

**Video Laryngoscope**

**Operator's Manual**

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# Instruction

Thank you for your purchasing the CLEARVUE DISPOSABLE video laryngoscope.

Please carefully read this operating manual in advance for correctly using this product.

Please appropriately keep this operating manual for reference.

|                                         |                                                                                                                                                                                                                                                 |
|-----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product name:                           | Video Laryngoscope                                                                                                                                                                                                                              |
| Specifications and models:              | CLEARVUE<br>DISPOSABLE                                                                                                                                                                                                                          |
| Manufacturing date:                     | See the product label                                                                                                                                                                                                                           |
| Service life:                           | 3 Year                                                                                                                                                                                                                                          |
| Amendment/revision date:                | 15th September,2022                                                                                                                                                                                                                             |
| Version of package insert:              | 1.0                                                                                                                                                                                                                                             |
| Issuing version of software:            | V1                                                                                                                                                                                                                                              |
| Performance, structure and composition: | Composed of two parts: display host and HC series handle.                                                                                                                                                                                       |
| Scope of application:                   | It is applicable in the clinical practice for picking up the epiglottis of the patient to expose the glottis, for guiding medical staffs on accurate airway intubation for anesthesia or first-aid, or for intraoral examination and treatment. |
| Manufacturer:                           | Infinium Medical                                                                                                                                                                                                                                |
| Company website:                        | <a href="http://www.infiniummedcial.com">http://www.infiniummedcial.com</a>                                                                                                                                                                     |

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## Statement

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Infinium Medical has the right to modify the content of this operating manual without prior notice. The modification of content of this operating manual will be reflected in the new published version.

Infinium Medical assumes no responsibility for software and equipment not provided by Infinium Medical and provided by its distributors.

Infinium Medical is responsible for the safety, reliability and performance of the product only in conditions of meeting all following requirements, i.e.,:

- The assembling, extension, readjustment, improvement and maintenance must be conducted by professionals accepted by Infinium Medical;
- All parts for replacement as well as matched accessories and consumables involved in maintenance are original from Infinium Medical or accepted by Infinium Medical;
- The related electric equipment comply with national standards and requirements in this operating manual;
- The product is operated as per this operating manual.

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# Warranty and repair services

For this product, the standard warranty period lasts for 1 year, and the warranty period for any main accessory including power adapter, connecting cable and battery lasts for half a year. Consumables: it refers to a disposable and consumable material without a warranty period which needs to be replaced after each use.

If the warranty period provision in the sales agreement between the distributor and you is inconsistent with above-mentioned standard warranty period or there is any other provision, please contact toll-free hotline of Infinium Medical at +1 (866) 918-8434 for consulting and confirming, and please confirm the warranty period with the distributor in time if it is not confirmed by Infinium Medical.

The warranty period begins from the "installation date" entered in a random *Product Warranty Card* which is the unique evidence for calculating warranty period. For protecting your rights and interests, please supervise and urge the personnel for installation to return the second sheet of *Product Warranty Card* to Infinium Medical within 30 days from the installation date; if the *Product Warranty Card* corresponding to your purchased product cannot be return to Infinium Medical on time, the warranty period will begin from the "outbound delivery date" labeled on the product package+45 days.

All products within the warranty period can enjoy post-sales service for free; but please note that Infinium Medical will charge for the maintenance service for products in the warranty period for the following reasons, and you need to pay for costs of maintenance and accessories:

- Man-made damage;
- Inappropriate use;
- Network voltage exceeding the range specified for the product;
- Irresistible and natural disaster;
- Change to or use of parts or accessories not accepted by Infinium Medical or maintenance by personnel not authorized by Infinium Medical;
- Other malfunctions not caused by the product itself.

After the warranty period expires, Infinium Medical can continue provide paid service for maintenance. If you refuse or delay the payment for maintenance service, Infinium Medical will temporarily suspend maintenance service until you make the payment.

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# After-sales service unit

Customer Service Department of Infinium Medical

12151 62<sup>nd</sup> ST N #5 Largo, FL 33773 USA

Official [website: www.InfiniumMedical.com](http://www.InfiniumMedical.com)

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## **Warning**

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- **This product will be used by professional clinicians, specialists of medical electronics or medical staffs following professional training under specified occasions. The personnel who uses this product shall receive sufficient training. Any personnel who is not authorized or trained is not allowed to make any operation.**
  - **Elaborate and careful work can avoid occurrence of possible accidents!**
  - **Routine cleaning and maintenance of instruments must be conducted.**
  - **In case of repair, it shall stick to use original accessories.**
-

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# Foreword

## Instruction

This operating manual (hereafter to be referred as "manual") has introduced the use, function and operation of products in details. Before use, please carefully read and understand this manual so as to ensure correctly using this product and guarantee safeties of patients and operators.

This manual introduces this product by its most complete configuration, and part of introduction may not be suitable for your purchased product. If there is any question, please contact our company.

These operating instructions contain precautions on how to operate the laryngoscope in a safe, correct and effective manner. They are helpful in reducing malfunction and maintenance cost, shortening down time and boosting reliability and service life of instruments. It cannot only be used as an operating manual, but also can be referred as a reference manual. Thus this operating guidance must be placed beside the equipment to be available at any time.

Please carefully read Chapter 1 "Safety" before first use.

## Suitable users

This manual is only suitable for medical staffs who have received professional trainings.

## Illustration

All illustrations provided in this manual is only for reference, and the settings or data in illustrations may be not complete in accordance with the real exhibition of product.

## Convention

- **Italics** This manual utilizes bold italics to show quoted chapters.
- This manual utilizes terms such as hazard, warning and careful to hint dangerous information and its degree of severity.

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# Chapter 1 Safety

## 1.1 Safety information

This chapter lists the basic safety information that users must pay attention to and abide by when using the video Laryngoscope (hereafter to be referred as laryngoscope). Same or similar safety information or other safety information related to detailed operations will be reflected in individual chapters.

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### Hazard

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- Hinting urgent hazard which may result in death, serious personal injury or property loss if not avoided.
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### Warning

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- Hinting potential hazard or unsafe operation which may result in death, serious personal injury or property loss if not avoided.
- 

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### Careful

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- Hinting potential hazard or unsafe operation which may result in mild personal injury, product failure, damage or property loss if not avoided.
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### Note

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- Emphasizing important precautions and providing description or explanation can better elucidate this product.
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### **1.1.1 Hazard**

There is no such safety risk.

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## 1.1.2 Warning

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- This laryngoscope is applicable in the clinical practice for picking up the epiglottis of the patient to expose the glottis, for guiding medical staffs on accurate airway intubation for anesthesia or first-aid, or for intraoral examination and treatment, and will only be used by professional clinicians, specialists of medical electronics or medical staffs following professional training under specified occasions.
  - The physician in charge must be responsible for operation process and technique application of the equipment! As per the actual application conditions, the physician trained (in charge) has the right to decide how to sufficiently use equipment.
  - Before first use, please carefully read the operating manual for laryngoscope.
  - The user must check the laryngoscope and its accessories before using them to ensure that they can normally and safely work.
  - Laryngoscopes should be disinfected as soon as they are used. Before cleaning, please consult or understand the regulations regarding the cleaning of medical equipment .
  - The laryngoscope is not allowed to be used in an environment where inflammables or explosives are placed to avoid fire hazard or exploding.
  - Please properly install or take this laryngoscope and its matched equipment to avoid damage by falling, crashing, strong oscillation or subject to other external force.
  - The electromagnetic field will impact performances of laryngoscope and its matched equipment, thus the equipment used near laryngoscope and matched products must comply with corresponding requirements of EMC, otherwise malfunction or breakdown of laryngoscope may be caused due to electromagnetic interference. Mobile phone, X-ray or MRI equipment are all potential interference sources which may emit high levels of electromagnetic radiation.
  - All other equipment. For example, some similar digital interference equipment, power adapters, when connected to the laryngoscope, must comply with the relevant requirements in the standard details (for example, GB 4943 requirements for digital processing equipment, GB9706 requirements for power adapters, electrical equipment). In addition, when other devices are connected over, involving the signal input or output of the device, the structure of the other device, as required by GB 9706.1, must conform to the system structure. The person responsible for connecting the equipment must ensure the operability of the system and must be responsible for meeting the system requirements. If there are any other questions, please consult your local equipment supplier or Infinium Medical service department.
  - The maintenance or update of laryngoscope must be conducted by the maintenance personnel trained and authorized by the company.
- 
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- 
- **The handling of packaging materials must comply with related local regulations or the waste management system in the hospital. The packaging material must be placed on which the child cannot access.**
  - **Infinium Medical is not responsible for personal injury and property loss caused by the following reasons:**
    - Accessories are not original from Infinium Medical;
    - Loss of operating manual;
    - The installation, commissioning, modification, update and maintenance are completed by personnel who are not employed by Infinium Medical.
  - **Infinium Medical is not responsible for damage or event caused by using consumables or accessories not supplied by Infinium Medical.**
  - **Please assemble the sealing plug before cleaning and disinfecting the HC series blade, otherwise it will cause irreversible damage to the product.**
- 
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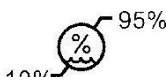
### 1.1.3 Note

