VL3R、VL3D

Video Laryngoscope

Instructions for Use

Shenzhen HugeMed Medical Technology Development Co., Ltd.

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CE 2797

Description

Thank you for purchasing the VL3R, VL3D anesthesia video laryngoscope.
Please read these instructions for use carefully before using this product for proper application.
Please keep this instruction for future reference.

Product Name:	Anesthesia Video Laryngoscope
Specification Model:	VL3R、VL3D
Date of Manufacture:	See product label
Term of use:	3 Year
Date of Development/Revision:	Nov 16, 2020
Insert Rev:	V1.3
Software Release Version:	V1
Product Structure：	It is composed of five parts, including power adapter, 8-inch display main unit, VLM signal transmission line, Hand-piece and camera assembly.
Product Scope：	It is used to clinically provoke the patient's epiglottis to expose the glottis, and guide the medical staff to accurately intubate the airway for anesthesia or emergency use, and for intraoral diagnosis and treatment.
Registrant/Manufacturer Name:	Shenzhen HugeMed Medical Technical Development Co., Ltd.
After-sale service unit:	Shenzhen HugeMed Medical Technical Development Co., Ltd..
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Intellectual property

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Statement

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HugeMed Medical Co., Ltd. Reserves the right to amend the contents of this manual without prior notice. Modifications to the contents of this specification will be reflected in the newly published edition.
HugeMed Medical assumes no liability for software and equipment provided by non-HugeMed Medical providers and distributors.

HugeMed Medical is responsible for the safety, reliability and performance of the product only if all of the following requirements are met:

- Assembly, expansion, re-alignment, improvement and maintenance must be carried out by HugeMed Medical accredited professionals;
- All repairs involve replacement parts and accessories, consumables are HugeMed Medical original (original) or approved by HugeMed Medical;
- The relevant electrical equipment shall conform to the requirements of the national standards and this Operating Manual;
- The operation of the product shall be carried out in accordance with this instruction manual.

Warranty and Maintenance Services

The standard warranty period of this product is one year, the main accessories warranty period is half a year, and the main accessories include: charging line, battery. Consumables: Refers to disposable consumable materials that need to be replaced after each use. There is no warranty for consumables.

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During the warranty period, the products can enjoy free after-sales service; However, please note that even during the warranty period, if the products need repair due to the following reasons, HugeMed Medical Medical will implement fee-based repair services, and you will have to pay maintenance fees and accessories fees:

- Man-made damage;
- Improper use;
- The grid voltage exceeds the range specified in the product;
- Irresistible natural disasters;
- Replacing or using parts, accessories or repairs not approved by HugeMed Medical or repaired by a person not authorized by HugeMed Medical ;
- Other faults not caused by the product itself.

After the warranty period expires, HugeMed Medical can continue to provide fee-for-service services. If you refuse to pay or delay in paying for the service, HugeMed Medical will temporarily suspend the service until you pay for it.

After Sales Service Unit

After-sales Service Unit: Customer Service Department of Shenzhen HugeMed Medical Technology Development Co., Ltd.
Address: 516-1, Building 2, No. 1, Mawu Road, Baoan Community, Yuanshan Street,Longgang District, Shenzhen, Guangdong Province, 518115, China

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After Sales Hotline: +86 755 222 75899
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Official website: www.hugemed.net

⚠Warning

- **This product should be used by professional clinicians, medical electrical specialists or trained clinicians on designated occasions. Personnel using this product should be adequately trained. No operation may be carried out by any person without authorization or training.**
- **Only careful and careful work can avoid the occurrence of possible accidents!**
- **Routine instrument cleaning and maintenance is essential.**
- **In case of need of repair, you should stick to the original accessories.**

Preface

Description

This instruction manual (hereinafter referred to as the "instruction manual") describes in detail the use, function and operation of the product. Before using the product, please read and understand the instructions carefully to ensure the correct use of the product and ensure the safety of patients and operators.

This manual describes the product in its most complete configuration, some of which may not be applicable to the product you are purchasing. If you have any questions, please contact us.

These instructions include precautions for safe, correct and effective operation of the laryngoscope. They help reduce breakdowns, maintenance costs and downtime, and improve the reliability and life of the instrument. It can be used not only as an operating instruction, but also as a reference manual for reference. This instruction must therefore be placed next to the equipment and readily available.

Read Chapter 1 "Safety" carefully before using it for the first time.

Applicable Object

This manual is only applicable to clinicians and nurses who have received professional training.

Illustration

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

Convention

- Italics Bold italics are used in this specification to denote the chapters cited.
- As use herein, that terms hazard, warning, and caution indicate hazard information and its severity.

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Chapter 1 Safety

1.1 Safety information

This chapter outlines basic safety information that the user must be aware of and follow when using the Anesthesia Video Laryngoscope (Laryngoscope).Other safety information that is the same, similar, or is related to a specific procedure will appear in each section.

⚠Danger

- **Indicates an emergency hazard which, if not avoided, could result in death, serious personal injury, or property damage.**

⚠Warning

- **Indicates a potential hazard or unsafe operation that, if not avoided, could result in death, serious personal injury, or property damage.**

⚠Caution

- **Indicates a potential hazard or unsafe operation that, if not avoided, could result in minor injury, product malfunction, damage or property damage.**

Attention

- **Highlight important precautions, provide instructions, or explain to better use this product.**

1.1.1 Danger

No safety risk in this category.

1.1.2 Warning

⚠Warning

- **The laryngoscope is used to expose the glottis to the patient's epiglottis and guide the healthcare professional to accurately intubate the airway for anesthesia or emergency use. The laryngoscope is also used for intraoral examination and treatment and may only be used by a trained clinician, medical electric specialist, or professionally trained clinical staff on a designated basis.**
- **The responsible physician must be responsible for the operational and technical application of the device! The trained physician, the responsible physician, has the right to decide on the adequate use of the equipment according to the actual conditions of use.**
- **Carefully read the anesthesia videolaryngoscope instructions for use before the first use.**
- **Before using this laryngoscope, the user must inspect the laryngoscope and its accessories to ensure that they are working properly and safely.**
- **The Laryngoscope should be used one time for disinfection, consult or understand the regulations concerning cleaning of medical equipment before cleaning.**
- **Do not use this laryngoscope in the presence of flammable or explosive materials to prevent fire or explosion.**
- **The laryngoscope and associated equipment should be fitted with or carried so as to prevent the laryngoscope from falling, colliding, being damaged by strong vibrations or other mechanical forces.**
- **Electromagnetic fields can affect the performance of the laryngoscope and its associated equipment, thus equipment used in the vicinity of the laryngoscope and its associated products must comply with the applicable EMC requirements, otherwise it may cause laryngoscope malfunction or laryngoscope crash due to electromagnetic interference.Mobile phones, X-rays, or MRI equipment are potential sources of interference, emitting high levels of electromagnetic radiation.**
- **All other equipment.For example, similar digital interference devices, when connected to the laryngoscope, must comply with the relevant requirements in the standard detail (e.g., GB 4943 for digital processing equipment, GB 9706 for electrical equipment).In addition, when other equipment is connected involving signal input or output of the equipment, the structure of other equipment must comply with the system structure according to GB 9706.1.The person responsible for connecting the devices must ensure that the system is operable and responsible for meeting the system requirements. If there are additional questions, consult with your local equipment supplier or the service center of Harmonic Medical.**
- **Repairs or upgrades to the laryngoscope must be performed by personnel trained**

and authorized by the Company.

