

VL3S Series

Video Laryngoscope

Instructions for Use



HugeMed Medical Technology Development Co., Ltd.

Address: 8th Floor, Block A, North Tengbang Building, Qingshuihe 1st
Road, Luohu District, Shenzhen, China



Illustrate

Thank you for purchasing anesthesia video laryngoscope of VL3S series.

Before using this product, please read this manual carefully so that it can be used correctly.

Please keep this instruction manual for reference.

Product name:	Video Laryngoscope
Product model, specification:	VL3S, including M28, M39, M52 and M58 operation handles
Medical device product registration certificate number:	GUANGZHOU 20192080779
Medical Device Product Technical Requirement Number:	GUANGZHOU 20192080779
Medical Device Manufacturing License Number:	NO. 20172951 MANUFACTURING GUANGZHOU MEDICATION SYSTEM
Date of production:	See product label
Service life:	3 years
Date of formulation / revision:	July 19, 2019
Manual version:	V1.1
Software release version:	V1
Product performance, structure and composition:	It consists of a power adapter, a display host, and an operating handle.
Product scope of application:	Guide the clinical staff to lift the patient's epiglottis to reveal the glottis and accurately perform tracheal intubation for anesthesia or first aid.
Name of registered person / production enterprise:	After-sales service unit: Shenzhen HugeMed technology Development Co. , Ltd.
Registered address:	Block 6B, Tengbang Building, Qingshuihe Road, Luohu District, Shenzhen, China
Production address:	516-1, Building 2, No. 1, Mawu Road, Baoan Community, Yuanshan Street, Longgang District, Shenzhen, Guangdong Province, 518115, P.R China
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Company website: <http://www.hugemed.net>

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- Assembly, expansion, re-adjustment, improvement and repair must be carried out by professionals recognized by HugeMed;
- All repairs involving replacement parts, accessories and consumables used are all originally matched (original) or approved by HugeMed;
- Relevant electrical equipment complies with the requirements of national standards and this Instruction Manual;
- Product operation is carried out in accordance with this Instruction Manual.

Warranty and Repair Services

The standard warranty period of this product is one year, and that of main accessories is half a year. The main accessories include: charging cable and battery. Consumables: refers to disposable consumables that need to be replaced after each use, and they are not warranted.

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- Man-made damage;
- Misuse;
- Grid voltage exceeds the specification of product;
- Irresistible natural disasters;
- Replacing or using parts or accessories not approved by HugeMed, or repaired by anyone other than medical personnel authorized by HugeMed;
- Other failures not caused by the product itself.

After the expiration of warranty period, HugeMed can continue to provide fee-based repair services. If you refuse to pay or delay the payment of repair service, HugeMed will temporarily terminate the repair service until payment is completed.

After-sales service unit

After-sales service unit: Shenzhen HugeMed technology Development Co., Ltd. Customer service department
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After - sales service hotline: +86 755 22275899

Sales hotline: +86 755 22275866

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Official website: www.hugemed.net

Warning

- **This product should be used by professional clinicians, medical electrical specialists or professionally trained clinical staff on designated occasions. Personnel using this product should receive adequate training. Anyone unauthorized or untrained is forbidden for any operation.**
- **Dedicated and careful work can avoid possible accidents!**
- **Daily cleaning and maintenance for equipment are necessary.**
- **You should stick to the original accessories in case of maintenance.**

Introduction

Illustrate

This Instruction Manual (the “Manual”) deals the use, functions, and operation of the product. Before using this product, please read and understand this Manual carefully to ensure correct use of it and the safety of patients and operators.

This manual introduces the product in its most complete configuration, some of which may not apply to the product you purchased. For any questions, please contact us.

These operating instructions include considerations on how to safely, correctly and effectively use the laryngoscope. They help reduce failures, maintenance costs and downtime, and increase reliability and lifespan of equipment. It can be used not only as an operating manual but also as a reference. Therefore, this Instruction Manual must be placed beside the equipment and always available.

Please read "Safety" in Section 1 carefully before using for the first time.

Applicable Object

This Manual is for professionally trained clinical staff only.

Illustration

All illustrations provided in this manual are for reference only. The settings or data in the illustrations may not be consistent with actual display of the product.

Usage

- ***Italic*** This Manual indicates quoted chapters in bold italics.
- This Manual uses terms such as danger, caution, and warning to indicate hazard information and its severity.

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Chapter 1 Safety

1.1 Safety Information

This section lists basic safety information that users must be aware of and follow when using the anesthesia video laryngoscope (the “laryngoscope”). Other safety information that is the same, similar, or related to the specific operation can be found in each chapter.

Danger

- Indicates an imminent danger that, if not avoided, could result in death, serious personal injury or property loss.

Warning

- Indicates potentially dangerous or unsafe practices that, if not avoided, could result in death, serious personal injury, or property loss.

Caution

- Indicates potentially dangerous or unsafe practices that, if not avoided, could result in minor personal injury, product failure, damage, or property loss.

Attentions

- Emphasize important considerations, provides instructions or explanations for better use of the product.

1.1.1 Danger

No safety risk in this category.

1.1.2 Warning

Warning

- This laryngoscope guides medical staff to accurately perform respiratory tract intubation for anesthesia or first aid. It is only for professional clinicians, medical electrical experts or professionally trained clinical personnel to use under specified circumstances.
- Doctor liable assumes responsibilities for operating procedures and technical applications of the equipment! Depending on actual application conditions, a trained doctor (doctor liable) has the right to decide how to fully use the equipment.
- Please read the Instruction Manual of anesthesia video laryngoscope carefully before using it for the first time.
- Before using this laryngoscope, the user must check it and its accessories to ensure that they work properly and safely.
- The laryngoscope should be disinfected every time after use. Before cleaning, please consult or understand cleaning regulations of medical equipment.
- To avoid fire or explosion, do not use this laryngoscope in an environment where flammable or explosive materials are placed.
- Please properly install or carry this laryngoscope and its supporting equipment, and prevent them from falling, colliding, being damaged by strong vibration or other external mechanical forces.
- When the tip end of laryngoscope is too close to the mucosa, intense light is concentrated on a small area where the tissue surface temperature will rise due to excessive light exposure time. When it exceeds 41 ° C, there is even a risk of burns. When the laryngoscope is used with its accessories, its surface temperature can exceed 41 ° C and the maximum temperature is 50 ° C in a short time.
- The risk of burns may increase under the following conditions:
 - The time of being near to mucosa and fixed-point observation is too long;
 - Video laryngoscope can be pushed in a narrow lumen;
- To reduce the risk of burns, please take the following measures:
 - Avoid fixed-point observation as much as possible.
 - To avoid accidents, turn off the light when it is not in use.
- DO NOT use this equipment while it is charging
- Electromagnetic fields can affect performance of the laryngoscope and its associated equipment, so equipment used near the laryngoscope and its ancillary products must comply with relevant EMC requirements, otherwise failure or collapse may occur due to electromagnetic interference. Mobile phones, X-ray, and MRI device are all possible sources of interference, since they all emit high-intensity electromagnetic

radiation.

- **All other equipment.** For example, some similar digital interference devices must meet the relevant requirements in standard details when connected to a laryngoscope (e.g. GB 4943 requirements for digital processing equipment, and GB 9706 requirements for electrical equipment). In addition, when other devices are connected, involving the signal input or output of the device, structure of the other devices, in accordance with the requirements of GB 9706.1, must conform to the system structure. The person responsible for connecting the equipment must ensure the operability of system and assume responsibilities to meet system requirements. For further questions, please consult local equipment supplier or HugeMed Technical Service Center.
- **Repairs or upgrades for the laryngoscope must be performed by service personnel trained and authorized by us.**
- **When taking care of packaging materials, you shall follow local regulations or waste disposal system of hospitals. Packaging materials must**
- **Be placed out of children's reach.**
- **HugeMed assumes no responsibility for personal injury and property loss caused by:**
 - Equipment parts are not original from HugeMed;
 - The instruction manual is missing;
 - Installation, commissioning, modification, upgrade, and maintenance work are not performed by authorized personnel of HugeMed.
- **HugeMed assumes no responsibility for damage or incidents caused by the use of consumables or accessories not from HugeMed.**

1.1.3 Caution

Caution

- The environment of use and power supply for this Laryngoscope must comply with the requirements in Product Specification A.
- If fluid is poured over the laryngoscope and the laryngoscope does not function properly, discontinue use and contact the distributor or manufacturer who sold you this product immediately.

