

CE0344

VATHIN VATHIN Medical
The Endoscopy Experts

Sterile

Instruction for Use

Vathin®H-SteriScope™
Single-use Flexible Bronchoscope



BC-P1600	BC-P1601	BC-P1602	BC-P1603	BC-P1604
BC-P1604-L	BC-P1600-L	BC-P1601-L	BC-P1602-L	BC-P1603-L
BC-P16001	BC-P16011	BC-P16021	BC-P16031	BC-P16041
BC-P16001-L	BC-P16011-L	BC-P16021-L	BC-P16031-L	BC-P16041-L

Caution: Federal law restricts this device to be sold by or on the order of a physician.

- ◆ For use by trained clinicians/physicians only.
- ◆ For professional Healthcare Facility Environment use.
- ◆ For use with Vathin display unit.
- ◆ Before use, thoroughly review this manual.
- ◆ Please keep all instruction manuals in a safe, accessible place.
- ◆ If you have any questions or comments about this manual, contact Vathin Medical.

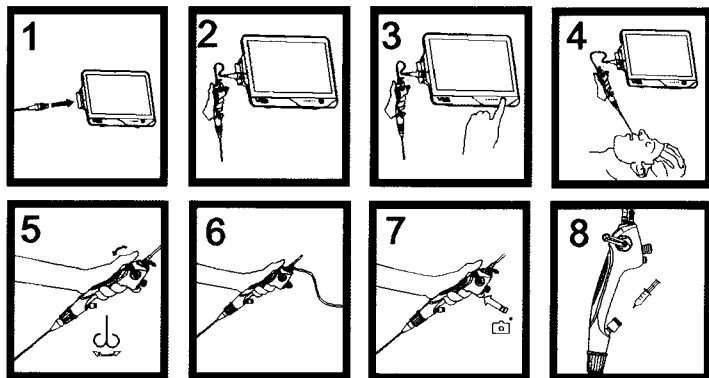
Hunan Vathin Medical Instrument Co., Ltd.

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Quickstart Guide



Important Information — Please Read Before Use

Read these safety instructions carefully before using Vathin®H-SteriScope™ Single-use Flexible Bronchoscope. The instruction for use may be updated without further notice. Copies of the current version are available upon request. The Bronchoscope System consists of Single-use Flexible Bronchoscope and digital video monitor. The flexible bronchoscope is inserted through the airways and tracheobronchial tree during Bronchoscopy. The video monitor receives the real-time image signal from Bronchoscope and displays the live image. Please be aware that these instructions do not explain or discuss clinical procedures. They describe only the basic operation and precautions related to the operation of Vathin®H-SteriScope™ Single-use Flexible Bronchoscope.

Before initial use of Vathin®H-SteriScope™ Single-use Flexible Bronchoscope, it is essential for operators to have received sufficient training in clinical endoscopic techniques and to be familiar with the intended use, warnings, cautions, indications and contraindications mentioned in these instructions. There is no warranty on Vathin®H-SteriScope™ Single-use Flexible Bronchoscope. In this document Vathin®H-SteriScope™ Single-use Flexible Bronchoscope refers to instructions which applies to the scope only and Vathin®H-SteriScope™ Single-use Flexible Bronchoscope system refers to information relevant for Vathin®H-SteriScope™ Single-use Flexible Bronchoscope and the Vathin video monitor and accessories. Unless specified otherwise, Vathin®H-SteriScope™ Single-use Flexible Bronchoscope refers to all Vathin®H-SteriScope™ Single-use Flexible Bronchoscope variants.

Intended use

The Single-use Flexible Bronchoscope is designed for use with Vathin Display Units. It is used for airway and bronchus examination, diagnosis and treatment.

Signal words

The following signal words are used throughout this manual:

Danger

It indicates an imminently hazardous situation, if not be avoided, will result in death or serious injury.

Warning

It indicates a potentially hazardous situation, if not be avoided, could result in death or serious injury.

Caution

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

Note

It indicates additional helpful information.

Essential Performance

Provide image for observation, excluding short-term auto-recoverable deration caused by electromagnetic interference.

Clinical Conditions for Use

- Unexplained coughing, hemoptysis, or blood in the sputum
- Diagnosis of lung shadow or mass
- Recurring or persistent lung infections
- Unexplained breathing difficulties
- Evaluate airway injury or malformation
- Remove of foreign bodies in the bronchus
- Treatment of certain lung diseases
- Staging of tumors such as lung cancer
- Monitor airway recovery after lung transplantation or certain chest surgeries.