#### Note

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- Please place the manual near the laryngoscope so as to consult in time as needed.
  - This manual introduces this product by its most complete configuration and function, and part of configuration and function may not be suitable for your purchased laryngoscope.
- 

### 1.2 Identification and its implication

|                                                                                     |                                                                                   |                                                                                     |                                                                       |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------|
|    | Precaution/careful/warning                                                        |    | Class II equipment                                                    |
|   | Applied part of BF model                                                          |   | Details of other content refer to the manual                          |
|  | Power adapter (AC)                                                                |  | Service life                                                          |
|  | Batch number                                                                      |  | Serial number                                                         |
|  | Manufacturer                                                                      |  | Manufacturing date                                                    |
|  | It is handled with a pollution-free method                                        |  | The humidity of transport package is limited in the range of 10%~95%  |
|  | The ambient pressure of transport package is limited in the range of 50kPa~106kPa |  | The temperature of transport package is limited in the range of 0~60℃ |
|  | The transport package contains fragile things, please handle with care            |  | The transport package is afraid of rain                               |
|  | It shall be straight up when transporting                                         |  | Same packages can be stacked for 5 layers at maximum                  |

# Chapter 2 Overview

## 2.1 Brief introduction

### 2.1.1 Scope of application

It is applicable in the clinical practice for picking up the epiglottis of the patient to expose the glottis, for guiding medical staffs on accurate airway intubation for anesthesia or first-aid, or for intraoral examination and treatment.

---

#### Warning

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- **This product will be used by professional clinicians, specialists of medical electronics or medical staffs following professional training under specified occasions. The personnel who uses this product shall receive sufficient training. Any personnel who is not authorized or trained is not allowed to make any operation.**
  - **The user must check the accessories before using them to ensure that they can normally and safely work.**
- 

---

#### Careful

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- **The operating environment and power supply of this laryngoscope must comply with requirements specified in *Product A*.**
- 

### 2.1.2 Contraindications

None

### 2.1.3 Product components and performances

CLEARVUE DISPOSABLE anesthesia video laryngoscope mainly consists of two parts: display host and handle.

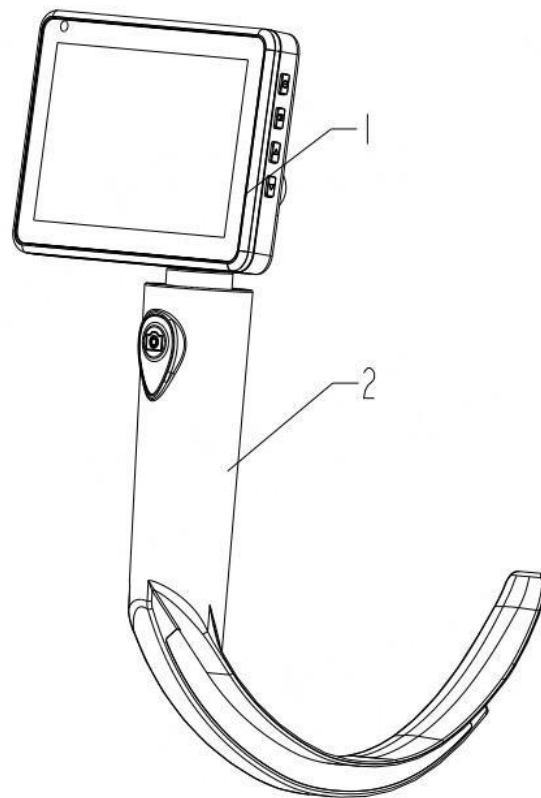
The CLEARVUE DISPOSABLE anesthesia video laryngoscope has the following functions and features:

- Compact, rotatable and integrated color display screen;
- The physiological structures of epiglottis and glottis are visualized via a camera of high resolution at video components before the lens, which is transferred to the liquid crystal display via the video transmission line to make the doctor clearly observe the whole process of tracheal intubation;

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## 2.2Product appearance

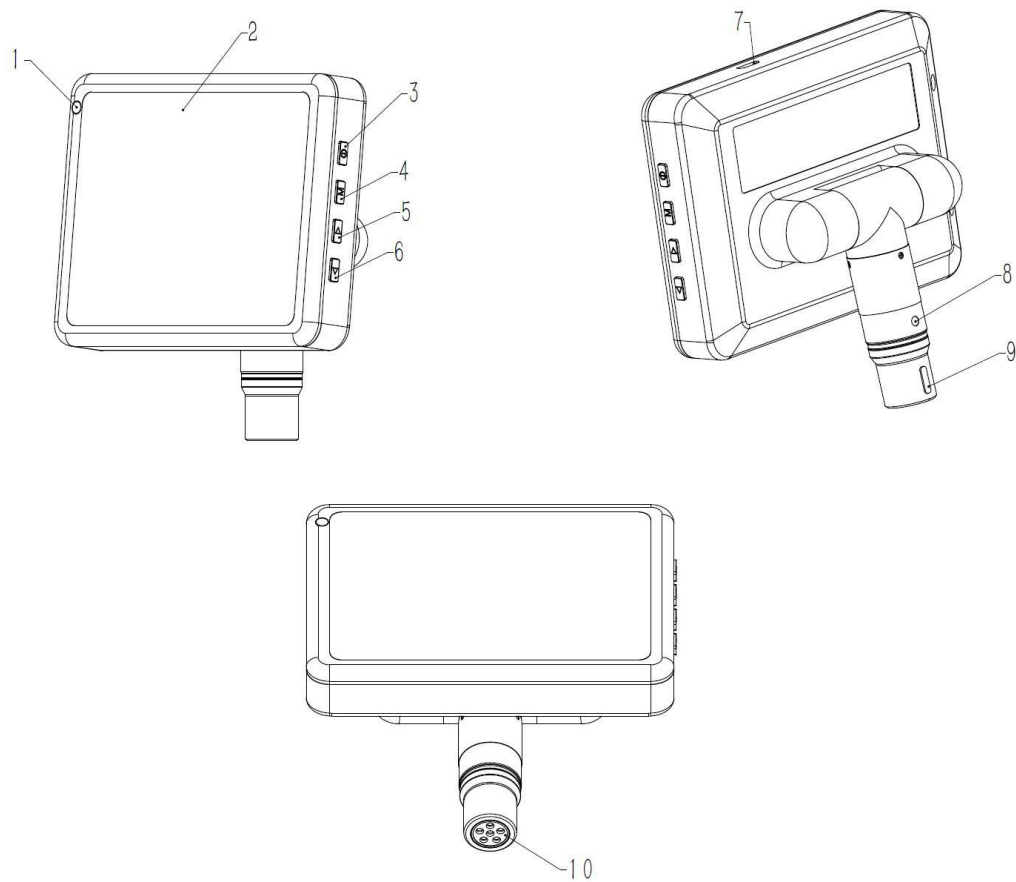
### 2.2.1 Product overview



|                |                    |
|----------------|--------------------|
| 1 Display host | 2 HC series handle |
|----------------|--------------------|