1.1.3 Attentions

Attentions

- Please place this Manual near the laryngoscope so that it can be easily and promptly consulted when needed.
- This Manual introduces the product in its most complete configuration and function. The laryngoscope you purchased may not have all the configurations or features herein.

1.2 Label Identification

1.2.1 Identification and Its Meaning

	Attentions/Caution/Warning		Equipment Type II
	BFModel Application Component		Refer to the instructions
	Power Adapter (AC)		Lifespan
	Batch No.		Serial No.
	Manufacturer		Date of Production
	Use pollution-free methods for processing		10%~95% Transport package humidity is limited to 10%~95%
	The environmental pressure of transport package is limited to 50~106kPa		Shipping package temperature is limited to -20 ~ 60oC
	The transport package contains fragile items, please handled with care		The transport packages should be protected from rain
	Should be upright when during transport		Same package can stack up to 5 layers

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Chapter 2 Overview

2.1 Product Introduction

2.1.1 Applicability

Guide medical staff to accurately perform tracheal intubation for anesthesia or first aid and conduct oral examinations and treatments.

Warning

- **This product should be used by professional clinicians, medical electrical specialists or professionally trained clinical staff on designated occasions.**
- **Responsible doctors must be responsible for the operating procedures and technical application of the equipment! According to the actual application conditions, trained doctors (responsible doctors) have the right to decide how to make full use of the equipment.**
- **Please read carefully the instructions of anesthesia video laryngoscope before using it for the first time.**
- **Before using this laryngoscope, the user must check its accessories to ensure they work properly and safely.**
- **Laryngoscope should be disinfected once in use. Before cleaning, please consult or understand the cleaning regulations for medical equipment.**

Caution

- **The operating environment and power supply of this laryngoscope must meet the requirements in Product Specification A.**

2.1.2 Contraindication

Contraindications of this product are equivalent to contraindications of clinical tracheal intubation.

2.1.3 Product Composition and Performance

It is composed of power adapter, display host (including battery), operation handle (including plug-in tube and camera). According to the difference of outer diameter, the operating handle can be divided into four specifications: M28, M39, M52 and M58. USB data line is attached.

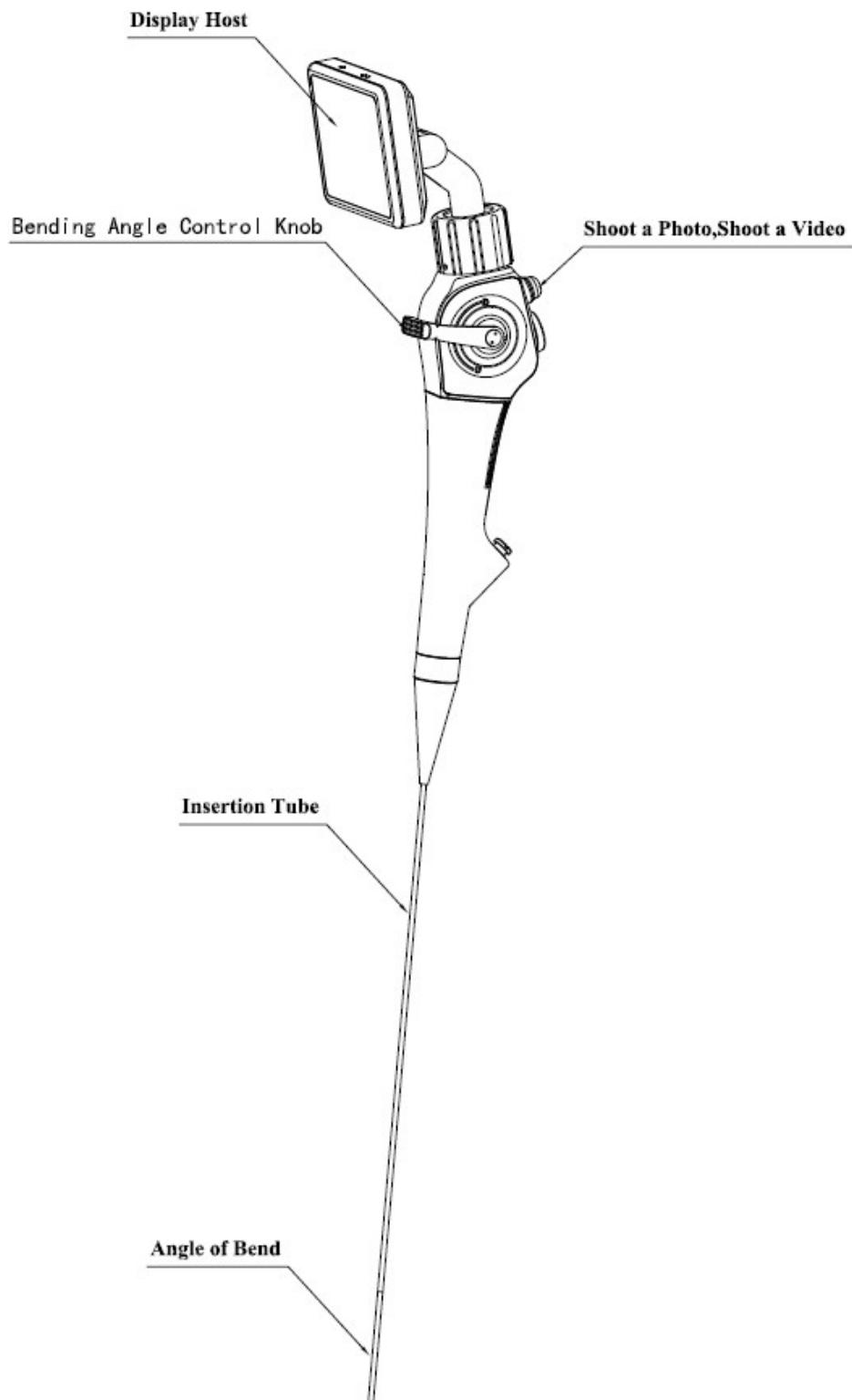
VL3S has the following functions and features:

- Compact, movable and integrated LCD;

- Different specifications, with camera and light source, clearly revealing the glottal anatomy; through high-pixel camera used in the operating handle, the physiological structure of the glottis can be visualized and transmitted to the LCD through the video transmission line, so that the doctor can clearly observe the entire process of endotracheal intubation;
- VL3S anesthesia video laryngoscope has four different types of operating handles: M28, M39, M52, and M58 (*See 5.1*) ;