Contraindications

- Coagulation disorder like Thrombocytopenia (low platelets), raised Prothrombin Time (PT), Activated Partial Prothrombin Time (APTT) etc.
- Diseases which are having Coagulation disorders are Cirrhosis of the liver, fulminant hepatitis, an acute viral infection like dengue, acute renal failure, leukemia etc.
- Malignant cardiac arrhythmia (arrhythmia which is not controlled by anti-arrhythmia drugs) like uncontrolled Atrial Fibrillation (AF), Supraventricular Tachycardia (SVT), Ventricular Tachycardia (VT), third-degree heart block etc.
- Severe congestive heart failure and acute myocardial infarction when ECG is showing active ST segment and T wave changes or Serum Troponin and CPK MB are elevated.
- Severe Hypoxia - This is commonly seen with ARDS (Acute Respiratory Distress Syndrome) due to severe pneumonia or swine flu, Type I respiratory failure etc.

Dangers, warnings and cautions

Failure to observe these dangers, warning and cautions may result in patient injury or damage to the equipment. Vathin medical is not responsible for any damage to the system or patient injury resulting from incorrect use.

Dangers

◆ Vathin®H-SteriScope™ Single-use Flexible Bronchoscope 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 Single-use Flexible Bronchoscope prior to insertion.

◆ As a TYPE BF applied part, the endoscope connected to the Video monitor must never be applied directly to the heart. Leakage current from the TYPE BF applied part may be dangerous and cause ventricular fibrillation or seriously affect the cardiac function of the patient. Always adhere to the following 2 points.

△ Never apply the Bronchoscope to the heart or any area near the heart.

△ Never apply an endo-therapy accessory or another endoscope applied to or near the heart to come in contact with this Bronchoscope.

◆ Never install and operate the Video Monitor in location where:

△ The concentration of oxygen is high

△ Oxidizing agent (such as nitrous oxide) or flammable anesthetics are present in the atmosphere

◆ Do not use the product in a MRI environment.

◆ Do not use the product during defibrillation.

◆ Do not use excessive force when advancing, operating or withdrawing the Single-use Flexible Bronchoscope.

◆ Always watch the live endoscopic image on the monitor when advancing or withdrawing the Single-use Flexible Bronchoscope, operating the bending section or suctioning. Failure to do so may harm the patient.

◆ Do not use Vathin®H-SteriScope™ Single-use Flexible Bronchoscope if the product sterilisation barrier or its packaging is damaged.

◆ The distal end of the endoscope may get warm due to heating from the light emission part. Avoid long periods of contact between the tip of the device and the mucosal membrane as long, sustained contact with the mucosal membrane may cause mucosal injury.

◆ When withdrawing the endoscope, the distal tip must be in neutral and non-deflected position. Do not operate the bending lever, as this may result in injury to the patient and/or damage to the Single-use Flexible Bronchoscope.

◆ Do not advance or withdraw the Bronchoscope, or operate the bending section, while endoscopic accessories are protruding from the distal end 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 bending lever and never use excessive force, as this may result in injury to the patient and/or damage to the Bronchoscope.

Warnings

- ◆ Do not attempt to clean and reuse the Vathin Single-use Flexible Bronchoscope as it is a single-use device. Reuse of the product can cause contamination, leading to infections.
- ◆ Always watch the live endoscopic image on the Vathin Digital Video Monitor when advancing or withdrawing a Vathin endoscope.
- ◆ Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- ◆ Strictly observe the following precautions. Failure to do so may place the patient and the medical personnel in danger
- ◆ When the instrument is used to examine a patient, do not allow metal parts of the endoscope or its accessories to touch metal parts of other system components.
- ◆ Keep fluids away from all electrical equipment. If fluids are spilled on or into the unit, stop operation immediately and contact VATHIN MEDICAL.
- ◆ Don't use Vathin Bronchoscope if it is damaged in any way or if any part of the functional check fails.
- ◆ Patients should be adequately monitored at all times during use.
- ◆ Always make sure that any tube connected to the suction connector is connected to a suction device.
- ◆ Electronic equipment and the Bronchoscope system may affect the normal function of each other. If the Bronchoscope system is used adjacent to or stacked with other equipment, observe and verify normal operation of both the Bronchoscope system and the other electronic equipment prior to using it. It may be necessary to adopt procedures for mitigation, such as reorientation or relocation of the equipment or shielding of the room in which it is used.
- ◆ Always check compatibility with endotracheal tubes and double lumen tubes.
- ◆ If any malfunction should occur during the endoscopic procedure, stop the procedure immediately and withdraw the endoscope.
- ◆ Unless used, please keep the rotary handle of the Single-use Flexible Bronchoscope at the 0 scale position, and confirm that the head end is straight, otherwise it will always be under stress and easy to break.
- ◆ When removing or inserting the Single-use Flexible Bronchoscope from the endotracheal tube, please keep the rotary handle of the bronchoscope at the 0 scale position, and confirm that the head end is straight, otherwise will cause it to become stuck in the endotracheal tube.
- ◆ Leakage current may increase when used with high frequency equipment.
- ◆ If this device is used in conjunction with other devices, please read the instructions and warnings of the connected device carefully first.
- ◆ When inputting inert gas or laser-assisted gas for patients before surgery, please pay attention to the operation to avoid gas embolism.