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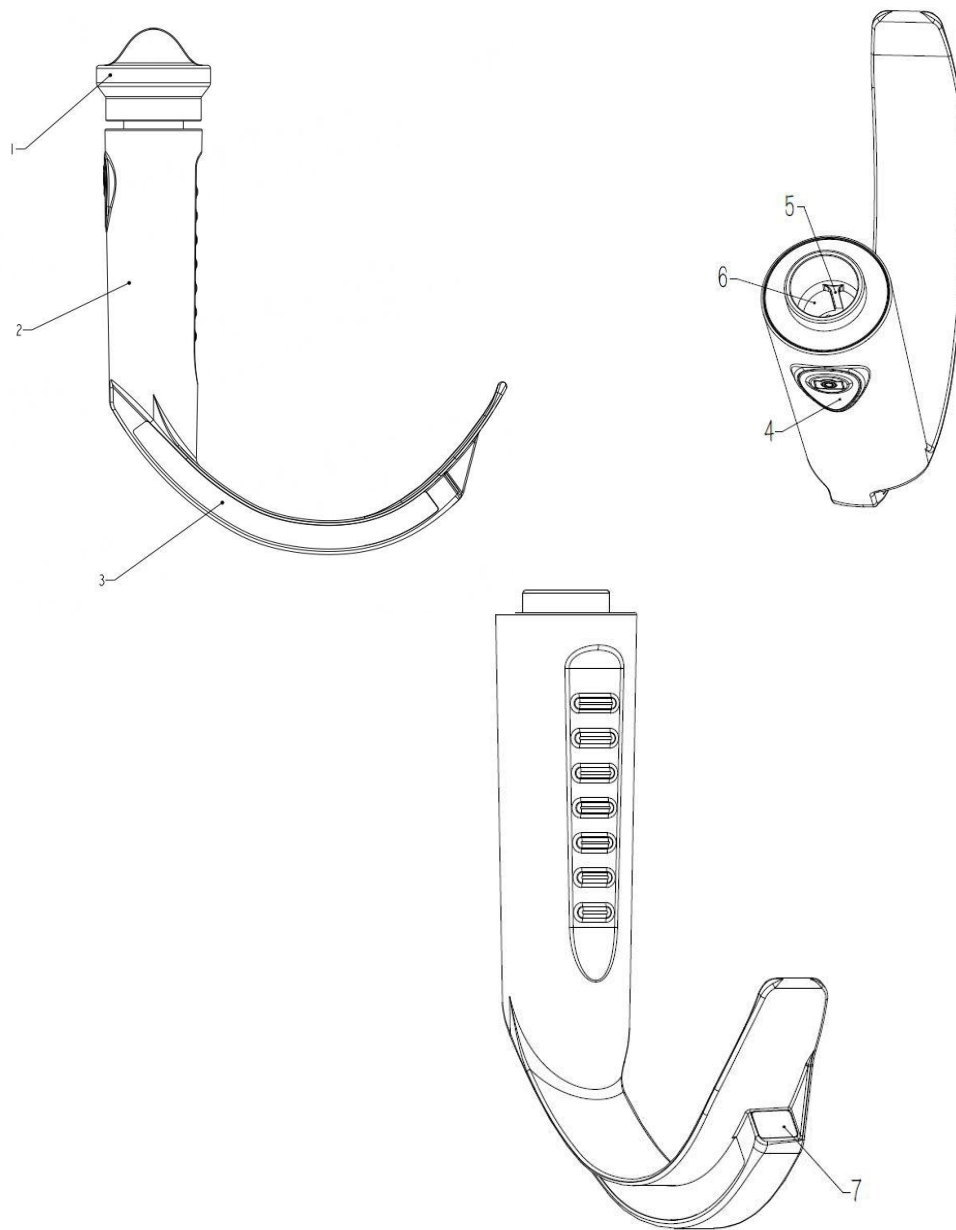
### 2.2.2 Display host overview



|                  |                           |
|------------------|---------------------------|
| 1 Light guide    | 2 Display area            |
| 3 Power button   | 4 Menu button             |
| 5 Up button      | 6 Down button             |
| 7 Charging port  | 8 Positioning mark        |
| 9 Limit flat key | 10 Signal connection port |

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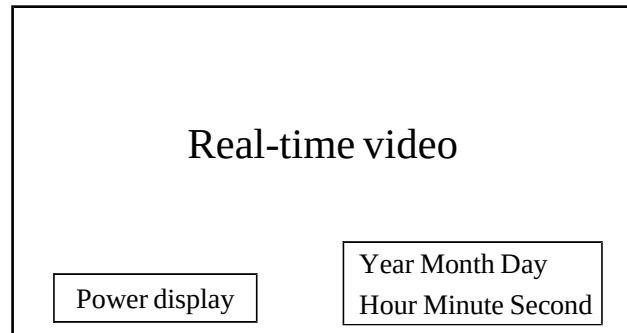
### 2.2.3 Overview of handsets of HC series



|                                       |                                 |
|---------------------------------------|---------------------------------|
| 1. Sealing plug                       | 2. Part of handset              |
| 3. Part of len                        | 4. Photograph/video button      |
| 5. para-position identification point | 6. Socket for signal connection |
| 7. Video components                   |                                 |

---

## 2.2.4 On screen display



『 Figure 2-3 』 Display main interface

1. Under normal operation, the real-time video is displayed in full screen with real time showed at lower right corner and battery level at lower left corner;
2. When the power is lower than 20%, a prompt of "low power" is popped out at top left corner of the screen;
3. When the power is lower than 10%, a prompt of "running out of power" is popped out at top left corner of the screen;
4. When taking a picture or shooting a video, a prompt of taking a picture or shooting a video is displayed at top right corner of the screen, when taking a picture, a photographing prompt is popped out, and when shooting a video, a video shooting prompt is flashing.

---

## 2.3 Battery

### 2.3.1 Overview

The laryngoscope has a built-in rechargeable battery (hereinafter referred to as "battery"). When the laryngoscope is connected to the power adapter, the battery will be charged. During charging, the laryngoscope will enter charging mode and cannot be operated in this state.

The battery power can only last for a while. The low power alert will be triggered at at least 30 minutes before running out of power, during which, the prompt information will be displayed. The running out of power alert will be triggered at at least 3 minutes before depletion of power, during which, the prompt information will be displayed and flashed.

#### Note

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- **Please do not recharge if supply voltage fluctuates greatly.**
  - **It will take 2-3 hours for full of charge, if the battery power is depleted.**
  - **If the product is out of service for a long time, please charge and discharge this product every 3 months to avoid damaging the battery.**
  - **The battery is a consumable and must be replaced upon running out of power.**
  - **If the battery needs to be changed, please contact to the distributor which sold this product to you or its manufacturer.**
  - **The replacement to battery can only be completed by the technical service engineer of the company!**
- 

### 2.3.2 Guidance on battery use

The service life of battery depends on its using-frequency and operating environment. If in appropriate use and maintenance, the service life is about 3 years; otherwise, it may be shortened. The battery shall be replaced once every 3 years.

Please pay attention to the following instructions in order for safe operation and to extend the service life of battery:

- The battery performance must be checked once every year. The battery performance also needs to be checked before maintenance of laryngoscope or when you suspects the battery as a fault source;
- The battery will be optimized for once every 3 months of use (or storage) or when the runtime of laryngoscope is obviously shortened;
- Every six months, use the power adapter provided by our company to charge the battery for about 0.5 hours to ensure that the battery is stored with power.

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 **Warning**

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- **Only the battery supplied by the manufacturer can be used.**
  - **If there is any sign of damage or leakage to the battery, it shall be changed immediately.**
  - **Please do not use the faulted battery to this laryngoscope.**
  - **The used battery can be sent back to the distributor which sells this product or its manufacturer and can also be handled as per the suitable laws and regulations.**
- 

### 2.3.3 Battery maintenance

#### 2.3.3.1 Optimization of battery performance

The battery will be optimized upon first use. A whole optimization cycle is from continuous charging to full of electricity, to discharging until to power off of laryngoscope, and then to continuous charging to full of electricity. The battery shall be regularly optimized during its use to extend its service life as much as possible.

#### Note

- 
- **With time lapsing and during battery use, the real storage capacity of battery will be reduced. During optimization, please change the battery if its power-on period is obviously shortened.**
- 

During the optimization, the following steps will be referenced and conducted:

1. The laryngoscope is connected to the power adapter to continuously charge for 8 hours;
2. Disconnect the power adapter and supply the power with the battery until the laryngoscope powers off;
3. The laryngoscope is connected to the power adapter to continuously charge for 8 hours;
4. The optimization of this battery is completed.

#### 2.3.3.2 Check the battery performance

The battery performance can be reduced over time, which shall be regularly examined. The battery performance is checked referencing to the following steps:

1. The laryngoscope is connected to the power adapter to continuously charge for 6-10 hours;
2. Disconnect the power adapter and continuously operate the laryngoscope until to its power off due to low power;
  - The battery is in good state if the time from starting run to power off of the laryngoscope is 100 minutes or more;

- 
- The battery accesses to the end of its service life if the time from starting run to power off of the laryngoscope is 30-100 minutes.
  - The battery reaches the end of its service life and needs to be replaced if the time span from starting run to power off of the laryngoscope is shorter than 30 minutes.
3. After checking the battery, it shall be re-charged for use of next time.

