Instructions for Use of Video Laryngoscope Blades

Instructions

Thank you for purchasing this video laryngoscope blade.

Please read the Instructions for Use (IFU) carefully prior to use for proper use of the product.

Please keep this IFU for future reference.

Product name:	Video Laryngoscope Blade
Model:	HT2/HT3/HT4
Production Date:	See product labels
Service life:	3 years
Preparation/Revision date:	March 31,2022
IFU version:	1.0
Product performance, structure and composition:	This product is mainly composed of the camera module, titanium alloy handle, spatula, and silicone buttons.
Intended Use	Video Laryngoscope Blade used to provide access, illumination, and allow observation or manipulation of pharynx and larynx in examine and visualize a patient's upper airway and aid placement of a tracheal tube.
Name of registrant/manufacturer:	Shenzhen HugeMed Medical Technical Development Co., Ltd.
After-sales service provider:	Shenzhen HugeMed Medical Technical Development Co., Ltd.
Accommodation:	401, 501, Building 4, Haizhi Technology Park, Fortis, No. 17, Bulan Road, Xialilang Community, Nanwan Street, Longgang District, Shenzhen, Guangdong, 518112, China
Site address:	401, 501, Building 4, Haizhi Technology Park, Fortis, No. 17, Bulan Road, Xialilang Community, Nanwan Street, Longgang District, Shenzhen, Guangdong, 518112, China 516-1, 416-1, and 415, Building 2, No. 1, Mawu Road, Bao'an Community, Yuanshan Street, Longgang District, Shenzhen, Guangdong, 518115, China
Contact details:	Tel.: +86-755-22275866 E-mail: service@hugemed.net
Website:	http://www.hugemed.net
IFU website address	https://hugemed.net/Product/Accessories/Video-Laryngoscope-Blade/IFU

Intellectual Property

The IFU and the intellectual properties of the product belong to Shenzhen HugeMed Medical Technical Development Co., Ltd.

HugeMed is a registered trademark or trademark of Shenzhen HugeMed Medical Technical Development Co., Ltd.

Declarations

Shenzhen HugeMed Medical Technical Development Co., Ltd. reserves all the rights of final explanation for the IFU.
Shenzhen HugeMed Medical Technical Development Co., Ltd. reserves the right to modify the contents of the IFU without prior notice. Modifications to the content of the IFU will be reflected in the newly published version.
Shenzhen HugeMed Medical Technical Development Co., Ltd. shall not be held responsible for any equipment not provided by Shenzhen HugeMed Medical Technical Development Co., Ltd. or its distributors.

Only when all of the following requirements are met will Shenzhen HugeMed Medical Technical Development Co., Ltd. be held responsible for the safety, reliability, and performance of the product:

- Assembly, expansion, adjustment, improvement, and repair shall be carried out by professionals recognized by Shenzhen HugeMed Medical Technical Development Co., Ltd.;
- All replaced parts involved in repair and supporting accessories and consumables are the genuine (original) parts of Shenzhen HugeMed Medical Technical Development Co., Ltd. or approved by Shenzhen HugeMed Medical Technical Development Co., Ltd.;
- The related electrical equipment complies with national standards and the requirements specified in the IFU;
- This product shall be operated according to the IFU.

Warranty and Repair Service

The standard warranty period for this product is one year, while the warranty period for the main accessories, including the data cable, is six months. Consumables refer to disposable materials that need to be replaced after each use, and there is no warranty for consumables.

If the warranty period in your sales contract with the seller is inconsistent with the above standard warranty period or there are other agreements, please consult and confirm with Shenzhen HugeMed Medical Technical Development Co., Ltd. through the free service hotline at +86-400-690-1290. If it is not confirmed by Shenzhen HugeMed Medical Technical Development Co., Ltd., please promptly negotiate and confirm with the seller.

The warranty period starts from the "Installation Date" filled in the *Product Warranty Card* attached to the product, which is the only proof for calculating the warranty period. To protect your rights and interests, please urge the installer to return the second page of the *Product Warranty Card* to Shenzhen HugeMed Medical Technical Development Co., Ltd. within 30 days from the date of installation. If the *Product Warranty Card* of the product you purchased is not returned to Shenzhen HugeMed Medical Technical Development Co., Ltd. in time, the warranty period will be extended for 45 days starting from the "Ex-warehouse Date" indicated on the product packaging box.

Within the warranty period, you may enjoy free after-sales services for the product. Please note that Shenzhen HugeMed Medical Technical Development Co., Ltd. will offer a fee-based repair service even within the warranty period if the product needs to be maintained due to the following reasons, and you need to pay for the repair and accessories:

- Artificial damage;
- Improper use;
- The grid voltage exceeds the specified range of the product;
- Irresistible natural disasters;
- The components or accessories not recognized by Shenzhen HugeMed Medical Technical Development Co., Ltd. are replaced or used. Repairs are conducted by personnel not authorized by Shenzhen HugeMed Medical Technical Development Co., Ltd.;
- Other faults not caused by the product itself.

After the warranty expires, Shenzhen HugeMed Medical Technical Development Co., Ltd. can continue to offer a fee-based repair service. If you do not pay for or delay the payment for the repair service, Shenzhen HugeMed Medical Technical Development Co., Ltd. will temporarily suspend the repair service until you make the payment.