Cautions

- ◆ 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 system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- ◆ Do not connect or disconnect the endoscope connector while the Video monitor is turned ON. This action may destroy the endoscope.
- ◆ Avoid applying excessive force to the connectors, as this may damage the instrument.
- ◆ Have a suitable backup system readily available for immediate use so the procedure can be continued if a malfunction should occur.
- ◆ Always perform a visual check according to the instructions in this Instructions for Use before placing the Single-use Flexible Bronchoscope in a waste container.

Standard Applied

The Vathin®H-SteriScope™ Single-use Flexible Bronchoscope function conforms with:

- Council Directive 93/42/EEC concerning Medical Devices.
- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-2-18 Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment.
- ISO 8600-1: Optics and photonics - Medical endoscopes and endotherapy devices - Part 1: General requirements.
- ISO 8600-3: Optics and Optical Instruments - Medical Endoscopes and Endoscopic Accessories - Part 3: Determination of Field of View and Angle of view of Endoscopes with optics.
- ISO 8600-4: Endoscopes - Medical Endoscopes and Certain Accessories - Part 4: Determination Of Maximum Width Of Insertion Portion.
- IEC 60601-1-2: Medical electrical equipment - Part 1-2 General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements for test.
- ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Labels and Symbols

Graphical Symbols	Meaning	Graphical Symbols	Meaning
	Refer to THE INSTRUCTION MANUAL		Warning
	Medical device lot number		Medical device manufacture date followed by YYYY-MM-DD

	Medical device unique identification		Medical device expiration date followed by YYYY-MM-DD
	Ethylene oxide sterilized, followed by the sterilization lot number		Single-use
	Do not use the product if the sterile barrier system or its packaging is damaged		Do not re-sterilize medical device
	Ambient humidity limit		Sterilization mark Blue indicates sterilized
	Atmospheric pressure limit		Ambient temperature limit
	Medical device manufacturer		Keep out of rain Keep dry
	Keep out of direct sunlight Keep out of light sources		Fragile, Handle With Care
	This side up		Number of products inside
	importer		Medical device
	Type BF applied part	IPX7	The degree of protection against harmful ingress is IPX7 (for the tip, bending part, insertion part only)
	Authorized representative in the European Community/European Union		CE marking of conformity
IPX2	The degree of protection against harmful ingress is IPX2 (for the handle only)		

The recommended combinations of equipment and accessories

monitor: Vathin® Digital Video monitor DVM-B1/B2.

Suction pump: Medical suction pump.

