



Instructions for Use Single-use Flexible Video Bronchoscope

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Instructions For Use

Single-use Flexible Video Bronchoscope

CE 2797

Model

Bry series Single-use Flexible Video Bronchoscope:

Bry-25A, Bry-25B, Bry-48A, Bry-48B, Bry-52A, Bry-52B, Bry-52LA, Bry-52LB.

Introduction

This instruction manual describes how to properly and safely use and maintain a single-use flexible video Bronchoscope (referred to as the " Bronchoscope " or this product).

How to get help

For technical support, ordering, service and return authorization, please contact us.

Equipment introduction

This product is a sterile, disposable endoscope, used in conjunction with the PV-20A digital video processor (hereinafter collectively referred to as the " digital video processor") produced by our company .

User Info

This product and its related instructions are only for use by doctors who have received training in endoscopic diagnosis and treatment.

Before using this product (coupled with our company's digital video processor) for diagnosis and treatment, it is recommended to fully understand the technology, principles, clinical applications and risks related to bronchoscopy.

It is essential for operators to have received sufficient training in clinical endoscopic techniques and to be familiar with the intended use, warnings and cautions described in these instructions

Intended conditions of use: Hospital operating room or endoscopy suite.

Intended Patient Population

Adult patients who, judging from a medical perspective, need to undergo bronchial endoscopy for diagnosis and treatment.

Packaging composition

This product packaging should contain:

- One with sterilized primary packaging for this product;

- An instruction manual for use;

Specifications

Performance specifications		
Model	Bry-25A	Bry-25B
Viewing angle	0 ± 10 ° (looking forward)	
Field of view	120 ° ± 15%	
Depth of field	3~100mm	
Insertion tube outer diameter	2.5 ± 0.2mm	
Maximum outer diameter of insert section	≤2.7mm	
Insert length	600 ± 50mm	
Working channel diameter	1.2 ± 0.1mm	
Bending properties	220° (tolerance -5% / + no limited, without instrument inserted)	
Use with endotracheal tube channel inner diameter	4.0mm	
Used with double lumen tube channel inner diameter	Fr28(9.3mm)	
Applicable instrument outer diameter for working channel	≤1.0mm	
Adapt to the inner diameter of the suction tube	6.5± 1mm	
Color of control lever	Orange	Black

Performance specifications		
Model	Bry-48A	Bry-48B
Viewing angle	0 ± 10 ° (looking forward)	
Field of view	110 ° ± 15%	
Depth of field	3~100mm	
Insertion tube outer diameter	4.8 ± 0.2mm	
Maximum outer diameter of insert section	≤5.2mm	
Insert length	600 ± 50mm	
Working channel diameter	2.2 ± 0.2mm	
Bending properties	220° (tolerance -5% / + no limited, without instrument inserted)	
Use with endotracheal tube channel inner diameter	6.0mm	
Used with double lumen tube channel inner diameter	Fr40(13.3mm)	
Applicable instrument outer diameter for working channel	≤1.8mm	
Adapt to the inner diameter of the suction tube	6.5± 1mm	
Color of control lever	Orange	Black

Performance specifications		
Model	Bry-52A	Bry-52B
Viewing angle	0 ± 10 ° (looking forward)	
Field of view	110 ° ± 15%	
Depth of field	3~100mm	
Insertion tube outer diameter	5.2 +0.2/-0.5mm	
Maximum outer diameter of insert section	≤5.5mm	
Insert length	600 ± 50mm	
Working channel diameter	2.2 ± 0.2mm	
Minimum Bending properties	220° (tolerance -5% / + no limited, without instrument inserted)	
Use with endotracheal tube channel inner diameter	6.5mm	
Used with double lumen tube channel inner diameter	Fr40(13.3mm)	
Applicable instrument outer diameter for working channel	≤1.8mm	
Adapt to the inner diameter of the suction tube	6.5± 1mm	
Color of control lever	Orange	Black

