Video Laryngoscope for Tracheal Intubation (UED-A series)

Product manual for operation,
maintenance and technical instructions

Zhejiang UE Medical Corp.

m|devices Exclusive Distributor

Thank you for purchasing our products.

This product can be used only by accredited practitioners and medical professionals who have received operation training.

Please read the manual carefully before using the product and keep for future use.

When using the product, please strictly follow the operating instructions and carry out maintenance, which will greatly reduce the occurrence of faults and prolong the service life of the product.

The paragraph marked with " ⚠ " should be carefully read and executed to avoid damage and injury to equipment, operators or patients.

In case of any problem during use, please contact m|devices® and we will provide you with quality service.

Commitment: : we are committed to further provide users with detailed and necessary technical files to deal with malfunction if needed.

This manual describes the ideal procedure for preparation and examination of the instrument before use. It does not specify the procedure for clinical use, nor does it intend to familiarise beginners with laryngoscope technology and medical knowledge.

This instrument should be used by accredited doctors who have mastered tracheal intubation technology and have received operation training.

Since the product is improved continuously, the appearance or specification of the product provided by our company may be different from that stated in this instruction without prior notice.

Registrant/Production/After-sales service: Zhejiang UE Medical Corp.
Location: No. 8, Youyi Road, Baita Economic Development Zone
Xianju, Zhejiang 317300, China
Postcode: 317300 Tel: +86 576-8778879 Fax: +86 576-87721129
E-mail: export@ueworld.com

m|devices®
27 Llewellyn Avenue, Villawood, NSW 2163, Australia
Tel: + 61(0)2 8718 2800
E-mail: info@mdevices.com.au

TABLE OF CONTENTS

⚠ CAUTION

1. This product cannot be used in places where there are fire hazards.
2. This product cannot be used in situations where there is a mixture of inflammable anesthesia gas, air or nitrous oxide.
3. Inside this product, there are special parts and users shall not disassemble or refit this product by themselves.
4. This product can only be charged with the charger provided by our company and cannot be used during charging.
5. The product can only be used together with the Laryngoscope Blades for Single Use produced by Zhejiang UE Medical Corp.
6. This product is a cold light source, prepare a spare laryngoscope for unexpected need.

⚠ SAFETY ADVICE

1. This product must be protected from any external adverse effects such as strong electromagnetic radiation or high temperature.
2. During transportation and use, this product shall be handled with care and prevented from impact, violent vibration and humidity.
3. This product can be repaired only by professionals authorised by m|devices®.
4. This product can only be charged with the charger provided by m|devices®.
5. In case of any failure in this product, please contact the customer service team at m|devices®.

⚠ NOTE

1. Please charge the device before the initial use.
2. Check the device before use to ensure that it is free from rust, indentation, scratch, burrs or protrusions.
3. Do not use excessive force in using the device.
4. The waterproof grade of display parts is IPX3 and the waterproof grade of handle part is IPX7, which shall be noted when cleaning.
5. When out of use for a long time, it shall be charged every 2-3 months.
6. The blade used together is disposable. It is strictly prohibited to re-sterilise and reuse it. After use, it shall be disposed of according to hospital/facility protocols.

CONTRAINDICATIONS

None.

Part 1 Video Laryngoscope

1.1 Intended Purpose

Video Laryngoscope for tracheal intubation is used together with UE laryngoscope blade UED-A for single use with CE mark. It is used for clinically lifting the epiglottis of patients to expose glottis, guiding medical personnel to accurately operate intubation and can also be used for oral diagnosis and treatment.

1.2 Main structure description

The Video Laryngoscope for tracheal intubation consists of display part, handle part (camera, LED light), and charger. The software version released is V1. (See diagram 1).