Specification of disposable bronchoscope

NO	Model	Mean Working Channel (ΦID)	Maximum outer diameter (ΦOD)	Outer diameter of main hose (ΦOD)	Working length	Bending section	Self-locking or not	Endo-tracheal tubes (ETT) Min ID	Double lumen tubes (DLT) Min ID
1	BC-P1600	3.6Fr	2.8mm	2.6 mm	680mm	Up210° / Down210°	NO	ID4.0	Fr28
2	BC-P1601	3.6Fr	2.8mm	2.6 mm	650mm	Up210° / Down210°	NO		
3	BC-P1602	3.6Fr	2.8mm	2.6 mm	600mm	Up210° / Down210°	NO		
4	BC-P1603	3.6Fr	2.8mm	2.6 mm	550mm	Up210° / Down210°	NO		
5	BC-P1604	3.6Fr	2.8mm	2.6 mm	500mm	Up210° / Down210°	NO		
6	BC-P1600-L	3.6Fr	2.8mm	2.6 mm	680mm	Up210° / Down210°	YES		
7	BC-P1601-L	3.6Fr	2.8mm	2.6 mm	650mm	Up210° / Down210°	YES		
8	BC-P1602-L	3.6Fr	2.8mm	2.6 mm	600mm	Up210° / Down210°	YES		
9	BC-P1603-L	3.6Fr	2.8mm	2.6 mm	550mm	Up210° / Down210°	YES		
10	BC-P1604-L	3.6Fr	2.8mm	2.6 mm	500mm	Up210° / Down210°	YES		
11	BC-P16001	3.6Fr	2.8mm	2.6 mm	680mm	Up210° / Down210°	NO		
12	BC-P16011	3.6Fr	2.8mm	2.6 mm	650mm	Up210° / Down210°	NO		
13	BC-P16021	3.6Fr	2.8mm	2.6 mm	600mm	Up210° / Down210°	NO		
14	BC-P16031	3.6Fr	2.8mm	2.6 mm	550mm	Up210° / Down210°	NO		
15	BC-P16041	3.6Fr	2.8mm	2.6 mm	500mm	Up210° / Down210°	NO		
16	BC-P16001-L	3.6Fr	2.8mm	2.6 mm	680mm	Up210° / Down210°	YES		

17	BC- P16011-L	3.6Fr	2.8mm	2.6 mm	650mm	Up210° / Down210°	YES	ID4.0	Fr28
18	BC- P16021-L	3.6Fr	2.8mm	2.6 mm	600mm	Up210° / Down210°	YES		
19	BC- P16031-L	3.6Fr	2.8mm	2.6 mm	550mm	Up210° / Down210°	YES		
20	BC- P16041-L	3.6Fr	2.8mm	2.6 mm	500mm	Up210° / Down210°	YES		
 Field of view					120° ±15%				
Depth of view					3~100mm				
Illumination method					LED				
Suction connector					Ø7 +/-1				
Method of Sterilization					EO				

Operating environment

Ambient temperature: +10°C – +40°C

Relative humidity: 30% – 80%

Atmospheric pressure: 80 – 106kPa

Use altitude range: < 2000m

Storage and transportation

Transportation Temperature: -10°C – 40°C

Storage Temperature: 10°C – 30°C

Relative humidity: 10% – 80%

Atmospheric pressure: 50 – 106kPa

Chapter 1 Checking the Package Contents

⚠ Caution:

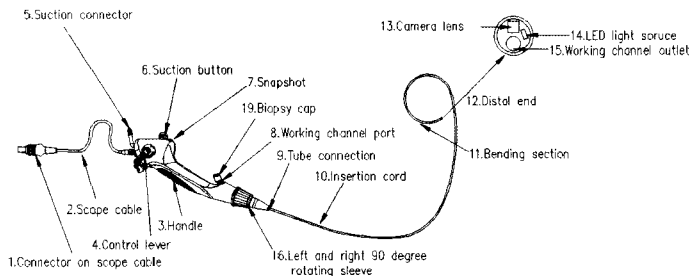
Match all items in the package with the components shown below. Inspect each item for damage. If a component is missing or damaged, please contact VATHIN MEDICAL.

Package Contents

Items	Quantities	Pictures
Vathin®H-SteriScope™ Single-use Flexible Bronchoscope	1pc	
Instruction for use	1pc	

Chapter 2 Nomenclature and Functions

2.1 Nomenclature



2.2 Functions

No.	Part	Function
1	Connector on scope cable	Connects to socket on video monitor
2	Scope cable	Transmits the image signal to video monitor
3	Handle	Suitable for left and right hand
4	Control lever	Moves the distal tip up or down in a single plane. Locking mechanism locks bending section in place
5	Suction connector	Allows for connection of suction tubing
6	Suction button	Activates suction when pressed down
7	Snapshot	Short press button to capture the real-time image; Long press button for 3s to capture the real-time video
8	Working channel port	Allows for instillation of fluids and insertion of endoscopic accessories
-	Working channel	Can be used for instillation of fluids, suction and insertion of endoscopic accessories
9	Tube connection	Allows for fixation of tubes with standard connector during procedure
10	Insertion Cord	Flexible airway insertion cord
11	Bending section	Manoeuvrable part
12	Distal end	Contains the camera, light source, as well as the working channel exit
13	Camera lens	Used for making images of objects
14	LED light	Provide the light source
15	Working channel outlet	The outlet of the fluids, suction and insertion of endoscopic accessories
16	Left and right 90 degree rotating sleeve	By rotating this part, the angle of view can be rotated 90° left and right.
17	Biopsy cap	The biopsy cap needs to be covered when using the suction function;

