Video Laryngoscope blade for Single Use (UED-D 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 certified doctors and medically trained professionals.

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

Please abide by the operation procedure strictly for correct maintenance when using this product, 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 performed to avoid damage 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 user with detailed and necessary technical files to deal with malfunction if needed.

⚠ This manual describes the ideal procedure required 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 device should be used by accredited clinicians who have mastered tracheal intubation technology and have been trained for procedure.

⚠ Since the product is improved continuously, the appearance or specifications of the products provided by our company may be different from this manual without prior notice.

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⚠ WARNING

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. As special units inside the product, any disassembly or refit to the product by user is prohibited.
4. This product is used with UE display (UED-M3-S series) and cannot be used during charging.
5. As for cold light source used in operation, please prepare a standby laryngoscope for unexpected needs during operation.
6. Directly shining the light on the front end of the laryngoscope into the eyes of patients or other people is prohibited.
7. This product is disposable and non-waterproof. It should be disposed of after use. Please do not disinfect and reuse it.
8. Heat dissipation from the light-emitting part may raise the temperature of the camera of the device to over 41°C. Prolonged contact between the device and mucosa is prohibited, as it may cause mucosa injury.

⚠ 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. In case of any failure in this product, please contact the customer service department at m|devices® as soon as possible.

⚠ PRECAUTIONS

1. Check the product before use to ensure that it is free from rust, indentation, scratch, burrs or protrusions.
2. Do not use excessive force in using the product.

CONTRAINDICATIONS

None.

Part 1.

1.1 Intended purpose

The video laryngoscope for single use, intended to work with the UE Display, can be used by accredited clinicians to lift the epiglottis, expose the glottis and then perform accurate tracheal intubation. It can also be used to provide images for oral diagnosis and treatment.

1.2 Main structure description

The video laryngoscope for single use consists of a camera and a shell and needs to be used together with the UED display. The laryngoscope blade is packaged in a sterile paper-plastic pouch and is disposable.
The material is acrylonitrile-butadiene-styrene (ABS). The structure is as shown in Figure 1.

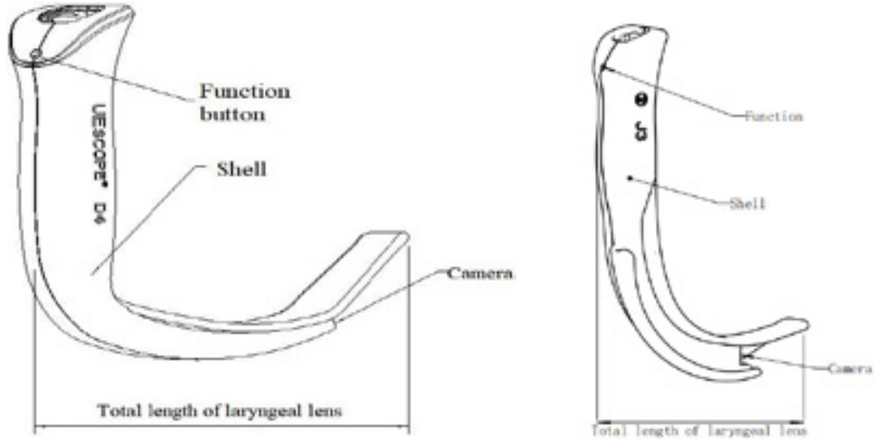

Figure 1 Structure

1.3 Model

Model and Specification Table **(Table 1)**

Model	m|devices® Product Code	Total length of blade	Remarks
UED-D0	AN016000	77±2mm	Common
UED-D1	AN016001	95±2mm	Common
UED-D2	AN016002	112±2mm	Common
UED-D3	AN016003	133±2mm	Common
UED-D4	AN016004	148±2mm	Common
UED-D5	AN016005	136±2mm	Common
UED-MD1	AN016101	105±2mm	Common
UED-MD2	AN016102	110±2mm	Common
UED-MD3	AN016103	136±2mm	Common

Part 2.

2.1 Basic performance

The video laryngoscope blade for single use UED-D is disposable. See working environment, transportation and storage requirements in **Table 2.**

Items	Technical name	Technical indicators
Working 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

2.2 Instructions for use

The video laryngoscope blade for single use is used with UE display and functions such as turning on and off the device and data transmission, can be done on the display.
Photo taking: Short press the function button for photo taking.
Video recording: Hold the function button for 1-2 seconds to start recording, double press the button to exit recording.
The common video laryngoscope for single use does not consist of guiding groove and the tracheal tube needs to be inserted into the glottis with a guide wire during intubation process.
The guiding video laryngoscope for single use is equipped with a guiding groove and the tracheal tube can be inserted into the glottis along the guiding groove during intubation process.