### Note

- 
- The battery may be damaged or has a fault if the power supply time is too short following full of charge. The supply time of battery depends on the configuration and frequency of use of laryngoscope, for example, the display screen is countered to light for a long time.
  - If the battery is obviously damaged (swelling, deformation or leakage) or fails to store power, it shall be changed and appropriately recycled.
- 

### 2.3.4 Battery recycling

If the battery is obviously damaged (swelling, deformation or leakage) or exhausts, it shall be changed and appropriately recycled. The handling of waste batteries shall follow corresponding regulations.

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### Warning

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- Please do not disassemble the battery, put it into fire or make it short out. Burning, exploding and leaking of battery may result in the injury of human body.
-

# Chapter 3 Installation and maintenance

## 3.1 Installation



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- **The copyright of software of this laryngoscope belongs to our company, and without a permission, any organization or individual is not allowed to falsify, copy or exchange it in any approach or form.**
- 

### 3.1.1 Out of package audit

Please carefully check the package before opening it so as to ensure whether the product is damaged during transportation. Please contact with the carrier or our company if any damage is found.

If the package is intact without any damage, please open the package in the right way, carefully take out the laryngoscope and other components, and count the items as per the packing list. Check whether the product has any mechanical deterioration and items are complete. Please do not hesitate to contact the after-sale service department of our company if there is any question.



- 
- **The user shall place the packaging materials at which a child cannot reach. The handling of packaging materials must comply with related local regulations or the waste management system in the hospital.**
- 

### Note

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- **Please keep the packaging box and packaging material for subsequent transportation and storage.**
  - **If you open the package and find some parts are lost, please contact with the distributor which sold the product to you or its manufacturer as soon as possible.**
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### 3.1.2 Environment requirements

The service environment of the laryngoscope shall comply with requirements of **A.2 environmental specification**.

The service environment of laryngoscope shall also avoid noise, vibration, dust, and corrosive, inflammable or explosive material, etc.

Transferring a laryngoscope from one environment to another environment may give rise to condensation of the laryngoscope due to difference in temperature or humidity, and in this moment, the laryngoscope can be booted up only after the condensation is resolved.

### 3.1.3 Requirements on power source

The power source used by this laryngoscope shall comply with requirements of **A.3 power source specification**.

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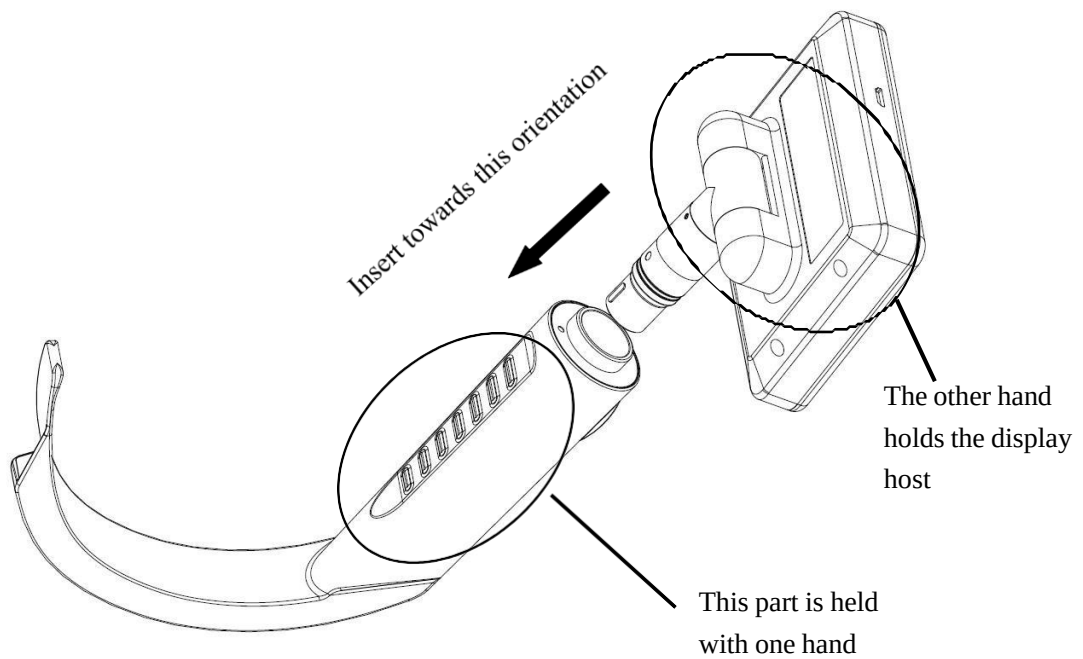
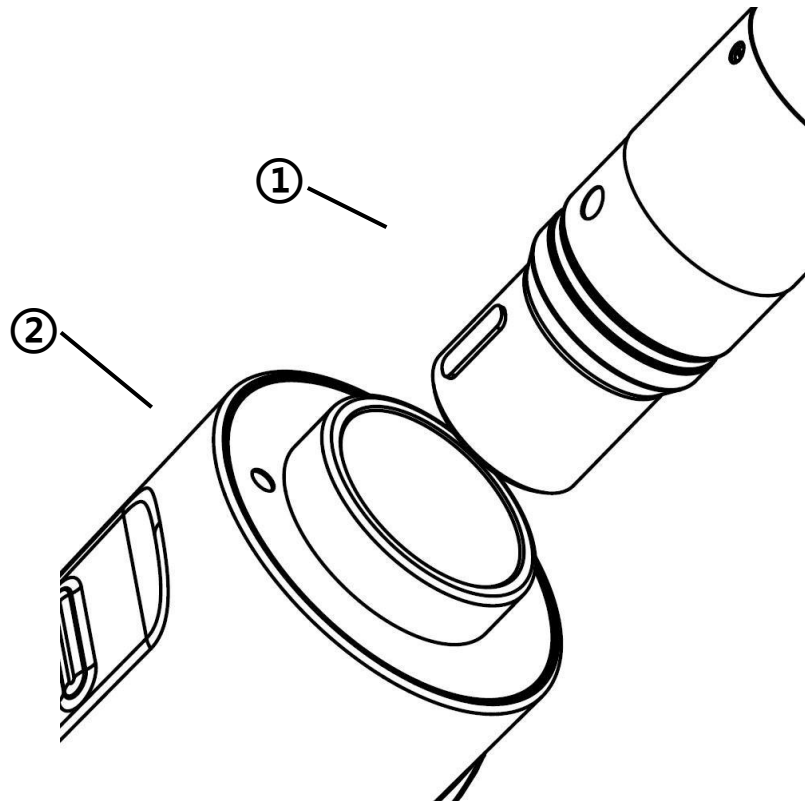
#### **Warning**

- **Please ensure that the laryngoscope works under requirements specified for environment and power source, or otherwise the technical specifications stated for product A cannot be fulfilled, possibly resulting in unpredictable outcomes such as failure of laryngoscope.**
  - **The appropriate power supply must be chosen as per the setting for power voltage of the laryngoscope. Otherwise, it may cause serious damage to the laryngoscope.**
- 

### 3.1.4 Connection and use

#### 3.1.4.1 HC Connection of HC blade and display host

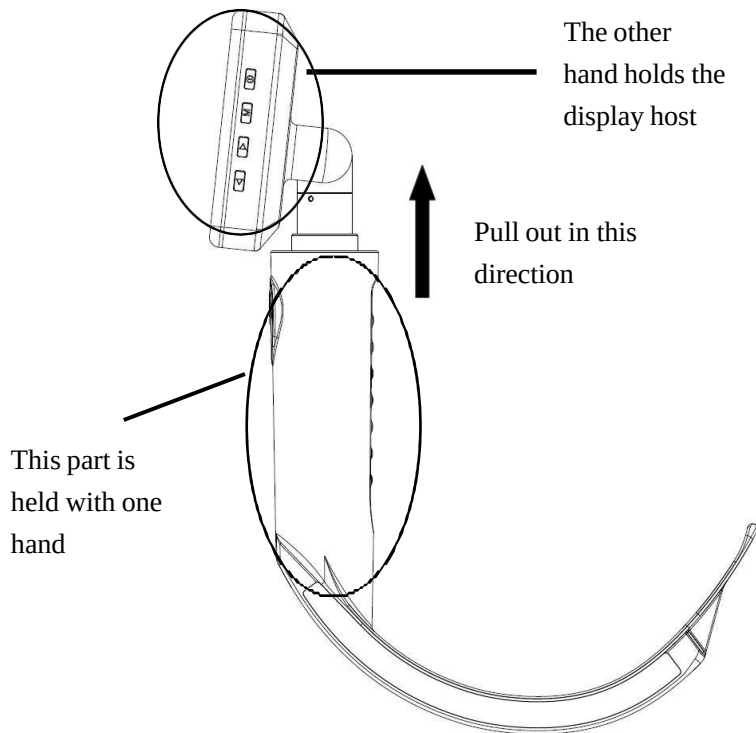
1. Select the appropriate len of HC series as per the size of patient and the oral cavity, and remove the sealing plug;
2. Please first identify the alignment markings of the signal connection port of the display host and the connection alignment markings of the HC series handle connection port respectively, as shown in Figure 3-1, mark ① and mark ②.
3. After identifying the para-position marks, align the two para-position points, position the two parts to the states as seen in Figure 3-1 by hand, Then slowly insert the signal connection port of the display host into the handle connection port;
4. Make sure that the signal connection port of the display host is fully inserted into the connection port of the HC series handle (there will be a clear sound when it is fully inserted).