Chapter 3 Use of Vathin®H-SteriScope™ Single-use Flexible Bronchoscope series

Before each case, prepare and inspect this instrument as instructed below. Inspect other equipment to be used with this instrument as instructed in their respective instruction manuals. If any irregularities are suspected after inspection, follow the instructions as described in Chapter 4, "Troubleshooting". If this instrument malfunctions, do not use it.

3.1 Preparation, Connection and Inspection

Dangers:

◆ Using an endoscope that is not functioning properly may compromise patient or operator safety and may result in more severe equipment damage.

3.1.1. Check that the pouch seal is intact.

3.1.2. Check that there are no impurities or damage on the product such as rough surfaces, sharp edges or protrusions which may harm the patient.

3.1.3. Inspect the control section and the endoscope connector for excessive scratching, deformation, loose parts or other irregularities.

3.1.4. Using both hands, bend the insertion tube of the endoscope into a semicircle, confirm that the entire insertion tube can be smoothly bent to form a semicircle and that the insertion tube is pliable.

3.1.5. Gently hold the midpoint of the bending section and a point 20 cm from the distal end. Push and pull gently to confirm that the junction between the bending section and the insertion tube is not loose.

3.1.6. Inspect the objective lens and light guide lens at the distal end of the endoscope's insertion tube for scratching, cracks, stains or other irregularities.

3.1.7. Confirm that the bending section angulates smoothly and correctly, that maximum angulation can be achieved, and that the bending section returns to its neutral position.

 **Caution:** For the bending section, do not bend or straighten a tube with your hands forcibly.

3.1.8. Prepare and inspect the Digital Video Monitor, display, suction pump and endo-therapy accessories as described in their respective instruction manuals.

3.1.9. Insert the endoscope connector completely into the scope socket of the video monitor.

Note: Refer to the Instruction for Use for preparation and inspection of the video monitor and display.

3.1.10. Verify that a live video image appears on the screen by pointing the distal end of Bronchoscope towards an object, e.g. the palm of your hand, and adjust the image preferences on the video monitor and display if necessary. If the object cannot be seen clearly, wipe the lens at the distal end using a sterile cloth.

3.1.11. White balance: For indoor use in hospitals, with the lighting turned on (illumination intensity is not less than 200lx), aim the endoscope insertion end and point it at the white gauze. The end of the insertion end of the endoscope is about 10 mm from the white gauze. Press and hold the white balance icon on the display of the Digital Video Monitor for about a second. When the display screen shows , it indicates that the white balance function has been executed.

Note: vathin does not provide any accessories for white balance, such as white caps, etc. Doctors can use white gauze, etc. for white balance operations.

⚠ Warning: Do not stare directly at the distal end of the endoscope while the examination light ON. Otherwise, eye injury may result.

3.1.12. Firmly connect the suction tube from the suction pump to the suction connector on the endoscope connector. Confirm that the place and suction performance of the suction pump is in good condition.

3.1.13. Prepare the apparatus for living tissue sampling.

3.1.14. Using a syringe insert 2ml of sterile water into the working channel port (if applying a Lu Lock syringe use the enclosed introducer). Press the plunger, ensure that there are no leaks, and the water is emitted from the distal end.

3.1.15. If applicable, verify that endoscopic accessory of appropriate size can be passed through the working channel without resistance.

⚠ Warning: Keep your eyes away from the distal end when inserting endo-therapy accessories. Extending the endo-therapy accessory from the distal end could cause eye injury.

3.1.16. If applicable, verify that endotracheal tubes and double lumen tubes are compatible with Vathin®H-SteriScope™ Single-use Flexible Bronchoscope before starting the procedure.

3.1.17. If applicable, carefully read information about how to use the electrosurgical snare and the instrument to avoid accidents.