Performance specifications		
Model	Bry-52LA	Bry-52LB
Viewing angle	0 ± 10 ° (looking forward)	
Field of view	120 ° ± 15%	
Depth of field	3~100mm	
Insertion tube outer diameter	5.2 +0.2/-0.5mm	
Maximum outer diameter of insert section	≤5.5mm	
Insert length	600 ± 50mm	
Working channel diameter	2.8 ± 0.2mm	
Minimum Bending properties	220° (tolerance -5% / + no limited, without instrument inserted)	
Use with endotracheal tube channel inner diameter	6.5mm	
Used with double lumen tube channel inner diameter	Fr40(13.3mm)	
Applicable instrument outer diameter for working channel	≤2.5mm	
Adapt to the inner diameter of the suction tube	6.5± 1mm	

Color of control lever	Orange	Black
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Intended use

The Single-use Flexible Video Bronchoscope has been designed to be used with the company's PV-20A Digital Video Processor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

Clinical Benefits

- This device can relieve patients' symptoms, provide adequate oxygenation with mechanical ventilation, and improve the quality of life of patients.
- This device can provide valuable diagnostic information to help diagnose infections or evaluate for certain lung diseases.
- This device can eliminate the risk of cross-contamination.

Contraindications

Contraindications related to the use of this device include:

- Observed and diagnosed with bronchoscopy from a medical point of view;
- Specific contraindications related to bronchial endoscopy and intubation.

Warning

- The endoscope is a single-use device and must be handled in a manner consistent with accepted medical practice for such devices in order to avoid contamination of the endoscope prior to insertion.
- Using this product, please read the product instruction manual, digital video processor instruction manual and monitor user manual. Failure to follow instructions or failure to observe warnings or precautions may cause harm to the patient. Use by untrained clinical users may cause harm to patients.
- Use this product in the presence of flammable liquids or gases such as detergents, anesthetics, nitric oxide (NO), or high concentrations of oxygen, as this may cause a fire and burn the operator and patient.
- The endoscope is not to be used when delivering high concentration oxygen or highly flammable anaesthetic gases to the patient. This could potentially cause patient injury.
- The endoscope is not to be used with electrosurgical equipment when delivering oxygen to the patient. This could potentially cause patient injury.
- Do not use if sterile packaging is damaged. Failure to do so will result in patient infection.
- This product is a single-use device and must not be reused, even after re-sterilization and re-sterilization. Failure to do so may result in equipment damage, leading to cross-infection.
- This product if it has expired.

- Do not perform treatment with the endoscope attachment out of the field of view or with the tip of the product pressed against the mucous membrane. Failure to do so may result in patient injury such as perforation, bleeding, or mucosal damage.
- The insertion tube needs to be advanced or withdrawn slowly and gently without excessive force, otherwise it may cause injuries to the patient, such as perforation, tissue tearing, bleeding, or mucosal damage. If resistance is felt when advancing or withdrawing the scope tube, the source of the resistance should be investigated and remedial measures should be taken (such as fluoroscopy, injection of contrast agent).
- Do not look directly at the light emitted by this product. Failure to do so may result in eye injury.
- Images should not be used as an independent diagnosis of any pathology. Physicians must use other methods and interpret and substantiate any findings based on the patient's clinical characteristics.
- The endoscope is not to be used in MRI environment.
- When this product is used together with other medical equipment whose applied part is connected to the power supply, it may cause excessive leakage current to the patient and cause injury to the patient.
- When this product is used together with active surgical equipment, the maximum rated repetitive peak-to-valley voltage value of the active surgical equipment acting on the patient should not exceed 3.5kV.
- Do not use spare parts, accessories or cables not specified or provided by Tuyun, otherwise it may cause failure of the disposable electronic bronchial imaging Bronchoscope, increase in radiation, or decrease in anti-interference performance.
- Always check the compatibility of this product with airway management accessories and endoscopic devices. Failure to do so may result in patient injury.
- The surface temperature of the light output part of the distal tip of Bronchoscope may be too high. In order to avoid scald the patient's tissue, the brightness of the light source should be reduced as low as possible and the direct contact time between the light exit surface of the distal tip and the target tissue should be shortened as much as possible or an appropriate distance should be maintained.
- When the tip of bronchoscope sticks to the surface of tissue, the tip surface temperature may exceed 41°C in a short time, with a maximum temperature of 51.5°C.
- The tip of bronchoscope is moving and rotating during procedure, and the continuous contact time between the tip of Bronchoscope and the tissue will not exceed one minute normally. There will be overheat hazard if the Bronchoscope remains static over one minute within the airways and tracheobronchial tree.
- This product is a single-use device with no serviceable parts. Do not repair a product that is damaged or inoperable. If you find or suspect damage to this product, do not use it.
- Do not apply this product and instrument to the heart or any area near the heart. This product is a BF type applied component, and leakage current may endanger cardiac function.
- This product should be removed from the patient before using the defibrillator. Failure to remove the product from the patient during use of the defibrillator may result in injury to the patient or damage to the product due to discharge from the defibrillator.
- When injecting inert gas or laser-assisted gas into the patient during surgery, please pay attention to avoid causing gas embolism.