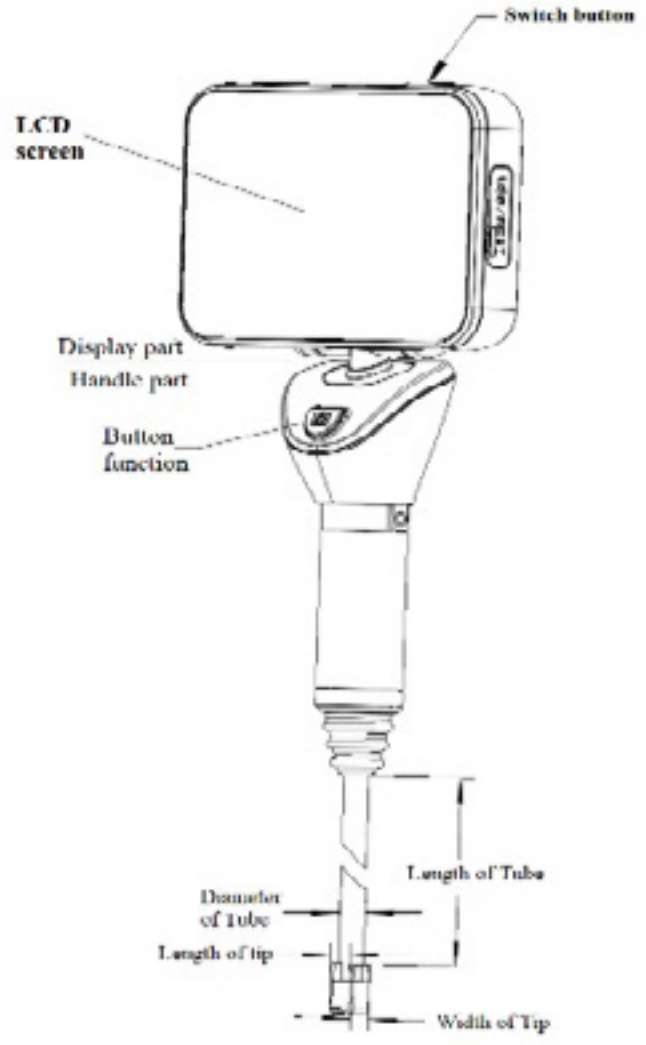


Figure 1

1.3 Model

1. Model and Specification Table (Table 1)

Series	Model and Specification
UED Series Laryngoscope handle	UED-A0 (m|devices® code AN012000) UED-A3 (m|devices® code AN012001)

2. UED Series function (Table 2)

UED Series	The display has touch /Wi-Fi function

A structural design mode of direct insertion ball plunger is adopted for positioning, and the connection is simple and reliable. The excluded patent technology, unique angle and radian at the tip of the laryngoscope blade for single use, maximises the focal definition of the camera, and makes tracheal intubation much easier. The tangent design between the edge of the field of view (FOV) and the tip of camera substantially improves vision.

See below table for compatibility.
Compatibility between the laryngoscope handle and laryngoscope blade for single use.

(Table 3)

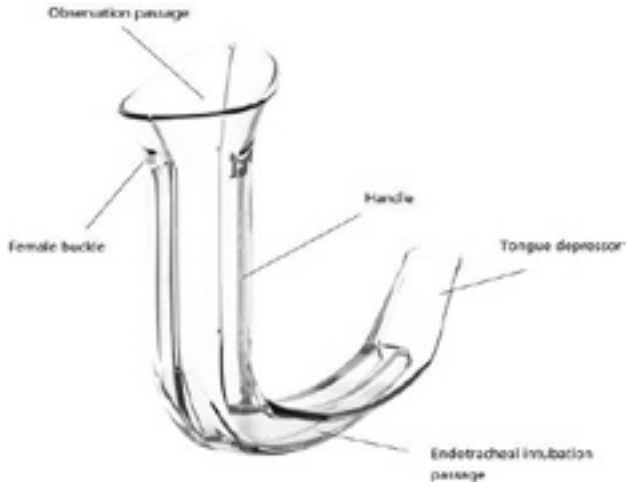
m|devices product code	Models	Compatible handle component	UED-A compatible laryngoscope blade
AN012000	UED-A0	UED-A0 Handle	Laryngoscope Blades for Single Use: UED-A0, UED-A1, UED-MA1
AN012001	UED-A3	UED-A3 Handle	Laryngoscope Blades for Single Use: UED-A2, UED-A3, UED-A4

Part 2 UED-A Single use blade

2.1 Intended Purpose

Video laryngoscope blade for single use, to be used with the video laryngoscope (UED series) is intended to be used by trained and accredited medical personnel to introduce an endotracheal tube for endotracheal intubation for anesthesia and rescue procedures. Designed for single use, it is made of polycarbonate material.

2.2 Structure and components

Compatible handle model	m|devices® blade product code	Blade Model	Structure and Components
UED-A0 (m|devices® product code AN012000)	AN013000	UED-A0	
	AN013001	UED-A1	
	AN013101	UED-MA1	
UED-A3 (m|devices® product code AN012001)	AN013002	UED-A2	
	AN013003	UED-A3	
	AN013004	UED-A4	

2.3 Caution

1. Please check if the package is damaged before use, if it is, please do not use.
2. Open the package and check to ensure the blade is intact and undamaged.
3. The product is for single use only, please dispose of the UED-A blade after use. Repeat use is not allowed
4. The product is sterilised by ethylene oxide and is valid for 3 years after sterilisation.
5. The product shouldn't be used for any purpose that extends beyond its intended uses.