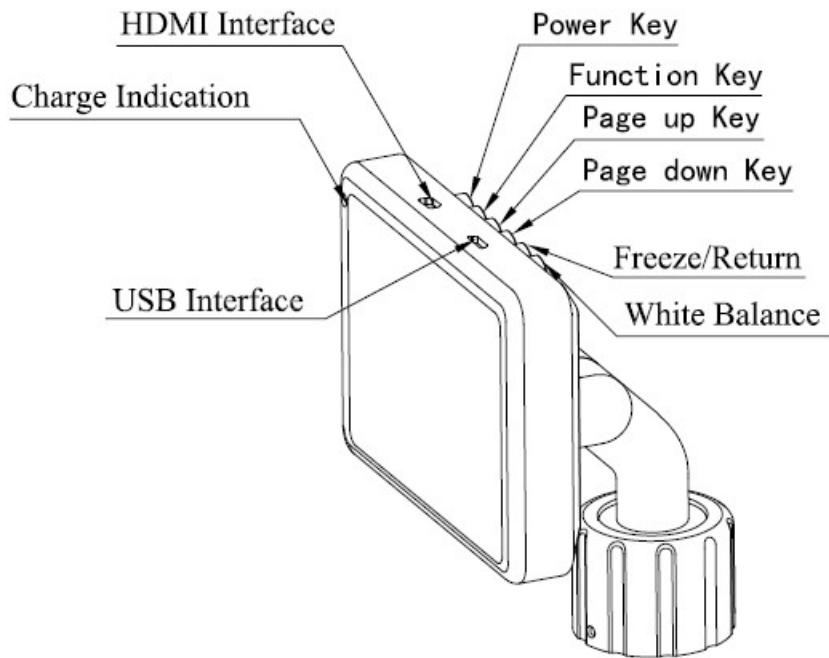
2.1.4 Side View

2.1.4.1 VL3SEquipment Side View



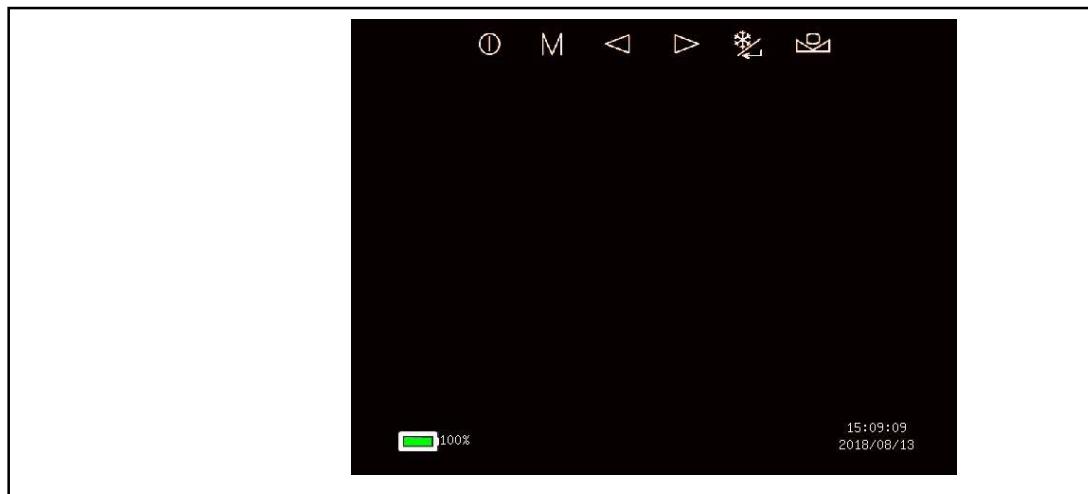
【Figure 0-1】 Side View of VL3S Equipment

2.1.4.2VL3SDisplay Host Side View



【Figure 0-2】 Side View of VL3S Display Host

2.1.5 Screen display



【Figure 0-3】 VL3S Display Main Interface

1. During normal operation, it displays real-time video in full screen, real time in the lower right corner, and battery status in the lower left corner;
2. When battery is lower than 20%, “Battery Low” prompt will pop up in the upper left corner of the screen;
3. When battery is lower than 10%, “Battery exhausted” prompt will pop up in the upper left corner of the screen;
4. When taking a photo or shooting a video, a prompt will be displayed on the screen. When taking a photo, a prompt jumps out in the middle of the screen; when recording, the camera prompt and real-time camera duration will be displayed above the power display area in the lower left corner of the screen.

2.2Battery

2.2.1 Overview

The laryngoscope has a built-in rechargeable battery (the "battery"), which will be charged when the laryngoscope is connected to the power adapter. When the laryngoscope is charged in the power-on state, it will enter charging mode and be unavailable for any operation.

Battery life is only a certain time. Low battery alarm will be triggered 30 minutes before the battery is exhausted, during which a message will be displayed. Battery exhaustion alarm will be triggered 3 minutes before the battery is exhausted, during which a message will be displayed and flash.

Attentions

- Please do not charge when the power supply voltage of network fluctuates greatly.
- If the battery is exhausted, full charge will take 4 to 6 hours. (verification)
- If this product will not be in use for a long, please charge and discharge every 3 months to avoid battery damage.
- The battery is consumable. It shall be replaced when it is out of work.
- To replace the battery, please contact the dealer or manufacturer who sold the product to you.
- Replacement of battery can only be performed by our technical service engineers!

2.2.2Battery Using Instruction

Life of the battery depends on use frequency and the operating environment. If the equipment is used and maintained properly, its battery lifespan shall be 3 years approximately, otherwise it may be shortened. The battery should be replaced every 3 years.

For operational safety, please protect the battery as much as possible. Please note the following instructions:

- Batter performance check once a year. Battery performance check is also suggested before repair of laryngoscope or when you suspect battery is the failure cause;
- Optimize the battery when run time of the laryngoscope run time is significantly reduced or every 3 months of use (or storage) ;
- Every half a year of storage, charge with a 1C current and a 4.2V voltage for about 0.5 hours to make sure that the it is stored with certain battery.

2.2.3 Battery Maintenance

2.2.3.1 Optimize battery performance

Please optimize the battery before using it for the first time. The complete optimization cycle is: continuous charging until full, discharging until the laryngoscope is turned off, then continuously charging until full again. During the use, the battery should be optimized periodically to maximize its useful life.

Attentions

- **As time goes by and the battery is used, its actual storage capacity would be reduced. When optimizing, if you find the power supply time is significantly shortened, please replace the battery.**
- **The power adapter provided by our company meets the requirements of GB 9706.1 - 2007.**

Please refer to the following steps for optimization:

1. Connect the laryngoscope to power adapter to continuously charge it for 8hours;
2. Disconnect the laryngoscope from the power adapter and use it until the it is turned off;
3. Reconnect the laryngoscope to power adapter to continuously charge it for 8hours;
4. Battery has been optimized.

2.2.3.2 Check Battery Performance

Battery performance may reduce over time. Battery performance check should be conducted on a regular basis.

Please follow the steps below to check battery performance:

1. Connect the laryngoscope to power adapter to continuously charge it for 6~10 hours;
2. Disconnect the power adapter and continuously use the laryngoscope until it is shut down for low battery;
 - If the time from start of the laryngoscope to its shutdown is 100 minutes or longer, the battery is in good condition;
 - If the time from start of the laryngoscope to its shutdown is 30 to 120 minutes, the battery is almost out of work;
 - If the time from start of the laryngoscope to its shutdown is less than 30 minutes, the battery is over used and should be replaced.
3. After checking the battery, you should recharge the battery for your next use.

Attentions

- If it has been fully charged but the power supply time is too short, the battery might have been damaged or malfunctioning. The battery's power supply time depends on configuration and use frequency of the laryngoscope, such as backlighting the display for a long time.
- If the battery is apparently damaged (swollen, deformed, leaking) or it cannot store power, it should be replaced and properly recycled.

Chapter 3 Installation and Inspection

3.1 Installation

Warning

- The software copyright of this laryngoscope is reserved by us. Any organization or individual is forbidden to alter, copy or exchange by any means or in any form without permission.

3.1.1 Unpacking Inspection

Before unpacking, please check the package carefully to determine if there is any damage caused to the during transportation. If any damage is found, please contact the carrier or us immediately.

If the package is intact, correctly unpack it, carefully take out the laryngoscope and other components, and check items according to the packing list one by one. Check whether the product is damage and whether the items are complete. For any questions, please contact our after-sales service department immediately.

Warning

- Users should place the packaging materials out of children's reach. When taking care of packaging materials, you shall follow local regulations or waste disposal system of hospitals.

Attentions

- Please keep the box and packaging materials for future transportation or storage.
- If you unpack and find some components are missing, please contact the dealer or manufacturer who sold the product to you as soon as possible.

3.1.2 Environmental Requirements

The environment in which the laryngoscope is used shall comply with the requirements
A.2 Environmental Specifications.