- Always ensure that all tubing connected to the suction connection on this product is connected to the suction device. The cannula must be correctly fixed on the suction port before suctioning. Failure to do so may result in injury to the patient or user.
- During suction, apply a negative pressure not exceeding 85kPa. Applying too much negative pressure may make it difficult to interrupt suction and may result in patient injury.
- Before aspiration, ensure that the biopsy cap and its bonnet are properly installed and connected. During manual aspiration, ensure that the syringe tip is fully inserted into the working channel port/biopsy valve before aspiration. Failure to do so may expose unprotected users to the risk of infection.
- For non-intubated patients, the use of a bite mouthpiece is recommended when inserting an endoscope orally to prevent the patient from biting on the Bronchoscope insertion tube and potentially damaging the teeth.
- The shape and size of the nasal cavity and its suitability for transnasal insertion may vary from patient to patient. Prior to surgery, the shape and size of the patient's nasal cavity must be considered, as well as individual differences in the patient's acceptance of transnasal insertion. Never use force during transnasal insertion or removal of the endoscope as this may cause injury to the patient.
- For prompt detection of oxygen desaturation events, patients should be monitored at all times during use.
- The device should not be used if adequate supplemental oxygen cannot be provided to the patient during the procedure. Failure to follow this principle may result in a decrease in the patient's oxygen saturation.
- Before using the imaging Bronchoscope, check whether the image on the screen is live or recorded, and verify that the image is oriented as expected
- The product should not be used in patients with malignant arrhythmias, unstable cardiac status, acute myocardial infarction within 4-6 weeks, refractory hypoxemia, bleeding diathesis, or severe thrombocytopenia if biopsy is required as directed by a physician.
- This product can only be used with the digital video processor produced by our company. Connecting it to other equipment may cause damage to the device and may also cause personal injury.
- Keep watching the live endoscopic image on the displaying unit when advancing or withdrawing the endoscope when operating. Failure to do so may cause injury to the patient.
- When withdrawing the endoscope, the distal tip shall be in neutral and non-deflected position. Do not operate the control lever, it may avoid injury to the patient and/or damaging to the endoscope.
- Do not advance or withdraw the endoscope, or operate the bending section, while endoscopic accessories are protruding from the distal tip of the working channel, as this may result in injury to the patient.
- Always make sure that the bending section is in a straight position when inserting or withdrawing an endoscopic accessory in the working channel. Do not operate the control lever and never use excessive force, as this may result in injury to the patient and/or damage to the endoscope.
- When using the ACDC adaptor, to avoid risk of electric shock, the system shall be connected to a supply mains with protective earth. To disconnect the system from mains, remove the ACDC adaptor mains plug from the wall outlet.
- 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

bronchoscope, including cables specified by the Tuyun. Otherwise, degradation of the performance of this equipment could result.