2.4 Instructions for use

1. UED-A laryngoscope blade is only for use with the video laryngoscope (UED series) manufactured by UE Medical.
2. Follow the instruction for use for video laryngoscope as outlined further below in section 3.
3. Tear the primary package, take out the blade maintaining aseptic technique and insert and secure to the UED video laryngoscope handle component.
4. Once the endotracheal intubation has been completed, disconnect the blade from video laryngoscope after use and discard as per facility protocols.

2.5 Symbols and indications

Symbol	Indication	Symbol	Indication
EU REP	Authorised representative in the European Community		Consult instructions for use
	Single sterile barrier system Sterilised using ethylene oxide		Keep away from sunlight
	Do not re-use		Keep dry
	Do not use if package is damaged	-40°C +55°C	Temperature limit -40°C - 55 °C
LOT	Batch Code	%	Humidity limitation 93%
	Date of manufacture		Do not re-sterilise
	Use-by date		Caution
	Manufacturer		Consult instructions for use
	Fragile, handle with care		Stack limit by number
MD	Medical device		This Way UP
UDI	UDI Unique Device Identifier		

2.6 Date of manufacture and service life

Date of manufacture: See date of manufacture on labelling

Use-by date: See use-by date on labelling

Sterility: 3 years

Part 3 Video Laryngoscope

3.1 Basic performance index

Classification by the type of electric shock protection: internal power supply.
Classification by the degree of electric shock protection: Type-BF Applied Part.
Classification by the operation mode: intermittent operation (180 min ON, 30 min OFF).
Equipment application part: laryngoscope blade for single use.
Classification according to the degree of safety in using flammable anesthetic gas mixed with air or mixed with oxygen or nitrous oxide: non-AP/AGP type equipment.
The device is a portable and handheld device.

(Table 4) Product performance parameter table

Performance	Technical indicators
Resolution	≥7.87lp/mm
Angle of vision	60°±15%
Illuminance	≥150Lux
Front and back rotation angle of display	0° - 110°(±10%)
Left and right rotation angle of display	0° - 270° (±10%)
Storage space	≥32GB
Data interface	Standard USB 2.0 Interface Standard Wi-Fi interface, the interface protocol is IEEE 802.11n
User access control	Copy photos/videos after USB connection
Wi-Fi transmission requirements	UED series have Wi-Fi transmission function

(Table 5) Charger related information

Charger input	100~240VAC 50~60Hz
Charger output	5V 1.2A
Charging time	<3 hours
Input power	0.3A

(Table 6) Other function information

Standby time	>3.5h
Display	3″TFT
Photo format	JPG
Video file format	MOV

(Table 7) Environmental requirements

Work environment	Temperature	5°C~40°C
	Humidity	10%~90%
	Atmospheric pressure	860hPa~1060hPa
Transportation and storage environment	Temperature	-40°C~+55°C
	Humidity	≤93%
	Atmospheric pressure	500hPa~1060hPa

3.2 Display function description

Button	Position	Function	Application Description
	Bottom left corner of LCD	Main Menu Button	Click to enter the main menu interface
	Top right corner of LCD	Main menu: video playback button	Click to enter the video playback function interface
	Top left corner of LCD	Main menu: photo viewing button	Click to enter the photo viewing function interface
	Bottom right corner of LCD	Main Menu: System Setup button	Click to enter the system setting function interface
	Bottom left corner of LCD	Main menu: Return button	Click to exit the main menu

3.3 Instruction for use

Switch button: Hold the switch button for 1-3 seconds to boot the device and repeat the procedure to shut it down.
Picture capturing: Press the photo and video button briefly and the photo symbol will flash on the upper left corner of the screen to indicate that a picture has been taken. The picture format is JPG and the pixel is 1088*720.
Video recording: Hold the photo and video button for 1-2 seconds, the video recording symbol will appear with a flashing red dot on the upper left corner of the screen. It starts timing on the upper right corner of the screen, indicating that it is recording. Double press the button to exit recording. The file format is AVI and the pixel is 1088*720.
Main menu button: After starting up, click the main menu button to enter the main menu interface.
Photo viewing button: In the main menu interface, click this button to enter the photo playback interface.
Video viewing button: In the main menu interface, click this button to enter the video playback interface.
System setting button: In the main menu interface, click this icon to enter the system setting interface.
Return button: In the main menu interface, click this button to exit the main menu interface.