The use of laryngoscope should also avoid noise, vibration, and dust, corrosive, or flammable or explosive substances.

When the laryngoscope is transferred from one place to another, condensation may occur due to differences in temperature or humidity. In such cases, you must wait for the condensation to disappear before turning it.

3.1.3 Power Requirements

Power used for this laryngoscope shall comply with the requirements of *A.3 Power Specifications*.

⚠️ Warning

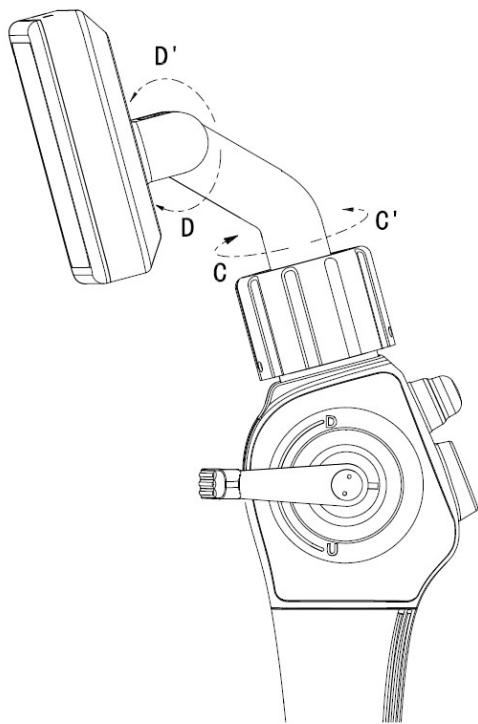
- Please ensure that the laryngoscope works under the specified environmental requirements and power requirements, otherwise it will not meet the technical specifications stated in *A Product Specifications* unpredictable consequences may be caused such as effectiveness loss.
- Applicable power supply must be selected according to power supply voltage setting of the laryngoscope. Otherwise it may result in serious damage to the laryngoscope.

3.1.4 Install Remove operating handle

1. Select proper operating handle for laryngoscope based on the patient and his/her oral size;
2. Insert the operating handle into the connection of display host in the direction of the limit slot;
3. Turn the knob clockwise to lock the operating handle;
4. Reverse the installation steps 2 and 3 to separate the operating handle from the display host.

Attentions

- The insertion of display host's plug is directional. When inserting, pay attention to the connector direction, do not forcibly plug. Forcibly plugging without aiming may damage the plug.



【Figure 0-1】 Schematic Diagram of VL3S Installation and Removal

3.1.5 Setting of Display Host

1. Boot up, and set the language;
2. Time adjustment setting;

Attentions

- Please install and carry the laryngoscope and its supporting equipment properly, and prevent it from falling, colliding, being damaged by strong vibration or other external mechanical forces.
- Mind your hand when operating the handle.

3.2 function check

Before each use of the laryngoscope, the user should perform a thorough examination to ensure that the laryngoscope functions and functions properly. The inspection items should include:

- The environment and power supply meet requirements;
- Endobody leak check;
- No mechanical damage to the device or accessories;
- Battery performance;
- Use of specified accessories;
- Functionally.

Prior to each clinical use, inspect according to the following procedures, even if minor defects or abnormalities are found, discontinue use and contact us promptly.

3.2.1 Inspection of insertion tube

1. Visually inspect surface of insertion tube for defects such as bumps and cracks.
2. Touch the entire insertion tube with your bare hands and feel for pits or internal slack.

3.2.2 Inspection of Flex Mechanism

1. Slowly bend the angle handwheel to the maximum bend angle in each direction. Confirm that the angled bend section can bend smoothly and can reach the maximum bend angle.
2. Check the angled hand wheel, it can move smoothly, bend smoothly and return to its original position.
3. Check the rubber at the angle bend for fine holes, cracks and other undesirable defects.

3.2.3 Display the check from the control unit

1. Verify that the display unit's visual and functional keys are represented in Figure 2-2 (see instructions for use)
2. Press the ON key, turn on the Display Unit, observe the image on the Display Unit and check that an object located approximately 10 mm from the tip is clearly visible.

Attention

- **Do not forcefully hold the angled bend; do not allow sharp contact with the tip.**
- **Angle bend cannot be twisted.**
- **If the On Display Unit indicates that it has a low battery, recharge as soon as possible.**

Chapter 4 Operation Guideline

4.1 Display Host Operation

4.1.1 Function Key

Key	Power Key	Menu Key	Option Key	Option Key	Function Key	Freeze key	White balance key
Identification							
Function	Turn on/off equipment	1、 Access settings interface 2、 Confirm option 3、 Save settings	Go left or up	Go right or down	1、 Tap to take a photo 2、 Long press to record a video 3、 Return	1、 Freeze function 2、 Return function	White balance function

4.1.2 Work interface



Press power key  to start the video laryngoscope, the company logo will be statically displayed, as shown in [Figure 4-1]. After 3s, it will automatically access normal work interface, as shown in Figure 4-2.



[Figure 4-1] Start-up LOGO interface



【Figure 4-2】 Normal work interface

- 1) During normal operation, it displays live video in full screen, date and real time are displayed in the lower right corner, and the battery icon is displayed in the lower left corner.
- 2) When power is lower than 20%, “Battery Low” prompt will pop up in the upper left corner of the screen;
When power is below 10%, “Battery exhausted” prompt will pop up in the upper left corner of the screen.
- 3) When taking a photo or shooting a video, a prompt will be displayed on the screen. When taking a picture, photo prompt pops up in the middle; when recording, video prompt and the live video duration are displayed above the battery status area in the lower left corner of the screen.

4) Press menu key to  access system settings interface;

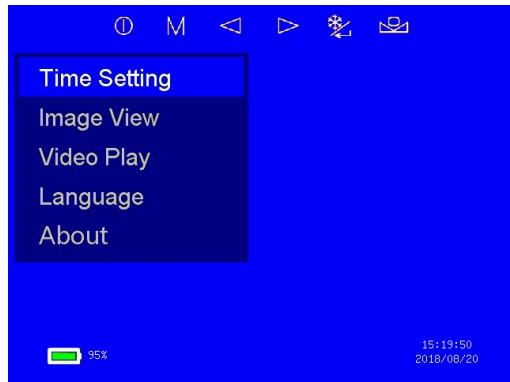
Press function key to  access photograph functions;

Long press function key to  access recording functions;

Long press go right or down to  access disk formatting functions;

4.1.3 System Settings Interface

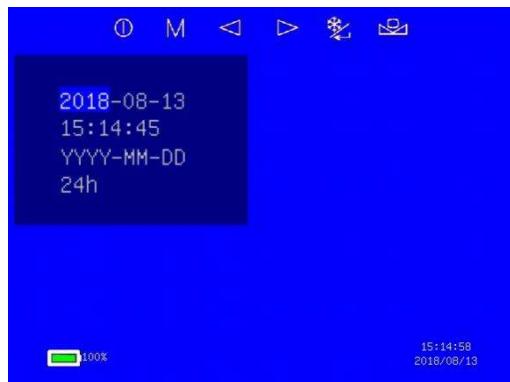
Press menu key  , the screen will display system settings interface with a blue  background.  Button or  exit the interface.



【Figure 4-3】

You can use 、 key to select and key to access sub-interface.
 Button or return to previous interface.

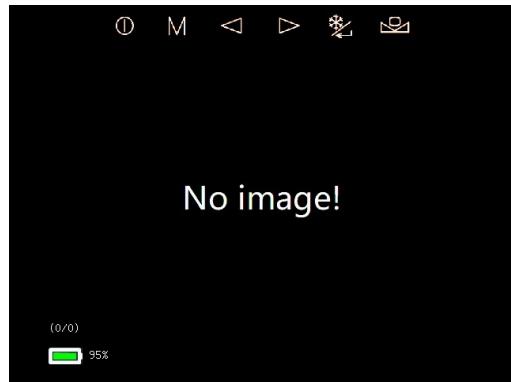
4.1.4 Timesetting interface



【Figure 4-4】

button to switch between year, month, day, hour, minute, second 、
 button to adjust values, button or return to previous interface.