Precautions

- Damage to the Bronchoscope cable interface may result in failure to develop or unexpected image disappearance. Please check whether the cable interface is intact before use.
- Do not insert a wet host plug into the digital video processor, otherwise it may cause image performance degradation or product damage.
- Before use, check whether the insertion part of this product has rough surfaces, sharp edges or protrusions that may cause safety hazards.
- Place this product and other connected equipment appropriately to avoid tripping over cables.
- Use of electrosurgical equipment with this product may interfere with the image on the display unit or external monitor.
- When used together with other medical equipment, the instructions for the jointly used equipment should be followed to avoid safety hazards.
- Do not apply lubricant to the distal tip of this product, otherwise it may affect the clarity and brightness of the field of view.
- Surgical instruments placed in the working channel of this product will reduce the suction force. To obtain the best suction capacity, it is recommended to remove the surgical instruments in the working channel before suctioning.
- When using, the operator is asked to wear disposable gloves.
- Before using other diagnostic and treatment accessories with this product, please read the instructions to check the compatibility and adaptability, including but not limited to the aperture fit of the working channel, the working length, the flexibility of the diagnostic and treatment accessories, etc.
- When the bend section of the imaging Bronchoscope is bent at a large angle, forcefully insert the instrument through the bend, which will cause damage to the bend section of the Bronchoscope or damage to the instrument channel and air leakage.
- If applicable, verify that endotracheal tubes and double lumen tubes are compatible with this product before starting the procedure.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Potential adverse events

Potential adverse events in relation to flexible bronchoscopy (not exhaustive):

Tachycardia/bradycardia, hypotension, bleeding, bronchospasm/laryngospasm, cough, dyspnoea, sore throat, apnoea, seizure, desaturation/hypoxemia, epistaxis, haemoptysis, pneumothorax,

aspiration pneumonia, pulmonary oedema, airway obstruction, reaction to drug or topical anaesthesia, fever/infection, and respiratory/cardiac arrest.

Conformance of standards

Essential Performance Statement:

Team has considered IEC60601-2-18 requirement and actual clinical situation of this system, below essential performance requirement has been identified:

ID	Requirement
1	Product provides a live image during an endoscopic procedure, rather than a recorded image.

How supplied

The Bronchoscope is supplied sterile in a tray.

Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

Use and storage

Environment During Transportation, Use, and Storage

The Bronchoscope should be stored in a cool, dry, dark place.

Usage environment

operating environment	
Ambient temperature (°C)	5~40
Relative humidity (%)	20~80
Atmospheric pressure (hPa)	700~1060
Transport and storage environment	
Ambient temperature (°C)	-20~60
Relative humidity (%)	10~90
Atmospheric pressure (hPa)	700~1060

Compatibility

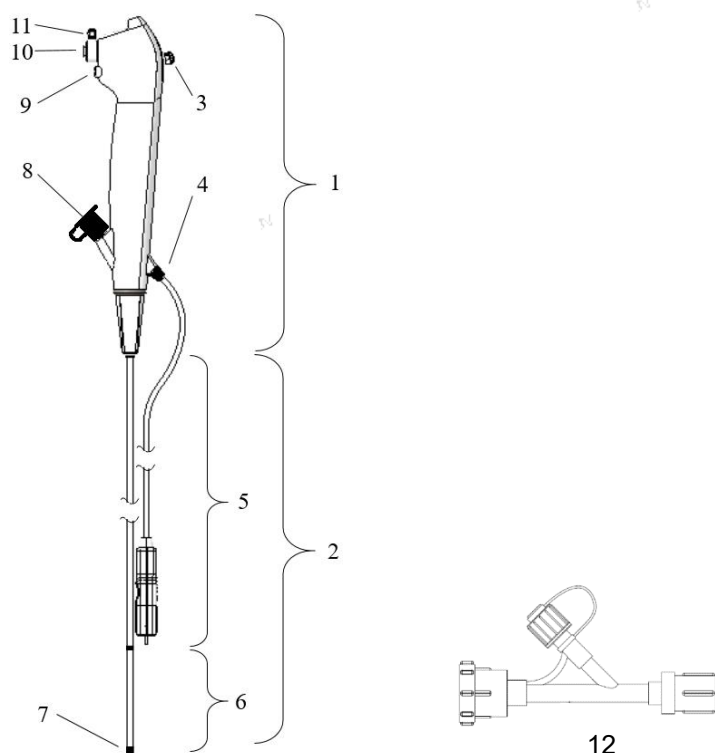
This product is compatible with the following auxiliary devices and accessories:

1. Used in conjunction with the electronic endoscope digital video processor produced by our company
2. Other accessories (devices used through working channels):
 - Accessory device compatible with 1.2mm working channel diameter (for Bry-25A, Bry-25B)
 - Accessory device compatible with 2.2mm working channel diameter (for Bry-48A, Bry-48B, Bry-52A, Bry-52B)
 - Accessory device compatible with 2.8mm working channel diameter (applicable to Bry-52LA, Bry-52LB)

Composition structure

The disposable electronic bronchial imaging Bronchoscope consists of a distal tip, a bending part, an insertion part, an operating part, and an electrical connector.

The following shows the structural composition of this product and the names of corresponding parts.



1-Operation Department	6- Bending part	11- Attract interface
2- Insertion section	7- Distal tip	12- Valve (optional accessories, including Y-shaped and T-shaped)
3- Control lever	8- Entrance to work channel	
4- Electrical connection	9- Button	
5- Insertion tube	10 - Attract button (Activates suction when pressed down)	

Figure 1. Structural diagram

Setup and operation

Unpack and inspect this product

- Open the shipping package and remove the sterile packaging.
- Check the expiry date on the sterile packaging. Do not use if expiry date expires.
- Make sure the sterile packaging is intact and has no holes or tears. Otherwise, do not use.
- Before use, check the distal tip and the entire insertion tube surface for any rough surfaces, sharp edges or protrusions that may cause safety hazards. Check the operating section to make sure there are no loose or damaged components.
- Rotate the control lever on the operating part and visually confirm that the bending part is working properly. Operation should be smooth and accurate. Do not straighten or bend the bend while holding the control lever, as this may cause damage to the device.
- Visually inspect the product cable and host plug for kinks or damage. Check the product for

damage. Do not use this product if parts are found to be damaged or missing. Various damages will affect the function of the product and may cause human injury.

- If you find that labels, silk screens on the product have fallen off, or the logo is unclear, causing the information to be unrecognizable, please do not use the product and contact Tuyun immediately.

The button on handle

There are two buttons on product handle, by default the A button is defined to freeze and save the live image during procedure, the B button is defined to switch the image enhancement mode on the digital video processor.

They also could be defined as the shortcut key of other functionalities on Digital Video Processor.

The details information about how to define the functionalities of these two buttons, please refer Digital Video Processor user manual.

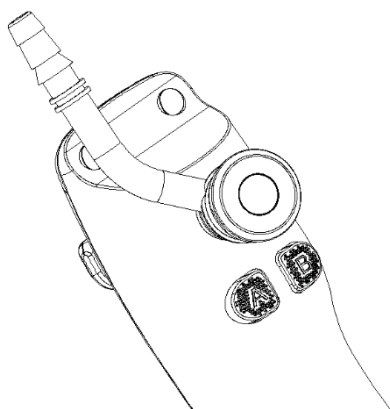


Figure 2. A button and B button on handle

Connect the digital video processor and check the image

Connect this product to the digital video processor.

After plugging in, confirm that the live image is displayed correctly on the monitor.

After insertion, confirm that a light beam emitted from the distal tip of the endoscope.

Point the distal tip of the endoscope at an object to be measured and move it between 1cm and 6cm.

Confirm that the image brightness of the measured object on the monitor is uniform. Align the end of the endoscopic lens with your palm and confirm that there is no noise, blur, or other abnormalities in the endoscopic image.

Set the A/B handle button functions on the digital video process according to the digital video processor instructions and confirm whether the button functions are normal.

WARNING: Do not direct the light emitted from the endoscope head end toward your eyes, as this may result in eye injury.