Data transmission

1. Use the supplied data cable, connect one end of the cable to the charging interface of the display and the other end to the USB interface of the computer, long press the switch button to start the display. After connecting to the computer, the display of the laryngoscope will get dark automatically. If the computer is connected to the laryngoscope for the first time, a USB driver will be installed automatically. After the connection is completed, click the "removable disk" in the computer for data processing.
2. Enter the Wi-Fi module on touch menu to turn on the Wi-Fi, search the UE display's Wi-Fi on app of device. After the connection between the device and the UE display is completed, photo taking or video recording can be synchronously controlled on the app, meanwhile the photo and video files in the UE display can be viewed as well.
3. Use the supplied high-definition connection cable to connect one end to the aviation plug of the handle part and the other end to the UE portable display. After the connection with the UE portable display has been achieved, enter the "UE Visual System" APP of the display terminal for photo and video operation.
4. The device has 32G storage. It can take at least 400,000 photos or record for over 16 hours. Once the storage card is full, it needs to be manually deleted by connecting to a computer.

Working state: During the normal operation, the light is green and it will be red when the power is insufficient. The battery symbol in the upper left corner of the screen will also indicate the power level.

Charging: It is highly recommended to fully charge the device before the first operation, using provided charger and charging cable. Please shut down when charging. The indicator light of the display flashes green when charging and the green light is stable when fully charged. The battery can be charged > 300 times.

3.4 Operating instructions

1. Hold the video laryngoscope handle component in one hand and hold the display part in the other hand. Position the handle component so you can see the blue button facing towards you, connect the display with the handle and secure in place (the positioning ball will make a slight sound once connected).
To apply the laryngoscope blade over the handle part of the video laryngoscope: peel open the packaging of the laryngoscope blade to reveal the opening of the blade cover. Holding the laryngoscope handle with the display facing towards you, feed the laryngoscope handle (camera/LED light) into the blade (you will notice that the blade opening has a shorter front and a longer back), the shorter opening should face towards you.
If you have the blade facing the other way, you won't be able to securely connect the blade to the laryngoscope handle. In this case, remove the laryngoscope handle from the blade and rotate the blade so the shorter side opening faces towards you. There are locking studs on the handle that lock in place with corresponding indents on the laryngoscope blade once correctly connected. To turn on the display, press the power button on the top right of the display screen for 1-2 seconds and the power indicator lights up and the display shows the scene taken by the HD camera.

2. The operation method of video laryngoscope is basically the same as that of direct laryngoscope. The patient takes the supine position, the operator uses the right index finger to pull the patient's upper incisor to stretch the atlanto-occipital joint, the right middle finger to push the chin downward to open the mouth of the patient and the left hand to hold the video laryngoscope to insert the blade into the patient's mouth along the middle position of the tongue. Slowly slide the laryngoscope blade downwards into the pharynx along the oral cavity and pharynx. Then the tongue root, uvula and epiglottis can be seen in sequence on the display.

3. Place the front tip of the laryngoscope blade in the epiglottic vallecula and gently lift the video laryngoscope to expose the glottis on the display. If the glottis is not well exposed, it is recommended to lift the lower jaw for assistance.

4. After the glottis is clearly revealed, insert the endotracheal tube into the mouth of the patient from the right side of the laryngoscope blade. Once the front tip of the endotracheal tube enters the vision field of the front tip of the laryngoscope blade, then the relationship between the front tip of the endotracheal tube and the glottis can be clearly viewed on the display. Align the front tip of endotracheal tube with glottis and slightly enter the subglottic region. The operator continues to push downwards the endotracheal tube under the monitoring of the display.

5. After inserting the endotracheal tube to the desired depth (about 1cm below the glottis), the operator fixes the endotracheal tube with his right hand and withdraws the blade from the mouth with the left hand. Check the relationship between the scale mark on the surface of the endotracheal tube and the incisor, to further confirm the insertion depth of the endotracheal tube. Then inflate the endotracheal tube cuff as clinically required and connect it with the ventilator to control breathing.

6. After use, hold the video laryngoscope handle part with one hand and pull out the display part with the other hand. Then clean and disinfect the display **(instructions are in section 4.3).** Take the laryngoscope blade for single use out of the handle part. The handle part shall be cleaned and disinfected according to facility protocols and infection control guidelines. The laryngoscope blade for single use shall be disposed of.

Part 4

4.1 Factors affecting the use

1. Not reading the operation guide carefully.
2. Low ambient temperature or strong sunlight outdoor environment.
3. Curvature of the front tip of the endotracheal tube with intubation stylet.
4. Inadequate lubrication of the laryngoscope blade for single use.
5. Improper placement of the laryngoscope blade for single use.