After-Sales Service Provider

Customer Service Department of Shenzhen HugeMed Medical Technical Development Co., Ltd.
401, 501, Building 4, Haizhi Technology Park, Fortis, No. 17, Bulan Road, Xialilang Community, Nanwan Street, Longgang District, Shenzhen, Guangdong, 518112, China
Service hotline: +86-755-22275833
Sales hotline: +86-755-22275866
Fax: +86-755-22275833
Official website: www.hugemed.net

⚠Warnings

- **This product should be used by professional clinicians, medical electrical specialists or trained clinical medical personnel in specified situations. Personnel using this product should be adequately trained. No operation should be performed by unauthorized or untrained personnel.**
- **Stay meticulous and attentive while working to avoid accidents!**
- **Routine instrument cleaning and maintenance is a must.**
- **In case repairs are needed, it is advisable to use the original parts.**

INTRODUCTION

Instructions

This Instructions for Use (hereinafter referred to as "IFU") details the purpose, functions and operation of the product. Prior to use of this product, please read carefully and understand the IFU to ensure its correct use as well as the safety of the patients and operators.

The IFU describe this product in its most complete configuration, and some of them may not apply to the product you have purchased. If you have any questions, please feel free to contact this Company.

These operation instructions contain precautions on how to operate the laryngoscope blade safely, correctly, and effectively. They help reduce failures, maintenance costs and downtime, and improve the reliability and service life of the instrument. It can be used not only as an operating manual, but also as a reference manual. Therefore, this IFU must be kept next to the device and available at any time.

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

Applicable population

The IFU are intended for use only by specially trained clinical medical staff.

Illustrations

All illustrations provided in the IFU are for reference only. The settings or data in the illustrations may not be exactly the same as the actual display of the product.

Conventions

- ***Italics Bold italics*** are used in the IFU to represent the chapters quoted.
- Terms such as danger, warning, and caution are used in the IFU to prompt any dangerous information and its severity.

Contents

Chapter 1. SAFETY

1.1 Safety Information

This chapter lists the basic safety information that users must pay attention to and observe when using the laryngoscope blade. Other safety information that is identical, similar, or relevant to specific operations will appear in respective chapters.

⚠Danger

- **Indicates an urgent danger that, if not avoided, may result in death, serious physical injury or property damage.**

⚠Warnings

- **Indicates a potentially dangerous or unsafe operation that, if not avoided, may result in death, serious physical injury, or property damage.**

⚠Caution

- **Indicates a potentially dangerous or unsafe operation that, if not avoided, may result in minor physical injury, product failure, damage, or property damage.**

Notice

- **Stresses important precautions, provides instructions or explanations for better use of the product.**

1.1.1 Danger

There is no such safety risk.

1.1.2 Warnings

⚠Warnings

- **This laryngoscope blade is used in conjunction with the HM-01 image processor produced by our company. It is only allowed to be used by professional clinicians, medical electrical experts, or professionally trained clinical medical personnel on designated occasions.**
- **The responsible surgeon must be responsible for the operating procedures and technical application of the equipment! The trained surgeon (responsible surgeon) is entitled to decide how to make full use of the equipment in light of the actual application conditions.**
- **Please read the IFU of the laryngoscope blade carefully before using it for the first time.**
- **Before using the laryngoscope blade, the user must check the laryngoscope blade and its accessories to ensure that they work properly and safely.**
- **It cannot be used in an environment where flammable or explosive items are placed to prevent fire or explosion.**
- **The laryngoscope blade and its accessories shall be installed or handled properly to protect the laryngoscope blade from falling, collision, intensive oscillation, or damage due to other external mechanical forces.**
- **The electromagnetic field may affect the performance of the laryngoscope blade and its accessories, so the equipment used near the laryngoscope blade and its accessories must meet the EMC requirements; otherwise, the laryngoscope blade may fail or collapse due to electromagnetic interference. Mobile phones, X-ray or MRI equipment are all possible sources of interference, as they emit high-intensity electromagnetic radiation.**
- **All other equipment. For example, some similar digital interference devices, when connected to a laryngoscope blade, must meet relevant requirements in the standards (e.g. requirements in iIEC60950 for digital processing devices and requirements in IEC 60601 for electrical devices). In addition, when other equipment involving signal input or output of the equipment is connected, the structure of such other equipment must comply with the system structure as required by ISO 60601-1. The person responsible for connecting the equipment must ensure the operability of the system and be responsible for meeting the system requirements. If you have any other questions, please consult the local equipment supplier or the technical service center of HugeMed.**
- **Repairs or upgrades to the laryngoscope blade must be made by the repair personnel trained and authorized by the Company.**
- **Relevant local regulations or the hospital's regulations on waste disposal must be**

followed when handling the packaging materials.

- **HugeMed shall not be held accountable for any personal injury and property damage due to:**
- **Equipment parts are not original parts of Shenzhen HugeMed Medical Technical Development Co., Ltd.;**
- **The IFU are lost;**
- **Installation, commissioning, revision, upgrading, and repair are done by personnel not authorized by Shenzhen HugeMed Medical Technical Development Co., Ltd.**
- **Shenzhen HugeMed Medical Technical Development Co., Ltd. will not be held responsible for any damages or incidents caused by the use of consumables or accessories not provided by Shenzhen HugeMed Medical Technical Development Co., Ltd.**
- **If there any serious incidents occurred, contact with Hugemed, we will report to European Union as described in its own procedures which compliant with MDR. The hospital can report to the European Union followed its own procedures too.**

1.1.3 Caution

⚠Caution

- **The use environment and power supply for the laryngoscope blade must meet the requirements in A *Product Specification*.**

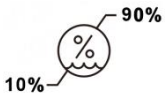
1.1.4 Notice

Notice

- **Please place the IFU near the laryngoscope blade so that it can be easily and promptly accessed when required.**
- **The IFU introduce this product in its most complete configuration and functions, and the laryngoscope blade you have purchased may not have certain configuration or functions.**

1.2 Labels and Identifications

1.2.1 Identifications and their meaning

	Notice/Caution/Warnings		Class II device
	Type BF Applied Part		Consulting the IFU
	AC Power		Service Life
	Batch No.		Serial Number
	Manufacturer		Manufacturing Date
	Disposed of in a pollution-free manner		Humidity limitation (10%–90%)
	Atmospheric pressure limitation (50 kPa–106 kPa)		Temperature limitation (-20ºC–60ºC)
	Fragile, handle with care		Keep dry
	Keep upright during shipping		Stacking limit by 5
	Information of European Authorized Representative (EAR)		CE Marking
	Medical Device		

Chapter 2. OVERVIEW

2.1 Product Description

2.1.1 Scope of application

Video Laryngoscope Blade used to provide access, illumination, and allow observation or manipulation of pharynx and larynx in examine and visualize a patient's upper airway and aid placement of a tracheal tube.