4.1.5 Photo Viewing Interface



【Figure 4-5】

Press , button can switch between photos, press button or return, long press button or button to delete the currently selected photos.

4.1.6 Video Playing Interface



【Figure 4-6】

Press , button can switch between videos, press button to play the video and press again to pause, press button or return, long press button or button to delete the currently selected videos.

4.1.7 Language Setting Interface



【Figure 4-7】

Press **◀**, **▶** key to select a language, and press **M** key to confirm.

4.1.8 About Interface



4.2 Operating handpiece usage

This section discusses the basic operation of the Anesthesia Video Laryngoscope Handpieces and outlines the general operating procedures for the Anesthesia Video Laryngoscope Handpieces. The anesthesia videolaryngologist should study the clinical factors involved in each procedure and decide on the technical details of each procedure.

4.2.1 Handle Grip

1. Hold the operating handle with your left hand and the insertion tube with your right hand.

The left index finger should now be able to manipulate the photograph button and the thumb should be able to manipulate the angled hand wheel.

2. Anesthesia Video Laryngoscopy can be performed both from the mouth and the nasal cavity. If inserted from the mouth, the subject must use the mouthpad (bite protector) and then, while watching, slowly insert the tip of the anesthesia video laryngoscopy into the throat from the patient's mouth.

4.2.2 Pre-use Preparation

1. Proper cleaning and disinfection of handpieces (see 5.3).
2. How to Use the Lubricant
 - (1). Apply clean, water-soluble medical-grade lubricant to the insert hose, and do not apply it to the lens of head end.
 - (2). Do not use olive oil, lidocaine ointment or other petroleum-based lubricants or those containing petrolatum. These may cause damage to some materials of the video laryngoscope.

4.2.3 Insertion and Observation

1. Gently insert the insertion tube from the mouth or nasal cavity.
2. The Anesthesia Video Laryngoscopist needs to manipulate the angled hand wheel to guide the angled curve during viewing of the image in order to visualize and gently push the angled hand wheel with the left hand thumb.
3. See 4.1 for the specific operation of the Display Console.

4.2.4 Deliver or flush

1. Verify that suction button is installed.
2. Confirm that the sealing cap on the working channel port is installed, if so, separate it and firmly insert the syringe into the working channel port.

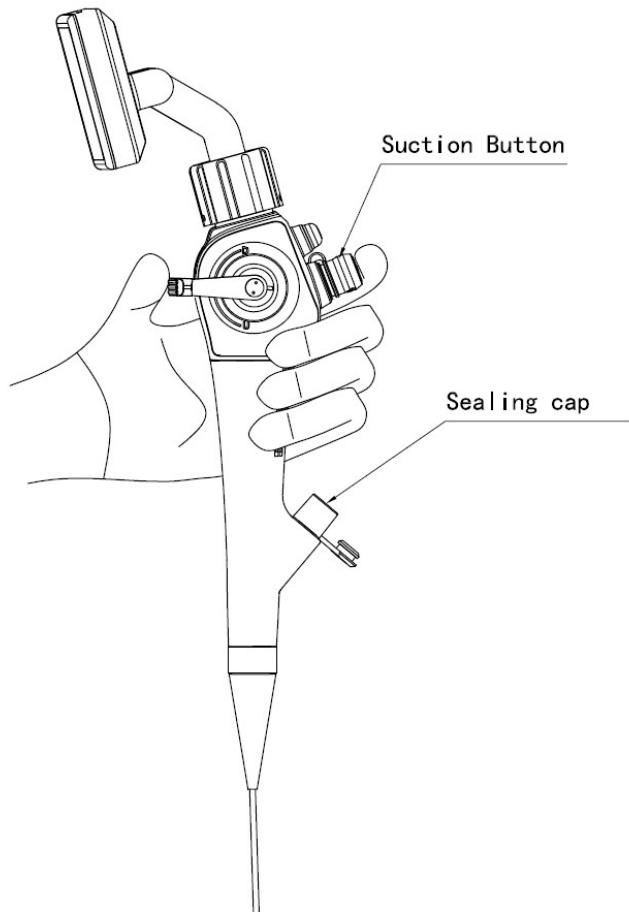
3. Depress the syringe plunger push rod.

4.2.5 Suction

1. Confirm that the suction button and seal cap on the working channel port are installed.
2. Connect suction pump and suction buttons using suction tubing.
3. Start the suction pump to the minimum pressure required and press the suction button as shown in Figure 4-8.

Attention

- The sealing cap and suction button for the working channel are not part of the product and are separate accessories.
- The suction pump is hospital equipment.
- The product is a flexible video laryngoscope and does not need to be used in conjunction with a snoop film



(Figure 4-8) Suction Diagram

⚠️ Warning

- Before using this laryngoscope, the user must check its accessories to ensure that they are working properly and safely.

Attention

- Always use mouthpiece pads (biting protectors) when inserting the insertion tube from the mouth to prevent the examiner from biting the insertion tube.
- If you notice anything unusual about the manipulation of the anesthesia video laryngoscope, stop the exam immediately. The angled hand wheel was placed in the neutral (center) position and then viewed with the anesthesia video laryngoscope carefully exiting.
- If you feel any unusual resistance when turning the angle wheel, do not forcefully bend it further.
- When suction is done, avoid drawing in solid objects or viscous fluids, as this may occlude the tube and the suction button. If blockage is present and does not stop suction, remove suction tube from suction button, turn suction pump off, remove suction button, and remove blockage.
- When performing suction, use the minimum suction pressure required to complete the examination. Excessive suction pressure can result in suction of the mucosa, or trauma to the mucosa. In addition, patient fluids may leak or spill out from the working channel, posing a risk of infection.
- Unable to completely fill the suction bottle on the suction pump during inspection may result in improper function of the suction pump.
- Do not press the suction buttons while feeding the fluid into the pump.

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Chapter 5 Care and Maintenance

5.1 Overview

The laryngoscope should be carefully cleaned before disinfected or sterilized. After each examination, turn off the display generator and remove it before reprocessing; if it is not reprocessed for an extended period of time, the performance of the laryngoscope may be abnormal.

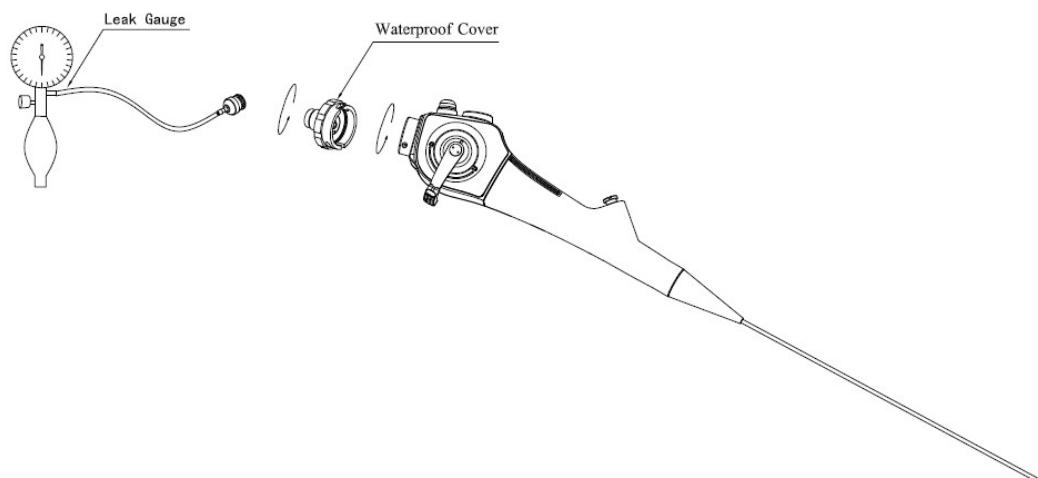
The method of washing and disinfecting the laryngoscope is at the discretion of the operating physician, the infection control committee of the hospital, etc. There are two methods for cleaning and disinfection of laryngoscope, automated cleaning, disinfection and manual cleaning and disinfection. Our company only describe manual cleaning, disinfection methods for laryngoscope, other automatic cleaning and disinfection methods please refer to related equipment instructions.