- **Local regulations or the hospital's waste disposal system must be observed when disposing of packaging material. Packaging materials must be kept out of reach of children.**
- **Harmonic Medical will not be responsible for any personal injury or property damage resulting from:**
  - The equipment parts are not the original parts of Hugemed Medical;
  - Missing IFU;
  - Installation, commissioning, modification, upgrade, and repair are to be performed by persons other than persons authorized by Macro Medical.
- **Hugemed Medical cannot be held responsible for any damage or incidents resulting from the use of consumables or accessories other than Hugemed Medical.**

1.1.4 Caution

⚠Caution

1.1.6 Attention

Attention

- **Place this insert next to the laryngoscope so you can see it in a timely and convenient manner if desired.**

- **This instruction sheet represents the most complete set of configurations and capabilities of this product, for which you may not have certain configurations or features.**

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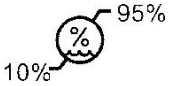
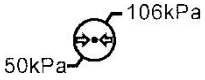
1.2 Labeling Identification

1.2.1 Identification and Their Meaning

	Pay attention/be careful/warn		Category II equipment
	BF-type application component		Consult instructions
	Power adapter (AC)		Term of Use
	Lot No.		Serial Number
	Manufacturer		Production date
	Use pollution-free methods for treatment		Humidity limits for transport packages are 10% ~ 95%
	The environmental pressure of transport packages shall be limited to 50 ~ 106 kPa		Transport package temperature limit is-20 ~ 60 ° C
	Fragile contents in transport packages Products should be handled		Transport packages are protected from rain
	Transportation shall be vertical and upward		Stack up to 5 layers of the same package

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Chapter 2 General Description

2.1 Product profile

2.1.1 Scope of Application

It is used to clinically provoke the patient's epiglottis to expose the glottis, and guide the medical staff to accurately intubate the airway for anesthesia or emergency use, and for intraoral diagnosis and treatment.

⚠Warning

- **This product should be used by specialized clinicians, medical electrical professionals, or professionally trained clinical personnel on a specified basis.Personnel using the product should be fully trained.Any personnel not authorized or trained shall not perform any action.**
- **Before using this laryngoscope, the user must check its accessories to ensure that they are working properly and safely.**

⚠Caution

- **The environment of use and power supply for this Laryngoscope must comply with the requirements in Product Specification A.**

2.1.2 Contraindication

None

2.1.3 Product Compositionand Performance

VL3R, VL3D are mainly composed of four parts: power adapter, display control unit, hand-piece and camera assembly.

VL3R, VL3D have following functions and features:

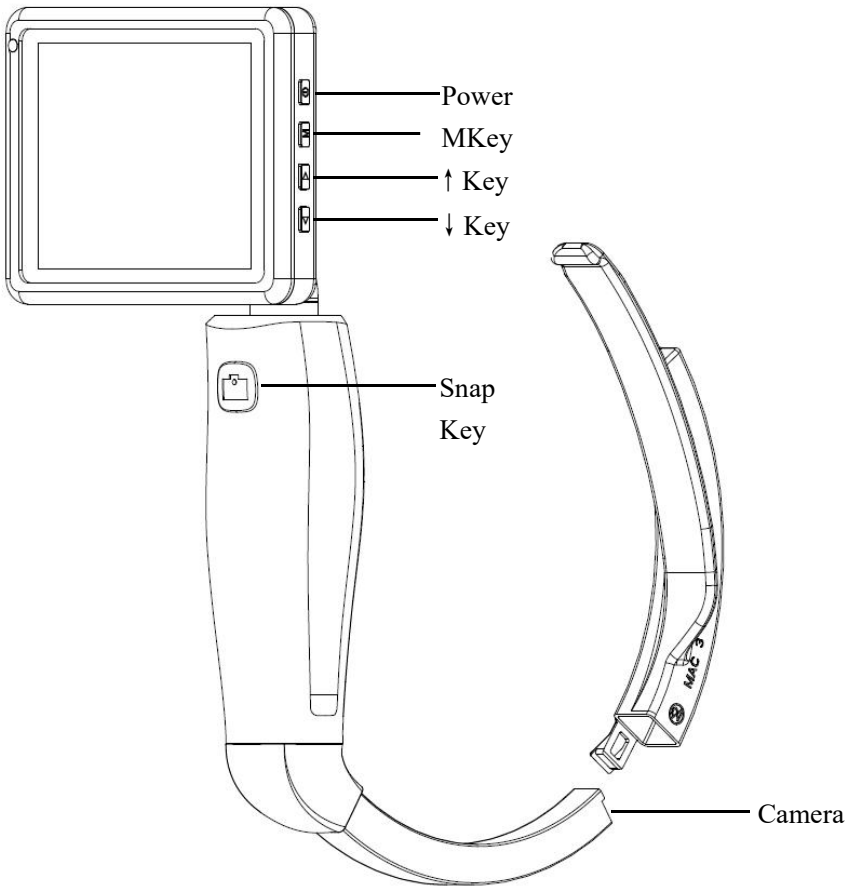
- Compact, movable and integrated LCD color screen;
- Different sizes, with camera and light source, can clearly show the anatomical structure of the glottis, and image the physiological structure of the epiglottis and glottis through the high-pixel camera used in the blade of the blade, which is transmitted to the liquid crystal display through the video transmission line, so that the doctor can clearly observe the entire process of tracheal intubation;

- VL3R Anesthesia Video Laryngoscopes have three different blade options for VLB2, VLB3 and VLB4（*see5.1*）;
- For the VL3D Anesthesia Video Laryngoscope, MAC2, MAC3 and MAC4 single-use laryngoscopes manufactured by Shenzhen Security Medical Product Co., Ltd.

2.2 Product Appearance

2.2.1 Side View

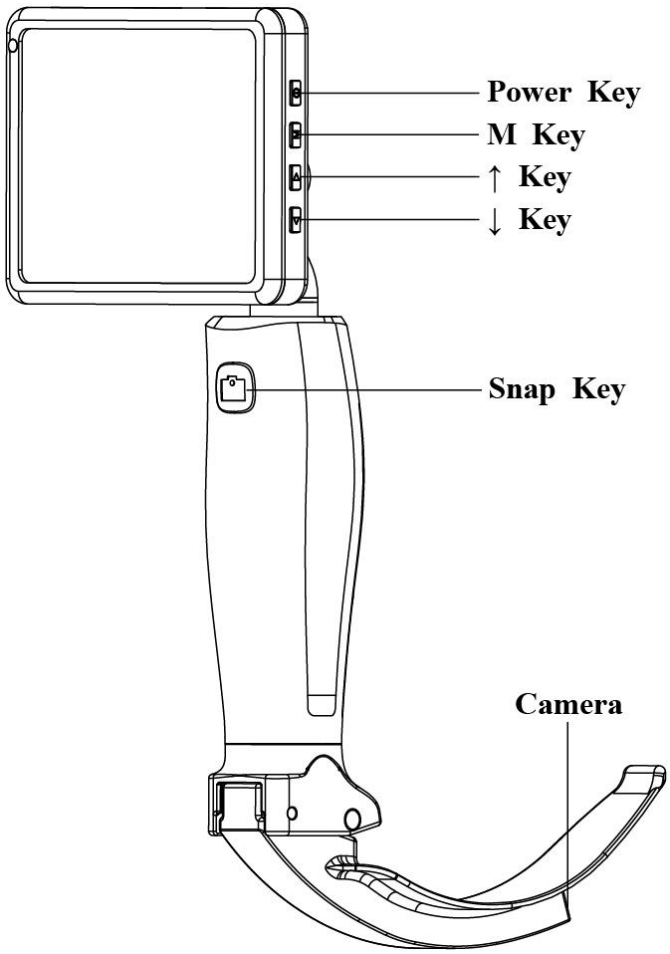
2.2.1.1 VL3D Anesthesia Video Laryngoscope (Disposable)



