Room 701, 291 Fumin Road, Shanghai
200031 P. R. China
Tel: +86 21 6170 1555
Fax: +86 21 6170 1655

PENTAX Medical Singapore Pte. Ltd.
438A Alexandra Road, #08-06
Alexandra Technopark, 119967 Singapore
Tel: +65 6507 9266
Fax: +65 6271 1691
Customer Service Toll Free:
400 619 6570 (within China)
1800 2005 968 (within India)
1300 PENTAX (within Australia)

CE 0123

88865

LCPM: 05/2021/07/35006102 2021. 01 6217001 P113 R03

PENTAX MEDICAL
Excellence in Focus

PENTAX
MEDICAL

EU DECLARATION OF CONFORMITY

We ; HOYA Corporation
6-10-1 Nishi-shinjuku, Shinjuku-ku, Tokyo
160-0023, Japan (SRN: JP-MF-000005227),

whose Authorized Representative in the European Union is :
PENTAX Europe GmbH, Julius Vosseler Straße 104, 22527 Hamburg, Germany
(SRN: DE-AR-000000006),

declare under our sole responsibility that PENTAX or PENTAX Medical brand product(s) below:

Product Category	:	Endoscopes, video processors and accessories
Model Name	:	See Attached
General Name	:	See Attached
Basic UDI-DI	:	See Attached
UDI-DI	:	See Attached
Risk Classification	:	I

conform(s) to;

1) the conformity assessment procedure in Annex II and III in accordance with the provisions of Regulation (EU) 2017/745 (**EU-MDR**) and the provisions of RoHS Directive (EU) 2015/863.

2) applicable common Specification(s): Not available as it has not been issued

Place:
Tokyo Japan

Signature:

Date:
May 27, 2021

Kazunori Shimada
RA Manager
Regulatory Affairs Department
PENTAX Lifecare Division
HOYA Corporation

No	Model Name	General name	Basic UDI-DI	UDI-DI	Initial DoC date	Note
1	SAS-M10	Polyp Detector	4961333010401XT	04961333247493	June 1, 2020	
2	BS-LL1	LED Light Sources(Battery Type)	4961333010304XU	04961333227259	May 20, 2021	
3	CP-1000	Endoscopic Video Image Processor	4961333010302XQ	04961333239771	May 20, 2021	
4	NCU-7000	Navigation Control Unit	4961333010402XV	04961333245659	May 20, 2021	
5	SHA-P6	Leakage Tester	4961333010508YE	04961333246342	May 20, 2021	
6	PVK-CP	Add-on Camera	4961333010114XM	04961333239368	May 20, 2021	
7	PVK-J10	Add-on Camera	4961333010114XM	04961333246304	May 20, 2021	
8	VNL9-CP	Video Naso-Pharyngo-Laryngoscope	4961333010105XL	04961333239801	May 20, 2021	
9	ONE-M	Mobile Processor	4961333010305XW	04961333248322	May 26, 2021	20210526 Added
10	ONE-DOCK	Mobile Processor Plug-in	4961333010306XY	04961333248339	May 26, 2021	20210526 Added

PENTAX
MEDICAL

EU DECLARATION OF CONFORMITY

We ; HOYA Corporation
6-10-1 Nishi-shinjuku, Shinjuku-ku, Tokyo
160-0023, Japan (SRN: JP-MF-000005227),

whose Authorized Representative in the European Union is :
PENTAX Europe GmbH, Julius Vosseler Straße 104, 22527 Hamburg, Germany
(SRN: DE-AR-000000006),

declare under our sole responsibility that PENTAX or PENTAX Medical brand product(s) below:

Product Category	:	Endoscopes, Video Processors and its accessories
Model Name	:	See Attached
General Name	:	See Attached
Basic UDI-DI	:	See Attached
Risk Classification	:	IIa

conform(s) to;

1) the conformity assessment procedure in Annex IX in accordance with the provisions of Regulation (EU) 2017/745 on Medical Devices (**EU-MDR**) which is based on EC Certificate issued by TUV SUD Product Service GmbH (No.0123), Ridlerstrase 65, 80339 Munchen, Germany(Certificate No.: G10 068357 0031) and the provisions of RoHS Directive (EU) 2015/863.

2) applicable common Specification(s): Not available as it has not been issued

Place:
Tokyo Japan

Signature:

Date:
December 27, 2022

IKEDA Takahiro
Vice President
Global Quality Assurance &
Regulatory Affairs
PENTAX Lifecare Division
HOYA Corporation

No	Model Name	General name	Basic UDI-DI	Initial DoC date	Note
1	EB11-J10	PENTAX Medical Video Bronchoscope	4961333010101XC	Feb.2, 2022	
2	EPK-i8020c	PENTAX Medical Video Processor	4961333010301XN	Dec.14, 2022	20221214 added
3	EC38-i20cL	PENTAX Medical Video Colonoscope	4961333010102XE	Dec.27. 2022	20221227 added
4	EC38-i20cF	PENTAX Medical Video Colonoscope	4961333010102XE	Dec.27, 2022	20221227 added
5	EC38-i20cM	PENTAX Medical Video Colonoscope	4961333010102XE	Dec.27, 2022	20221227 added
6	EG29-i20c	PENTAX Medical Video Upper GI Scope	4961333010104XJ	Dec.27, 2022	20221227 added