3.1.18. Inspection of the suction function

3.1.18.1. If the suction button does not operate smoothly, detach it and reattach it, or replace it with a new one. The maximum withstand negative pressure is 70kpa. Exceeding this value may cause the suction button to fail to rebound. At this time, you can gradually reduce the suction negative pressure to make it rebound and stop suction. If the endoscope is used while the suction button is not working properly, it may be impossible to stop suction, which could cause patient injury. If the reattached or replaced suction button fails to operate smoothly, the endoscope may be malfunctioning; stop using it and contact Vathin.

3.1.18.2. If the biopsy cap leaks, replace it with a new one. A leaking biopsy cap can reduce the efficacy of the endoscope's suction system, and may leak or spray patient debris or fluids, posing an infection-control risk.

3.1.18.3. Check steps

3.1.18.3.1. Place the container of sterile water and the endoscope on the same height. For the inspection, adjust the suction pressure to the same level as it will be during the procedure.

3.1.18.3.2. Immerse the distal end of the insertion tube in sterile water with the endoscope instrument channel port at the same height as the water level in the water container. Press the suction button and confirm that water is continuously aspirated into the suction bottle of the suction pump.

3.1.18.3.3. Release the suction button. Confirm that suction stops and the button returns to its original position.

3.1.18.3.4. Depress the suction button and aspirate water for one second. Then, release the suction button for one second. Repeat this several times and confirm that no water leaks from the biopsy cap.

3.1.18.3.5. Remove the distal end of the endoscope from the water. Depress the suction button and aspirate air for a few seconds to remove any water from the instrument channel.

3.2 Operating Vathin®H-SteriScope™ Single-use Flexible Bronchoscope

⚠ Warning:

◆ Wear personal protective equipment to guard against dangerous chemicals and potential

infectious material during the procedure.

- ◆ Whenever possible, avoid close stationary viewing and do not leave the distal end of the endoscope close to the mucous membrane for a long time.
- ◆ Whenever possible, do not leave the endoscope illuminated before and/or after an examination.
- ◆ Connect the Vathin video monitor and turn on the power. The Vathin® H-SteriScope™ | Single-use Flexible Bronchoscope will automatically adjust the brightness.
- ◆ If an abnormal endoscopic image or function is observed, but quickly corrects itself, the endoscope may have malfunctioned. (In this case, please refer to Chapter 4 Troubleshooting)
- ◆ Never perform flexibility adjustment while the endo-therapy accessory extends from the distal end of the endoscope.
- ◆ Transnasal insertion is accompanied by the risk of inflammation of the nasal cavity. If this happens, the nasal passage will be constricted, making it more difficult to withdraw the endoscope. In this case, do not use force to withdraw the endoscope because patient injury such as bleeding or perforation may result.
- ◆ Transnasal insertion is accompanied by the risk of bleeding in the nasal cavity. Be sure to be prepared to deal with any bleeding. When withdrawing the endoscope, observe the inside of the nasal cavity to ensure that there is no bleeding. Even when the endoscope has been withdrawn without bleeding, do not allow the patient to blow his or her nose strongly because this could cause it to start bleeding.
- ◆ Before transnasal insertion, apply the appropriate pretreatment and lubrication to the patient to enlarge the nasal cavity. Otherwise, operator and/or patient injury can result or the endoscope could become lodged and be difficult to withdraw. When applying a pretreatment agent through a tube, insert the tube into the same path as the path planned for the endoscope insertion. Otherwise, the treatment will have no effect. The effects of the pretreatment agent and lubricant will decrease the longer the procedure lasts. Apply the pretreatment agent or lubricant as required during the procedure – for example, when withdrawal seems to be difficult.
- ◆ If it becomes impossible to withdraw the transnasally inserted endoscope, pull its distal end out of the mouth, cut the flexible tube using wire cutters, and after ensuring that the cut section will not injure the body cavity or nasal cavity of the patient, withdraw the endoscope carefully. Therefore, always prepare wire cutters in advance.
- ◆ When using endo-therapy accessories, keep the distance between the distal end of the endoscope and the mucous membrane greater than the endoscope's minimum visible distance so that the endo-therapy accessory remains visible in the endoscopic image. If the distal end of the endoscope is placed closer than its own minimum visible distance, the position of the accessory cannot be seen in the endoscopic image, which could cause serious patient injury and/or equipment damage.
- ◆ If blood unexpectedly adheres to the surface of the insertion tube of the withdrawn endoscope, carefully check the condition of the patient.