[Figure 0- 1]　VL3D Side View

1. Power Key: Switch on/off the device;
2. M key: menu key / video play Pause key / Enter / time selection.
3. ↑ key: Last image or video / increase value .
4. ↓ key: Next image or video / Decrease value .
5. Snapkey : short press camera / long press video / return .
6. Camera: for being filmed.

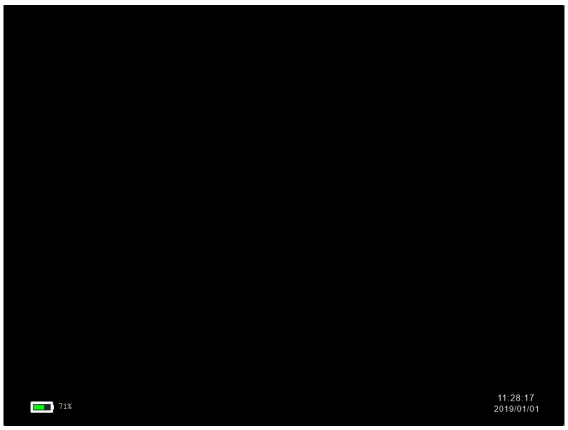
2.2.1.2 VL3R Anesthesia Video Laryngoscope (Repetitive)



1. Power Key: Switch on/off the device ;
2. M key: menu key / video play Pause key / Enter / time selection.
3. ↑ key: last image or video / increase value .
4. ↓ key: next image or video / Decrease value .
5. Snap key : short press camera / long press video / return .
6. Camera : for being filmed .

[Figure 0-2], VL3R Side View

2.2.2 Screen Display



[Figure 0-3] The VL3R/VL3D displays the main screen

1. In normal operation, the screen full screen displays real-time video, the lower right corner displays real-time time, and the lower left corner displays battery power;
2. When the power is lower than 20%, the "low battery" prompt jumps out in the upper left corner of the screen;
3 If the charge is lower than 10%, the prompt "battery empty" appears in the upper left corner of the screen;
4. When take a photograph or take a video, a photograph or take a video prompt appears in the top right corner of the screen, when take a photograph, the photograph prompt jump out, when take a video, the video prompt continuously blink.

2.3 Battery

2.3.1 General

This laryngoscope has a removable rechargeable battery (hereafter referred to as"battery") that is placed on an 8-inch host, the battery can be replaced, the battery can be charged when the laryngoscope is connected to the power adapter, the laryngoscope can enter the charging mode when powered on, and the laryngoscope can be operated in this state.

Battery power is maintained for a period of time only. A Low Battery Alert is triggered at least 30 minutes prior to battery depletion and an advisory message is displayed during this time. An alarm for battery depletion is triggered at least 3 minutes before battery depletion, during which a prompt appears and this message blinks.

Attention

- **Do not recharge if mains voltage is fluctuating.**
- **A depleted battery requires 4 to 6 hours of recharging to full.**
- **If using this product for an extended period of time, please charge and discharge the battery every 3 months to avoid battery damage.**
- **The battery is a depleted component and must be replaced if depleted.**
- **If you would like to replace this battery, please contact the distributor or manufacturer who sold you this product.**
- **The replacement of batteries must be performed only by a company technical service engineer!**

2.3.2 Battery Usage Guide

The battery life depends on the frequency of use and the operating environment.With proper use and maintenance, it has a service life of approximately 3 years; otherwise, its service life may be shortened. The battery should be replaced every 3 years.

For operational safety and to maximize battery life, pay attention to the following instructions:

- A battery performance check must be performed annually. A battery performance check is also required before the laryngoscope is repaired or when you suspect the battery is the source of the malfunction;
- Optimization of the battery every 3 months of use (or storage) or when laryngoscopy is significantly shorter;
- Charge the battery with 1C current (when 1C current is greater than the operating current of the panel, the maximum charge current of the panel is the operating current of the panel) 4.2V for approximately 0.5 hours with each half year of storage ensuring live storage.

⚠Warning

- **Use only battery specified by the manufacturer.**
- **If the battery shows signs of damage or leakage, replace it immediately.**
- **Do not apply a faulty battery to this laryngoscope.**
- **The used batteries may be returned to the distributor or manufacturer where they are sold, or they may be disposed of in accordance with applicable laws and regulations.**

2.3.3 Battery Maintenance

2.3.3.1 Optimize Battery Performance

Refine when battery is first used. A complete optimized cycle consists of a continuous charge to a full charge, then a discharge to laryngoscope shutdown and then a continuous charge to a full charge. Batteries should be routinely optimized to maximize their service life during use.

Attention

- **With time and battery usage, the actual storage capacity of the battery will decrease. When optimized, replace the battery if a significant decrease in battery power time is observed.**

Refer to these steps for optimization:

1. Connect the laryngoscope to the power adapter and charge continuously for 8 hours;
2. Disconnect the Laryngoscope Power Adapter and use battery power until the Laryngoscope shuts down;
3. Reconnect the laryngoscope to the power adapter and charge continuously for 8 hours;
4. This battery is optimized.

2.3.3.2 Check Battery Performance

Battery performance may deteriorate over time and should be checked periodically for battery performance.
To check the battery performance, follow these steps:

1. Connect the laryngoscope to the power adapter and charge continuously for 6-10 hours;
2. Disconnect the power adapter and continue to run the laryngoscope until the battery goes low and shutdown;
   - If the time from the start of laryngoscopy to shut-down is 100 minutes or longer, the battery is in good condition;

- If the time from the start of laryngoscopy to shut-down is 30-120 minutes, the battery is approaching the end of its useful life;
- If the time from laryngoscope start to shutdown is less than 30 minutes, the battery has reached the end of its useful life and will need to be replaced.

3. After checking the battery, you must recharge it for further use.

Attention

- **If the power time is too short after the battery is fully charged, the battery may have been damaged or faulty. The amount of time the battery is powered will depend on the configuration of the laryngoscope and the frequency at which it is used, e.g. the display screen backlit for an extended period of time.**
- **If the battery is visibly damaged (bulging, deformation, leakage) or it is unable to hold charge, it should be replaced and properly recycled.**

2.3.4 Battery Recovery

If there is evidence of damage (bulging, deformation, fluid leakage) or depletion, replace the battery and properly recycle. Follow appropriate regulations when disposing of discarded batteries.

