Video Laryngoscope

CR-31 / CR-31D

User Manual

Shenzhen Coreray Technology Co., Ltd

Issuing Date: Nov. 01, 2023

Version: V1.0.13

Manufacturer Profile

Shenzhen Coreray Technology Co., Ltd. is a manufacturer dedicated to the creation of high-quality medical equipment, consumables medical products. Coreray focuses on the construction of the R&D team, has been providing professional visualization solutions for video intubation especially airway management for users worldwide.

Foreword

Thank you for purchasing the Video Laryngoscope.

Please read this user manual carefully before using this product for proper use.

Please keep this user manual in a safe place for your reference.

Product Name	Video Laryngoscope
Model	CR-31/ CR-31D
Software version	V1.0.0
Production Date	See label on product
Period of Validity	3 years
Structure and composition	It mainly consists of three parts: power adapter, display host and visual blade.
Scope of application	It can be used to provoke patients' glottis and expose epiglottis, guide medical staff to accurately intubate airway for first aid, and also for oral inspection and treatment.
User Manual Version And Issuing Date	V1.0.13, Nov. 01, 2023
Manufacturer	**Shenzhen Coreray Technology Co., Ltd**
After-sales service	Shenzhen Coreray Technology Co., Ltd
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Intellectual property right statement

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It is a registered trademark of Coreray.

Statement

Coreray has the final right to interpret this manual.

Coreray has the right to amend the contents of this manual without prior notice. The revision of the contents of this manual will be reflected in the newly published version.

Coreray is not responsible for the software and equipment provided by non-Coreray and distributors.

- Coreray is responsible for the safety, reliability and performance of the product only if all the following requirements are met:
- Assembly, expansion, re-adjustment, improvement and maintenance must be carried out by professionals accredited by Coreray.
- All repairs involving replacement parts, accessories and consumables for matching use are original Coreray (original) or approved by Coreray.
- Relevant electrical equipment meets the requirements of the national standards and the use manual.
- The operation of the product is carried out in accordance with the manual.

Warranty and Maintenance Services

The standard warranty period of this product is one year, and the main accessories guarantee period is half a year. The main accessories include charging lines and batteries. Consumables: refers to disposable consumables that need to be replaced after each use. Consumables are not guaranteed.

If the seller and your sales contract do not agree with the above standard warranty period or have other agreements, please consult and confirm through the Coreray Free Service Hotline + 86 755 21010817. If it is not confirmed by Coreray, please consult and confirm with the seller in time.

The warranty period starts from the "Purchasing Date" filled in the "Product Warranty Card", and "Product Warranty Card" is the only voucher for calculating the warranty period. In order to safeguard your rights and interests, please urge the loader to return the second "Product Warranty Card" to Coreray within 30 days from the Purchasing Date; if the corresponding "Product Warranty Card" of the products you purchased fails to return to Coreray on time, the warranty period will be delayed by 45 days from the "Production Date" of the product package label.

During the warranty period, all products can enjoy free after-sales service. But please note that even during the warranty period, if the products need to be repaired due to the following reasons, Coreray will implement a fee-based maintenance service. You need to pay for the maintenance fee and spare parts fee:

- The voltage of the power is beyond the scope specified by the product.
- Artificial damage;
- Improper use; Irresistible natural disasters;
- Replacement or use of parts, accessories not approved by Coreray or maintenance by non-Coreray Authorized Personnel;
- Faults caused by other non-products themselves.

After the expiration of the warranty period, Coreray can continue to provide fee-based maintenance services. If you refuse to pay or delay to pay for the maintenance service, Coreray will suspend the maintenance service until you pay for it.

After-sale service

Shenzhen Coreray Technology Co., Ltd

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Fax: +86 755 23771460

Email: info@core-ray.com

Website: www.core-ray.ltd

⚠ **WARNING**

- This product should be used by a professional clinician, medical electrical specialist or a specially trained clinical nurse in a designated occasion. Personnel using this product should receive adequate training. No person without authorization or training shall perform any operation.
- Careful work can avoid possible accidents!
- Daily cleaning and maintenance of instruments are necessary.
- In case of maintenance, we should insist on using original parts.

Preface

Statement

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

This manual describes the product in the most complete configuration. Some of the contents may not be applicable to the products you purchase. If you have any questions, please contact us.

These instructions include considerations for how to operate laryngoscopes safely, correctly and effectively. They help to reduce failure, reduce maintenance costs and downtime, and improve the reliability and service life of the instrument. It can not only be used as operating instructions, but also as a reference manual for reference. So, this manual must be placed beside the equipment and accessible at any time.

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

Applicable object

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

Illustrations

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

Convention

- The ***italic*** text is used in this instruction to indicate the chapters cited.
- Terms such as danger, warning and caution etc. are used in this manual to indicate hazard information and its severity.

Catalog

Chapter 1 Security

1.1 Security Information

This chapter lists the basic security information that users must pay attention to and observe when using Video Laryngoscope (hereinafter referred to as laryngoscope). The same, similar or other security information related to specific operations will appear in the chapters.

⚠ DANGER

- Indicate an emergency risk, if not avoided, that may lead to death, serious bodily injury or property damage.

⚠WARNING

- Potential dangerous or unsafe operations, if not avoided, may lead to death, serious personal injury or property damage.

⚠NOTE

- Indicate potential dangerous or unsafe operation, if not avoided, which may result in minor personal injury, product failure, damage or property loss.

NOTE

- Emphasize important precautions, provide instructions or explanations for better use of the product.

1.1.1 Danger

There is no such security risk.

1.1.2 WARNING

⚠WARNING

- This laryngoscope is only allowed to be used by professional clinicians, medical electrical experts or specially trained clinical medical staff on designated occasions.
- The responsible doctor must be responsible for the operation procedure and technology application of the equipment. According to the actual application conditions, trained doctors (responsible doctors) have the right to decide how to use the equipment adequately.
- Before first use, please read the instructions of the Video Laryngoscope carefully.
- Before using the laryngoscope, the user must check the laryngoscope and its accessories to ensure that they can work normally and safely.
- Laryngoscope should be disinfected before use. Before cleaning, please consult or learn about the cleaning regulations of medical equipment.
- Do not place the device in a location where it is difficult to disconnect the power adopter.
- This laryngoscope should not be used in the environment where inflammable or explosive articles are placed in order to prevent fire or explosion.
- Please properly carry the laryngoscope and its supporting equipment to prevent the laryngoscope from falling, collision, strong oscillation or other mechanical damage.
- Electromagnetic field will affect the performance of laryngoscope, so the equipment used near laryngoscope must meet the corresponding EMC requirements, otherwise it may cause laryngoscope failure or laryngoscope collapse due to electromagnetic interference. Mobile phones, X-ray or MRI devices are all possible sources of interference, and they emit high-intensity electromagnetic radiation.
- All other equipment. For example, some similar digital interference devices, when connected with laryngoscopes, must meet the relevant requirements in the standard specifications (such as IEC 60950 for digital processing equipment, IEC 60601 for electrical equipment). In addition, when other devices are connected to each other and involve the input or output of signals, the structure of other devices must conform to the system structure according to IEC 60601-1. The person responsible for

connecting the equipment must ensure the operability of the system and be responsible for meeting the requirements of the system. If you have any other questions, please consult the local equipment supplier or Coreray Technical Service Center.