⚠ 4.2 Notes on clinical uses

As the operation techniques of the video laryngoscope are basically the same as that of the ordinary direct laryngoscope, accredited clinicians who can skillfully use the ordinary direct laryngoscope will be able to freely use the video laryngoscope after reading the product instructions in detail, without additional training. However, special attention should be paid to the following factors that may affect the use of the video laryngoscope for endotracheal intubation.

1. Strong sunlight will reduce the display of LCD on airway structure and endotracheal intubation operation. It is not recommended to be used in an outdoor environment with strong sunlight.

2. If a stylet is used, it should bear certain elasticity and rigidity and the front tip of the endotracheal tube with the stylet should be molded to an angle of about 60º to ensure that the front tip of the endotracheal tube can correctly face the glottis and successful tracheal intubation can be achieved.

3. Although a proper amount of lubricant is required to lubricate the ventral side of the laryngoscope blade before each use, it is not appropriate to apply too much lubricant. The laryngoscope blade might be difficult to place in the oral cavity due to excessive lubrication.

4. Withdraw the laryngoscope from the oral cavity if there is fog on the protective cover at the front tip of the laryngoscope blade for single use due to cough and spontaneous breathing of the patient, or if the front tip of the laryngoscope blade for single use is contaminated by a large amount of blood or secretions in the oral cavity. Perform tracheal intubation after removing the fog or debris with a lint free cloth/wipe.

5. The laryngoscope blade is inserted overly deep. If the laryngoscope blade is inserted into the throat too deep, the whole laryngeal may be lifted, so what is revealed is the gullet opening rather than the glottis opening. In the course of tracheal intubation, slide the video laryngoscope slowly along the center line of the oral cavity and the root of tongue, palate and epiglottis can be clearly seen.

6. In women with barrel chest, obesity, large breasts or patients with a chin-chest scar adhesion, it may be difficult to insert the video laryngoscope into the oral cavity because the anterior chest wall of the patient may hinder the movement of the handle part and the display. For these patients, the video laryngoscope can obtain a larger operation space by further stretching the atlanto-occipital joint and reclining the patient's head. By rotating the video laryngoscope 90 degrees to the right, the laryngoscope blade can be smoothly inserted into the oral cavity of the patient. Then the interference of the anterior chest wall on the operation of the video laryngoscope can be avoided.

7. If it is difficult to push down the endotracheal tube after withdrawing from the stylet, the force of lifting the laryngoscope should be reduced to return the patient's head to the neutral state and then gently guide down the endotracheal tube.

4.3 Maintenance, cleaning, and disinfection

Component Risk Classification

Equipment parts	Packaging situation	Usage mode	Spaulding classification	Disinfection level		Sterilisation
				Low	High	
Display	Non-sterile	Reuse	Non-critical items	O	X	X
Data cable	Non-sterile	Reuse	Non-critical items	X	X	X
Connecting cable	Non-sterile	Reuse	Non-critical items	X	X	X
Handle part	Non-sterile	Reuse	Non-critical items	√	O	X

Note:

X Indicates that there is no requirement for disinfection/sterilisation level or the level is not applicable to equipment.

√ Indicates the minimum disinfection level requirement.

O Indicates the allowable disinfection or sterilisation level (based on the compatibility with equipment materials).

- When used abiding by instruction, the handle part is a non-sterile, reusable device. It works with a video laryngoscope blade for single use (sterile disposable device) to avoid direct contact with mucous membrane and broken skin. It is recommended to disinfect the video laryngoscope handle part at a low level after every time use. If the handle part gets obviously contaminated, a high level of disinfection is required.

Note: Facility protocol for infection control guidelines and reprocessing policies for the reusable instruments/devices and frequency of high-level disinfection, must take precedence over these guidelines. These are recommendations only.

4.4 Cleaning, disinfection or sterilisation procedures

1. After use, separate the video laryngoscope handle part from the display part.
2. Cleaning and disinfection of the display part and HD cable:

Type of disinfectant	Disinfection level	Condition and cycle
Ethanol	Low	Thoroughly wipe clean with a 75% alcohol impregnated wipe (Isopropyl alcohol) for up to 1 minute, allow to dry. Up to 3000 cycles.

Note: the highest cycle represents the number of compatible cycles for the tested part. Exceeding the recommended number of cycles may reduce the service life of the product.