⚠Warnings

- **This product should be used by professional clinicians, medical electrical specialists or trained clinical medical personnel in specified situations. Personnel using this product should be adequately trained. No operation should be performed by unauthorized or untrained personnel.**
- **Before using the laryngoscope blade, the user must check its fittings and accessories to ensure that they work properly and safely.**

⚠Caution

- **The use environment and for the laryngoscope blade must meet the requirements in A.3 *Environment Specification*.**

2.1.2 Structural composition

This product is mainly composed of the camera module, titanium alloy handle, spatula, and silicone buttons.

2.1.3 Contraindications

Patients with acute inflammation of the upper respiratory tract with dyspnea, severe heart and lung disease, allergic to decaine, and unexplained severe laryngeal obstruction can be regarded as contraindications.

2.1.4 Product structural diagram

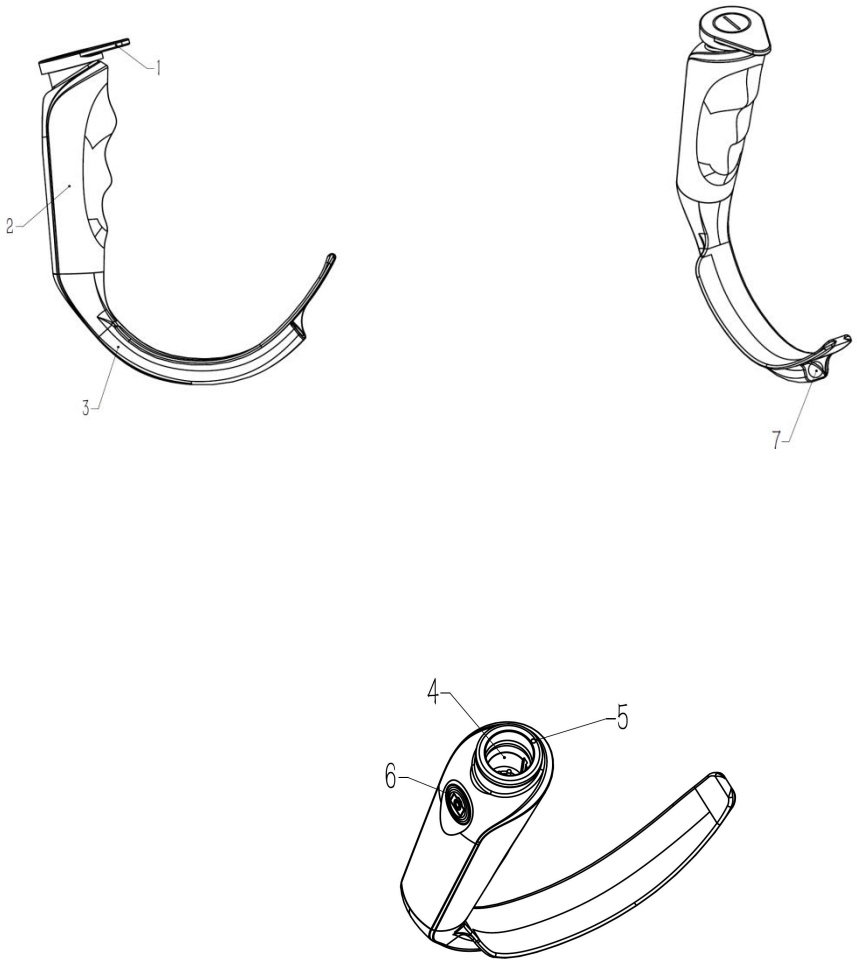


Figure 2-2. Diagram of the laryngoscope blade

1. Waterproof plug	2. Handle
3. Blade	4. Signal transmission socket
5. Alignment identification	6. Photographing/Videoing button
7. Camera assembly	

2.1.5 Detailed introduction of each component of the product

2.1.5.1. Waterproof plug

The waterproof plug is made of silicone, which is used as a seal during the cleaning and disinfection of laryngoscope blades to prevent any liquid from entering the internal part of the blades.

2.1.5.2. Handle

The handle is designed based on ergonomics, providing a comfortable grip and high strength. It provides force support during the surgical process.

2.1.5.3. Blade

The blade is the main part that enters the oral cavity. It is designed based on the curvature of the

human oral cavity, which can minimize the pressure on the patient's oral tissues and ensure the smooth progress of intubation surgery.

2.1.5.4. Signal transmission socket

The structural component is equipped with a 10-pin aviation chip. The function of each pin is defined, through which the communication between the laryngoscope blade and the host is realized. The structural component also has functions such as foolproofing, waterproofing, and stable connection, and possesses a certain degree of universality.

2.1.5.5. Alignment identification

It is mainly used as an identifier to prevent users from inserting the part without aligning the direction properly, thus avoiding damage to the device.

2.1.5.6. Photographing/videoing button

After the device is turned on, the user can activate the function of photographing by short pressing the button, and activate the function of videoing by long pressing the button.