『 Figure 3-1 』 installation Step I

#### 3.1.4.2 HC blade and display host disassembly

1. Hold the HT series blade with one hand, hold the display host with the other hand, and lift it upward with a little force to complete disassembly, as shown in Figure 3-2 ;



『Figure 3-2』 Disassembly step

## 3.2 Maintenance

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### Warning

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- The hospital or medical institution which uses this laryngoscope shall establish a complete maintenance plan, or otherwise, unforeseeable outcomes such as failure of laryngoscope may occur, which possible endangers the personal safety.
  - The safety inspection or maintenance work for all laryngoscopes requiring disassembly shall be conducted by the professional maintenance men from our company, and the operation from non-professionals may result in failure of laryngoscope which possible endangers the personal safety.
  - Please contact with the distributor which sold this product or its manufacturer if any abnormality of this laryngoscope is found.
  - The equipment must be disinfected and cleaned before rework.
  - Please assemble the sealing plug before cleaning and disinfecting the HC series blade, otherwise it will cause irreversible damage to the product.
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### 3.2.1 Inspection

Before use, one overall check of laryngoscope shall be conducted by the user so as to ensure the normal running and work of laryngoscope. The test items should include:

- The environment and power supply should comply with requirements;
- The equipment and accessories have no mechanical damage;
- Performance of battery;
- Accessories designated for use;
- The function is normal.

If any damage or abnormality is found, the use of this laryngoscope must be temporarily suspended, and you must contact with the distributor which sold this product or its manufacturer.

### 3.2.2 Cleaning and disinfection

The laryngoscope must be cleaned or disinfected with materials and methods listed in this chapter, and our company does not guarantee for any damage or accident resulting from other materials or methods.

The chemicals or methods listed by our company are only the approaches for infection control, and no responsibility for their effectiveness is assumed. Please consult the infection prevention department in the hospital or epidemiologists for methods of infection control.

Please ensure keeping the laryngoscope out of dust. The following regulations must be followed to avoid damaging the laryngoscope.

- The detergent and disinfectant are diluted as per requirements from the manufacturer, or they are used with concentrations as low as possible;
- The display host of the laryngoscope should not be submerged in liquid.;
- No liquid should be allowed to pour on the display host of the laryngoscope;
- No liquid should be allowed to enter the display host of the laryngoscope.;
- The laryngoscope must not be cleaned with abrasive materials (such as steel wool or silver polishing agent) and solvents like dimethylbenzene and acetone to avoid damaging the housing.
- Before disinfection and cleaning, it should be ensured that the HC series blade have been assembled with sealing plugs.



- 
- 
- **Before cleaning the laryngoscope, turn off the power and disconnect the USB cable with the power adapter.**
  - **The cleaning and disinfection measures as mentioned in the manual cannot replace rules and regulations established for routine use of the equipment under any condition!**
  - **Please assemble the sealing plug before cleaning and disinfecting the HC series blade, otherwise it will cause irreversible damage to the product.**
- 



- 
- **If you accidentally dump the liquid on the laryngoscope resulting in its failure to work, please temporarily stop its use and contact with the distributor which sold this product or its manufacturer.**
- 

Recommended surface disinfection method:

This product is intended to contact with the oral mucosa of the patient and is disinfected by the end user before use, or otherwise is not allowed to be use; the methods for cleaning and disinfection are as follows:

1. Display host cleaning and disinfection:

After use of laryngoscope, the dirt on the outer surface is wiped with wet gauze or alcohol gauze, and then the cleaned displayer and handset are wiped and disinfected with 75% ethanol.



- 
- **It cannot be disinfected by high temperature and high pressure.**
  - **It cannot be disinfected with organic acid or non-organic acid at high concentration or the equipment may be corroded.**
  - **It cannot be disinfected with chemicals containing chloral formamide, phenol derivative or anionic surfactant or the plastic material outside the instrument will be aged with fissure.**
  - **The use of disinfectant containing acetaldehyde and amine on the same surface may**
-

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result in surface discoloration.

- Please assemble the sealing plug before cleaning and disinfecting the lens of HC series, or otherwise, the product will be irreversible damaged.
- 

### 3.2.3 Regular maintenance

1. Maintenance of battery performance

Refer to 2.3.3.

2. Regular maintenance

| Interval time                                        | Routine maintenance procedure                                                                                                                                                                                                                     |
|------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| According to the policy of hospital                  | The surface of laryngoscope needs to be thoroughly cleaned before or after long-term storage.                                                                                                                                                     |
| The detection needs to be conducted for once a year. | <ol style="list-style-type: none"><li>1. Detect the power adapter and USB cable.</li><li>2. Run the laryngoscope until the alert of low power rings out, then re-charge the battery, and confirm the operation and charging are normal.</li></ol> |

### 3.2.4 Pollution-free handling and recycling

The service life of this product is about 3 years. The laryngoscope out of the service life shall be scraped, and please contact with the distributor which sold this product or its manufacturer to obtain more related information.

You can handle as follows:

1. The laryngoscope to be scraped can be sent back to the distributor which sold this product or its manufacturer for properly recycling.
2. The waste battery can be sent back to the distributor which sold this product or its manufacturer for handling or handled as per corresponding regulations.

# Chapter 4 Operation guidance

## 4.1 Display host operation

### 4.1.1 Function key

| Key            | Power key                                                                         | Menu key                                                                            | Option key                                                                        | Option key                                                                         | Function key                                                                        |
|----------------|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Identification |  |    |  |  |  |
| Function       | Power on an off of the device                                                     | I Enter into the setting interface<br>II Confirm the selection<br>III Save settings | Upward selection                                                                  | Downward selection                                                                 | I Short press to take photo<br>II Long press to take video<br>III Return            |

### 4.1.2 Work interface

After press the power button  to activate the laryngoscope, the company LOGO is displayed at rest as seen in 『Figure 4-1』 , and the normal work interface is entered in 3 minutes, as seen in 『Figure 4-2』 .

『Figure 4-1』 LOGO interface upon booting



『Figure 4-2』 Normal work interface

- 1) During the normal work, the real-time video is displayed on the full screen, and year, month and date as well as time is real-time displayed at lower right corner and the power icon is displayed at lower left corner.
- 2) When the power is lower than 20%, a prompt of "low power" is popped out at top left corner of the screen;  
When the power is lower than 10%, a prompt of "running out of power" is popped out at top left corner of the screen.
- 3) When taking a picture or shooting a video, a prompt of taking a picture or shooting a video is displayed on the screen. When taking a picture, a photographing prompt is popped out; when shooting a video, a video shooting prompt and the duration of real-time camera shooting is shown above the power display area at the lower left corner of screen.
- 4) Press the menu key  to enter into the system setting interface;  
Press the function button  to activate the camera function;  
Press the function button  to activate the video function;  
Long press the rightwards and upwards keys  to activate the disk formatting function.

### 4.1.3 Interface of system settings

After pressing the menu key , the screen shows the interface of system settings, the background of screen is blue.  Press the key to exit the interface.



『 Figure 4-3 』

Available pressing key ,  options, press the key  to enter into the sub-interface.  Press the key to return to the upper level of interface.