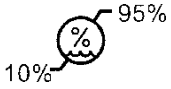
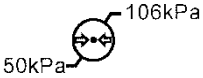
- The maintenance or upgrade of laryngoscope must be carried out by the maintenance personnel trained and authorized by our company.
- Battery replacement by inadequately trained personnel may result in an unacceptable risk.
- Unauthorized personnel are prohibited from modifying device.
- When handling packaging materials, local regulations or hospital waste disposal systems must be complied with. Packaging materials must be placed out of reach of children.
- Coreray is not responsible for any personal injury or property loss caused by the following reasons:
    - Equipment parts are not original parts of Coreray.
    - Loss of manual
    - Responsible for installation, debugging, modification, upgrade and maintenance is performed by non-Coreray authorized personnel.
- Coreray is not responsible for any damage or incident caused by the use of non-Coreray consumables or accessories.

1.1.3 NOTE

NOTE

- Please place this manual near laryngoscope so that it can be consulted conveniently and promptly when necessary.
- This manual describes the product according to the most complete configuration and function. The laryngoscope you purchase may not have some configuration or function.

1.2 Label Marking

MD	Medical device		Direct current
	Caution		CLASS II equipment
	Type BF Applied Part		Use-by date
	Refer to instruction manual	EC REP	Authorized representative in the European
	Do not use if the packaging is damaged		Do not reuse
LOT	Batch code	SN	Serial number
	Manufacturer		Date of manufacture
	Humidity limitation 10%~95%		Atmospheric pressure limitation 50~106kPa
	Temperature limitation -20～60ºC		This way up
	Fragile; handle with care		Keep away from rain
	Waste electrical and electronic equipment must be disposed of in accordance with the local applicable regulations, not with domestic waste.		
CE	This product conforms to the EU Medical Device Regulation 2017/745 and meets the basic requirements of MDR, so it bears the CE mark.		

Chapter 2 Overview

2.1 Product Profile

2.1.1 Intended Use

It can be used to provoke patients' glottis and expose epiglottis, guide medical staff to intubate airway accurately for first aid, and also for oral inspection and treatment.

⚠WARNING

- This product should be used by a professional clinician, medical electrical specialist or a specially trained clinical nurse in a designated occasion. Personnel using this product should receive adequate training. No person without authorization or training shall perform any operation.
- Before using the laryngoscope, the user must check the accessories to ensure that they can work normally and safely.

⚠NOTE

- The operating environment and power supply of this laryngoscope must meet the requirements of Annex A product Specification.

2.1.2 Contraindication

None

2.1.3 Composition and Properties of Products

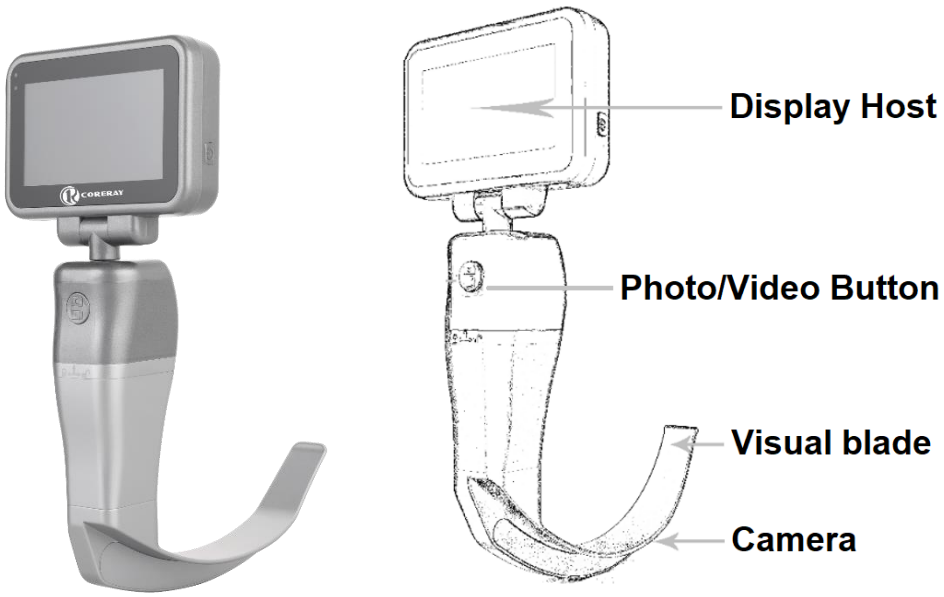
Video Laryngoscope mainly consists of three parts: power adapter, display host and visual blades / visual blade holders.

Video Laryngoscope has the following functions and characteristics:

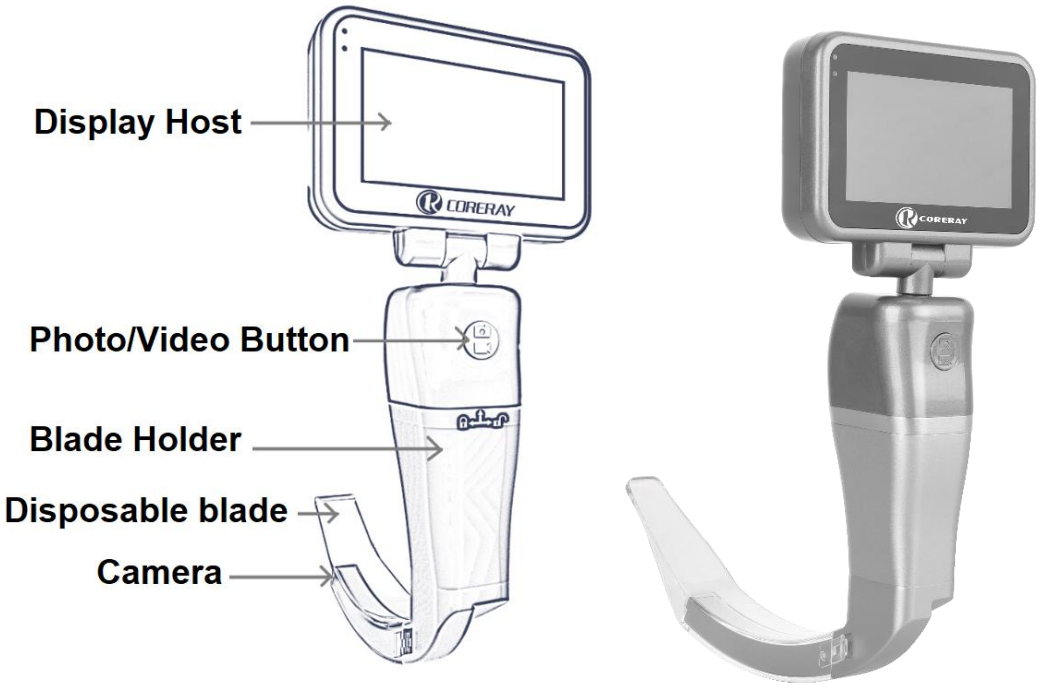
- Compact, portable and integrated LCD color screen;
- Different specifications, with cameras and light sources, can clearly reveal the glottis anatomical structure. Though the visual blades, a high-resolution camera will show the glottis and its physiological structure. The real-time image is transmitted to the LCD screen so that the doctor can clearly observe the entire process of endotracheal intubation or inspect oropharynx.
- The display host is available in 3.0” and 4.5” screen.
- CR-31: There are 11 different types of multiple use of metal blades.
- CR-31D: 2 different sizes of holders which can be used with 6 different sizes of disposable blades (see 5.1).
- CR-31 metal blades and CR-31D metal holders are removable.
- Video Laryngoscope is a portable device (metal blade).