2.1.5.7. Camera assembly

The optical image generated by the lens is projected onto the surface of the image sensor, which is then converted to an electrical signal. After being converted through A/D (analog-to-digital) conversion, it becomes a digital image signal and is sent to the digital signal processing (DSP) chip for processing. It is then transferred to the computer for processing through the USB port and can be viewed on the display.

Chapter 3. USE AND MAINTENANCE

3.1 Installation and use

⚠Warnings

- **The laryngoscope blade must be connected to the HM-01 image processor produced by HugeMed. HugeMed assumes no responsibility for any damage or incident caused by connecting to displays not manufactured by HugeMed.**
- **When the laryngoscope blade is connected to energized displays or accessories not manufactured by HugeMed, patient leakage current may increase.**
- **Do not use this product in the presence of high-frequency electrosurgical equipment, as it may cause patient injuries or equipment damage.**

3.1.1 Open package inspection

Before unpacking, please carefully check the packing box to determine whether the product is damaged during transportation. Notify the carrier or this Company immediately if any damage is noted.

If the package is intact, please unpack the package using the correct method, carefully take out the laryngoscope blade and other components from the packing box, and count them one by one according to the packing list. Check whether the product has suffered from any mechanical damage and whether the items are complete. If you have any questions, please feel free to contact the After-Sales Service Department of this Company.

⚠Warnings

- **The user shall place the packaging materials out of the reach of children. Relevant local regulations or the hospital's regulations on waste disposal must be followed when handling the packaging materials.**

Notice

- **Please keep the packaging box and packaging materials for later transportation or storage.**
- **If you open the package and find that some fittings are missing, please contact the distributor or manufacturer whom you purchased this product as soon as possible.**

3.1.2 Environmental requirements

The use environment for the laryngoscope blade shall meet the requirements in ***A.3*** *Environment Specification*.

The use environment for the laryngoscope blade shall be free from noise, vibration, dust, corrosive or flammable and explosive substances.

When the laryngoscope blade is transferred from one environment to another, differences in temperature or humidity may cause condensation on the laryngoscope. In this case, it is necessary to wait for the condensation to disappear before starting the laryngoscope.

3.1.3 Power requirements

The laryngoscope blade can only be used with the Company's HM-01 Image Processor.

⚠Warnings

- **Please ensure that the laryngoscope blade works under the specified environmental and power conditions; otherwise, it will not meet the technical specifications stated in A *Product Specification* and may lead to unexpected consequences such as laryngoscope blade failure.**
- **The appropriate power supply source must be chosen according to the setting of the supply voltage of the laryngoscope blade. Otherwise, it may cause serious damage to the laryngoscope blade.**

3.1.4 Connection and use

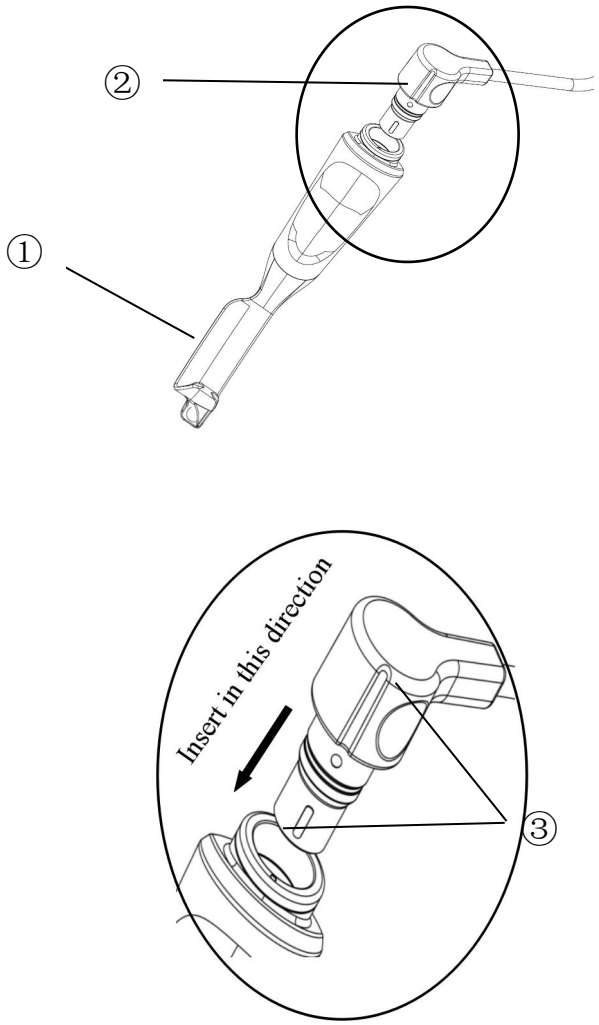
3.1.4.1 Connection of the laryngoscope blade and the signal connecting line

1. Choose the appropriate size of the laryngoscope blade based on the patient's mouth size, and remove the waterproof plug;

2. Please first identify the alignment identification point for the handle connection socket of the signal connecting line and the alignment identification point for the connection socket of the laryngoscope blade, as shown by ③ in Figure 3-1;

3. Align the two alignment identification points and slowly insert the handle connection socket of the signal connecting line into the connection socket of the laryngoscope blade;

4. Make sure the connection socket of the signal connecting line is fully inserted into the connection socket of the laryngoscope blade.



① Laryngoscope blade ② Signal connecting line ③ Alignment identification

Figure 3-1. Connection of the laryngoscope blade and the signal connecting line

3.1.4.2 Disassembly of the laryngoscope blade from the signal connecting line

1. Hold the laryngoscope blade with one hand, and use the fingers of the other hand to grip the holding area of the connection socket of the signal connecting line. Gently lift it up to disassemble it, as shown in Figure 3-2 below.