5.2 Leak

1. as shown in image3-2screw on the waterproof cover.
2. as shown in image3-2screw on the waterproof cover.
3. Pressurize the leak gauge to 30Kpa (, which M58 and M52 model), 24Kpa (applies to M39 and M28 model), then stop pressurizing it, and observe whether the pointer index on leak gauge drops.
4. If the pointer index is slowly dropping, continue to gently pressurize the leak gauge. (But M58 and M52 model cannot exceed 30Kpa, M39 and M28 model cannot exceed 24Kpa, or the laryngoscope may be damaged). Meanwhile, put the inserted part of laryngoscope into the water to see if there are continuous bubbles on the surface of the laryngoscope. Continuous bubbles indicate there is a leak, and the product shall no longer be immersed for disinfection. You shall stop using and contact after-sales service department of the company in time.
5. No bubbles coming out means the laryngoscope has good leak proofness and can be used or cleans for disinfection.

Attentions

- Leak gauge is an optional accessory instead of part of the product, please refer to figure 5-1 for connection.



【Figure 5-1】 Installation Diagram of VL3S Leak Tool

5.3 Cleaning and disinfecting the Laryngoscope

Use only the materials and methods listed in this section only to clean or disinfect the laryngoscope. We does not provide any warranty for damage or accident caused by the use of other materials or methods.

The chemicals or methods we listed are only used as a means of controlling infection. We assumes no responsibility for their effectiveness. For information of infection control, please consult the infection prevention department or epidemiologist of the hospital.

Please make sure the laryngoscope is dust-free. To prevent damage to the laryngoscope, the following rules must be observed:

- Dilute detergent and disinfectant or use those whose concentration is as low as possible as required by the manufacturer;
- The whole machine must be covered for waterproof before getting immersed for cleaning and disinfection;
- The immersion disinfection shall not be longer than 1h. Repreated or long-time immersion in disinfectant solution would increase internal humidity of the laryngoscope, blur or even damage the lens.
- Before immersion disinfection, leakproof test must be carried out according to requirements. If there is any leak, then immersion shall be forbidden;
- Do not immerse display host of the laryngoscope in liquid;
- Do not pour liquid onto display host of the laryngoscope;
- No liquid shall enter display host of the laryngoscope;
- Do not use abrasive materials (such as steel wool and silver polish) and solvents like xylene or acetone to clean the laryngoscope in case of any damage to the casing.

Warning

- **Before cleaning the laryngoscope, it must be turned off and charging cable must be disconnected from the power adapter.**
- **The cleaning and disinfection measures described in the manual cannot, in any case, replace the rules and regulations that are routinely used for the use of equipment!**

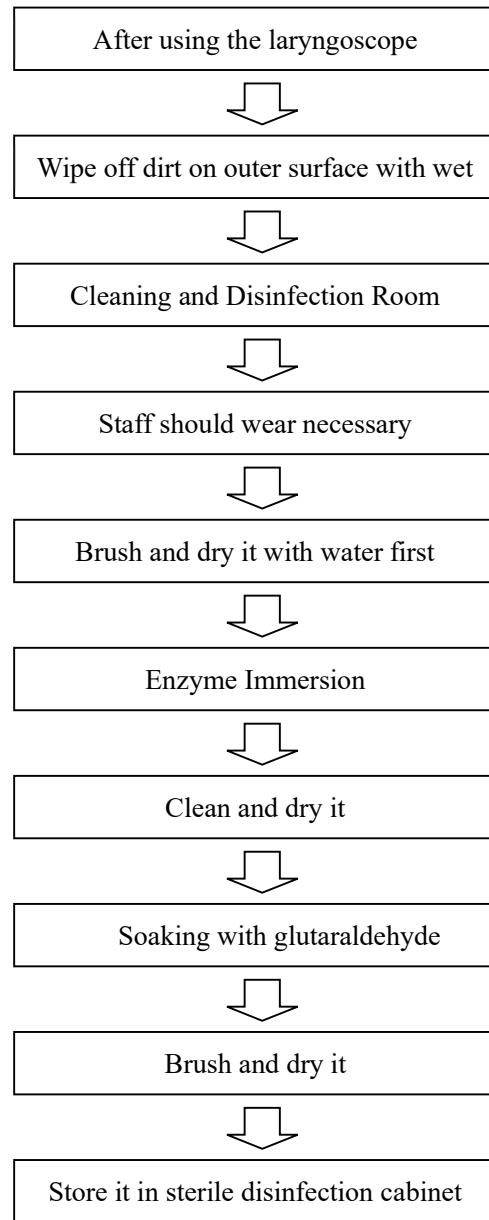
Caution

- **If you accidentally pour liquid onto the laryngoscope and cause malfunction, please immediately stop using and contact the dealer or manufacturer who sold the product to you.**

5.4 Cleaning Instructions

After using the laryngoscope, medical staff shall immediately wipe off the dirt on outer surface of display host and operating handle with 75% alcohol wet gauze; the gauze shall be discarded in yellow medical garbage bags; then take the laryngoscope to cleaning and disinfection room.

Standard process of cleaning and disinfection of operating handles is as follows:



⚠️ Warning

- The laryngoscope should be disinfected every time after use. Before cleaning, please consult or understand cleaning regulations of medical equipment.

- Before cleaning the laryngoscope, it must be turned off and charging cable must be disconnected from the power adapter.
- The display host is not waterproof, so do not flood it or place it in excess liquid. It is recommended to wipe with a disinfectant tissue.

5.4.1 Wash with Water

1. Wipe the insertion tube of handle with gauze or a soft sponge in clean water to remove turbidity from the hose.
2. Immerge the inserted part in the cleaning solution and gently scrub the insertion tube with gauze or a soft sponge.
3. You can wipe surface of the host surface with a damp cloth. Be careful when cleaning other parts to prevent liquid from entering the interior.
4. Cleaning gauze should be used only for once.
5. Wipe the cleaned display host with dry gauze.

5.4.2 Enzyme Wash

It is used to remove organic matter such as body fluid secretions to prevent organic substances from affecting the efficacy of disinfectants. Timely do the enzyme wash to avoid protein dryness, which can be difficult to remove?

1. Configuration and soaking time of the multi-enzyme lotion shall be in accordance with the product manual.
2. Place the dried laryngoscope in the enzyme washing tank, and wipe the operation part with multi-enzyme washing solution.
3. Multi-enzyme lotion should be replaced every time after an operation handle is cleaned.

5.4.3 Wash

After soaking and cleaning the laryngoscope with multi-enzyme lotion (Timed according to the multi-enzyme lotion instructions), rinse and dry its outer surface with a high-pressure water gun or sterile gauze.

5.4.4 Disinfection

This product is fully waterproof and may be immersion sterilized. However, do the leak test before the soak (please refer to 5.2 Leak Test).

This product is intended to contact the patient's oral mucosa and should be disinfected prior to use by the end user.

5.4.4.1 Soaking with antibacterial liquid

1. Place the cleaned and dried handled in a disinfection tank/or a disinfection bucket in the disinfectant. Disinfection time: use timer to ensure disinfection time is

20minutes Laryngoscopes used by patients with special infections such as *Mycobacterium tuberculosis* and other mycobacteria should be immersed for at least 45minutes.

2. Display host must be wiped with water and then wiped 75% ethanol.
3. After the end of the daily treatment, the laryngoscope that will no longer be used should be disinfected for 30 minutes when sterilized with disinfectant for the last time.
4. The repetitive laryngoscope to be used must be resterilized before starting daily treatment. Soak with recommended disinfectant for at least 20 minutes. After rinsing and drying, it can be used for diagnosis and treatment.