2.2 Product Appearance

2.2.1 Side View of CR-31



2.2.2 Side View of CR-31D



2.2.3 Screen display

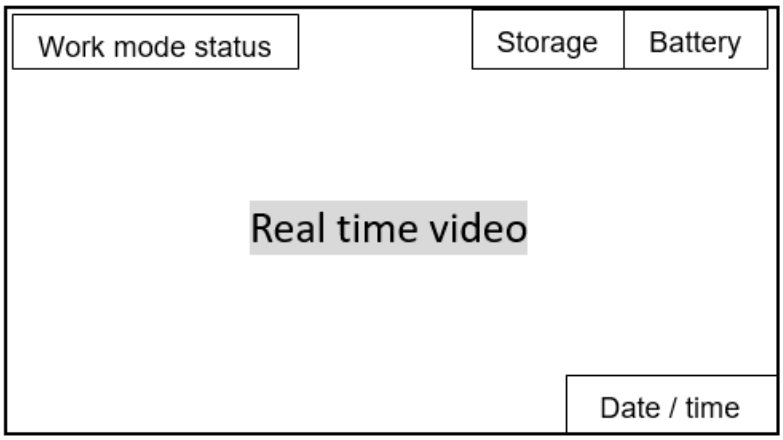


Fig. Screen display diagram of Display host

a) When working normally, the LCD screen displays real-time video in full screen; The icon of battery capacity and SD card are displayed in the upper right corner.

b) When the power is less than 10%, the screen displays Low Battery icon 【 】.

c) When taking photos or videos, the icon of Photo mode【📷】or Video mode【📹】will be displayed in the upper left corner of the screen; The date and time are displayed in the lower left/right corner.

2.2.4 User Interface

3.0” Display Host

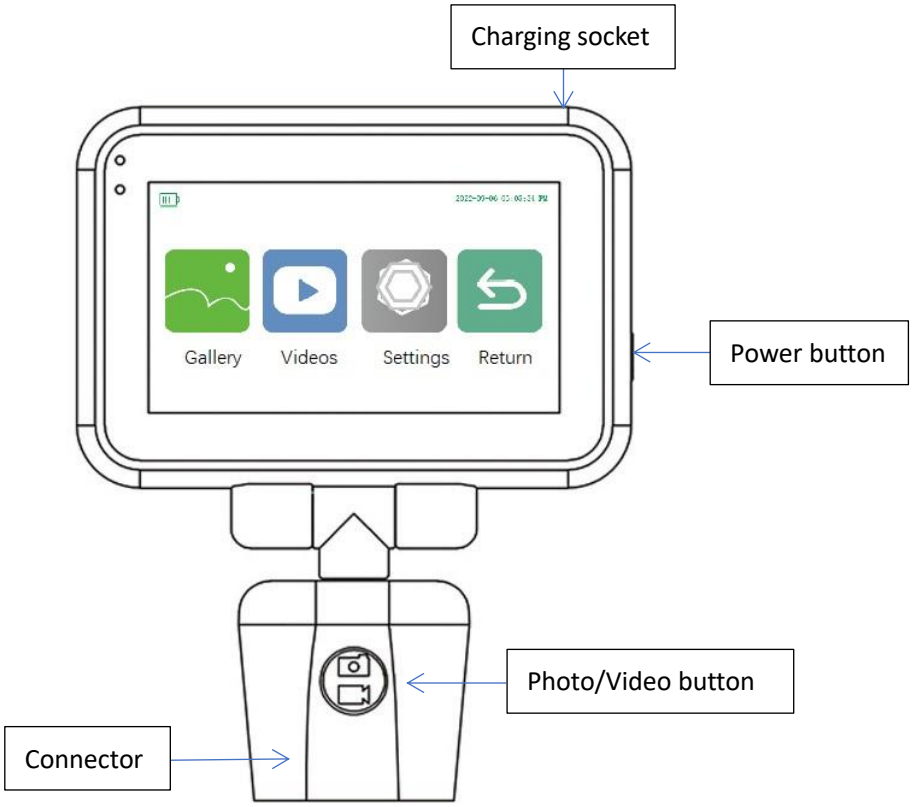


Fig. 3.0” Display host diagram

a) Power button
- Long press for 3 seconds to turn on/off the device.
- Press to enter MENU in PHOTO mode.
- Press to switch selected items.

b) Photo/Video button
- Long press for 3 seconds to switch work mode.
- Press to take a photo in PHOTO mode.
- Press to start / stop to shooting in VIDEO mode.
- Long press for 3 seconds to return to the upper MENU.

c) LCD screen

To display real time video and records.

d) Charging socket

To connect with power adapter for charging.

e) Connector

To connect with visual blade or blade holder.

4.5” Display Host

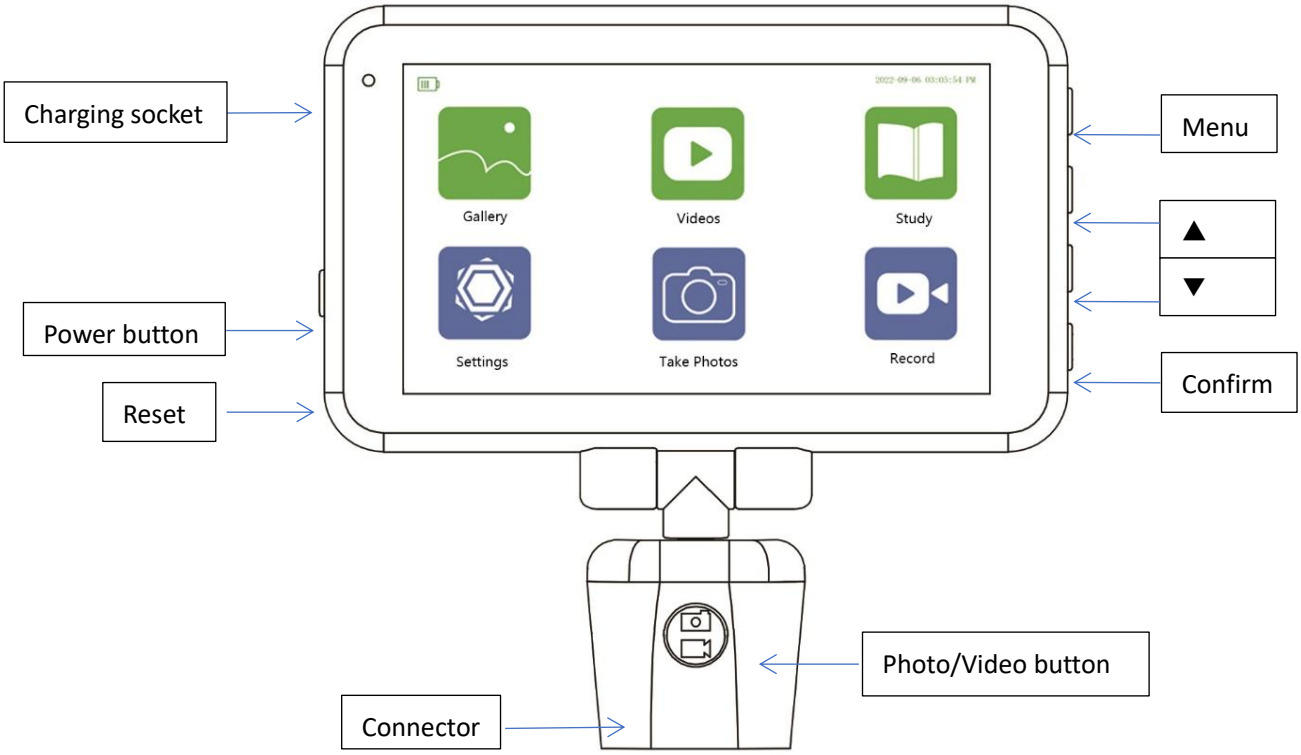


Fig. 4.5” Display host diagram

a) Power button
- Long press for 3 seconds to turn on/off the device.