3. Please refer to the below recommended methods for cleaning and disinfection of the handle component only:

Type of disinfectant	Disinfection level	Condition and cycle
Ethanol	Low	Thoroughly wipe clean with an alcohol impregnated wipe (70% Isopropyl alcohol) for up to 1 minute, allow to dry. Up to 3000 cycles.
Enzyme Cleaner	High	According to the chemical manufacturer's instructions.
Glutaraldehyde	High	Soak in 2% neutral glutaraldehyde disinfectant for 20 minutes, up to 3000 cycles or follow the instructions of the chemical manufacturer.
Phthalaldehyde	High	Soak in 0.5%-0.6% o-phthalaldehyde disinfectant for more than 5 minutes, up to 3000 cycles or according to the instructions of chemical manufac-turers.
Hydrogen Peroxide	High	Soak in 1% peracetic acid disinfectant for 30 minutes for up to 500 cycles, or follow the instructions of the chemical manufacturer.

Note:

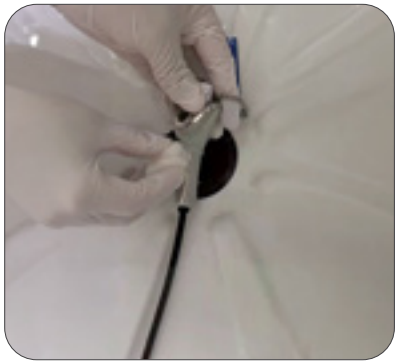
- The highest cycle refers to the number of compatible cycles tested on the component. Exceeding the recommended number of cycles may affect the service life of the product.
- The above disinfectants and corresponding conditions refer to technical specifications for disinfection in China (Edition: 2009). If the corresponding areas are not applicable, please refer to the local guidance or follow the instructions of the chemical manufacturer.
- If the concentration or disinfection time exceeds that of the above table, it may affect the effective service life of the product.

⚠ The waterproof grade of the display parts is IPX3. Immersion disinfection is strictly prohibited.

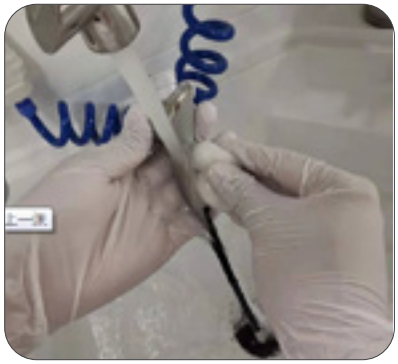
4. Instructional steps for the cleaning and disinfection of the handle component:

The video laryngoscope handle part is a non-sterile, reusable device. It works with a video laryngoscope blade for single use (sterile disposable device) to avoid direct contact with mucous membrane and broken skin. It is recommended to disinfect the handle part at a low level after every time use. If the handle part gets obviously contaminated, a high level of disinfection is required.

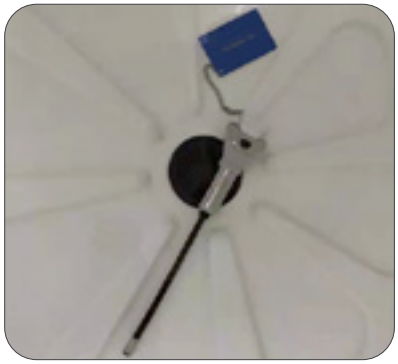
A) Remove the laryngoscope blade for single use from the handle part after use and install the disinfection cap on the handle component. Ensure the cap is secure.



B) Use a medical-grade enzyme cleaner to manually clean the handle component to ensure that all foreign matters, such as debris or organic matters on the surface are removed. To prevent scratches, use a lint free cloth/wipe to clean the area around the camera window. Allow the handle to soak in the enzymatic cleaning solution as per the chemical manufacturers instructions and/or the facilities infection control policies and practices for reprocessing medical equipment.

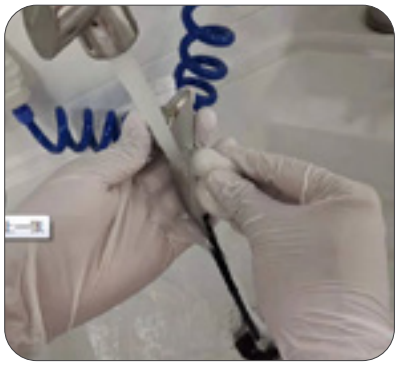


C) Rinse the handle part with clean running water. (purified water or sterile water) to remove the medical-grade enzyme cleaner and residue. The handle component is now ready for high level disinfection (if determined).



D) When cleaning the handle component, do not use hard objects which could scratch the camera protection cover and subsequently reduce the image quality.

E) High level disinfection soaking- Immerse the handle part in the selected disinfectant solution. The soaking time shall be based on the instructions of the chemical manufacturer.