Caution:

- ◆ If required, apply a medical grade lubricant on the appearance of the insertion tube on the bending section and the soft section. (★ Don't apply lubricant on the observation window and the illuminating window. Otherwise, it will affect the clearness and brightness of view).
- ◆ Avoid forcible or excessive angulation, as this imposes load on the wire controlling the bending

section. This may cause stretching or tearing of the wire, which could impair the movement of the bending section.

◆ It is easier to insert an endo-therapy accessory into the instrument channel port if the biopsy valve's cap is detached from the main body. As a result, the open biopsy valve can reduce the efficacy of the endoscope's suction system, and may leak or spray patient debris or fluids, posing an infection-control risk. When not using an endo-therapy accessory, attach the cap to the main body of the biopsy valve.

Note:

◆ When passing an endo-therapy accessory through the instrument channel while the angulation is locked, the angle of the distal end may change. When it is necessary to keep the angulation stationary, hold the angulation control knob in place with your hand.

3.2.1. Holding the Bronchoscope and manipulating the tip.

The handle of the Bronchoscope can be held in either hand. The hand that is not holding the Bronchoscope can be used to advance the insertion cord into the patient's mouth or nose. Use the thumb to move the control lever and the index finger to operate the suction button. The control lever is used to flex and extend the tip of the Bronchoscope in the vertical plan. Moving the control lever downward will make the tip bend anteriorly (flexion). Moving it upward will make the tip bend posteriorly (extension). The insertion cord should be held as straight as possible at all times in order to secure an optimal tip bending angle.

3.2.2. Insertion of the Bronchoscope

Lubricate the insertion cord with a medical grade lubricant when the Bronchoscope is inserted into the patient. If the image of the Bronchoscope becomes unclear the tip can be cleaned by gently rubbing the tip against the mucosal wall or remove the Bronchoscope and clean the tip. When inserting the Bronchoscope orally, it is recommended to use a mouthpiece to protect the Bronchoscope from being damaged.

3.2.3. Instillation of fluids

Fluids can be instilled through the working channel by inserting a syringe into the working channel port at the top of the Bronchoscope. When using a Luer Lock syringe, use the included introducer. Insert the syringe completely into the working channel port or the introducer and press the plunger to instill fluid. Make sure you do not apply suction during this process, as this will direct the instilled fluids into the suction collection system. To ensure that all fluid has left the channel, flush the channel with 2ml of air.

3.2.4. Aspiration

When connecting the suction system to the suction connector, you can press the suction button with your index finger to suck. After releasing the button, the suction will stop.

The product can withstand a negative pressure of 70Kpa. In order to ensure the normal suction function, it is recommended that the suction system should not exceed 70Kpa when used.

If the introducer and/or endoscope accessories are placed in the working channel, please note that the suction power will decrease. In order to obtain the best suction capacity, it is recommended to completely remove the introducer or syringe during the suction process.

3.2.5. Insertion of endoscopic accessories

Always make sure to select the correct size endoscopic accessory for the Bronchoscope. Inspect the endoscopic accessory before using it. If there is any irregularity in its operation or external appearance, replace it. Insert the endoscopic accessory into the working channel port and advance

it carefully through the working channel until it can be seen on the monitor.

3.2.6. Rotating endoscope

when the viewing angle needs to be adjusted, use the rotating ring, and the lens angle of view will rotate accordingly. The red dot of the rotating part is aligned with the central axis of the handle as the starting point, and the rotatable angle is 90° left and right.

3.2.7. Bending

Hold the handle and move the lever up and down to move the bending part of the distal end up and down, and it will gently return to a straight state when released. If you need to lock it, move the lever to the left, When the lever moves to the right, it will unlock

3.2.8. Withdrawal of the Bronchoscope

When withdrawing the Bronchoscope, make sure that the control lever is in the neutral position. Slowly withdraw the Bronchoscope while watching the live image on monitor.

3.3 After Use

3.3.1 Visual check: Are there any missing parts on the bending section, lens, or insertion cord? Is there any evidence of damage on the bending section, lens, or insertion cord? Are there cuts, holes, sagging, swelling or other irregularities on the bending section, lens, or insertion cord? If yes, then examine the product to conclude if there are any missing parts, then take corrective action to locate the missing parts. In case of corrective actions needed act according to local hospital procedures. The elements of the insertion cord are radio opaque.