b) Photo/Video button
- Press to take a photo in PHOTO mode.
- Press to start / stop to shooting in VIDEO mode.

c) ▲ / ▼ button
- Press to switch selected items.

d) Confirm button
- Press to enter selected item.
- Press to confirm current parameter.

f) LCD screen

To display real time video and records, and provide touch control interface.

g) Charging socket

To connect with power adapter for charging.

h) Connector

To connect with visual blade or blade holder.

2.3 Battery

2.3.1 Overview

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

Battery power can only be maintained for a period of time. At least 30 minutes before battery exhaustion triggers a low battery power alarm, during which prompt information is displayed. Trigger battery depletion alarm at least 3 minutes before battery depletion, during which prompt information is displayed and flashed.

NOTE

- When the battery runs out, it needs to be charged for 3.5 hours for 3.0” display host and 4 hours for 4.5” display host before it can be fully charged.
- The working time is over 3.5 hours for 3.0” display host and over 5 hours for 4.5” display host after the battery is fully charged.
- If this product is not used for a long time, please charge and discharge the battery every three months to avoid battery damage.
- Batteries are consumable components and must be replaced when they are depleted.
- If you want to change batteries, please contact the distributor or manufacturer who sells this product to you.
- Replacement of batteries can only be done by the company's technical service engineer!

2.3.2 Battery Use Guidance

The service life of batteries depends on the frequency of use and operating environment. If used and maintained properly, its service life is about 3 years; otherwise, its service life may be shortened. Batteries should be replaced every

three years.

In order to ensure safe operation and prolong battery life as much as possible, please pay attention to the following usage instructions:

- Performance checking of battery should be carried out annually. Performance checking is also required before laryngoscope repair or when you suspect that the battery is the source of the failure.
- The battery should be optimized every 3 months of use (or storage) or when the operating time of laryngoscope is significantly shortened.
- Every half year, the battery is charged with 5V/2A for about 0.5 hours to ensure the live storage of the battery.

⚠WARNING

- Use only batteries specified by the manufacturer.
- If there is any sign of damage or leakage of the battery, please replace it immediately.
- Do not apply damaged batteries to the laryngoscope product.
- Used batteries can be sent back to the distributor or manufacturer who sells the product to you, or can be processed in accordance with applicable laws and regulations.

2.3.3 Battery Maintenance

When first using batteries, they should be optimized. A complete optimization cycle is: Charging continuously until full, then discharging until the laryngoscope shuts down, and then charging continuously until full. During the use of batteries, optimization should be carried out periodically to extend their service life as much as possible.

NOTE

- With the passage of time and the use of batteries, the actual storage capacity of batteries will be reduced. When optimizing, if the battery power supply time is significantly shortened, please replace the battery.

When optimizing, please refer to the following steps:

1. Connect the laryngoscope to the power adapter and charge it continuously for about 5 hours.
2. Disconnect the laryngoscope power adapter and use battery power until the laryngoscope is turned off.
3. Connect the laryngoscope to the power adapter again and charge it continuously for about 5 hours.
4. The battery has been optimized.

NOTE

- If the battery is fully charged and the power supply time is too short, the battery may have been damaged or malfunctioned. The battery power supply time depends on the laryngoscope configuration and frequency of use, such as: long time to display.
- If the battery leaks or the battery capacity is exhausted, it should be replaced and recycled reasonably.

2.3.4 Battery Recycling

When dealing with waste batteries, corresponding regulations should be followed.

⚠WARNING

- Do not disassemble the battery, and/or put it into the fire or short it. Battery burning, explosion and leakage may cause personal injury.

Chapter 3 Installation and Maintenance

3.1 Installation

⚠WARNING

- The software copyright of this laryngoscope belongs to our company. Without permission, no organization or individual may tamper with, copy or exchange it by any means or form.

3.1.1 Open-Case Inspection

Before unpacking, please check the packing box carefully to determine whether the product is damaged during transportation. If any damage is found, please contact the carrier or our company immediately.

If the package is intact, please open it in the correct way, carefully remove laryngoscopes and other components from the packing box, and count them one by one according to the packing list. Check whether there is any mechanical damage to the product and whether the items are complete. If you have any questions, please contact our after-sales service department immediately.

⚠WARNING

- Users should place the packaging materials out of reach of children. When handling packaging materials, please comply with the relevant local regulations or the waste disposal system of hospitals.

NOTE

- Please keep the packing boxes and materials for future transportation or preservation.
- If you open the package and find that some parts are missing, please contact the distributor or manufacturer who sells this product to you as soon as possible.

3.1.2 Environmental requirements

The operating environment of this laryngoscope product should meet the requirements of *Annex A.2 environmental specifications*.

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

When the laryngoscope is transferred from one environment to another, the difference of temperature or humidity may lead to the condensation of the laryngoscope. At this time, the laryngoscope can be activated only after the condensation disappears.

3.1.3 Power Supply Requirements

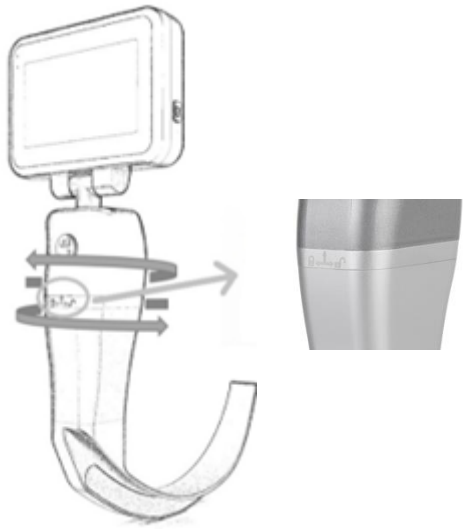
The power supply used in this laryngoscope shall meet the requirements of *Annex A.3 power supply specifications*.

⚠WARNING

- Please ensure that the laryngoscope works under the specified environmental and power requirements, otherwise it will not meet the technical specifications claimed in *Annex A product specifications*, and may lead to unexpected consequences such as laryngoscope failure.
- The appropriate power supply must be selected according to the voltage setting of laryngoscope power supply. Otherwise, it may cause serious damage to laryngoscope.

3.1.4 Installation and Disassembly

Below installation and disassembly diagram is DEVICE disassembly model.



1. For CR-31, Choose appropriate metal blades according to patient and oral size. For CR-31D, choose appropriate metal holders and choose the disposable blades according to patient and oral size.

2. As shown, the visual blade connection point is clipped to the display host handle connection along the arrow direction.

3. As shown, hold the visual blade and the display host in both hands and rotate the lock clockwise.

4. Reverse with Step 3, separates the visual blade from the display host and rotates counter clockwise to separate and pull out the visual blade.