#### 4.1.4 Interface of time settings

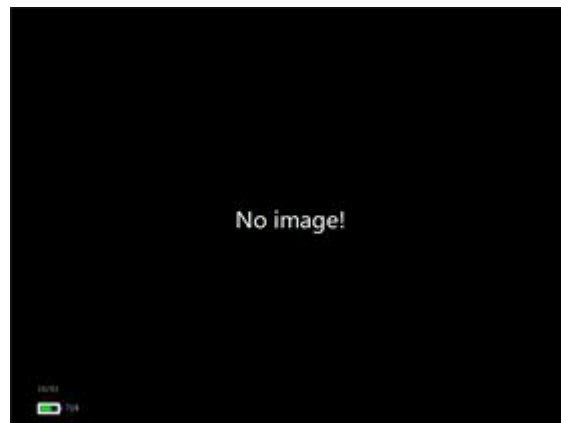


『 Figure 4-4 』

Press the key  to alternatively switch the year, month, day, hour, minute and second , , and to adjust the value, and press the key  to return to the upper level of interface.

---

### 4.1.5 Interface of photograph browsing



『 Figure 4-5 』

Press key ,  to switch photographs, press key  to return, and long press the key  to delete the currently chosen photograph files.

### 4.1.6 Interface of video display



『 Figure 4-6 』

Press key ,  to switch video displays, press key  to display the video and then press the key again to switch pause and display, press key  to return, and long press  to delete the currently chosen video files.

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### 4.1.7 Interface of language settings



『Figure 4-7』

Press the key ,  to select the language, and press the key  again to confirm the selection.

---

## 4.2 Operation guidance

The still image and video of intubation processes for respiratory tract and trachea can be recorded and auto-saved into the memory of host display.

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### Warning

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- **The video laryngoscope can be used in combination with the system technology similar to direct laryngoscope. Please consult professionals in the field of tracheal intubation technology before using the laryngoscope in the human body.**
- 

### 4.2.1 Lens of HC series

- Please assemble the sealing plug before cleaning and disinfecting the HC series blade, otherwise it will cause irreversible damage to the product.
- Cleaning: please clean and disinfect the handset and lens before use (refer to 3.2.2 , 4.3 ).
- Antifogging: the video shots of lens of HC series are made of electric heating materials, so as to clear away the fog in the trachea produced by the warm and humid environment in the airway. Driven by the battery of handset, the LED light on the len starts lighting while the heating element starts running. Due to the temperature of the len itself, the fog on the len can be eliminated within 30 seconds after connecting the len with handset.

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### Warning

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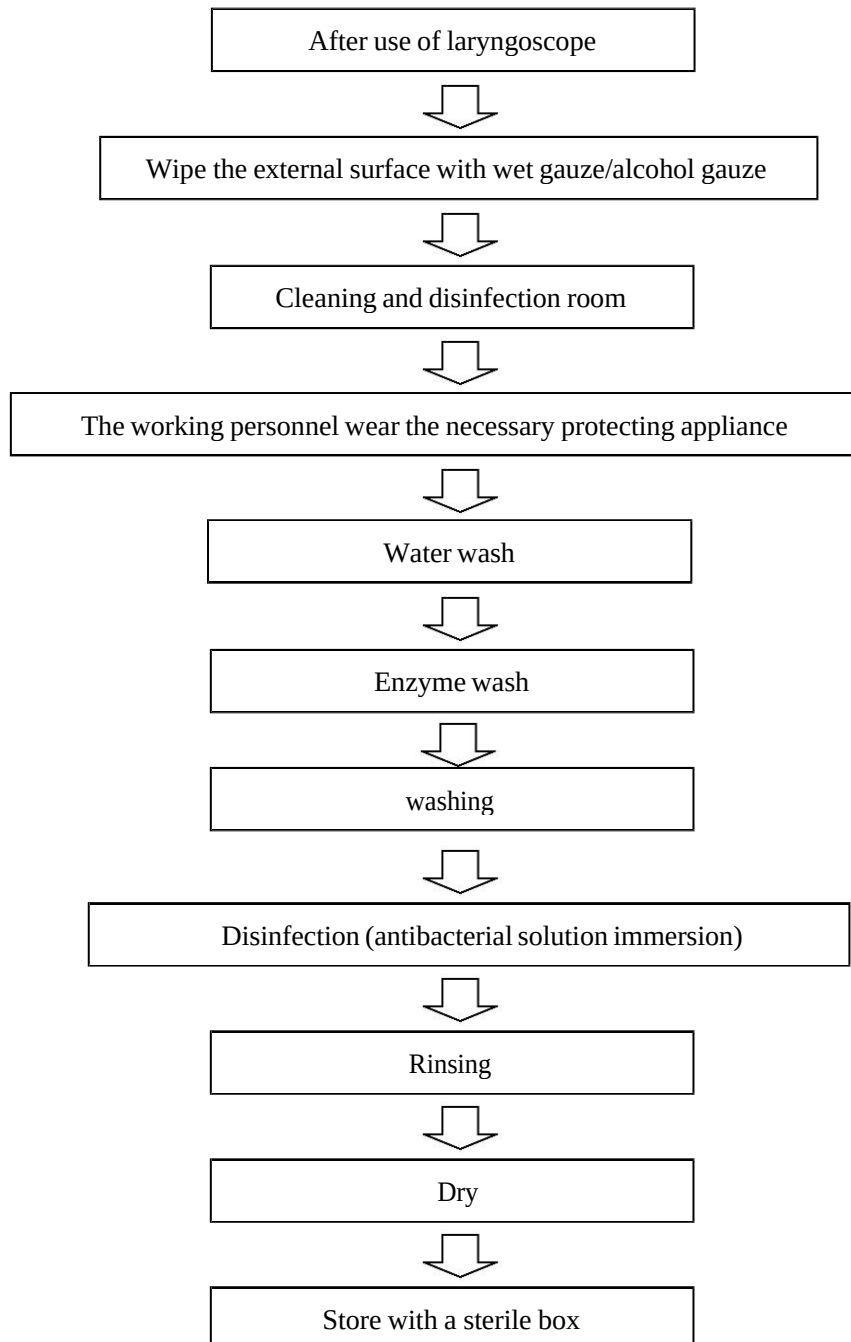
- **The user must check the laryngoscope and its accessories before using them to ensure that they can normally and safely work.**
  - **Please assemble the sealing plug before cleaning and disinfecting the HC series blade, otherwise it will cause irreversible damage to the product.**
-

---

## 4.3 Cleaning instruction

After diagnosis and treatment with the laryngoscope, the medical personnel shall wipe off host and repetitive blade with 75% alcohol gauze; then the gauze is discarded into a yellow garbage bag for medical wastes; the non-operational hand-held lens are immediately sent into the cleaning and disinfection room.

The standard procedure for cleaning and disinfection of lens of HC series is as follows:



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 **Warning**

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- **The laryngoscope shall be disinfected for each use, and before use, please consult or understand regulations about cleaning of medical equipment.**
  - **Before cleaning the laryngoscope, turn off the power and disconnect the USB cable with the power adapter.**
  - **Handle and display host are not water-proof, it shall avoid being submerged or placed in excess liquid, recommending wiping it with a disinfecting wipe.**
  - **Please assemble the sealing plug before cleaning and disinfecting the HC series blade, otherwise it will cause irreversible damage to the product.**
- 

#### **4.3.1 Aqueous Cleaning**

1. Rinse blades thoroughly under running water for 2min and wipe clean with wet gauze until visibly clear.
2. Use a small brush to clean the unevenness part of the HC series blade with running water, especially the small gap between the camera and the upper interface. Then, clean all the surface of the blade with brush thoroughly, 5 times of each cleaning .
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 Infinium Medical validated conditions to achieve cleaned: Cleaning Solution: Metrex EmPower  
Concentration: 1:128  
Temperature: 20°C~40°C  
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

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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 Wash

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 Infinium Medical validated conditions to achieve disinfection:

Disinfection Agent: MetriCide 28 Long-life Activated Dialdehyde Solution

Concentration: 2.5%

Temperature: 25°C

Soaking time: 90 min

2. The display host and operating handle must be wiped clean and then disinfected with a 75% alcohol wipe.
3. At the end of the daily diagnosis and treatment, when the blade that is no longer in use is disinfected with a disinfectant for the last time, the terminal disinfection should be extended for 30 minutes.
4. The laryngoscope to be used for the day must be disinfected before the daily routine. Soak in the recommended disinfectant for not less than 20 minutes, rinse, dry before use.
5. Laryngoscopes to be disinfected must be soaked for 10 hours in 2% alkaline glutaraldehyde.