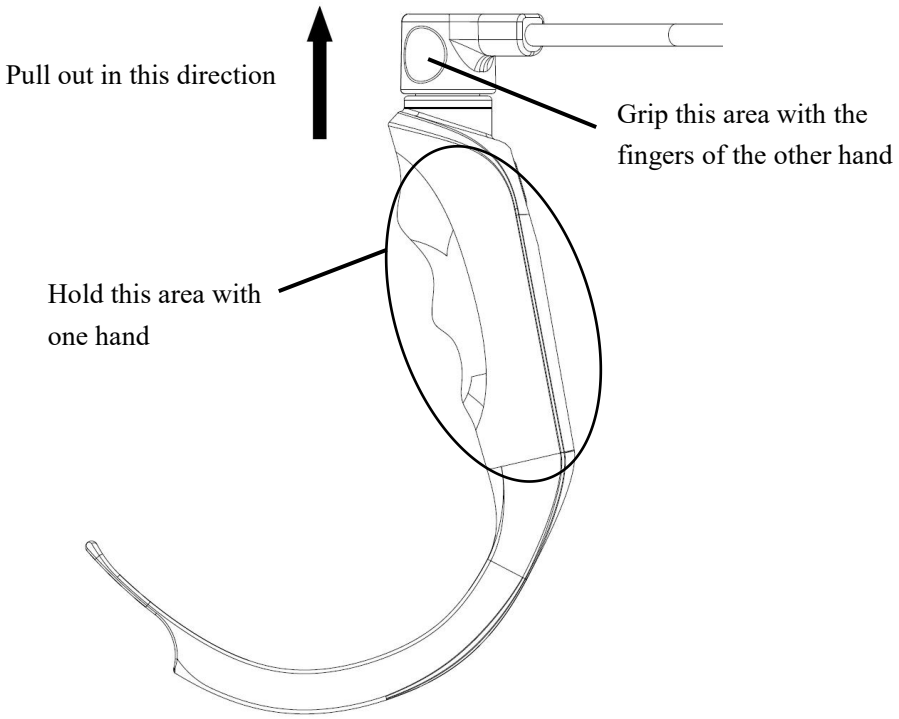


Figure 3-2. Disassembly of the laryngoscope blade from the signal connecting line

Notice

- **The laryngoscope blade and its accessories shall be installed or handled properly to protect the laryngoscope blade from falling, collision, intensive oscillation, or damage due to other external mechanical forces.**
- **Beware of pinching hands when inserting and disassembling the laryngoscope blade.**

3.1.4.3 Connection of the display host and the signal connecting line

1. First identify the signal connection port of the display and the connection socket of the display host;
2. Find the alignment identification points of the signal connection port of the display and the connection socket of the display host identified in the previous step, as shown by ① and ② in Figure 3-3 below;
3. Align the two alignment identification points, and insert the connection socket of the display host of the signal connecting line (laryngoscope) into the signal connection interface of the display. Make sure the connection socket is fully inserted, as shown in Figure 3-3;
4. Reverse the operation of step 3, and gently lift it up to disassemble it.