F) Final rinse of the handle component under running water (purified water or sterile water) to remove excess disinfectant solution.

G) Drying -After removing the handle, wipe it dry with a lint-free cloth and blow dry with an air gun. Store the handle component in a aseptic pouch (do not store it in the manufacturer's original packaging box to prevent cross infection).

5. Maintenance

The equipment should be charged to 50%~80% if it is not used for a long period of time and it should be charged every 3 months, in order to avoid the irreversible capacity loss caused by exceedingly insufficient electricity of battery for a long period of time.

The connecting base on the display shall be cleaned with a lint free cloth/wipe at least once every 3 days to prevent plug holes from becoming blocked which can lead to poor equipment contact.

The camera at the tip of the handle component should be cleaned with a lint free cloth/wipe every 3 days to prevent foreign matter (dust) coming in contact with the camera cover. This will prevent image quality issues.

Part 5

5.1 Storage and transportation

Keep the device clean and away from extreme temperature variations during transportation.
It should be stored in a well-ventilated room.

5.2 Troubleshooting (Table 5)

Problem	Possible Cause	Recommended Action
Unclear Images	The camera is contaminated	Clean the camera
Unable to boot	Battery off	Charging
No Image After turn on	Poor connection between display and handle part	Clean the pins at the connection area between the display and the handle part and reboot the machine

5.3 Product recovery

Laryngoscopes and accessories in their late service life: Non-degradable.

Recommendation: Dispose of end-of-life laryngoscopes and accessories, including lithium batteries and electronic components, in accordance with all applicable government regulations for electronic waste and battery disposal. For on loan electronic devices please organise pick up through m|devices® Customer Service.

5.4 Warranty period

The electronic device is warranted against defects in materials and workmanship for a period of one (1) year from the date of delivery, in accordance with industry standards for medical devices. Warranty coverage is subject to the terms and conditions outlined in this manual and excludes damage resulting from misuse, unauthorised modifications, or improper maintenance.

Note: For the infection control management and safety of maintenance personnel, the devices shall be cleaned and disinfected by high-level disinfection operation before being delivered to m|devices for maintenance or repair.

5.5 Date of manufacture and service life

Date of manufacture: See the label for details

Service life: 6 years or 3000 disinfection cycles of glutaraldehyde.

Date of Compilation (Revision) of Instruction Manual: 30 October 2025.

5.6 Customer service

m|devices® Exclusive Distributor

27 Llewellyn Avenue, Villawood, NSW 2163, Australia
Tel: + 61(0)2 8718 2800
E-mail: info@mdevices.com.au

Zhejiang UE Medical Corp.

No. 8, Youyi Road, Baita Economic Development Zone, Xianju, Zhejiang, China

Tel: 0576-87788798 Fax: 057687721129

Email: export@ueworld.com Zip code: 317300

5.7 Symbol index (Table 6)

Symbol	Indication	Symbol	Indication
CE	CE marking of conformity		Use-by Date
	TYPE BF APPLIED PART		Electric quantity indication
	Switch button		Low power
	Photo taking		Direct current
	Caution		Consult instructions for use
	Waste electrical and electronic equipment shall be treated separately (please observe local laws and regulations)		Atmospheric pressure limitation
			Temperature limit
			Humidity limitation
	Non-ionizing electromagnetic radiation		Do not use if package is damaged
	Manufacturer	SN	Serial number
EU REP	Authorised representative in the European Community	MD	Medical device
#	Product model		Date of manufacture
	Unique device identifier		

5.8 Packing list

Video laryngoscope for tracheal intubation accessories	Replacement time
Disinfection cap x1, Charger x1, Data cable x1, HD connection cable x1, Main unit	6 years
Laryngoscope blade for single use (optional)	Subject to registration information
Packing list *1, warranty card *1, certificate *1, instruction manual *1	/

Appendix: Electromagnetic compatibility

Basic performance of products (Table 7)

Mode	Specific description
Image orientation	If the operator is observing an image with unexpected image orientation, ensure that there is no unacceptable risk.
Image Observation	The operator observes real-time images rather than video recordings and ensure that there is no unacceptable risk during laryngoscopy operation

For this equipment, special precautions on electromagnetic compatibility (EMC) shall be taken and it must be installed and used according to the EMC information specified in this manual. Portable and mobile RF communication equipment may affect this equipment.