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### **Warning**

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- **Do not use any highly alkalic/highly acidic disinfectant to disinfect the laryngoscope.**
  - **Do not immerse the laryngoscope in medicinal alcohol or iodine.**
  - **Please do not place the laryngoscope where organic solvents such as acetone and butanone are placed.**
  - **Do not disinfect the laryngoscope by high temperature or high pressure.**
  - **Upon disinfection, pay attention to cleaning of cover lens of laryngoscopes to avoid**
-

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impacting the observation.

- **Please assemble the sealing plug before cleaning and disinfecting the HC series blade, otherwise it will cause irreversible damage to the product.**
- 

#### 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.

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#### **Warning**

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- **The lens immersed in chemical disinfectants must be thoroughly washed with sterile water before use to remove the residual disinfectant.**
  - **Please assemble the sealing plug before cleaning and disinfecting the HC series blade, otherwise it will cause irreversible damage to the product.**
- 

#### 4.3.6 Dry

Drying with sterile gauze or clean compressed air, etc.

#### 4.3.7 Storage

The disinfected or sterilized laryngoscopes are stored in the airtight instruments box after sterilization.

#### **Note**

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- **The operation specification for cleaning is written as per Standardized Technical Manipulations for Cleaning and Disinfection of Endoscopes (2004).**
  - **The above-mentioned operations are only for references and the disinfecting effectiveness shall be validated with appropriate methods.**
-

# Chapter 5 Accessories



## Warning

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- Only the accessories specified in this chapter can be used, and other accessories may damage this laryngoscope or cannot meet the specification as stated in this manual.
  - The disposable accessory can only be used for once, and reuse may result in performance reduction or cross-infection.
  - If there is any sign of damage of accessory or its package found, please stop to use this accessory, and contact with the distributor which sold the product or its manufacturer.
- 

## 5.1 Lens

Models of lens of HC series are as follows:

| Model | Size                            |
|-------|---------------------------------|
| HC2   | 130.5(L)*31.5mm(W)*142.7mm(H)   |
| HC3   | 142.5mm(L)*31.5mm(W)*146.5mm(H) |
| HC4   | 153.5mm(L)*31.5mm(W)*150.8mm(H) |

Note: for reference to medical professionals.

# A Product specifications

## A.1 Safety specifications

**A.1.1** It is classified as Class II equipment with internal electric source as per types of electric shock protection

**A.1.2** It is classified as BF type application equipment as per degrees of electric shock protection

**A.1.3** It is classified as Class A equipment as per electromagnetic compatibilities

**A.1.4** Rated voltage, frequency and power

Input of power adapter: 100-240V~, 50/60Hz and 0.5A max

External input of host display: 10VA

Internal electric source: DC3.7V, lithium ion battery

**A.1.5** Equipment of non-permanent installation

**A.1.6** Classification as per degrees of safety when used in flammable anesthetic gas mixed with air or with oxygen or nitrous oxide: equipment which cannot be used in flammable anesthetic gas mixed with air or with oxygen or nitrous oxide.

**A.1.7** Classification as per operation modes: continuous operation.

**A.1.8** Classification of electromagnetic compatibility: Class A in Group 1 as per IEC 60601-1-2

## A.2 Environmental specification

| Parameter                                           | Specification                                        |
|-----------------------------------------------------|------------------------------------------------------|
| Operating temperature                               | 5~40°C                                               |
| Operating humidity                                  | 20~80%, non-condensing                               |
| Working atmospheric pressure                        | 86~106kPa                                            |
| Storage temperature                                 | -20~60°C                                             |
| Storage humidity                                    | 10~95%, non-condensing                               |
| Atmospheric pressure for storage and transportation | 50~106kPa                                            |
| Description of storage condition                    | Room without corrosive gas and with good ventilation |

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### A.3 Power source specification

| Parameter               | Specification       |
|-------------------------|---------------------|
| <b>Power adapter</b>    |                     |
| Voltage input           | 100-240V~           |
| Current input           | 0.5A max            |
| Frequency input         | 50/60Hz             |
| Voltage output          | DC5V                |
| Current output          | 2A                  |
| <b>Battery</b>          |                     |
| Number of batteries     | One                 |
| Type of battery         | lithium ion battery |
| Nominal battery voltage | DC 3.7V             |
| Battery capacity        | 1800mAh             |

## A.4 Names and contents of toxic and harmful substance or element in the product

| Name of part                                                                                                                                                                                                                                                                                                                                            | Toxic and harmful substance or element |                 |                 |                                  |                                      |                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|-----------------|-----------------|----------------------------------|--------------------------------------|---------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                         | Lead<br>(Pb)                           | Mercury<br>(Hg) | Cadmium<br>(Cd) | Hexavalent<br>chromium<br>(Cr6+) | Polybrominated<br>biphenyls<br>(PBB) | Polybrominated diphenyl<br>ethers<br>(PBDE) |
| Components of printing circuit board                                                                                                                                                                                                                                                                                                                    | ○                                      | ○               | ○               | ○                                | ○                                    | ○                                           |
| Shell                                                                                                                                                                                                                                                                                                                                                   | ○                                      | ○               | ○               | ○                                | ○                                    | ○                                           |
| Metallic shell                                                                                                                                                                                                                                                                                                                                          | ○                                      | ○               | ○               | ○                                | ○                                    | ○                                           |
| Display screen                                                                                                                                                                                                                                                                                                                                          | ○                                      | ○               | ○               | ○                                | ○                                    | ○                                           |
| Battery                                                                                                                                                                                                                                                                                                                                                 | ○                                      | ○               | ○               | ○                                | ○                                    | ○                                           |
| <p>Note:</p> <p>○: the content of this toxic and harmful substance in all homogeneous materials of the part is below the limits specified in SJ/T11363-2006.</p> <p>×: means that the content of such hazardous substance in at least some homogeneous material of this part exceeds requirements for limits specified in SJ/T11363-2006 standards.</p> |                                        |                 |                 |                                  |                                      |                                             |



The "environmentally friendly service life" of this product is 10 years, the label is shown in the left figure, the environmentally friendly service lives of replaceable parts such as battery may be different from that of the product. The "environmentally friendly service life" is valid only when this product is used under the normal condition described in the this manual.

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## A.5 List of accessories

Please contact with the manufacturer if the following entity is not consistent with this information.

| Serial number | Name of part       | Quantity | Note |
|---------------|--------------------|----------|------|
| 1             | Host               | 1        |      |
| 2             | Blade HC2          | 1        |      |
| 3             | Blade HC3          | 1        |      |
| 4             | Blade HC4          | 1        |      |
| 5             | Power adapter      | 1        |      |
| 6             | USB data cable     | 1        |      |
| 7             | Instruction manual | 1        |      |
| 8             | Certificate        | 1        |      |
| 9             | Warranty card      | 1        |      |
| 10            | Sealing plug       | 6        |      |

## B EMC

This laryngoscope complies with the EMC standard- EN 60601-1-2.

### Note

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- The laryngoscope conforms to the electromagnetic compatibility requirements of 60601-1-2 standards ;
- Users should install and use according to the EMC information provided in the accompanying documentation ;
- Portable and mobile RF communication devices may affect the performance of this laryngoscope, avoid strong electromagnetic interference when using, such as close to cell phones, microwave ovens, etc. ;
- Guidelines and manufacturer's statements are detailed in the annex