NOTE

- Please properly install or carry the laryngoscope to prevent falling, collision, strong oscillation or other mechanical damage.

3.2 Maintenance

⚠WARNING

- Hospitals or medical institutions using the laryngoscope should establish a sound maintenance plan, otherwise it may cause unexpected consequences such as laryngoscope failure, and may endanger personal safety.
- All safety inspection or maintenance of dismantling laryngoscope shall be carried out by the professional maintenance personnel designated by the company. The operation of non-professional personnel may cause the failure of laryngoscope and may endanger personal safety.
- If laryngoscope abnormality is found, please contact the dealer or manufacturer who sells this product to you.
- Before the equipment reuses, it must be disinfected and cleaned.

3.2.1 Inspection

Before each use of laryngoscope, the user should conduct a comprehensive examination to ensure the normal operation and work of laryngoscope. The inspection items shall include:

- The environment and power supply meet the requirements.
- No mechanical damage to equipment and accessories;
- Performance of battery;
- Use specified accessories;
- Function is normal.

If any damage or abnormal phenomena are found, please temporarily stop using this laryngoscope and contact the distributor or manufacturer who sells this product to you.

3.2.2 Cleaning and Disinfection

We only use the materials and methods listed in this chapter to clean or disinfect laryngoscopes. We do not provide any guarantee for damage or accidents caused by using other materials or methods.

Chemicals or methods listed by our company are used only as means of infection control and are not responsible for their effectiveness. For methods of infection control, consult the infection prevention department or epidemiologist in the hospital.

Please ensure that the laryngoscope is in a dust-free environment. To prevent damage to laryngoscopes, the following requirements must be observed:

- Dilute detergents and disinfectants as required by the manufacturer or use as low a concentration as possible.
- The display host of laryngoscope should not be immersed in liquid.
- The liquid should not be poured on the display host of laryngoscope.
- Liquids should not be allowed to enter the display host of laryngoscope.
- Wearable materials (such as steel wool or silver polishing agent) and solvents such as xylene and acetone should not be used to clean Laryngoscopes in order to avoid damage to the enclosure.

⚠WARNING

- Before cleaning the laryngoscope, the laryngoscope must be turned off and the connection between the charging line and the power adapter must be disconnected.
- In any case, the cleaning and disinfection measures described in the manual cannot replace the rules and regulations for the daily use of equipment.

⚠NOTE

- If the liquid is dumped on the laryngoscope and the laryngoscope cannot work properly, please stop using it temporarily and contact the distributor or manufacturer who sells this product to you immediately.

Recommend surface disinfection methods:

The product is expected to be in contact with patients' oral mucosa and disinfected by terminal users before use, otherwise it is forbidden to use. The cleaning and disinfection methods of the product are as follows:

1. Visual blade / blade holder cleaning and disinfection:

After the laryngoscope was used, use wet gauze/alcohol gauze to wipe off the dirt on the external surface of visual blade / blade holder, and then soak it in 2% glutaraldehyde disinfectant solution for 30 minutes.

2. Display host

After the laryngoscope is used, use wet gauze/alcohol gauze to wipe off the dirt on the external surface of display host, then wipe them with 75% ethanol to disinfect.

⚠NOTE

- High temperature or pressure disinfection is not allowed.
- No high concentration of organic or non-organic acids should be used to disinfect and corrode equipment.
- Chemical substances containing chloral formamide, phenol derivatives and anionic surfactants should not be used. Plastic substances outside the instrument are prone to aging and cracking.
- If a disinfectant containing acetaldehyde and amine is used on the same surface, the surface of the object may fade.

3.2.3 Periodic Maintenance

1) Maintaining battery performance

2) Routine maintenance

Interval time	Routine maintenance procedures
According to hospital policy	Laryngoscope surfaces need to be thoroughly cleaned before or after long storage periods.
Testing is required at least once a year.	1. Detection of power adapter and charging line. 2. Run the laryngoscope until the low battery notice when the battery power is 10% left, and then charge the battery to confirm that the operation and charging are normal.

3) Replacement of fuses

⚠NOTE

- Power adapter with built-in fuse cannot be replaced by itself. If damaged, please contact the distributor or manufacturer who sells this product to you immediately.

3.2.4 Pollution-free treatment and recovery

The service life of this product is about 3 years. Laryngoscopes that exceed their service life should be disposed of as scrap. Please contact the distributor or manufacturer who sells this product to you for more information.

You can do the following:

1. The laryngoscopes that have been discarded can be sent back to the distributor or manufacturer that sells this product for proper recovery.

2. Waste batteries can be sent back to the distributor or manufacturer who sells this product for disposal, or according to the relevant regulations.

Chapter 4 Operational Guidance

4.1 Instructions for use

4.1.1 Instruction for 3.0” Display host

a) Power on/off

Long press Power button for 3 seconds to turn on/off.

b) Work mode switch

- Connect the visual blades / visual blade holders and startup, automatically enter PHOTO mode;
- Long press Photo/Video button for 3 seconds to switch work mode;
- Press Power button to enter MENU, and then long press Photo/Video button for 3 seconds to enter PHOTO mode.

c) Photo taking

In PHOTO mode, press Photo/Video button to take photos, while the icon of PHOTO mode will flash yellow.

d) Video recording

In VIDEO mode, press Photo/Video button to start video recording, while the icon of VIDEO mode will turn yellow; Press Photo/Video button again to end video recording.

e) MENU

Connect the visual blades / visual blade holders and startup, and then press Power button to enter MENU; Or disconnect the blade/holder after device on, automatically enter MENU. Then press Power button to switch menu options.

f) Gallery

- In MENU, select Gallery option and press Photo/Video button to enter.
- Press Power button to browse the next photo;
- Long press Photo/Video button for 3 seconds to return.

g) Videos

- In MENU, select VIDEOS option and press Photo/Video button to enter.
- Press Power button to browse the next video;
- Press Photo/Video button to play/pause the current video.
- Long press Photo/Video button for 3 seconds to return.

h) Language setting

- In MENU, select SETTINGS option and press Photo/Video button to enter.
- Press Power button to select Language Setting option, and press Photo/Video button to enter.
- Press Power button to switch the selected language, and press Photo/Video button to confirm.
- Long press Photo/Video button for 3 seconds to return.

i) Time setting

- In MENU, select SETTINGs option and press Photo/Video button to enter.
- Press Power button to select Time Setting option, and press Photo/Video button to enter.
- Press Power button to modify the selected parameter, then press Photo/Video button to confirm and enter the next.
- Long press Photo/Video button for 3 seconds to return.

4.1.2 Instruction for 4.5” Display host

Method / Operation	Button control	Touch screen
Power on/off	Long press Power button for 3 seconds to turn on/off.	/
Work mode switch	Connect the visual blades / visual blade holders and startup, automatically enter PHOTO mode; Long press Photo/Video button for 3 seconds to switch work mode; Press Menu button to enter MENU.	Click Photo or Video icon to enter related work mode in MENU.
Photo taking	In PHOTO mode, press Photo/Video button to take photos.	/
Video	In VIDEO mode, press Photo/Video	/

recording	button to start video recording; Press Photo/Video button again to end video recording.	
MENU	Press Power button to enter MENU; Or disconnect the visual blades / visual blade holders after device on, automatically enter MENU. Then press Power button to switch menu options.	/
Study	/	In MENU, click Study icon to enter and choose [Operation guide] or [Technical files] to learn.
Gallery	Press ▲ / ▼ button to switch photo, and press Confirm button to open/enlarge the current photo.	In MENU, click Gallery icon to enter, and view photo by click.
Videos	Press ▲ / ▼ button to switch video, and press Confirm button to play/pause the current video.	In MENU, click Videos icon to enter, and view video by click it.
Settings	Press ▲ / ▼ button to switch items or parameters, and press Confirm button to save.	In MENU, click Settings icon to enter, and choose programs by click.