Cables to be used to meet the Requirements of Electromagnetic Emission and Anti-interference (Table 8)

Cable	Length
USB cable	1.4 m

In addition to cables (transducers) sold as spare parts for internal components, the use of accessories and cables (transducers) other than those specified may result in increased emission or reduced immunity of the equipment or system.
The equipment or system should not be used close to or stacked with other equipment. If it must be used close to or stacked, it should be observed and verified that it can operate normally under its used configuration.

Guidance and Manufacturer's Statement - Electromagnetic Emission (Table 9)

Guidance and Manufacturer's Declaration – Electromagnetic Emission		
The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should ensure that it is used in this electromagnetic environment.		
Immunity Test	**IEC 60601-1-2 Test Level**	**Electromagnetic Environment - Guidance**
Radiated Emission CISPR11:2016	Group 1	The product 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
Radiated Emission CISPR11:2016	Class A	The video laryngoscope is suitable for use in non-domestic and all facilities that are not directly connected to the public low-voltage power supply network of domestic houses.
Harmonic Emission IEC61000-3-2(ed 5.0):2018	Not applicable	
Fluctuation/Flicker Emission IEC61000-3-3(ed 3.1):2017	Not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Table 10)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should ensure that it is used in this electromagnetic environment.			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge IEC61000-4-2:2008	±6 kV contact ± 8 kV air	±6 kV contact ± 8 kV air	The ground shall be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity shall be least 30%.
Electrical Fast Transient Burst IEC61000-4-4:2012	±2 kV for mains supply lines ±1 kV for input / output lines	±2 kV for mains supply lines Not applicable	The network power supply shall have the quality used in a typical commercial or hospital environment.
Surge IEC61000-4-5:2017	±1kV line(s) to line(s) ±2kV line(s) to earth	±1kV line(s) to line(s) Not applicable	The network power supply shall have the quality used in a typical commercial or hospital environment.
Voltage dips and interruption IEC61000-4-1:2017	<5% Ut (>95%dip in Ut) for 0.5 cycle 40% Ut (100% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles 5% Ut (>95% dip in Ut) for 5 sec.	<5% Ut (>95%dip in Ut) for 0.5 cycle 40% Ut (100% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles 5% Ut (>95% dip in Ut) for 5 sec.	The network power supply shall have the quality used in a typical commercial or hospital environment. If the user of the monitor needs to operate continuously during a power interruption, it is recommended to use an uninterruptible power supply or battery power supply for the product.
Power Frequency Magnetic Field (50Hz/60Hz) IEC61000-4-8:2009	3 A/m	3 A/m	The power frequency magnetic field shall have the horizontal characteristics of power frequency magnetic field in typical places in a typical commercial or hospital environment.
NOTE: U_T refers to the voltage of the AC network before the implementation and test of voltage.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Table 11)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should ensure that it is used in this electromagnetic environment.			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted susceptibility IEC61000-4-6:2013 Radiated susceptibility IEC61000-4-3:2010	3 V RMS 150 kHz – 80 MHz 3V/m 80MHz-2.5GHz	3V/m	Portable and mobile RF communications equipment should be used no closer to any part of The product, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz-800MHz $d = 2.3\sqrt{P}$ 800MHz-2.5GHz 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 meters (m). The field strength of the fixed transmitter is determined by surveying the electromagnetic site[a], and in each frequency range[b] should be lower than the compliance level. Interference may occur near equipment marked with the following symbols. 
NOTE 1 At 80 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) Field strengths from fixed transmitters, such as base stations for radio (celluar/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 shall be considered. If the measured field strength in the location in which the product is used exceeds the applicable RF compliance level above, the product shall be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the product. **b)** Over the frequency range 150 kHz to 80 MHz, field strengths shall be less than 3 V/m.			

Recommended Separation Distances Between Portable and Mobile RF Communication Equipment and the device (Table 12)

Recommended Separation Distances Between Portable and Mobile RF Communication Equipment and the device			
The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters and the product as recommended below, according to the maximum output power of the communication equipment.			
Rated maximum output power (W) of transmitter	**Isolation distance corresponding to different frequencies of transmitter (m)**		
	150kHz-80MHz **d= 1.2** $\sqrt{P}$	**80MHz-800MHz** **d= 1.2** $\sqrt{P}$	**800MHz-2.5GHz** **d= 2.3** $\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (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.			

Zhejiang UE Medical Corp.
No. 8, Youyi Road, Baita Economic Development Zone, Xianju, Zhejiang, China
Tel: 0576-87788798 Fax: 057687721129
Email: export@ueworld.com Zip code: 317300

27 Llewellyn Avenue, Villawood, NSW 2163, Australia
Tel: + 61(0)2 8718 2800
E-mail: info@mdevices.com.au