⚠Warning

- **Do not remove, fire, or short-circuit the batteries. Combustion, explosion or leakage of batteries may cause physical injury.**

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Chapter 3 Installation and Service

3.1 Install

⚠Warning

- **The software copyright of this laryngoscope is owned by this company, and it may not be tampered with, duplicated or exchanged in any way or by any organization or person without permission.**

3.1.1 Out of Box Inspection

Before opening the box, carefully examine the box to determine if any damage has occurred during shipment of product. Contact the carrier company or the company immediately if any damage is found.

If the package is intact and undamaged, unpack it in the correct way, carefully remove the laryngoscope and the other components from the box, and perform inventory one by one according to the box list. The product was inspected for any mechanical damage and the items were present. If you have any questions, please do not hesitate to contact our service department.

⚠Warning

- **Users should keep packaging materials out of reach of children. Local regulations or the hospital's waste disposal system must be observed when disposing of packaging material.**

Attention

- **Please keep the box and packing material for future shipping or storage.**
- **Contact the distributor or the manufacturer who sold you this product as soon as possible if there are any missing accessories that are found out of the opened package.**

3.1.2 Environmental requirements

This laryngoscope should be used in accordance with***A.2 Requirements*** for environmental specifications.

The Laryngoscope should also be used in an environment that eliminates noise, vibration, dust, corrosive or flammable, explosive materials, etc.

When the laryngoscope moves from one environment to another, it can condensate due to differences in temperature or humidity, and must wait until the condensate disappears before starting the laryngoscope.

3.1.3 Power requirement

The power supply used for this laryngoscope shall meet the requirements of ***A.3 power supply*** specification.

⚠Warning

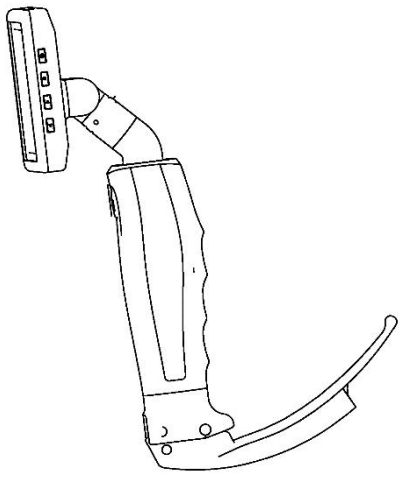
- **Please ensure that the laryngoscope works within the specified environmental and power requirements otherwise it will not be possible to meet the specifications stated in Product Specification A and possible unforeseen consequences such as laryngoscope failure.**
- **The appropriate power supply must be selected based on the Laryngoscope supply voltage setting. Severe damage to the laryngoscope may occur.**

3.1.4 Mounted with a removal blade

3.1.4.1 VL3R Anesthesia Video Laryngoscope (Repetitive) Loading and Handling of Blades

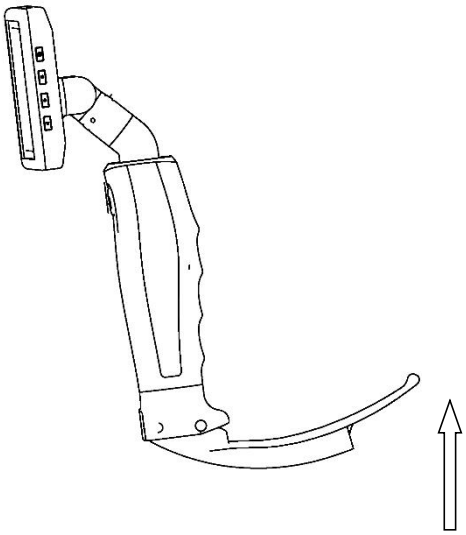
1. Select the appropriate blade for laryngoscopy, depending on the patient and the size of the mouth;
2. Stuck the blade connection point at the video handpiece connection in the direction of the arrow as shown in Figure 3-1;
3. Leaf tips pushed down into blade as in Fig 3-2;

[Figure 3-1] VL3R installation step



[Figure 3 - 2] VL3R installation step two

4. To install step two in reverse as shown in Figure 3-3, separate the blade from the handpiece and pull the top of the blade upward to disengage the blade attachment points from the handpiece snaps.



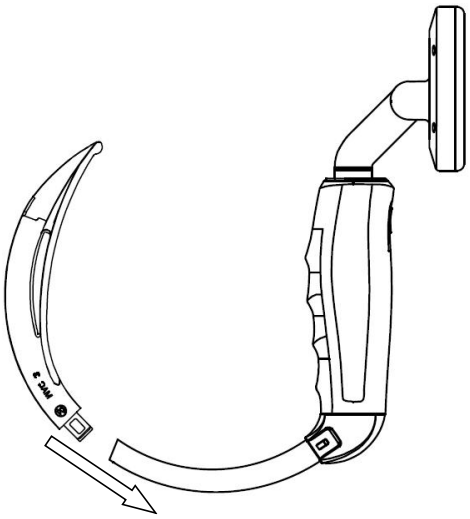
[Diagram 3-3] for VL3R disassembly steps

Attention

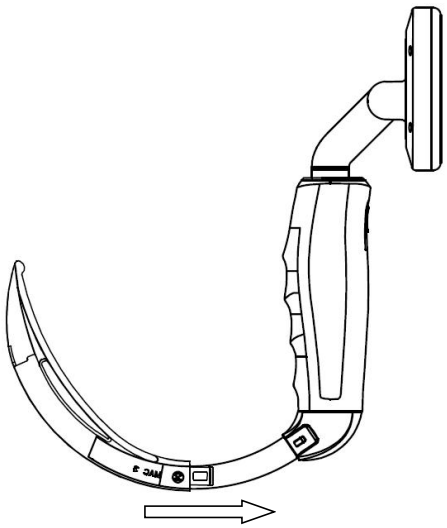
- **This laryngoscope and its associated equipment should be fitted with or carried so that it will not be dropped, bumped, damaged by strong vibrations or other mechanical forces.**
- **Handle carefully when handling the blade.**

3.1.4.2 Handling of the VL3D Anesthesia Video Laryngoscope (Disposable) Mirror

1. Choose an appropriate single-use laryngeal lens, based on the patient and oral cavity size;
2. Insert the mirror into the support tube along with the arrow as shown in Figures 3-4 and 3-5;