NOTE

- Display Host has a USB socket, which can be connected to PC computer through the equipped USB cable to view and export the pictures or videos taken during the operation.

4.1.3 NFC Connection for 4.5” Display host

NFC module of 4.5” Display host supports connection with Coreray Workstation by wireless communication, which can transmit real-time images and data, to achieve synchronous display and operation.

1) After turn on the device, bring it close to and touch the NFC signal receiving area of Coreray Workstation for pairing.

2) After pairing successfully, Coreray Workstation will give a prompt tone. It will be automatically connected next time.

3) Coreray Workstation displays real-time images synchronously and access to pictures and videos.

4) Turn off the device to disconnect.

4.2 Operational Guide

Video Laryngoscope is used in conjunction with system technology similar as direct laryngoscope. Please consult a professional in tracheal intubation technology before using it on human body. Still photos and videos of respiratory and tracheal intubation programs can be recorded and automatically saved into the SD card in the display host.

- Cleaning: Clean visual blade properly before use (see 4.3). This is for CR-31 only.

- Antifogging: The video lens for visual blades is made of electrically heated material to remove the fog generated in the trachea due to the warm and humid environment of the respiratory tract. Driven by the battery, the LED lamp on the blade starts to illuminate, and the heating element also starts to run. Because of the blade's self-heating, the fog of the lens can be eliminated within 30 seconds after the visual blade and display host are connected.

⚠WARNING

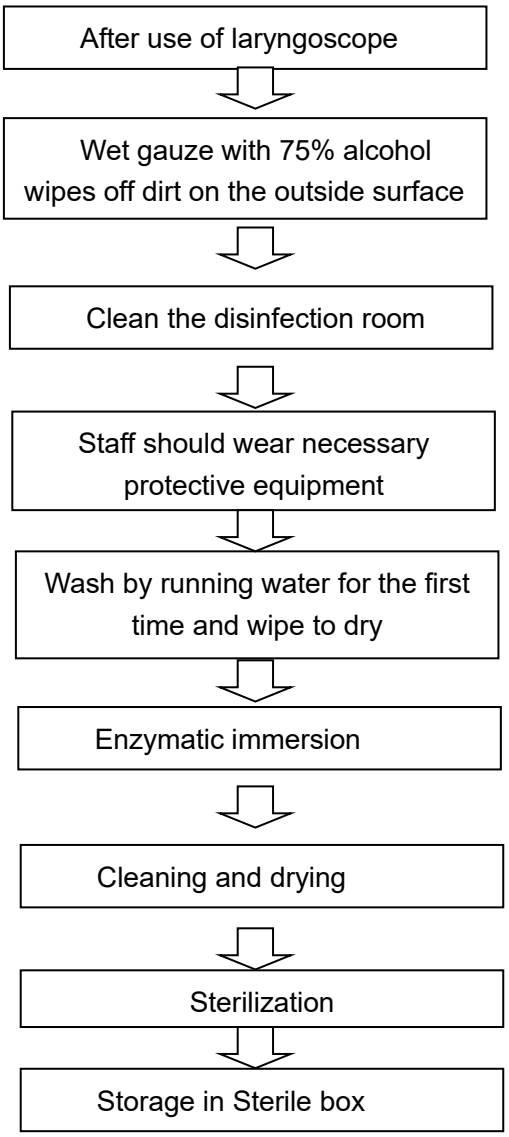
- Before using the laryngoscope, the user must check the accessories to ensure that they can work normally and safely.

4.3 Cleaning / Disinfection / Sterilization

(For CR-31 metal blades and CR-31D metal blade holders, are reused.)

After using the laryngoscope, the medical staff immediately wiped the external surface dirt with 75% alcohol wet gauze, discarded the gauze in the Yellow medical waste bag, and then sent to the cleaning and disinfection room.

The standard cleaning and disinfection process are as follows:



⚠WARNING

- Laryngoscope should be disinfected at one time. Before cleaning, please consult or learn about the cleaning regulations of medical equipment.
- Before cleaning the laryngoscope, the device must be turned off and the connection between the charging line and the power adapter must be disconnected.
- Display host is not waterproof, so avoid submerging them or placing them in excessive liquids.

4.3.1 Washing

a) Rinsing the visual blades / visual blade holders thoroughly under flowing water and rinse them with wet gauze until no stain is found on the naked eye.

b) Brushing the inner surface of the visual blades / visual blade holders thoroughly with a clean brush, and then to dry.

c) The surface of the display host can be wiped with a wet cloth, but it should be carefully cleaned to avoid liquid entry.

d) After cleaning, dry with clean gauze.

e) The gauze should be disposable, and the brush should be disinfected after each use.

4.3.2 Enzymatic Washing

It is used to remove organic substances such as body fluid secretions, to prevent organic substances from affecting the efficacy of disinfectants, and to timely enzymatic washing to avoid protein drying up and difficult to remove.

a) The preparation of multi-enzyme lotion and soaking time are in accordance with its product manual.

b) Place the dried visual blades / visual blade holders in the enzyme wash tank and wipe it with multi-enzyme wash solution.

c) After drying, the visual blades / visual blade holders need to be cleaned in the ultrasonic cleaner for 5-10 minutes.

d) The multi-enzyme lotion should be replaced after each time.

4.3.3 Cleaning

After visual blades / visual blade holders finish enzymatic washing, rinse and dry the external surface of visual blades / visual blade holders with high pressure water gun or sterile gauze.

4.3.4 Disinfection

For CR-31 visual blades / CR-31D visual blade holders

After cleaning and drying, place the reusable visual blades / visual blade holders in the disinfection tank/barrel and immerse them in the disinfectant. It must be re-disinfected before the start of daily diagnosis and treatment.

1) 2% alkaline glutaraldehyde Disinfection

   The disinfection time was controlled by a timer for 30 minutes. Immersion time is not less than 45 minutes using for patients with tuberculosis, other Mycobacterium and other special infections.

2) 0.5%-0.6% phthalaldehyde Disinfection

   The disinfection time was controlled by a timer for 5 minutes. Immersion time is not less than 10 minutes using for patients with tuberculosis, other Mycobacterium and other special infections.

For Display host

The display host must be wiped with clean water and then disinfected with 75% ethanol.

4.3.5 Sterilization

Sterile by low temperature Hydrogen Peroxide Gas Plasma (HPGP)

The HPGP sterilization process shall comply with the requirements of the hospital's relevant procedures. The recommended sterilization parameters of visual blades / visual blade holders are as follows:

- Sterilization time: 45-50 min
- Sterilization temperature: 50±5℃
- Sterilizing agent: 55% to 65% H_2O_2

Sterile by Glutaraldehyde immersion

1) Place the reusable visual blades / visual blade holders in 2% alkaline glutaraldehyde disinfection tank/barrel and immerse them in the disinfectant.
2) Immersion time is not less than 10 hours.
3) Before removed from the disinfection tank, rinsing the disinfectant with sterile water, and then dry them with sterile gauze.