Prepare

- Carefully slide the flex lever back and forth to bend the flex as far as possible. Slowly slide the bend lever to its natural position. Make sure the curved portion functions smoothly and correctly back to the neutral position.
- Use a syringe to inject 2 ml of sterile water into the access port (if using a screw-top syringe, use the included introducer). Squeeze the cuff to make sure there are no leaks and water comes out from the tip end.
- If applicable, prepare the suction equipment according to the supplier's manual instructions. Connect the suction tube to the suction connector and check that suction is possible by pressing the suction button.
- If it is anticipated that the use of suction equipment will be required while performing a procedure, prepare the suction equipment according to the supplier's manual instructions.
- If applicable, verify that the endoscope accessory is compatible with this product before starting the procedure.

CAUTION: Do not use the flush tube without a disposable backflow prevention check valve. Failure to do so may result in contamination of the device or lead to patient infection or cross-contamination.

Hold and manipulate the top of the viewing Bronchoscope

- Hold the handle and insertion part of this product, push the intubation tube into the patient's mouth or nose, and slowly push it to the expected examination position.
- Use your thumb to move the control lever to deflect the distal tip of the endoscope. The Bronchoscope tube should always be held as straight as possible to ensure the best top bending angle.

Insert Bronchoscope

- Use medical grade lubricant to lubricate the cannula when inserting this product into the patient.
- If the image is unclear, clean the top by gently rubbing it against the mucosal wall, or clean the top.
- When inserting this product through the mouth, it is recommended to place a mouth pad over the mouth to protect the product from damage.

Freeze and save images

- When you need to freeze and save an image, press the button on the operating part to indicate that the image is in a frozen state;
- When it is necessary to unfreeze, press the button on the operation part again, the frozen state of the interface will disappear and the real-time image will be restored.

Suction

- When connecting the suction system to the suction interface, you can use your index finger to press the suction button to perform suction;
- If there are introducers and/or endoscope accessories placed in the operating channel, the suction power will decrease;
- For optimal aspiration, it is recommended to completely remove the introducer or syringe during aspiration.

Inserting endoscope accessories

- Using the correct size endoscope attachment, insert the attachment into the working channel entrance and carefully push it through the working channel until it is visible on the screen;
- Use the included guide to facilitate insertion of soft accessories.
- If necessary, valves can be installed to increase the access to the working channels of auxiliary equipment.

WARNING: Nasal insertion of this product may be accompanied by restriction of the nasal passageway due to inflammation of the nasal passages, in which case the insertion tube should not be withdrawn with force, as this may result in patient injuries, such as hemorrhage and mucous membrane tearing.

WARNING: Nasal insertion of this product may result in nasal bleeding; be prepared to deal with bleeding.

WARNING: Properly prep and lubricate the patient prior to transnasal insertion of this product, as failure to do so may result in nasal bleeding or mucosal tears, and the user needs to take into account the fact that the longer the procedure, the less effective the prep and lubricant will be.

Remove accessories from Bronchoscope

- With live video, the attachment is withdrawn to the tip of the insertion part.
- Slowly remove the accessory from the insertion part. If resistance is felt, identify the cause of the resistance before withdrawing the accessory.
- Attachments can be removed and replaced at any time throughout the procedure.

Safely terminate the operation of this product during surgery

During surgery, follow these steps to terminate the operation of this product:

- Remove this product from the patient;
- Pulling out this product, keep the bend in a relaxed state.
- Press the plug latch on the host plug and pull the host plug outward to disconnect from the digital video processor;
- Turn off the digital video processor power.

Disposal of this product and packaging materials

- Dispose of this product in accordance with hospital regulations for biohazards.
- Dispose of packaging materials in accordance with the relevant laws and regulations of your country/region.
- Products must be repaired and serviced by the manufacturer or a manufacturer-authorized customer service representative.

Appendix

Includes:

- Appendix 1 -- Guidance and Manufacturer's Statement -- Electromagnetic Radiation
- Appendix 2 -- Guidance and Manufacturer's Declaration -- Electromagnetic Immunity
- Appendix 3 -- Guidance and Manufacturer's Declaration -- Electromagnetic Immunity -- Applicable to non-life supporting ME EQUIPMENT and ME SYSTEMS
- Appendix 4 -- Recommended separation distance between portable and mobile RF communications equipment and this product
- Appendix 5 -- Medical Design Standards and Specifications

Single-use electronic Bry series bronchoscopy (Bry-25A, Bry-25B, Bry-48A, Bry-48B, Bry-52A, Bry-52B, Bry-52LA, Bry-52LB) are hereinafter referred to as this product.