3.3.2 Final steps: Disconnect Vathin®H-SteriScope™ Single-use Flexible Bronchoscope from the video monitor. Vathin®H-SteriScope™ Single-use Flexible Bronchoscope is a single use device. It is considered infected after use and must be disposed of in accordance with local guidelines for collection of infected medical devices with electronic components. Do not soak rinse, or sterilize this device as these procedures may leave harmful residues or cause malfunction of the device. The design and material used are not compatible with conventional cleaning and sterilization procedures.

Chapter 4 Troubleshooting

Problem	Possible Cause	Recommended action
No live image on the screen	Bronchoscope not connect- ed to Digital Video Monitor.	Connect Bronchoscope to the DVI port on Digital Video Monitor.
	Bronchoscope and Digital Video Monitor have commu- nication problems.	Restart Digital Video Monitor by power switch.
	Bronchoscope is damaged.	Replace the Bronchoscope with a new one.
Low picture quality	Blood, saliva etc. on the lens (distal tip).	Gently wipe the distal tip with sterile gauze.
Absent or reduced suction capability or difficulty in inserting endoscopic accessory through the channel	Channel blocked.	Clean the working channel using a cleaning brush or flush the working channel with sterile saline using a syringe.

Biopsy valve	Difficulty inserting an endotherapy instrument through the working channel.	Ensure compatibility of endotherapy instrument to working channel size. When the cap of the biopsy valve is detached, it may be easier to insert an endotherapy instrument into the instrument channel port.
Endoscope buttons.	The setting of the endoscope buttons differs from preferred setting.	Set the endoscope button function as preferred using the Instructions for use for the displaying unit.
Suction button.	Suction button detached from endoscope.	Remount suction button and test the suction function according to preparation step 5e. If that does not work then use new endoscope.

Appendix 1. Electromagnetic Compatibility

Below cables information are provided for EMC reference.

Cable	Max. cable length, Shielded/unshielded		Number	Cable classification
Bronchoscope line	2.8m	shielded	1 Set	Signal

Important information regarding Electro Magnetic Compatibility (EMC)

This electrical medical equipment needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; The equipment conforms to this IEC 60601-1-2:2020 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

The equipment with following ESSENTIAL PERFORMANCE is intended used in Professional healthcare facility environment except for near active HF SURGICAL EQUIPMENT and the RF shielded room of the ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

ESSENTIAL PERFORMANCE

Provide image for observation, excluding short-term auto-recoverable deration caused electromagnetic interference.

◆WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

◆The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

◆WARNING: Portable RF communications equipment (including peripherals such as antenna cable and external antennas) should be used no closer than 30 cm (12 inches) to any part of the product including cables specified by the manufacturer. Otherwise, degradation of the performance of the equipment could result.

◆WARNING: Electromagnetic interference may occur on this endoscope near the equipment with unique medical emitters such as electrocautery, MRI, electrosurgical units, and diathermy equipment. If electromagnetic interference occurs, mitigation measures may be necessary, such

removing the equipment mentioned above, reorienting or relocating this endoscope, or shielding the location.

◆**STATEMENT:** The equipment is designed compatible with high frequency surgical equipment; the condition includes working or standby in close proximity to high frequency surgical equipment.

◆When the AC input voltage is interrupted, the equipment will shut down and if the power supply restored, it could be recovered by operator manually, this degradation could be accepted because it will not lead to unacceptable risks and it will not result in the loss of basic safety or essential performance.

◆Following degradation caused by Electrostatic Discharge or Electrical fast transients/burst could be accepted because it will not lead to unacceptable risks and it will not result in the loss of basic safety or essential performance.

◆Vertical bars flash appears on the screen, it can recover to previous condition automatically.

EMI Compliance Table (Table 1)

Table 1 - Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class A	Professional healthcare facility environment
Harmonic distortion	IEC 61000-3-2 Class A	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Professional healthcare facility environment

NOTE: 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.

EMS Compliance Table (Table 2-6)

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ± 5 kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

Table 4 – Input a.c. power Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	± 2 kV 100kHz 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	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz
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

Table 5 – Signal input/output parts Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz

Table 6. Proximity magnetic fields

Test frequency	Modulation	Immunity test levels
		Professional healthcare facility environment
134,2 kHz	Pulse modulation 2,1 kHz	65 A/m
13,56 MHz	Pulse modulation 50 kHz	7,5 A/m

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