Warning

- **Do not use any strong alkaline/strongly acidic disinfectant to sterilize the laryngoscope?**
- **Do not use medical alcohol or iodophor to soak the laryngoscope.**
- **Do not place the laryngoscope in an organic solvent such as acetone and methyl ethyl ketone.**
- **Do not sterilize the laryngoscope with high temperatures and pressures.**
- **When disinfecting, be careful with the cleaning of window glass of the laryngoscope so as not to affect the observation effect.**

5.4.5 Rinse and Dry

Before taking the laryngoscope out from the disinfection tank, the personnel should replace the gloves and dry them with sterile gauze or clean compressed air. Note that it is necessary to inject enough air into the working channel before storage to ensure that inner wall of the pipe is dry.

Warning

- **The operating handle, which has been immersed in a chemical disinfectant and sterilized, must be thoroughly rinsed with sterile water to remove residual disinfectant before use.**

Attentions

- The cleaning operation specifications are prepared in accordance with the "Operational Specifications of Endoscope Cleaning and Disinfection Technology (2004 Edition)".
- The above operations are for reference only, and the disinfection effect should be verified by appropriate methods.

5.5 Regular Maintenance

warning

- Hospitals or health care institutions that use this laryngoscope should have adequate maintenance plans that may cause unforeseen consequences such as laryngoscope failure and may endanger personnel safety.
- All safety checks or repairs requiring the disassembly of the laryngoscope should be performed by qualified service personnel designated by the company whose operation could cause failure of the laryngoscope and could endanger personal safety.
- If you notice a laryngoscope problem, contact the distributor or the manufacturer who sold you this product.
- Instruments must be disinfected and cleaned before being returned for service.

5.5.1 Maintain Battery Performance

See0.

5.5.2 Safekeeping and Maintenance of Operating Handle

1. Operating handle of the laryngoscope should be completely wiped dry before storage. This includes injecting enough air into working channel to dry inner wall of the pipe. Pay close attention to the head end and all lens surfaces. Carefully dry the objective and light guide lens with dry cotton swabs. Apply lens cleaner (silicone wax) to a piece of gauze and gently wipe lens surface with it. This shall prevent the residue of water droplets on the lens.
2. Storage place should be clean, dry, well ventilated and maintained at normal temperatures. Avoid direct sunlight, high temperatures, high humidity and X-ray radiation.
3. Operating handle of the laryngoscope should be stored where its insertion hose can be as straight as possible. For example, be stored in a disk shape. Please do not wrap the insertion hose tighter than it is in the laryngoscope case.
4. Please do not use laryngoscope case for storage. Laryngoscope case is for shipping only. In wet, dark, poorly ventilated environments, using laryngoscope case for storage may cause problems with infection management. Please do not wrap tight.

Interval	Routine Maintenance Procedures
In accordance with	Thoroughly clean the laryngoscope surface before and

the hospital's policy	after a long period of storage.
At least one test every year	<ol style="list-style-type: none">1. Test power adapter and charging cable.2. Run the laryngoscope until low battery alarms, then charge to confirm that the operation and charging are normal.

5.6 Pollution-free Treatment and Recycling

The service life of this product is about 3 years. Laryngoscopes that exceed their lifespan should be scrapped. Please contact the dealer or manufacturer who sold you this product for more information.

You may do the following: Laryngoscopes that have been scrapped may be sent back to the distributor or manufacturer who sold you this product for proper recycling.

Chapter 6 Transport, Storage and Repair

6.1 Transport storage precautions

This product is transported and stored after packaging, and the packaged anesthesia video laryngoscope should be stored in a room with no more than 80% relative humidity, no corrosive gases and good ventilation. See Appendix A for specific storage and shipping conditions.

6.2 Laryngoscope Service

If the laryngoscope requires repair, it should be loaded into the original scope box and sent to the company or company service station with instructions on device malfunction or injury. Please also inform the service personnel at your address, postal code, contact person, and telephone number.

Some minor problems with laryngoscope use can be resolved by the laryngoscope operator or assistant. All other repairs may only be made by Shenzhen Hongji Medical Technology Development Co., Ltd or its dedicated repair station. Regarding any injury or impairment resulting from repairs performed by persons other than those specified above. The Company assumes no liability.

To prevent infection, and for the safety of all personnel who repair the instruments, wash them thoroughly and carefully disinfect them before returning them for service. If the device is used on HA positive patients or other infectious patients, explain to the service personnel.

Chapter 7 Accessory

⚠️ Warning

- Use the accessories specified in this section only. Using other accessories may damage the laryngoscope or fail to meet the specifications stated in this Manual.
- One-time accessory can only be used once. Repeated use may result in performance degradation or cross-contamination.
- If any damage of the accessory package or the accessories is found, please stop using and contact the dealer or manufacturer that sold the product to you as soon as possible.

7.1 Operating Handle

Operation handles are all bent up 160 ° and down 130 ° and available in the following sizes:

Specification	Insertion Tube Size (L x OD x ID)
M28	650mm × 2.8mm × 0mm
M39	650mm × 3.9mm × 1.2mm
M52	650mm × 5.2mm × 2.6mm
M58	650mm × 5.8mm × 3.0mm

Note: For your healthcare professional.

⚠️ Warning

- To reduce the risk of burns, avoid site observation as much as possible and increase the risk of burns under the following conditions:
 - Observation too long approaching or localizing the mucosa;
 - Slowly advance the anesthesia video laryngoscope in the narrow lumen.

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A Product Specifications

A.1 Safety Specifications

A.1.1 Equipment Type II classified by shock proof, with internal power supply

A.1.2 Applied Equipment Model </5123BF classified by shock proof degree

A.1.3 Equipment Type </5141A classified by electromagnetic compatibility </5147

A.1.4 Rated voltage, frequency, and power

Power adapter input: 100-240V~, 50/60Hz, 0.2-0.1A

Power adapter output: DC5V, 2A

External output of display host: DC5V, 2A

Internal power supply: DC3.7V, polymer battery.

A.1.5 Impermanent Installation Equipment

A.1.6 Classified by flammable anesthetic gas mixed with air, oxygen or nitrous oxide: the equipment cannot be used in flammable anesthetic gas mixed with air, oxygen or nitrous oxide.

A.1.7 Classified by operation mode: continuous operation

A.2 Environmental Specifications

Parameter	Specification
Working Temperature	5~40°C
Working Humidity	20~80%, non-condensing
Working Atmospheric Pressure	86~106kPa
Temperature of Storage and Transportation	-20~60°C
Humidity of Storage and Transportation	10~95%, non-condensing
Atmospheric Pressure of Storage and Transportation	50~106kPa
Description of Storage Conditions	Well ventilated indoor environment without corrosive gas

A.3 Power Specifications

Parameter	Specification
Power Adapter	
Input Voltage	100-240V~
Input Current	0.2-0.1A
Input Frequency	50/60Hz
Output Voltage	DC5V
Output Current	2A
Battery	
Number of Battery	1battery
Type of Batter	Polymer battery
Nominal Battery Voltage	DC 3.7V
Battery Capacity	1800mAh

A.4 Basic Parameter

Parameter	Specification
Rotation angle	Front and rear rotation angle $\geq 120^\circ$ Left and right rotation angle $\geq 120^\circ$
Working Distance	3~50mm
Spatial resolution	≥ 10.10 lp/mm
Visual Angle	$\geq 100^\circ$
Lighting Range	$\geq \Phi 40$ mm, h=20mm
Source Illumination	≥ 400 lx, h=20mm
Color Temperature	≥ 2300 K
Special Functions	Settings of photo, video, storage, time, etc.
Alarm Function	Battery low, battery exhausted, operating handle not connected

A.5 Names and contents of toxic and hazardous substances or elements in the product

Name of Component	Toxic and Hazardous Substances or Elements					
	Plumbum (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent Chromium (Cr6+)	Polybrominated Biphenyls (PBB)	Polybrominated Diphenyl Ether (PBDE)
Component of Printed Circuit Board	×	○	○	○	○	○
Shell	○	○	○	○	○	○
Metal Shell	○	○	○	○	○	○
Display	○	○	○	○	○	○
Battery	×	○	○	○	○	○

Remarks:

- Indicates that the content of the toxic and hazardous substances in all homogeneous materials of the components is below the limit requirement specified in the SJ/T11363-2006 standard.
- ×: Indicates that the content of the toxic and hazardous substances in at least one of the homogeneous materials of the component exceeds the limit requirement specified in the SJ/T11363-2006 standard.