Warning: Except for transducers and cables sold by the manufacturer of this product as spare parts for internal components, the use of accessories, transducers and cables other than those specified may result in increased emissions or reduced immunity of this product.

Warning: This product should not be used close to or stacked with other equipment. If it is necessary to be used close to or stacked, you should observe and verify that it can operate normally under the configuration used.

Warning: Use of unspecified accessories, transducers or cables with this product may result in increased emissions or reduced immunity of this product.

Appendix 1 — Guidance and Manufacturer's Declaration-Electromagnetic Emissions

The Bronchoscope is intended for use in the electromagnetic environment specified below (Table 1)

Table 1. Guidelines and manufacturer's declaration - electromagnetic radiation IEC 60601-1-2:2014+A1:2020

Emission standard	Compliance	Guidance
RF emissions CISPER 11	Group 1	This instrument uses RF (Radio Frequency) 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 CISPER 11	Class A	The equipment is suitable for use in all establishments, other than non-domestic or domestic establishments directly connected to the public low-voltage power supply network that supplies buildings used.
Main terminal conducted emissions CISPER 11	Class A	

Appendix 2 — Guidance and Manufacturer's Declaration-Electromagnetic immunity

The Bronchoscope is intended for use in the electromagnetic environment specified below (Table 2)

Table 2. Guidance and Manufacturer's Declaration-Electromagnetic immunity IEC 60601-1-2:2014+A1:2020

Immunity test	IEC 60601-1-2:2014+A1:2020 test level	Compliance level	Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8KV Contact ±2 , ±4,±8, ± 15 KV Air	Same as left	Floors should by be made of wood, concrete, or ceramic tile that hardly produces static. If floors are covered with synthetic material that tends to produce static, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2KV AC power lines	Same as left	Mains power quality should be that of a typical commercial (original condition feeding the

Surge IEC 61000-4-5	±0.5, ±1 KV AC power line(s) to line(s) ±0.5, ±1, ± 2 KV AC power line(s) to ground	Same as left	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips: < 5 % UT(>95% dip in UT) For 0.5 and 1 cycle 70% UT(30% dip in UT) for 25 and 30 cycles Voltage interruptions: <5% UT(>95% dip in UT) For 250 and 300 cycles	Same as left	Mains power quality should be that of a typical commercial or hospital environment. If the user of this instrument required continued operation during power mains interruptions, it is recommended that this instrument be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A / m 50 and 60Hz	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current.
Note — UT is the ac mains power supply prior to application of the test level.			

Appendix 3—Guidance and Manufacturers Declaration—Electromagnetic Immunity

The Bronchoscope is intended for use in the electromagnetic environment specified below (Table 3).

The customer or the user of the Controller should assure that it is used in such an environment.

Table 3. Guidance and manufacturers declaration—electromagnetic immunity IEC 60601-1-2:2014+A1:2020

Immunity Test	IEC 60601-1-2:2014+A1:2020 test level	Compliance Level	Electromagnetic Environment (Guidance)
Proximity fields From RF wireless communications equipment (IEC 61000-4-3)	Refer to next table	Same as left	Portable and mobile RF communications equipment should be used no closer to any part of the product
Proximity magnetic fields (IEC 61000-4-39)	134.2 kHz, PM, 2.1 kHz, 65 A/m 13.56 MHz, PM, 50 kHz, 7.5 A/m	Same as left	The sources of proximity magnetic fields should be used no closer than 0.15 m to any part of the product