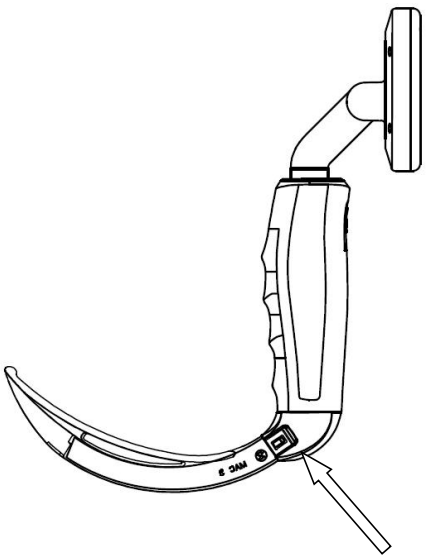


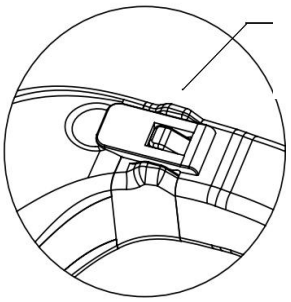
[Figure 3-4]VL3D installation step one



[Figure 3- 5] VL3D installation step two

3. Lock tabs as shown below;

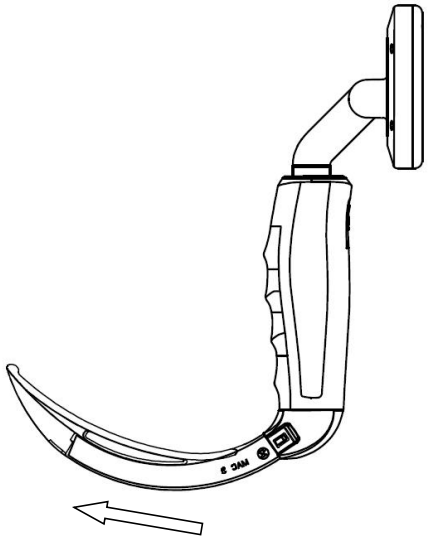




When using the disposable videolaryngoscope, be sure to make sure the card and connection are compact and have no gaps.

[Figure 3-6] VL3D installation step three

4. In the figure below, reverse step 3 to separate the lens from the support tube, raise the lens button and remove the lens from the support tube in the direction of the arrow.



[Figure 3- 7] VL3D disassembly steps

⚠Warning

- **Never use a single-use laryngeal lens with a damaged or inelastic crimp.**
- **The Disposable Laryngoscope is for single use only; do not use if package is damaged.**
- **After using the single-use laryngeal mirror, it should be handled according to the requirements of hospital or environmental protection department.**
- **The Disposable Laryngoscope is intended for use by qualified healthcare professionals.**

3.2 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.**

3.2.1 Inspection

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;
- No mechanical damage to the device or accessories;
- Battery performance;
- Use of specified accessories;
- Functionally.

If any damage or abnormalities are found, discontinue use and contact the distributor or manufacturer who sold you this product.

3.2.2 Cleaning, disinfection

The Laryngoscope can only be cleaned or disinfected using the materials and methods listed in this chapter, and we do not offer any warranty against damage or injury caused by other materials or methods.

The chemicals or methods listed by the Company do not assume any responsibility for their effectiveness other than as a means of infection control. Consult with your hospital's infection prevention department or epidemiological specialist about ways to control infections.

Keep the laryngoscope free of dust. To prevent damage to the laryngoscope, the following must be observed:

- Dilute the detergent and disinfectant as required by the manufacturer, or to use as low as possible;
- Do not immerse the display host and the handpiece of the laryngoscope in fluids;
- Do not pour fluid on the display main frame and handle of the laryngoscope;
- Do not allow fluid to enter the display mainframe and handpiece of the laryngoscope;
- Do not use abrasive materials (such as steel wool or silver polishing compound) and solvents similar to xylene and acetone to clean the laryngoscope to avoid damage to the housing.

⚠Warning

- **Always turn the power off and disconnect the charging cable from the power adapter before cleaning the laryngoscope.**
- **The cleaning and disinfection measures described in this manual are, in either case, not a substitute for the daily rules and regulations for using the equipment!**

⚠Caution

- **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.**

Recommended surface disinfection method:

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

1. Blade Cleaning Disinfection:

After the laryngoscope is used, wipe off the outer surface with a wet/alcohol gauze and immerse the cleaned blade in a disinfecting solution: The disinfection is performed by immersion in a 2% mass fraction solution of glutaraldehyde for 30 min to 60 min.

2. Display Host and Handpiece Cleaning Disinfection:

After the laryngoscope is used, moist/alcohol gauze is used to remove exterior dirt, and then the display unit and handpiece are cleaned and disinfected with a 75% alcohol wipe.

⚠Caution

- **Do not use heat, autoclave.**
- **Do not disinfect with high concentrations of organic or non-organic acids, as this may**

cause corrosion of the device.

- **Do not sterilize chemicals containing chlorfor mamide, phenol derivatives, anionic surfactants, plastic materials on the outside of the instrument are susceptible to aging and cracking.**
- **Disinfectants containing aldehydes and amines on the same surface may discolor the surface.**

3.2.3 Regular maintenance

1. Maintain battery performance
   See0.
2. General maintenance

Time between	ROUTINE MAINTENANCE PROCEDURES
Per hospital policy	Thoroughly cleaning the laryngoscope surfaces is required before and after longer storage.
Tested at least annually	1. Test power adapter and charging cable. 2. Run the laryngoscope until the low battery alarm sounds, then charge the battery to verify proper operation and charging.

3.2.4 Treatment, recycling

The product life time is about 3 years. Laryngoscopes beyond their useful life should be scrapped, please contact the distributor or the manufacturer who sold them to you for more information.

You may do the following:

1. A scrapped laryngoscope can be sent back to the distributor or manufacturer who sold you this product for proper retrieval.
2. Obsolete batteries may be sent back to the distributor or manufacturer who sold them to you for disposal, or they may be disposed of in accordance with appropriate regulations.

Chapter 4 Operating Instructions

4.1 Display Console operation

4.1.1 Function key

keying	Power key	Menu Button	selection key	selection key	function key
Identification					
function	Switching devices	1、Enter the Settings screen 2、Validation Options 3、save settings	Up Selection	Down Selection	shoot

4.1.2 Work Screen

Power key pressed  After the video laryngoscope is activated, the company LOGO is statically displayed, as shown in 'Figure 4-1', and automatically enters the normal working interface after 3 seconds, as shown in 'Figure 4-2'.

[Figure 4-1] Power on LOGO Screen

[Figure 4-2] normal working interface

1) For normal operation, live video is displayed on the screen at full screen, real time, month, day, and year at lower right corner, and power icon at lower left corner.

2) When < 20% of capacity, "Low Battery" prompt pop up in the top left corner of the screen;

   A battery depleted prompt appears in the upper left corner of the screen when the charge level is below 10%.

3) When a picture or photograph is taken, the picture or photograph prompt is displayed on the screen. When a photograph is taken, the image prompt in the center of the screen is tripped; when the photograph is taken, a photographic prompt is shown above the power display area in the lower left corner of the screen, along with the amount of time spent in live photography.