### Warnings :

- This laryngoscope should not be used in close proximity or stacked with other equipment, and if it must be used in close proximity or stacked, it should be observed to verify proper operation in the configuration in which it is used ;
  - Class A equipment is intended for use in industrial environments, there may be potential difficulties in ensuring electromagnetic compatibility in other environments due to conducted and radiated harassment from this laryngoscope ;
  - Except for the cables sold by the manufacturer of this laryngoscope as spare parts for internal components, the use of accessories and cables other than those specified may result in increased emission or reduced immunity of this laryngoscope
- 

| Guidance and statement of manufacturer-electromagnetic emission                                                                                                                                     |             |                                                                                                                                                                                                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| This laryngoscope is intended to use in the following specified electromagnetic environments, the purchaser or the user shall guarantee that it can be used in such an electromagnetic environment: |             |                                                                                                                                                                                                       |
| Emission test                                                                                                                                                                                       | Conformance | Electromagnetic environment-guidance                                                                                                                                                                  |
| Radio-frequency emission<br>CISPR 11                                                                                                                                                                | Group 1     | This laryngoscope uses the radio-frequency energy only for fulfilling its internal function. Thus, its radio-frequency emission is low, with a slim chance to disturb the nearby electronic equipment |

|                                                           |                |                                                                                                                                                                           |
|-----------------------------------------------------------|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Radio-frequency emission<br>CISPR 11                      | Class A        | This laryngoscope is suitable for non-domestic facilities and all facilities not directly connecting to the domestic residential public low voltage power supply network. |
| Harmonic emission<br>IEC 61000-3-2                        | Not applicable |                                                                                                                                                                           |
| Voltage fluctuation/scintillant emission<br>IEC 61000-3-3 | Not applicable |                                                                                                                                                                           |

| Guidance and statement from the manufacturer-electromagnetic immunity                                                                                                                               |                                                 |                                                 |                                                                                                                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|-------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| This laryngoscope is intended to use in the following specified electromagnetic environments, the purchaser or the user shall guarantee that it can be used in such an electromagnetic environment: |                                                 |                                                 |                                                                                                                                                                            |
| Immunity test                                                                                                                                                                                       | IEC60601 test electrical level                  | In compliance with electrical level             | Electromagnetic environment-guidance                                                                                                                                       |
| Electrostatic discharge<br>IEC 61000-4-2                                                                                                                                                            | ±8 kV contact<br>±2 kV, ±4kV, ±8 kV, ±15 kV air | ±8 kV contact<br>±2 kV, ±4kV, ±8 kV, ±15 kV air | The ground shall be covered with woodiness, concrete or ceramic tiles, and if the ground is covered with synthetic materials, the relative humidity shall be less than 30% |
| Electrical fast transient burst<br>IEC 61000-4-4                                                                                                                                                    | ±2kV to power wire                              | ±2kV to power wire                              | The network power source shall have a typical quality for use under commercial or hospital environment                                                                     |
| Surging<br>IEC61000-4-5                                                                                                                                                                             | ±1 kV wire to wire<br>±2 kV wire to ground      | ±1 kV wire to wire<br>±2 kV wire to ground      | The network power source shall have a typical quality for use under commercial or hospital                                                                                 |

|                                                                                                        |                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                           |
|--------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                        |                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                | environment.                                                                                                                                                                                                                                                                                              |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | $<5\% U_T$ , lasting for 0.5 cycles<br>(On $U_T$ , sagging for $>95\%$ )<br>$40\% U_T$ , lasting for 5 cycles<br>(On $U_T$ , sagging for $60\%$ )<br>$70\% U_T$ , lasting for 25 cycles<br>(On $U_T$ , sagging for $30\%$ )<br>$<5\% U_T$ , lasting for 5s<br>(On $U_T$ , sagging for $>95\%$ ) | $5\% U_T$ , lasting for 0.5 cycles<br>(On $U_T$ , sagging for $>95\%$ )<br>$40\% U_T$ , lasting for 5 cycles<br>(On $U_T$ , sagging for $60\%$ )<br>$70\% U_T$ , lasting for 25 cycles<br>(On $U_T$ , sagging for $30\%$ )<br>$<5\% U_T$ , lasting for 5s<br>(On $U_T$ , sagging for $>95\%$ ) | The network power source shall have a typical quality for use under commercial or hospital environment. If the user needs to continuously run this laryngoscope during the period of power interruption, it recommended to supply power to this laryngoscope with uninterruptible power supply or battery |
| Power frequency magnetic field<br>(50/60Hz)<br>IEC 61000-4-8                                           | 3A/m                                                                                                                                                                                                                                                                                            | 3A/m, 50/60Hz                                                                                                                                                                                                                                                                                  | The power frequency magnetic field shall have the characteristics of power frequency magnetic field in typical places under commercial or hospital environments                                                                                                                                           |
| Note: $U_T$ refers to the alternating voltage before applying the test voltage                         |                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                           |

| Guidance and statement from the manufacturer-electromagnetic immunity                                                                                                                               |                                                                                         |                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| This laryngoscope is intended to use in the following specified electromagnetic environments, the purchaser or the user shall guarantee that it can be used in such an electromagnetic environment: |                                                                                         |                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Immunity test                                                                                                                                                                                       | IEC60601 test electrical level                                                          | In compliance with electrical level                                                     | Electromagnetic environment-guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Conducted RF<br>IEC61000-4-6                                                                                                                                                                        | 3 V r.m.s.<br>150 kHz to 80 MHz<br>6 V RMS in the ISM bands between 0.15 MHz and 80 MHz | 3 V r.m.s.<br>150 kHz to 80 MHz<br>6 V RMS in the ISM bands between 0.15 MHz and 80 MHz | <p>The distances from portable and mobile RF communication devices to any part of this laryngoscope (including the cable) shall not be shorter than recommended isolation distances. This distance shall be calculated with an equation corresponding to the frequency of transmitter.</p> <p><b>Recommended isolation distance</b></p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80 \text{ MHz} \sim 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz} \sim 2.5 \text{ GHz}$ <p>Where:</p> <p><math>P</math> —the maximum rated output power as per the transmitter provided by its manufacturer, in the unit of watt (W);</p> <p><math>d</math>—recommended isolation distance, in the unit of meter (m) <sup>b</sup>.</p> <p>The field strength of fixed radio-frequency transmitter is determined by survey <sup>c</sup> of an electromagnetic place, and each radio-frequency range <math>d</math> shall be lower than the electrical level in compliance. The interference may occur near the equipment with the following marks.</p>  |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                               |                                                     |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|-----------------------------------------------------|--|
| Radiated RF<br>IEC61000-4-<br>3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 3 V/m<br>80 MHz – 2,7 GHz<br>80 % AM at 1 kHz | 3 V/m<br>80 MHz –<br>2,7 GHz<br>80 % AM at<br>1 kHz |  |
| <p>Note:</p> <ol style="list-style-type: none"> <li>For frequencies of 80MHz and 800MHz, the equation of the higher frequency band is adopted.</li> <li>These guidances may not be suitable for all cases, the electromagnetic propagation is impacted by absorption and reflection by buildings, objects and human bodies.</li> </ol> <p>a) For fixed transmitters, e.g., base stations of air (cell/cordless) telephone and ground mobile radio, amateur radio, AM and FM radio broadcasting as well as television broadcasting, their field intensities cannot be accurately and theoretically predicted. The survey of electromagnetic place shall be considered for assessing the electromagnetic environment of fixed radio-frequency transmitter. If the field intensity where the laryngoscope is located is measured higher than the suitable electrical level in compliance of radio frequency, this laryngoscope shall be observed to validate that it can normally run. If abnormal performance is observed, the supplement measure may be necessary, e.g., readjust the direction or location of this laryngoscope.</p> <p>b) Within the whole frequency range of 150KHz~80MHz, the field intensity shall be less than 3 V/m.</p> |                                               |                                                     |  |

| Recommended isolation distance between portable and mobile radio-frequency communication devices and this laryngoscope                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                |                                       |                                        |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|---------------------------------------|----------------------------------------|
| This laryngoscope is intended to use in an electromagnetic environment with disturbance of radiofrequency radiation controlled. As per the maximum rated output power of communication device, the purchaser or user can prevent the electromagnetic interference by maintaining the minimum distance between the portable and mobile radio-frequency communication equipment (transmitter) and VLRM as recommended below.                                                                                                                                                                                                                                                |                                                                                |                                       |                                        |
| The maximum rated output power of transmitter<br>W                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Isolation distance/m corresponding to different frequencies of the transmitter |                                       |                                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 150 kHz ~ 80 MHz<br>$d = 1.2\sqrt{P}$                                          | 80 MHz ~ 800 MHz<br>$d = 1.2\sqrt{P}$ | 800 MHz ~ 2.5 GHz<br>$d = 2.3\sqrt{P}$ |
| 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                                     |
| <p>The equations in the corresponding transmitter frequency list can be used to identify the maximum rated output power of transmitter and recommended Isolation distance <math>d</math> in the unit of meter (m), the <math>p</math> here is maximum rated output power of transmitter provided by its manufacturer in the unit of watt (W).</p> <p>Note:</p> <ol style="list-style-type: none"> <li>1. For 80 MHz and 800 MHz, use the equation with higher frequency range.</li> <li>2. These guidances may not be suitable for all cases, the electromagnetic propagation is impacted by absorption and reflection by buildings, objects and human bodies.</li> </ol> |                                                                                |                                       |                                        |