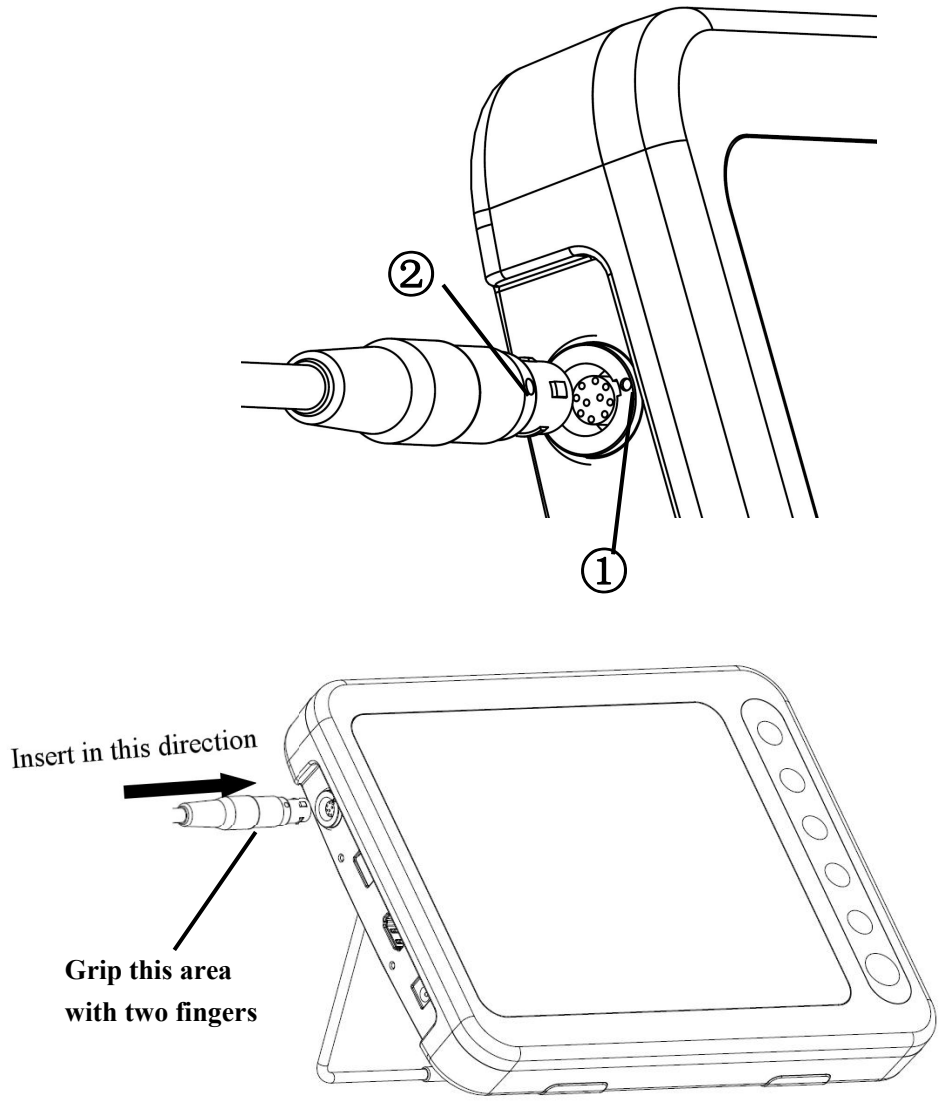


Figure 3-3. Connection of the signal connecting line and the display host

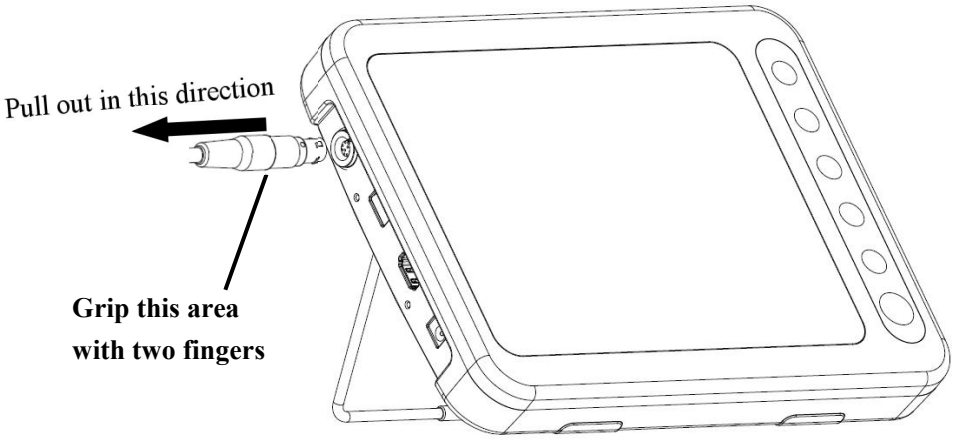


Figure 3-4. Disassembly of the signal connecting line from the display host

3.2 Maintenance

⚠Warnings

- **Hospitals or medical institutions using the laryngoscope blade shall establish a sound maintenance plan to prevent unforeseen consequences, such as the failure of the laryngoscope lens, which may pose a risk to personal safety.**
- **All safety inspections or repairs requiring the disassembly of the laryngoscope blade shall be conducted by professional repair personnel designated by the Company. Operation by non-professionals may cause failure of the laryngoscope blade and may pose a risk to personal safety.**
- **If you find any abnormality in the laryngoscope blade, please contact the distributor or manufacturer whom you purchased this product.**
- **Before the laryngoscope blade is returned for repair, it must be disinfected and cleaned.**

3.2.1 Inspection

Before each use, the laryngoscope blade shall be thoroughly inspected by the user to ensure its proper functioning and operation. Inspection items include:

- The environment meet the requirements;
- The laryngoscope blade and its accessories are free from mechanical damage;
- The specified accessories are used;
- The laryngoscope blade functions normally.

If any damage or abnormality is found, please temporarily stop using the video laryngoscope blade, and contact the distributor or manufacturer from whom you purchased this product.

3.2.2 Cleaning and disinfection

Only the materials and methods listed in this chapter shall be used for cleaning or disinfecting the laryngoscope blade. The Company does not provide any guarantee for any damage or accidents caused by the use of other materials or methods.

The chemicals or methods listed by the Company are only intended as means to control infection, and the Company does not assume any responsibility for their effectiveness. For methods of infection control, please consult the infection prevention department of the hospital or the epidemiology experts.

Please ensure that the laryngoscope blade is in a dust-free environment. To prevent damage to the laryngoscope, the following regulations must be followed:

- Dilute detergents and disinfectants according to the manufacturer's instructions or use them at the lowest possible concentration;
- Do not immerse the display host and the signal connecting line of the laryngoscope blade in liquid;
- Do not pour liquid on the display host and the signal connecting line of the laryngoscope blade;
- Do not allow liquid to enter the display host and the signal connecting line of the laryngoscope blade;
- Do not clean the laryngoscope blade with abrasive materials (steel wool, silver polish, etc.) or solvents such as xylene and acetone, as they may cause damage to the shell.

⚠Warnings

- **Before cleaning the video laryngoscope blade, it is necessary to turn off the power and disconnect the charging cable from the power adapter.**
- **The waterproof plug must be installed before immersing the laryngoscope blade in disinfectant.**
- **The cleaning and disinfection measures described in the IFU cannot replace the regulations established for the daily use of the laryngoscope blade in any situation.**

⚠Caution

- **If the liquid is accidentally poured on the laryngoscope blade, causing it to malfunction, please temporarily stop using it and immediately contact the distributor or manufacturer from whom you purchased this product.**

Recommended surface disinfection methods:

This product is expected to come into contact with the patient's oral mucosa and shall be disinfected by the end user before use; otherwise, it prohibited to be used. The cleaning and disinfection methods of this product are as follows:

1. Cleaning and disinfection of the laryngoscope blade:

After using the laryngoscope blade, wipe off the external dirt with a moist gauze/alcohol gauze, then assemble the waterproof plug, and immerse the cleaned laryngoscope blade in the disinfectant for sterilization. The recommended disinfectant is a 1.0 % glutaraldehyde solution, with a minimum immersion disinfection time of 45 min.