Immunity Test	IEC 60601-1-2:2014+A1:2020 test level	Compliance Level	Electromagnetic Environment (Guidance)
Conducted RF IEC 61000-4-6	3Vrms 150kHz-80MHz 6Vrms _ In ISM band 150kHz-80MHz; 80% AM at 1kHz	3Vrms 150kHz-80MHz 6Vrms _ In ISM band 150kHz-80MHz; 80% AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ 150 KHz- 80 MHz outside ISM $d = 1.2 \sqrt{P}$ 150 KHz- 80 MHz in ISM ^a $d = 1.2 \sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.7GHz 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) ^b. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^c, should be less than the compliance level in each frequency range ^d. Interference may occur in the vicinity of equipment marked with the following Symbol: 
Radiated RF IEC 61000-4-3	3V/m 80 MHz - 2.7 GHz	3V/m 80 MHz - 2.7 GHz	
Note 1 : At 80MHz and 800MHz, 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.			

A: The ISM (industrial, scientific and medical) bands between 150kHz and 80MHz are 6.765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz.

B: The compliance levels in the ISM frequency bands between 150kHz and 80MHz and in the frequency range 80MHz to 2.7GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formula used in calculating the recommended separation distance for transmitters in these frequency ranges.

C: 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 Workstation is used exceeds the applicable RF compliance level above, the Workstation should be observed to verify normal operation. If abnormal performance is

observed, Additional measures may be necessary, such as re-orienting or relocating the Workstation.
D: Over the frequency range 150kHz to 80MHz, field strengths should be less than [3] V/m.

Recommended minimum separation distances:

Nowadays, many RF wireless equipment have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. This Systems has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and this Systems as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900;	Pulse modulation 217Hz	2	0.3	28
1845						
1970						

		DECT; LTE Band 1, 3, 4, 25; UMTS				
2450	2400- 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100- 5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

Appendix 4- Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the Bronchoscope

The Bronchoscope is used in a controlled electromagnetic radiation environment. When using portable and mobile RF communication equipment, refer to the recommended separation distance in Table 4 to prevent electromagnetic interference.

Table 4. Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the Bronchoscope.

Max Output Power (Watts)	Separation distance based on transmitter frequency (m)			
	$d = 1.2\sqrt{P}$ 1 50KHz - 80MHz _ outside ISM bands	$d = 1.2\sqrt{P}$ 1 50KHz - 80MHz _ in ISM bands	$d = 1.2\sqrt{P}$ 80MHz - 800MHz _	$d = 2.3\sqrt{P}$ 800MHz - 2.7GHz
0.01	0.12	0.12	0.12	0.23 _
0.1	0.38	0.38	0.38	0.73 _
1	1.2	1.2	1.2	twenty three
10	3.8	3.8	3.8	7.3 _
100	12	12	12	twenty three

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: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3: An additional factor of 10/3 has been incorporated into the formula used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix 5-Medical design standards and specifications

The Bronchoscope meets the medical design standards and specifications in Table 5.

Table 5. Medical design standards and specifications

Design Specifications against Standards	
Degree of protection against electric shock of applied part	TYPE BF applied part
Degree of protection against ingress of materials	IPX7(distal end)
Mode of operation	Continuous operation
Installation and use	Hand-held Device
Pollution degree classification	2
Overvoltage category	II
Altitude	Less than 3000 meters

【Symbol】

1.  Refer to instruction manual/booklet
2.  Country of manufacture
3.  Manufacturer
4.  Type BF applied part
5.  Caution
6.  Batch code
7.  Keep away from sunlight
8.  Keep dry
9.  Temperature limit
10.  Humidity limitation
11.  Atmospheric pressure limitation
12.  Catalogue number
13.  Model number.
14.  Use-by date
15.  Sterilized using ethylene oxide
16.  Do not resterilize
17.  Do not use if packaging is damaged
18.  Do not re-use
19.  Single sterile barrier system
20.  Single sterile barrier system with protective packaging outside

21.  Working length
22.  Medical device
23.  Unique device identifier
24.  Authorized representative in the European Community/European Union
25.  WEEE symbol
26.  CE mark
27.  Fragile, handle with care
28.  This way up
29.  Stacking limit by number

Related Information

【Date of Manufacture】 Refer to the labelling

【Use-by date】 Refer to the labelling

【Name of EU representative】 Shanghai International Holding Corp. GmbH (Europe)

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