“Environmental Use Period” of this product is 10 years, and its logo is shown on the left. The environmental use period of replaceable parts such as batteries may differ from that of the product. “Environmental Use Period” is valid only when the product is used under normal conditions as described in this instruction manual.

A.6 List of Accessories

If the following items are found inconsistent with this information, please contact the manufacturer.

Serial No.	Name of Component	Quantity	Remarks
1	Display host	1	
2	M58 Operating handle	1	
3	M52 Operating handle	1	
4	M39 Operating handle	1	
5	M28 Operating handle	1	
6	Power Adapter	1	
7	USB data cable	1	
8	Certificate of Qualification	1	
9	Instruction Manual	1	

B EMC

This laryngoscope meets the domestic YY0505-2012 "Medical Electrical Equipment Part 1-2: Safety General Requirements Parallel Standard: Electromagnetic Compatibility Requirements and Tests"



Attention:

- The laryngoscope comply with the requirements of YY0505, GB 9706.19;
- The user shall install and use according to the electromagnetic compatibility information provided in the accompanying documents;
- Portable and mobile RF communication equipment may affect the performance of this laryngoscope and avoid strong electromagnetic interference during use, such as proximity to a cell phone, microwave ovens, etc.;
- Guidance and manufacturer's declaration are attached.



Caution:

- The laryngoscope should not be used adjacent to or stacked with other equipment, and if adjacent or stacked use is necessary, it should be observed to verify normal operation in the configuration in which it was used;
- Class A equipment is intended for use in industrial environments, where the potential for electromagnetic compatibility in other environments may be difficult due to conducted and radiated disturbances of this laryngoscope;
- The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the Laryngoscope, with the exception of cables sold by the Laryngoscope Manufacturer as a spare part for internal components.

Guide and Manufacturer's Statement – Electromagnetic Emissions		
This laryngoscope is intended for use in the electromagnetic environment specified below, so the purchaser or user should ensure that it is used in such environment:		
Emission Test	Compliance	Electromagnetic Environment – Guide
Radio Frequency Emission GB 4824	Group 1	This laryngoscope uses RF energy only for its internal function. Therefore, its RF emissions are low and there is little possibility of interference with nearby electronic equipment.

Radio Frequency Emission GB 4824	Type A	
Harmonic Emission GB 17625.1	Not Applicable	The laryngoscope applies to all facilities that are not home and those not directly connected to the public residential low-voltage power supply network.
Voltage Fluctuation / Flicker Emission GB 17625.2	Not Applicable	

Guide and Manufacturer's Statement – Electromagnetic Immunity			
This laryngoscope is intended for use in the electromagnetic environment specified below, so the purchaser or user should ensure that it is used in such environment:			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic
Electrostatic Discharge GB/T 17626.2	±6 kV Contact Discharge ±8 kV Air Discharge	±6 kV Contact Discharge ±8 kV Air discharge	The floor should be wood, concrete or ceramic. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient Burst GB/T 17626.4	±2kV Power Cord	±2kV Power Cord	Quality of network power should reach typical commercial or hospital level
Surge GB/T 17626.5	±1 kV Wire to Wire ±2 kV Wire to Ground	±1 kV Wire to Wire ±2 kV Wire to Ground	Quality of network power should reach typical commercial or hospital level
Voltage dip, short interruption and voltage change of the power input line GB/T 17626.11	<5 % U_T , lasts 0.5 cycle (On U_T , sag >95%) 40 % U_T , lasts 5 cycles (On U_T , 60% sag) 70 % U_T , lasts 25 cycles (On U_T , 30% sag) <5 % U_T , lasts 5s (On U_T , sag >95%)	<5 % U_T , lasts 0.5 cycle (On U_T , sag >95%) 40 % U_T , lasts 5 cycles (On U_T , 60% sag) 70 % U_T , lasts 25 cycles (On U_T , 30% sag) <5 % U_T , lasts 5s (On U_T , sag >95%)	Quality of network power should reach typical commercial or hospital level If the user of this laryngoscope needs continuous operation during a power outage,

			uninterruptible power supply or battery is recommended.
Power Frequency Magnetic Field (50/60Hz) GB/T 17626.8	3A/m	3A/m,50/60Hz	The power frequency magnetic field should have the characteristics of that in a typical site in commercial or hospital environment.
Note: U_T refers to the AC network voltage before the test voltage is applied.			

Guide and Manufacturer's Statement – Electromagnetic Immunity			
This laryngoscope is intended for use in the electromagnetic environment specified below, so the purchaser or user should ensure that it is used in such environment:			
Immunity Test	IEC 60601/YY 0505Test level	Compliance Level	Electromagnetic Environment – Guide
Radio Frequency Conduction GB/T 17626.6	3 V (Effective Value) 150 kHz~80 MHz	3 V (Effective Value)	<p>Portable and mobile RF communication devices should not be used closer to any part of the laryngoscope (including cables) than the recommended isolation distance. This distance should be calculated by corresponding formula of the transmitter frequency.</p> <p>Recommended Isolation Distance</p> $d = 1.2\sqrt{P}$ <p>$d = 1.2\sqrt{P}$ 80 MHz~800 MHz $d = 2.3\sqrt{P}$ 800 MHz~2.5 GHz</p> <p>Formula:</p> <p>P — In watts (W) according to the transmitter's maximum rated output power.</p> <p>d — Recommended isolation distance in meters (m) $< 6952^b$.</p> <p>The field strength of fixed RF transmitter is determined by survey ^c of the electromagnetic field, and each frequency range ^d should be lower than the compliance level.</p> <p>Interference may occur near devices marked with the following symbols.</p> 
<p>Note:</p> <ol style="list-style-type: none"> 1. Formula for the higher frequency band is used at 80MHz and 800MHz. 2. These guidelines may not apply to all situations. Electromagnetic propagation may be affected by the absorption and reflection of buildings, objects and the human body. 			

- a) Fixed transmitters, such as base stations for wireless (cellular/cordless) phones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts, are not theoretically predictable. In order to assess the electromagnetic environment of fixed RF transmitter, the survey of the electromagnetic field should be considered. If field strength at the location where the laryngoscope is located is higher than the applicable RF compliance level above, the laryngoscope should be observed and verified for proper operation. Additional measures, such as reorienting direction or position of the laryngoscope, may be necessary if abnormal performance is found.
- b) Field strength should be less than 3 V/m over the entire frequency range from 150 kHz to 80 MHz.

Recommended isolation distance between portable and mobile RF communications equipment and this laryngoscope

The laryngoscope is intended for use in an electromagnetic environment where radio frequency disturbances are controlled. Depending on the maximum rated output power of communication device, the purchaser or user can prevent electromagnetic interference by maintaining the minimum distance from the portable and mobile RF communication device (transmitter) and the VL3S as recommended below.

Rated Maximum Output Power of Transmitter W	Corresponding distance/m for transmitters with different frequencies		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 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 rated maximum output power of the transmitter not listed above, the recommended isolation distance d in meters (m), and it can be determined by the formula in corresponding transmitter frequency column. Here P is the transmitter's maximum output rated power in watts (W), provided by the transmitter manufacturer.

Note:

1. Formula for the higher frequency band is used at 80MHz and 800MHz.
2. These guidelines may not apply to all situations. Electromagnetic propagation may be affected by the absorption and reflection of buildings, objects and the human body.

NO	Name	Cable Length (m)	Whether to mask
1	USB CABLE	1 m	YES