2. Cleaning and disinfection of the display host and the signal connecting line:

After using the laryngoscope blade, wipe off the external dirt with a moist gauze/alcohol gauze, then assemble the waterproof plug, and then clean the display and handle with 75% ethanol for

disinfection.

⚠Caution

- **Do not use high-temperature or high-pressure sterilization.**
- **Do not use high concentrations of organic acids or inorganic acids for disinfection as it may corrode the laryngoscope blade.**
- **Do not use chemical substances containing chloralformamide, phenol derivatives, or anionic surfactants for disinfection, as the external plastic material of the laryngoscope blade is prone to aging and cracking.**
- **Do not use disinfectants containing formaldehyde and amine on the same surface, as it may cause fading of the surface of the laryngoscope blade.**
- **Please assemble the waterproof plug before cleaning and disinfecting the laryngoscope blade; otherwise, it may cause irreversible damage to the laryngoscope blade.**

3.2.3 Periodic maintenance

Time interval	Procedures for Routine Maintenance
As per hospital policies	The surface of the laryngoscope blade shall be thoroughly cleaned before or after prolonged storage.

3.2.4 Pollution-free disposal and recycling

The service life of this product is about 5 years. Laryngoscope blades that have exceeded their service life shall be scrapped. Please contact the distributor or manufacturer from whom you purchased this product for more information.

You can do the following:

1. Send the scrapped laryngoscope blades back to the distributor or manufacturer from whom you purchased this product for appropriate recycling.
2. Send the used batteries back to the distributor or manufacturer from whom you purchased this product for disposal, or dispose of them in accordance with applicable regulations.

3.2.5 Laryngoscope blade

■ Cleaning: Properly clean and disinfect the handles and blades before use (see ***3.2.2*** and ***4.3***).

- Anti-fog: The video lens of the laryngoscope blade uses an electrically heated material to remove fog generated inside the trachea due to warm and humid environments. Energized by the batteries inside the handle, the LED lamp on the blades start to illuminate, and the heating element also begins to operate. Under the effect of the blade's temperature, the fog on the lens can be cleared within 30 s after it is connected to the handle.
- The cleaning and disinfection of laryngoscopes and other devices shall follow the washing procedure of the laryngoscope.
- How to use the lubricant

1. Apply the water-soluble medical-grade lubricant to the laryngoscope blade, taking care not to apply it to the distal end lens.

2. Do not use olive oil, lidocaine ointment, or any other petroleum-based or petroleum jelly-containing lubricants. These substances will cause damage to some materials of the video laryngoscope.

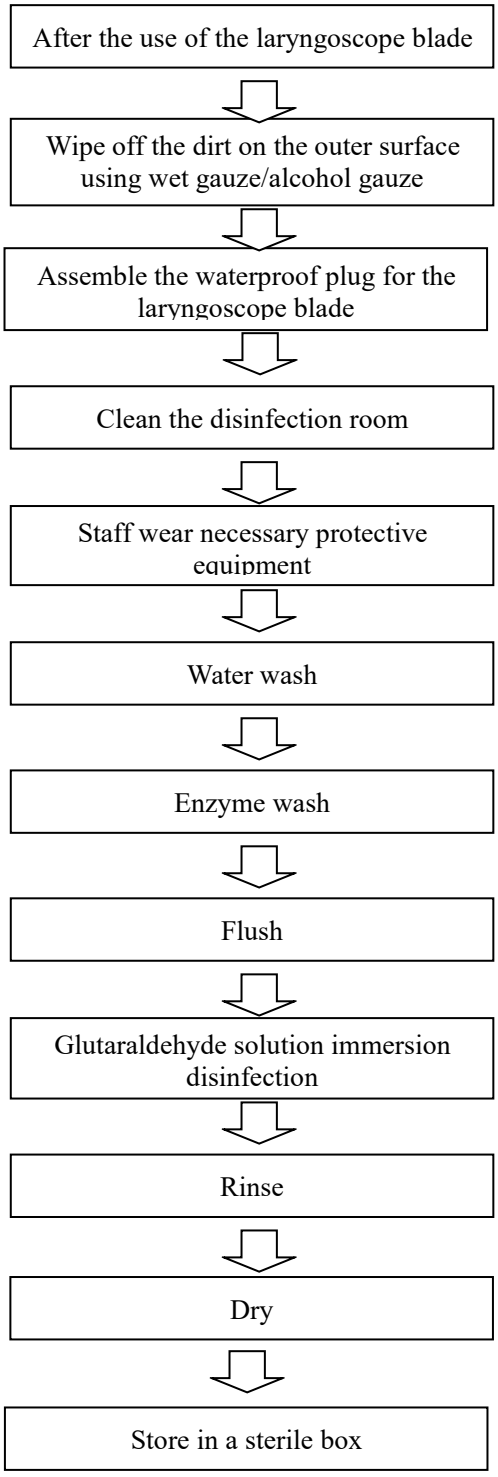
⚠Warnings

- **Before using the laryngoscope blade, the user must check its fittings and accessories to ensure that they work properly and safely.**

3.3 Instructions for Cleaning

After using the video laryngoscope for diagnosis and treatment, medical staff shall immediately use 75% alcohol-moistened gauze to clean the surface of the host and the laryngoscope blade. The gauze shall be put into a yellow medical waste bag. Immediately, the non-operating hand-held blade shall be sent to the cleaning and disinfection room.