⚠**WARNING**

- The visual blade / blade holder that sterilized by immersing in chemical disinfectant must be thoroughly rinsed with sterile water before use to remove residual disinfectants.

4.3.6 Storage

The disinfected or sterilized laryngoscope is stored in a sealed sterile instrument box.

NOTE

- The above operations are for reference only, and the disinfection effect should be verified by appropriate methods.
- The above operations only aim at the cleaning and disinfection of CR-31 model. CR-31D only needs to wipe the host machine with alcohol with a cleaning cloth.

4.4 Troubleshooting

Video Laryngoscope is generally reliable and simple to operate, requiring minimal maintenance for extended periods. However, the following is offered to help deal with unexpected device conditions:

No.	Trouble Description	Problem Solution
1	Display is non-functional, shows no signal.	1. Recharge the device, and restart. 2. Wipe contact points of visual handle, and restart. 3. If still, directly contact the manufacturer or authorized reseller for maintenance.
2	Camera light is off or blinking.	1. Tighten the visual handle, and restart. 2. Wipe contact points of visual handle, and restart.

		3. If still, directly contact the manufacturer or authorized reseller for maintenance.
3	The device cannot turn on.	1. Recharge the device, and restart. 2. If still, directly contacts the manufacturer or authorized reseller for maintenance.
4	The edge of the screen is yellow.	1. Wipe the camera from dust. 2. If still, directly contacts the manufacturer or authorized reseller for maintenance.
5	The display screen is blue.	1. Change the lighting environment and check the display. 2. If still, directly contacts the manufacturer or authorized reseller for maintenance.
6	The visual handle is loose.	1. Replace a new handle if there is any damage. 2. Wipe contact points if there is any stain. 3. If still, directly contacts the manufacturer or authorized reseller for maintenance.

Chapter 5 Visual Blade

5.1 Reusable Visual Blade of CR-31

CR-31 removable visual blades are made of medical metal, and there are 11 models as follows:

- CR-MIL00: for Premature
- CR-MIL0: for Neonate
- CR-MIL1: for Pediatric
- CR-MIL2: for Small Adult
- CR-MIL3: for Adult
- CR-MIL4: for Large Adult
- CR-MAC1: for Pediatric
- CR-MAC2: for Small Adult
- CR-MAC3: for Adult
- CR-MAC4: for Large Adult
- CR-D-BLADE: for Difficult airway

Blade Model	Length of blade ±3mm	Width of blade ±1mm	Height of blade ±2mm	Angle(θ) ±2°
CR-MIL00	74 mm	12 mm	76 mm	78°
CR-MIL0	84 mm	12 mm	76 mm	80°
CR-MIL1	108 mm	12 mm	76 mm	64°
CR-MIL2	160 mm	13 mm	76 mm	67°
CR-MIL3	200 mm	14 mm	77 mm	67°
CR-MIL4	216 mm	16 mm	78 mm	67°
CR-MAC1	105 mm	23 mm	85 mm	68°
CR-MAC2	122 mm	23 mm	87 mm	62°
CR-MAC3	142 mm	23 mm	92 mm	64°
CR-MAC4	161 mm	23 mm	94 mm	67°
CR-D-BLADE	150 mm	23 mm	104 mm	65°

Remarks: For the reference of professional medical staff.

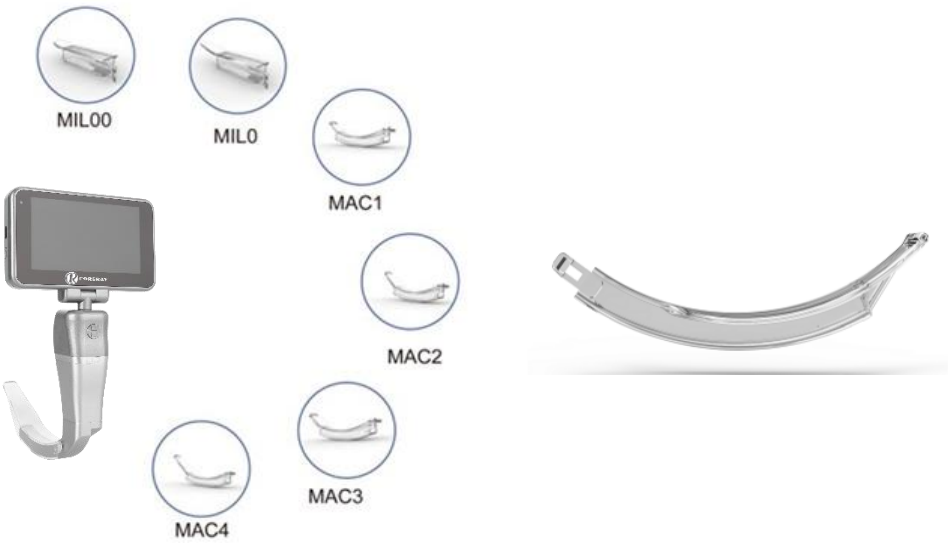
Picture of Reusable Visual Blade

5.2 Disposable Visual Blade of CR-31D

CR-31D disposable visual blades are disposable consumable products, made of medical polymer plastics, and there are 6 models as follows:

Model	Length of blade ±3mm	Width of blade ±1mm	Height of blade ±2mm	Angle(θ) ±2
CR-D-MIL00	47mm	12.5mm	14mm	80°
CR-D-MIL0	55mm	12.5mm	14mm	81°
CR-D-MAC1	94.5mm	23mm	34mm	74°
CR-D-MAC2	101mm	23mm	39mm	75°
CR-D-MAC3	105mm	23mm	43mm	76°
CR-D-MAC4	117.5mm	23mm	51.5mm	67°

Remarks: For the reference of professional medical staff.



Picture of disposable Visual Blade

⚠WARNING

- Use only the accessories specified in this chapter. Use of other accessories may damage the laryngoscope or fail to meet the specifications stated in this specification.
- Disposable accessories can only be used once, and reuse may lead to performance degradation or cross-infection.
- If there is any sign of damage to the package of the accessories or accessories, please stop using the accessories and contact the distributor who sells the products to you or manufacturer as soon as possible.

Annex A. Product Specification

A.1 Safety Specification

A.1.1 According to the type of electric shock protection, it belongs to Class II equipment and power supply equipment with internal power supply.

A.1.2 According to the degree of electric shock prevention, it belongs to type BF applied part.

A.1.3 According to EMC classification, it belongs to Class A equipment.

A.1.4 Rated voltage, frequency and power

Power adapter input: 100-240V～,50/60Hz, 0.5A max

Power adapter output: DC5V,2A

Display host external input: DC5V, 2A

Internal power supply: DC3.7V, Lithium-ion battery

A.1.5 Non-permanent installation equipment

A.1.6 According to the degree of safety in the use of flammable anaesthetic gas mixed with air or in the case of flammable anaesthetic gas mixed with oxygen or nitrous oxide: equipment that cannot be used in the case of flammable anaesthetic gas mixed with air or in the case of flammable anaesthetic gas mixed with oxygen or nitrous oxide.

A.1.7 Classified by operation mode: continuous operation.

A.1.8 According to IEC/CISPR 11:2010, magnetic compatibility belongs to group A.