4) Press the menu button  Enter the System Setup screen;

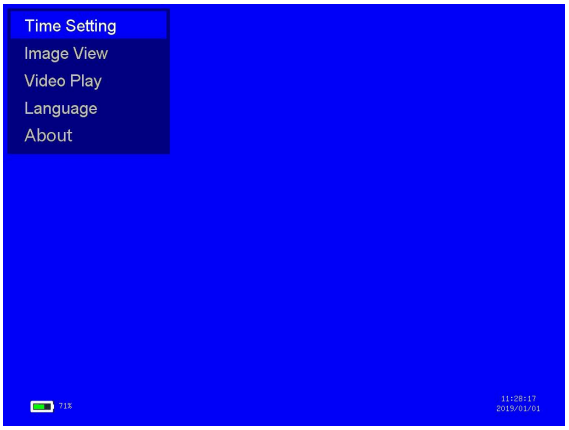
Functional keys are pressed  entering the photograph function;

Functional keys are pressed  entering the camera function;

Press and hold right, down selection key  enter the disk formatting function;

4.1.3 System Setup Screen

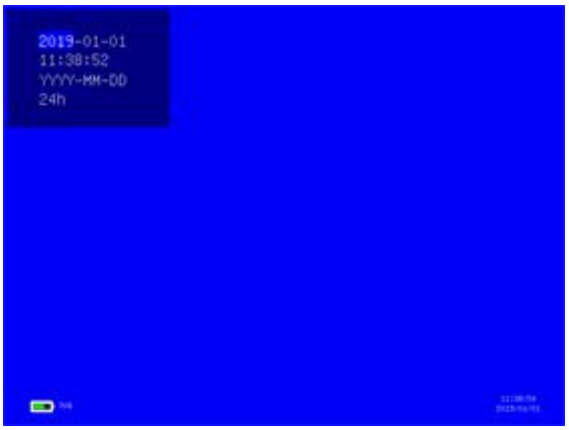
Press the menu button M; the screen displays the System Setup screen with a blue color background. The keys exit the screen.



[Figure 4-3]

Available ◁ , ▷ select， M key in subscreen. The keys return to the upper screen.

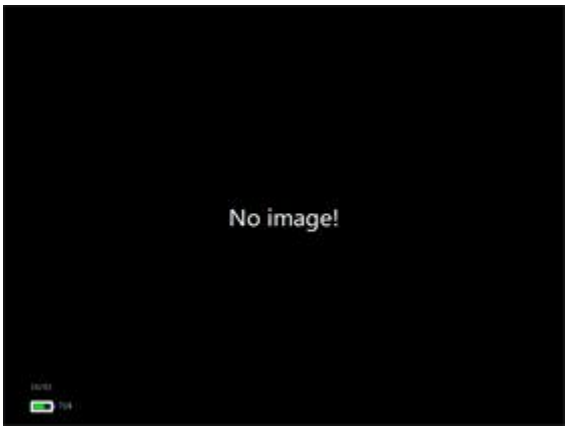
4.1.4 Time Settings Screen



[Figure 4-4]

Press M Key toggles year, month, day, hour, minute, second, ◁, ▷ key adjusts value, key returns upper screen.

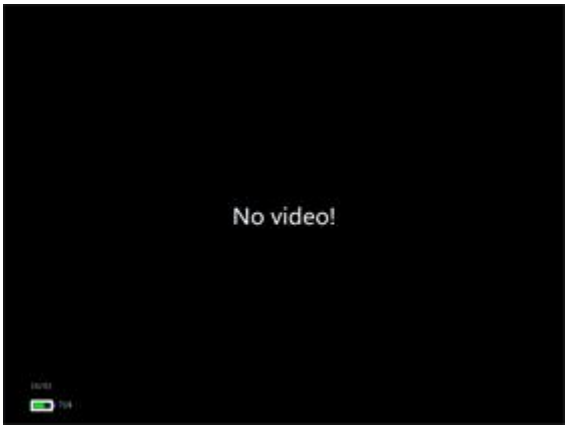
4.1.5 Photo Review Screen



[Figure 4-5]

Press  、  toggles photo, press Key  return, press and hold  to delete the currently selected photo file.

4.1.6 Video play screen



[Figure 4-6]

Press  ,  the key to toggle the video, press  the key to confirm and play the video Press toggle pause and play again, press  the key to return, press and hold  the key to delete the currently selected video.

4.1.7 Language settings screen

[Figure 4-7]

Press ◁ , ▷ key to select the language, press M key to select the language, press the key to confirm the selection.

4.2 Operating Instructions

Static images and videos of respiratory and endotracheal intubation procedures can be recorded and automatically saved to in-memory of the Display Host.

⚠Warning

- **The anesthesia video laryngoscope is used in conjunction with a system technique similar to direct laryngoscopy. Consult with personnel involved in endotracheal intubation techniques prior to use in humans.**

4.2.1 Blades

- Cleaning: Prior to use, clean and disinfect the handpiece and blades appropriately (see***0***,***0***).
- Anti-fogging: The video lens for the blade is electrically heated to remove fogging in the trachea due to warmed and humid environment of the airway, etc. Driven by the handpiece battery, the LEDs on the blades begin to illuminate and the heating element starts to operate. Due to the temperature of the blade itself, the haze from the lens is eliminated within 30 seconds after the blade and handle are connected.

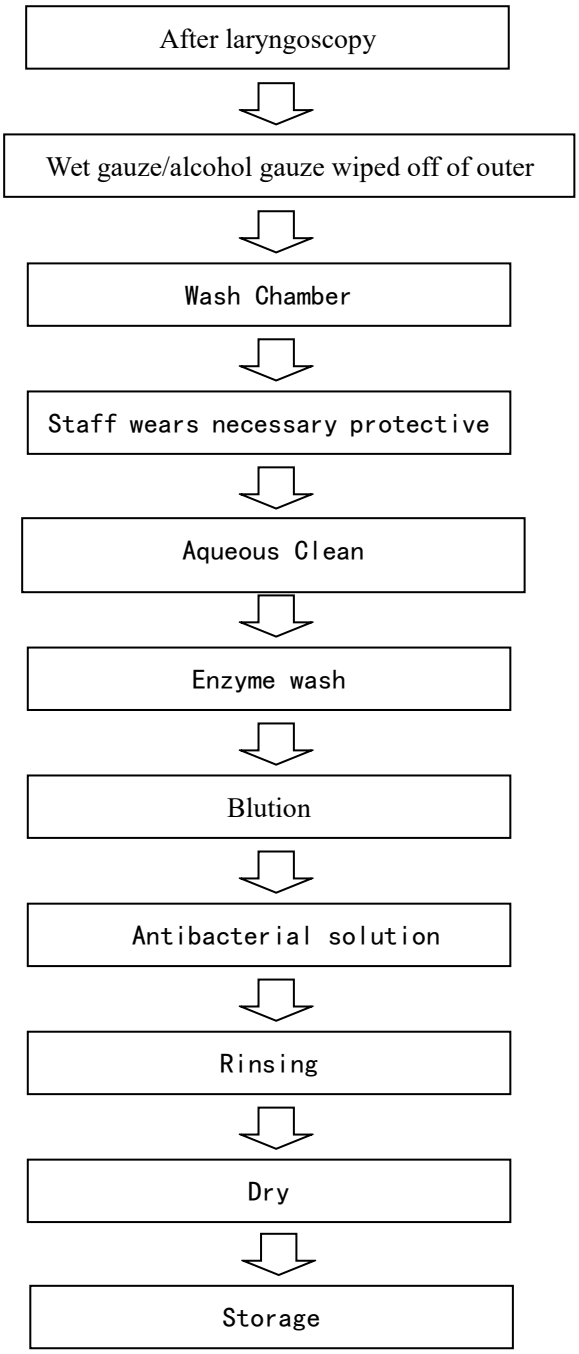
⚠Warning

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

4.3 Cleaning Instructions

Immediately following use of the laryngoscope, the health care professional wiped off the host and the external surface of the repeating blades with 75% alcohol wet gauze; the gauze was disposed of in a yellow medical garbage bag; and the non-operating hand piece was sent to the washer-disinfector.