The standard cleaning and disinfection procedure for the laryngoscope blade is as follows:



⚠Warnings

- **Laryngoscope blades shall be disinfected after each use. Before cleaning, please consult or familiarize yourself with the regulations regarding medical device cleaning.**
- **Before cleaning the laryngoscope, you must turn off the power and disconnect the charging cable from the power adapter.**
- **The display is not waterproof, so it is recommended to avoid submerging it or placing it in excessive liquid. It is suggested to use disinfecting wipes for cleaning.**
- **Before cleaning and disinfecting the laryngoscope blade, make sure the signal connection socket of the laryngoscope blade is securely sealed with a waterproof plug. Otherwise, no cleaning or disinfection shall be performed.**

3.3.1 Water wash

1. Rinse the blade thoroughly with running water for 2 min, then wipe it clean with the moistened gauze until no stains are visible to the naked eye.
2. Clean the uneven parts of the laryngoscope blade using a small brush, especially the small gaps around the camera and the upper port. Then thoroughly clean the surface of the blade using a cleaning brush. Repeat the above brushing 5 times.
3. The part of the signal connecting line and the surface of the display host that are sealed can be wiped with a damp cloth. Other parts shall be handled with care during cleaning to prevent liquid from entering into the interior.
4. The gauze shall be used in a disposable manner, and cleaning brushes shall be disinfected after each use.
5. After cleaning, wipe dry with gauze.

3.3.2 Enzyme wash

Clear body fluids, secretions, and other organic matters to prevent them from affecting the effectiveness of disinfectants. Enzyme wash shall be performed promptly to prevent protein drying and make it difficult to remove.

1. The preparation of the multi-enzyme detergent and the immersion time shall follow the IFU.

   The verified cleaning conditions recommended by Shenzhen HugeMed Medical Technical Development Co., Ltd. are as follows: Metrex EmPower detergent with a dilution ratio of 1:128; recommended temperature: 20ºC–40ºC; minimum immersion time: NLT 1 min.
2. Place the dried laryngoscope blade into the enzyme wash sink and wipe the portion that enters the body with the multi-enzyme detergent 5 times.

3. After drying, the laryngoscope blade shall be immersed in the multi-enzyme detergent, and the blade shall be cleaned in an ultrasonic cleaner for 5–10 min.
4. The multi-enzyme detergent shall be replaced after each cleaning of the laryngoscope blade.

3.3.3 Flush

Rinse the laryngoscope blade immersed in the multi-enzyme detergent (immersion time: as per the IFU) with a high-pressure water gun for 10 s, and dry the outer surface of the laryngoscope blade with sterile gauze.

3.3.4 Disinfection

3.3.4.1 Immersion in antibacterial solution

1. Place the cleaned and dried laryngoscope blade in the disinfection tank or disinfection bucket and immerse it in the disinfectant.

The verified immersion conditions recommended by Shenzhen HugeMed Medical Technical Development Co., Ltd. are as follows:

Disinfectant: Belimed Protect

Concentration: 1.0 %

Temperature: 25°C

Immersion time: 45 min

2. Wipe the display host and the handle with clean water, then wipe with 75% ethanol for disinfection.
3. After the daily diagnosis and treatment, when the laryngoscope blade is disinfected with disinfectants for the last time, the disinfection time shall be extended to 30 min.
4. Before starting daily diagnosis and treatment, the laryngoscope blade intended for use on that day must be disinfected again. When using the recommended disinfectant to immerse the laryngoscope blade, the disinfection time shall not be less than 20 min. Then it should be washed and dried before used for patient diagnosis.

⚠Warnings

- **Do not disinfect the laryngoscope blade using any strong alkaline/acidic disinfectant.**
- **Do not immerse the laryngoscope blade in medical alcohol or iodine**
- **Do not place the laryngoscope blade in areas with organic solvents such as acetone or butanone.**
- **Do not disinfect the laryngoscope blade with high temperature or high pressure.**
- **During the disinfection process, the observation glass window shall be cleaned to ensure optimal observation results.**

3.3.5 Rinse

Before removing the laryngoscope blade from the disinfection tank, the disinfection personnel shall change gloves and place the blade in 5 L of sterile water. The laryngoscope blade shall be thoroughly wiped using sterile gauze and rinsed 3 times.

⚠Warnings

- **The laryngoscope blade immersed in chemical disinfectant for disinfection must be thoroughly rinsed with sterile water before use to remove any residual disinfectant.**

3.3.6 Dry

Dry the laryngoscope blade with sterile gauze or clean compressed air.

3.3.7 Storage

The sterilized or disinfected laryngoscope blade shall be stored in a sealed device box.

Notice

- **The SOP for cleaning shall be prepared in accordance with the *Regulation for Cleaning and Disinfection Technique of Flexible Endoscope*.**
- **The above operation is for reference only, and the disinfection effect shall be verified using appropriate methods.**

A.1 Shape Parameters

Table 1. Models of laryngoscope blades

Models of Laryngoscope Blades	Length L (mm)	Width W (mm)	Height H (mm)
HT2	127±5.0	33±5.0	146.5±5.0
HT3	139±5.0	33±5.0	150.5±5.0
HT4	150±5.0	33±5.0	154.5±5.0

A.2 Performance Parameters

Parameter	**Specification**
Surface roughness	≤1.6μm
Operating distance	30～90mm
Spatial resolution	≥8.0lp/mm
View	66°±15%
Lighting range	≥Φ30mm，h=30mm
Illuminance	≥500lx，h=30mm
Color temperature of the light source	≥5500K
Special functions	Photographing, video recording

A.3 Environment Specification

Parameter	Specification
Operating temperature	5 – 40ºC
Operating humidity	20%–80%, non-condensing
Operating atmospheric pressure	86 – 106kPa
Storage and transport temperature	-20 – 60ºC
Storage and transport humidity	10%–90%, non-condensing
Storage and transport atmospheric pressure	50 – 106kPa
Description of storage conditions	Well-ventilated room without corrosive gases

A.4 List of Accessories

If you find that the following items are inconsistent with this information, please contact the manufacturer.

No.	Name of component	Quantity	Note
1	Waterproof plug	3	