A.2 Environmental Specification

Parameters	Specifications
working temperature	5～40ºC
Working humidity	20～80％, non-condensing
Working atmospheric pressure	86～106kPa
Storage and transportation temperature	-20～60ºC
Storage and transportation humidity	10～95％, non-condensing

Storage and transportation atmospheric pressure	50～106kPa
Description of storage conditions	Non-corrosive gases and well-ventilated indoors

A.3 Power Supply Specification

Parameters	Specifications
The power adapter	
Input voltage	100-240V～
Input current	0.5A max
Input frequency	50/60Hz
output voltage	DC 5V
Output current	2A
Battery	
Number of batteries	1
Battery type	Lithium-ion battery
Nominal battery voltage	DC3.7V
Nominal battery voltage	2500mAh (3.0” display host) 3500mAh (4.5” display host)

A.4 Hardware Specification

Parameters	Specifications
Complete machine	
Packing dimensions	350mm×260 mm×100mm（L×W×H）
Gross weight	≈2-2.5kg

LCD Display Screen	
type	LCD
size	3.0'' inch / 4.5'' inch
Resolution	640*360P (3.0" display host) 854*480P (4.5" display host)
Aspect ratio	16:9
refresh rate	30FPS
Camera	
Resolution	1280*720P
Aspect ratio	16:9
Storage card	
Storage capacity	16GB, Maximum≤64GB
Indicator light	
amount	2

A.5 Basic Parameters

Parameters	**Specifications**
Display Rotating Angle	Vertical: 0~150º, Horizontal: 0~270°
Working distance	15～70mm
Spatial resolution	≥6.35lp/mm
Angle of view	≥60°
Lighting range	≥Φ30mm, h=30mm
Illuminance of light source	≥1000lx, h=30mm
Special Functions	Photography, Video Recording and Storage
Prompt function	Low battery

A.6 Names and contents of toxic and harmful substances or elements

Component Name	Toxic and harmful substances or elements					
	Pb	Hg	Cd	Cr6+	Polybrominated biphenyls (PBB)	Polybrominated diphenyl ether (PBDE)
Printed Circuit Board Components	○	○	○	○	○	○
Shell	○	○	○	○	○	○
Metal Shell	○	○	○	○	○	○
Display	○	○	○	○	○	○
Battery	○	○	○	○	○	○
Remarks: ○: It means that the content of this toxic and harmful substance in all homogeneous materials of components is below the limit specified in directives RoHS and 2013/56/EU (for battery).						

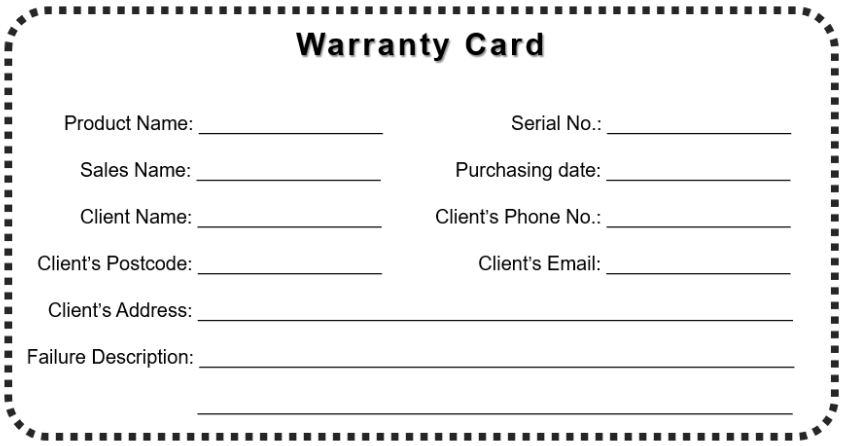
A.7 Packing List

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

No.	Component Name	Amount	Specification	Remark
1	Display Host	1	CR-31 / CR-31D	*
2	Metal Visual blade	/	CR-MIL00 / CR-MIL0 / CR-MIL1 / CR-MIL2 / CR-MIL3 / CR-MIL4 / CR-MAC1 / CR-MAC2/ CR-MAC3 / CR-MAC4/ CR-D-BLADE	The quantity is subject to actual conditions.
3	Metal Visual blade holders	/	CR-MIL / CR-MAC type	The quantity is subject to actual conditions.
4	Waterproof cap	/	White, silicone	The quantity is subject to actual conditions.
5	Power adapter	1	/	*

6	Charging cable	1	/	*
7	Certificate of conformity	1	/	*
8	User manual	1	/	*

Warranty card



Warranty Card

Product Name: _____ Serial No.: _____

Sales Name: _____ Purchasing date: _____

Client Name: _____ Client's Phone No.: _____

Client's Postcode: _____ Client's Email: _____

Client's Address: _____

Failure Description: _____

_____

Annex B. EMC

This product meets the EMC standard IEC 60601-1-2.

NOTE

- The use of unspecified accessories, sensors and cables may increase the electromagnetic emission of the laryngoscope and/or reduce the electromagnetic immunity of the laryngoscope.
- This laryngoscope shall not be used in close proximity or stacking with other devices. When necessary, the laryngoscope should be closely observed to ensure its normal operation under the used configuration.
- The EMC of the laryngoscope needs special protection, and needs to be installed and maintained in an environment that meets the following EMC information.
- Avoid using this laryngoscope and MRI or similar equipment at the same time, otherwise equipment failure or equipment collapse may occur due to electromagnetic interference.
- The laryngoscope product may be disturbed even if other equipment meets the CISPR launch requirements.
- When the input signal amplitude is lower than the minimum specified in the technical specifications, it may lead to inaccurate measurement.
- Portable and mobile RF communication devices can affect the performance of laryngoscopes.

Guidance and manufacturer's declaration – electromagnetic emissions- for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emission		
The ***DEVICE*** is intended for use in the electromagnetic environment specified below. The customer of the user of the ***DEVICE*** should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The ***DEVICE*** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The ***DEVICE*** is suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The ***DEVICE*** is intended for use in the electromagnetic environment specified below. The customer or the user of ***DEVICE*** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	± 0.5 kV, ± 1 kV differential mode line-line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25/30 cycles at 0° 0 % UT (100 % dip in UT) for 250/300 cycle at 0°	0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25/30 cycles at 0° 0 % UT (100 % dip in UT) for 250/300 cycle at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models EVS100 product name requires continued operation during power mains interruptions, it is recommended that the models EVS100 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity –

for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The DEVICE is intended for use in the electromagnetic environment specified below. The customer or the user of DEVICE should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF

IEC 61000-4-3</td><td>3 Vrms
150 kHz to 80 MHz
6 Vrms 150 kHz to 80 MHz in ISM bands[a]

3 V/m
80 MHz to 2.7 GHz</td><td>3 Vrms
150 kHz to 80 MHz
6 Vrms 150 kHz to 80 MHz in ISM bands

3 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the Models DEVICE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz to 800MHz
$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800MHz to 2.7GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). [b]
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each frequency range [d]
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
</table>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EVS100 is used exceeds the applicable RF compliance level above, the EVS100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EVS100.

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

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the *DEVICE*

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

Rated maximum output of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.7
10	3.7	1.11	2.22
100	11.7	3.5	7.0

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

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between RF wireless communications equipment

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

Frequency MHz	Maximum Power W	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum output power rating of the ransmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					
2450	2	0.3	28	28	
5240	0.2	0.3	9	9	
5500					
5785					

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.