The standard process for standard cleaning and disinfection of repeat blades is as follows:



⚠Warning

- **The Laryngoscope should be used one time for disinfection, consult or understand the regulations concerning cleaning of medical equipment before cleaning.**
- **Always turn the power off and disconnect the charging cable from the power adapter before cleaning the laryngoscope.**
- **The handpiece and display unit are not waterproof, so avoid submersion or excess fluid, it is recommended that they be wiped with a disinfecting wipe.**

4.3.1 Aqueous Clean

1. Rinse blades thoroughly under running water for 2min and wipe clean with wet gauze until visibly clear.
2. Using a small brush under running water, clean and dry the interior surface of the blade attachment points and handpiece snaps, brush the blades thoroughly with a clean brush. Repeat brush steps for 5 times.
3. The sealing of the handle and display surface can be wiped with a damp cloth for 5 times. Other parts should be carefully cleaned to allow fluid to enter the interior.
4. The gauze shall be cleaned in a single-use manner, and the brushes shall be disinfected.
5. Cleaned and dried with gauze.

4.3.2 Enzymatic Wash

Used to remove organic substances, such as body fluid secretions, to prevent organic substances from affecting the efficacy of the disinfectant, timely enzymatic washing to prevent protein drying and difficult removal.

1. Multi-enzymatic bath configuration and soak time per product insert.

   Use the following Hugemed validated conditions to achieve cleaned:

   Cleaning Solution: Metrex EmPower

   Concentration: 1:128

   Temperature:20℃~40℃

   Immersion:≥1 min
2. Place the dried laryngoscope in an enzymatic bath and the procedure wipe with multi-enzymatic wash solution for 5 times.
3. The dried accessory is soaked with multi-enzymatic detergent, and the attachment is cleaned in an ultrasonic cleaner for 5-10 minutes.

4. The multi-enzymatic detergent should be changed after each blade has been cleaned.

4.3.3 Ablution

Post-soak laryngoscopes were washed with multi-enzymatic detergent (time according to instructions), the external surface of the laryngoscope was irrigated 10s with a high-pressure water pistol or sterile gauze.

4.3.4 Disinfection

4.3.4.1. Antibacterial solution soak

1. Place cleaned, dried blade into a basin/drum and immerse in the disinfectant solution. Disinfect according to the time, concentration and temperature recommended by the disinfectant manufacturer.

   Use the following Hugemed validated conditions to achieve disinfection:

   Disinfection Agent: MetriCide 28 Long-life Activated Dialdehyde Solution

   Concentration:2.5%

   Temperature: 25℃

   Soaking time: 90 min
2. The display unit and handpiece must be wiped clean and then disinfected with a 75% alcohol wipe.
3. When a laryngoscope that is no longer in use at the end of a day of treatment is last disinfected with a disinfectant, terminal disinfection should be prolonged to 30 minutes
4. The reusable laryngoscope to be used for the day must be resterilized before the daily routine. Soak in the recommended disinfectant for not less than 20 minutes, rinse, dry before use.
5. Laryngoscopes to be sterilized must be soaked for 10 hours in 2% alkaline glutaraldehyde.

⚠Warning

- **Do not use any strong alkaline/acidic disinfectant solution for the Laryngoscope.**
- **Do not use a medical alcohol or betadine soak laryngoscope.**
- **Do not place laryngoscopes in the presence of organic solvents such as acetone or butanone.**
- **Do not sterilize laryngoscope products with high heat or pressure.**
- **When disinfecting, pay attention to the cleaning of the laryngoscope window glass so**

that the observation effect is not affected.

4.3.5 Rinsing

Before the laryngoscope is removed from the basin, the washer-disinfector should change the gloves. Put the Laryngoscope into a container with 5L sterile water, wipe the Laryngoscope thoroughly with sterile gauze. Repeat rinsing steps for three times.

⚠Warning

- **Immerse sterilized blades in a chemical disinfectant and thoroughly rinse in sterile water to remove residual disinfectant prior to use.**

4.3.6 Dry

Dry them using sterile gauze or clean compressed air.

4.3.7 Storage

Store disinfected or sterilized laryngoscopes in sealed, sterilized cases.

Attention

- **Cleaning practices are written in accordance with the Endoscope Cleaning and Disinfection Technical Operating Specification, 2004.**
- **This is for informational purposes only, and should be verified by an appropriate method for disinfection efficacy.**

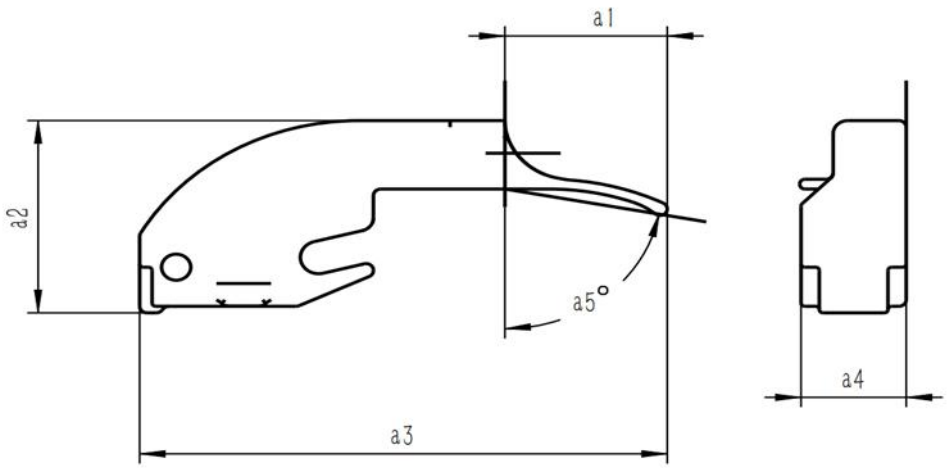
Chapter 5 Attached

⚠Warning

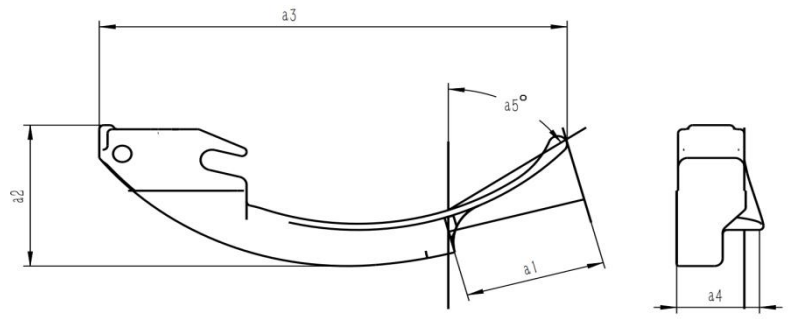
- **Using only the accessory specified in this chapter, using other accessories may damage the laryngoscope or may not meet the specifications stated in the instructions.**
- **Single use accessories should be used only once, and repeated use may result in reduced performance or cross-infection.**
- **If the accessory package or accessory shows signs of damage, discontinue use and contact the distributor or manufacturer who sold you this product as soon as possible.**

5.1 Blades

The repeat blades are the following:



Model	a1	a2	a3	a4	a5
mil00	22	29.5	72	14.4	81
mil0	25	29.5	84	15	78
mil1	26	29.5	110	15	71



Model	a1	a2	a3	a4	a5
MAC1	30	34	101	18	56
MAC2	29	36.5	115	21	50
MAC3	34	39.5	126.5	21	46
MAC4	40	43	136	22.5	48
MAC5	38	51	149.5	23	44
DMAC1	30	34	101	18	56
DMAC2	30	50	115	22	30
DMAC3	34	53	127	22	30

A Product Specifications

A.1 Safety specifications

A.1.1 Class II equipment, with internal power supply, by type of protection against electric shock

A.1.2 Equipment classified as type BF applied part by the degree of protection against electric shock

A.1.3 Class A equipment classified by electromagnetic compatibility

A.1.4 Rated voltage, frequency and power

Power Adapter Input: 100-240V ~, 50/60Hz, 0.2-0.1A

Power Adapter Output: DC5V, 1A

Display of host external inputs: DC5V,1A

Internal Power Supply: DC3.7V, Lithium Ion Battery

A.1.5 Not permanently installed

A.1.6 Classification according to the safety degree of device used in the flammable anesthesia gas mixed with air or with oxygen or nitrous oxide: cannot be used in the flammable anesthesia gas mixed with air or with oxygen or nitrous oxide.

A.1.7 Classification according to the operation mode: continuous operation.

A.1.8 Electromagnetic compatibility is classified in Group 1 Class B per GB 4824.

A.2 Environmental Specifications

Parameter	Specification
Working temperature	5 to 40℃
Operating Humidity	20-80%, non-condensing
Operating Atmospheric Pressure	86～106kPa
Shipping Temperature	-20～60ºC
Transport & Storage Humidity	10 to 95%, non-condensing
Storage Atmospheric Pressure	50～106kPa
Description of storage conditions	Non-corrosive gas and a well-ventilated room

A.3 Power Specification

Parameter	Specification
Power Adapter	
Input voltage	100-240V ~
Input current	0.2-0.1A
Input Frequency	50/60Hz
Output Voltage	DC5V
Output current	1A
Battery	
Number of batteries	1 each
Type of battery	Lithium Ion Battery
Nominal battery voltage	DC 3.7V
Battery capacity	≥ 3200 mAh

A.4 Basic Parameters

parameter	specification
Rotation angle	A/P rotation range ≥ 120 ° A rotation range ≥ 120 °
Working distance	30-90 mm
Spatial resolution	≥ 6.35 lp/mm
Viewing angle	≥ 60 °
Illumination range	≥ Φ 30 mm, h = 30 mm
Light Source Illumination	≥ 400 lx, h = 30 mm
Light Source Color Temperature	≥ 2300K
Special Functions	Photographs, Video, Storage and Time Settings, etc.
Alarm functions	Low battery, depleted battery, blades not connected

A.5 List of Accessories

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

Serial number	Part Name	Abundance	Remark
1	Main Unit	1	
2	Blade VLB2	1	
3	Blade VLB3 blades	1	
4	Blade VLB4	1	
5	Power Adapter	1	
6	USB cable	1	
7	Certificate	1	
8	Instruction manual	1	

B EMC

The laryngoscope complies with EMC Standard YY 0505/EN 60601-1-2.

Attention

- **Use of accessories, sensors, and cables other than those specified may increase electromagnetic emissions and/or decrease electromagnetic immunity of the laryngoscope.**
- **The laryngoscope should not be used adjacent to or stacked with other equipment. This laryngoscope should be kept under close observation when necessary to ensure that it will function properly in the configuration in which it will be used.**
- **The EMC of this laryngoscope needs special protection and needs to be installed and serviced in an environment that meets the following EMC information.**
- **Avoid using this laryngoscope and MRI (magnetic resonance imaging) or similar equipment simultaneously as it may cause device malfunction or device breakdown due to electromagnetic interference.**
- **Interference may occur with this laryngoscope, even if other equipment meets CISPR emission requirements.**
- **Inaccurate measurements may result when the input signal amplitude is less than the minimum amplitude specified in the specification.**
- **Portable and mobile RF communications equipment can affect the performance of laryngoscopes.**

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The laryngoscope is intended for use in the electromagnetic environment specified below, and the customer or user of the laryngoscope should assure that it is used in such an environment:</td></tr>
<tr><th>Emission Test</th><th>Conformity</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF Emissions
GB 4824</td><td>Arm 1</td><td>This laryngoscope uses RF energy only for its internal function.Therefore, its RF emissions are low and are not likely to cause any interference in nearby electronic equipment</td></tr>
<tr><td>RF Emissions
GB 4824</td><td>Class A</td><td rowspan="3">The laryngoscope is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emission
GB 17625.1</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations/flicker emissions
GB 17625.2</td><td>Not applicable</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity			
The Laryngoscope is intended for use in the electromagnetic environment specified below, and the customer or user of the Laryngoscope should assure that it is used in such an environment:			
Immunity test	**IEC 60601 Test Level**	**Compliance level**	**Electromagnetic environment - guidance**
Convective discharge GB/T 17626.2	± 6 kV contact contact discharge ± 8 kV Air Discharge	± 6 kV contact contact discharge ± 8 kV Air Discharge	Floors should be wood, concrete, or ceramic tile, and relative humidity should be at least 30% if floors are covered with a synthetic material
Electrical fast transient/burst GB/T 17626.4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge GB/T 17626.5	± 1 kV line – to - line ± 2 kV line – to- earth	± 1 kV line – to - line ± 2 kV line – to-earth	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines GB/T 17626.11	< 5% UT for 0.5 cycle (> 95% dip in UT) 40% UT for 5 Cycles (60% dip in UT) 70% UT for 25 cycles (30% dip in UT) < 5% UT for 5s (> 95% dip in UT)	< 5% UT for 0.5 cycle (> 95% dip in UT) 40% UT for 5 Cycles (60% dip in UT) 70% UT for 25 cycles (30% dip in UT) < 5% UT for 5s (> 95% dip in UT)	Mains power quality should be that of a typical commercial or hospital environment.If the user of the laryngoscope requires continued operation during power mains interruptions, it is recommended that the laryngoscope be powered from an uninterruptible power supply or a battery
Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Note: UT is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity

The Laryngoscope is intended for use in the electromagnetic environment specified below, and the customer or user of the Laryngoscope should assure that it is used in such an environment:

Immunity test	IEC 60601 Test Level	Compliance level	Electromagnetic environment - guidance
Radio-frequency conducted GB/T 17626.6 radiofrequency radiation GB/T 17626.3	3 V r.m.s. 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V (r.m.s.) 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the laryngoscope, including cables, than the recommended separation distance. This distance shall be calculated by the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz～2.5 GHz Where: P —The maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer; D is the recommended separation distance in meters (m) b. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, c should be less than the compliance level in each frequency range d. Interference may occur in the vicinity of equipment marked with the following symbol. 

Note:
1. At 80 MHz and 800 MHz, the higher frequency range applies.
2. These guidelines may not apply in all situations where electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

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

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Laryngoscope

The Laryngoscope is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.The customer or the user of the communications equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VL3R as recommended below, according to the maximum output power of the communications equipment.

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

Note:

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