Important note: check to ensure the view observed through the video laryngoscope provides a live image (rather than a stored one) and has the correct image orientation.

2.3 Instructions for operation

1. The video laryngoscope blade for single use is used in combination with the UE display to show the anatomical landmarks required for endotracheal intubation captured by the high-definition camera.

2. The operation method of video laryngoscope is basically the same as that of the 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 with 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 field of vision at the front tip of the laryngoscope blade, 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 the endotracheal tube with the glottis and slightly enter the subglottic region. The operator continues to gently push down the endotracheal tube under the monitoring of the display.

5. After inserting the endotracheal tube to the desired depth (the cuff is about 1cm below the glottis), the operator fixes the endotracheal tube with his right hand and withdraws the video laryngoscope from the mouth with his 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 per clinically determined and connect it with the ventilator to control breathing.

6. After use, the single use blade shall be disposed of as per facility protocols.

Part 3.

3.1 Maintenance, cleaning, and disinfection

Component Risk Classification (Table 3)

Equipment parts	Packaging situation	Usage mode	Spaulding classification	Disinfection level		Sterilisation
				Low	High	
Display monitor	Non-sterile	Reuse	Non-critical items	O	X	X
Video laryngoscope single use blade UED-D	Packaged in pouch and sterilised	Single-use	Semi-critical items	X	X	X
Charger	Non-sterile	Reuse	Non-critical items	X	X	X
Connecting cable	Non-sterile	Reuse	Non-critical items	X	X	X
Data cable	Non-sterile	Reuse	Non-critical items	X	X	X

Note:

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

O Indicates the acceptable disinfection or sterilisation level (based on the suitability with equipment materials).

3.2 Cleaning, disinfection or sterilisation procedures

The Video laryngoscope blade for single use has been sterilised by ethylene oxide. It is disposable and should be discarded after use. Repeated use or immersion disinfection is strictly prohibited.

1. After use, separate the single use blade from the display monitor. Dispose of the single use blade as per facility protocols.
2. Cleaning and disinfection of the display monitor:

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.

Part 4.

4.1 Storage and transportation conditions

Keep the device clean and keep away from extreme temperature variations in the course of transportation.

Store the product in a well-ventilated room.

4.2 Product recovery

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

4.3 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.

4.4 Date of manufacture and service life

Date of manufacture: See the label for details.

The video laryngoscope blade is disposable, sterilisation validity: 3 years from date of manufacture.

The video laryngoscope display monitor and accessories: Service life: 6 years or 3000 cycles.

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

4.5 Customer service

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4.6 Marker index

Symbol	Indication	Symbol	Indication
⚠	Caution		Consult instructions for use
	Do not use if package is damaged	STERILE EO	Sterilised using ethylene oxide
	Use-by Date	LOT	Batch code
	Manufacturer	EU REP	Authorised representative in the European Union
	Date of manufacture		Unique Device Identifier
-40°C 55°C	Temperature limit		Keep dry
	Atmospheric pressure limitation	10% 93%	Humidity limitation
	Keep away from sunlight		Do not re-use
	TYPE BF APPLIED PART	MD	Medical Devices
CE	CE marking of conformity	#	Product Model
	Single sterile barrier system sterilised using ethylene oxide		

4.7 Packing list

The video laryngoscope for single use	Subject to registration information
Certificate x1, Instruction manual x1	Low

Appendix: Electromagnetic compatibility

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.
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

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 such an environment.

Emission Test	Compliance	Electromagnetic Environment Guidance
Radiated Emission	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 product 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	
Voltage fluctuations / flicker emissions IEC/EN 61000-3-3(ed 3.1):2017	Not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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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 such an environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2:2008	±6 kV contact ± 8 kV air	±6 kV contact ± 8 kV air A	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 IEC 61000-4-4:2012	±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 IEC 61000-4-5: 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, short interruptions and voltage variations on power supply input lines IEC 61000-4-11: 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 (50/60 Hz) magnetic field IEC 61000-4-8: 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 typical commercial or hospital environments.

NOTE: U_T refers to the AC network voltage before the test voltage is applied

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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 such an environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted susceptibility IEC 61000-4-6:2013 Radiated susceptibility IEC 61000-4-3:2010	3 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

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.

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