

Video Laryngoscope

HYHJ-KC

Technical Instructions

Xi'an Haiye Medical Equipment Co.Ltd.

Before using the device, please read this manual in detail

Preface

- Thank you for using our products.
- Before using this product, please read this manual carefully and keep it in a safe place for future use.
- When using, please strictly abide by the operating procedures, and properly maintain and care for it.
- Paragraphs marked "CAUTION" or with an "*" should be read and followed carefully to avoid damage or injury to equipment, operators, and patients.
- If there is any problem during the use of the equipment, please contact your local dealer or our company, we will provide you with quality service and assistance.
- Please contact us if you need more information such as circuit diagrams, component lists or product descriptions.
- Commitment: When dealing with faults, we undertake to provide the user with the necessary more detailed technical information if you need it.

Version Information

The version number of this manual may be upgraded at any time due to changes in software or technical specifications. Please understand we won't notify you individually. The version information of this manual is as follows:

- Release date: August 1, 2024

1. Product Name: Video Laryngoscope

2. Model: HYHJ-KC

3. Device Manufacturer Information:

Manufacturer:Xi'an Haiye Medical Equipment Co.Ltd.

Production Address:Factory Building 9, Shaanxi Guanghui Science and Technology Industrial Park, No. 8, Lijun Road, Fengjing Industrial Park, Huyi District, Xi'an City,Shaanxi Province,P.R.China

Tel: 029-68069217

E-mail: haiyeyiliao@haiyemedical.com

Website: www.haiyemedical.commedical.com

National toll-free number: 400 011 0281

4. After-sales service unit: Xi'an Haiye Medical Equipment Co.

This product has a 3-year warranty on the monitor and a 2-year warranty on the camera parts from the date of sale.

If the seller and the user have other provisions on the warranty period in the sales contract, please confirm with our company in time through the toll-free number 400 011 0281.

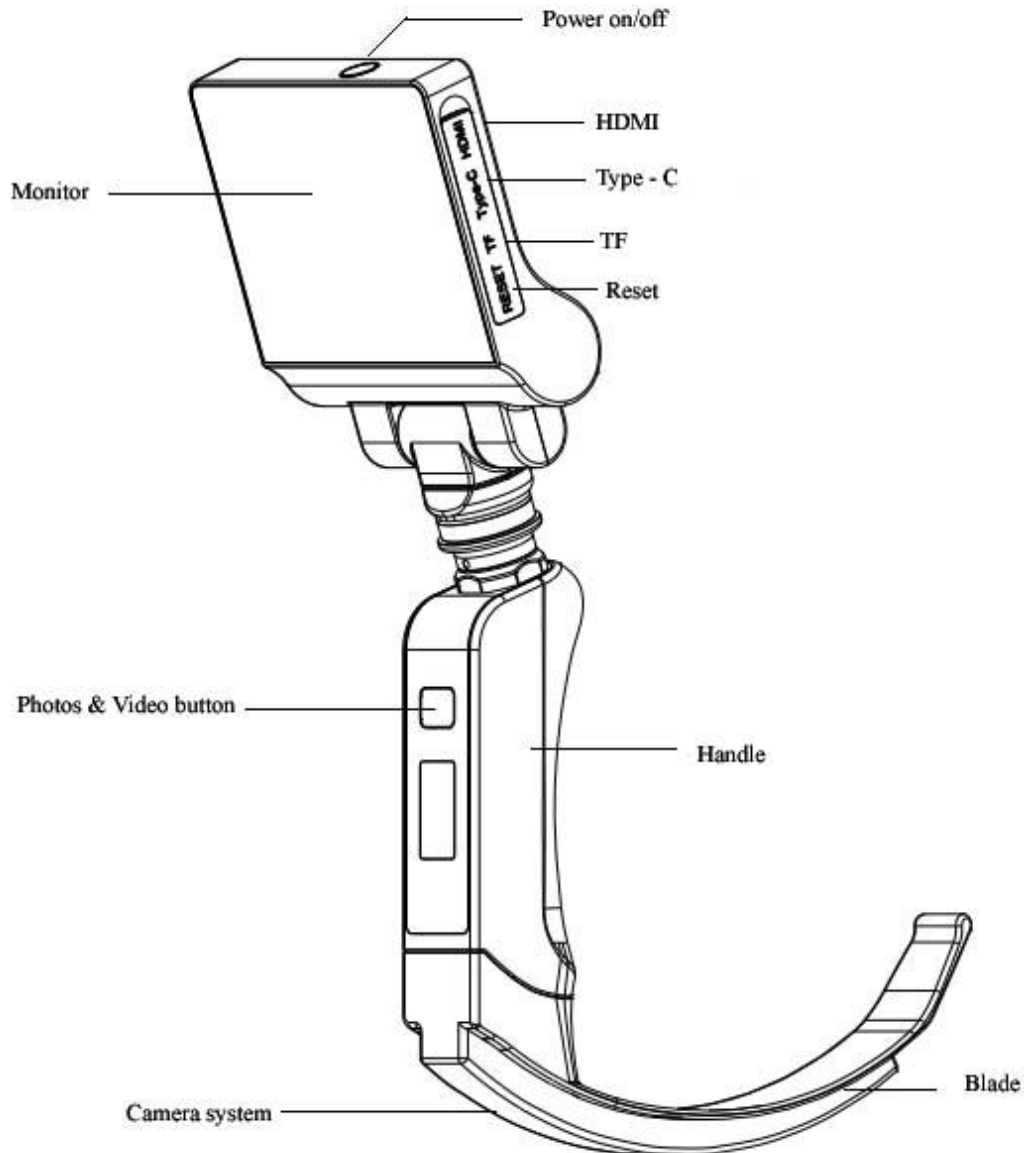
After the expiration of the warranty period, our company will continue to provide maintenance services for a fee. If the user refuses to pay or delays in paying for the maintenance service, our company will temporarily suspend the maintenance service until the user pays.

If the product needs repair during the warranty period due to the following reasons, our company will implement a chargeable repair service:

- Private disassembly or modification of this product;
- Man-made damage or improper use;
- Grid voltage exceeds the range specified for the product;
- Irresistible natural disasters;
- Failure to use the product in accordance with these instructions, or use of accessories that do not comply with these instructions;
- Other malfunctions not caused by the product itself.

5. The structural composition of the product:


The product consists of a display component, laryngoscope blades (not supplied sterile), a camera component, and a power adapter.



Note: The handle, camera system and laryngoscope blades of HYHJ-KC model are integrated.

6.Product Performance Indicators

6.1Basic Product Characteristics

- ① Classified by type of protection against electric shock: internal power supply equipment;
- ② Classified according to the degree of protection against electric shock: BF type application section  ;
- ③ Classification of the degree of protection against incoming liquids according to GB4208 (monitor): IPX4;
- ④ Classification of the degree of protection against incoming liquids according to GB4208

(camera system): IPX7;

⑤ Classification according to the degree of safety when used in the presence of flammable anesthetic gases mixed with air or flammable anesthetic gases mixed with oxygen or nitrous oxide: Equipment that cannot be used in the presence of flammable anesthetic gases mixed with air or flammable anesthetic gases mixed with oxygen or nitrous oxide;

⑥ Classification by mode of operation: continuous operation;

⑦ Rated voltage and frequency of the device: Internal power supply is lithium-ion battery 3.6Vd.c.; charger power supply is grid power input: 100-240Va.c. 50/60Hz, 0.5A max. output: 5Vd.c. 2A;

⑧ Input power of the device: 1.7VA;

⑨ Whether the device has an application section on protection against defibrillation discharge effects: Not applicable;

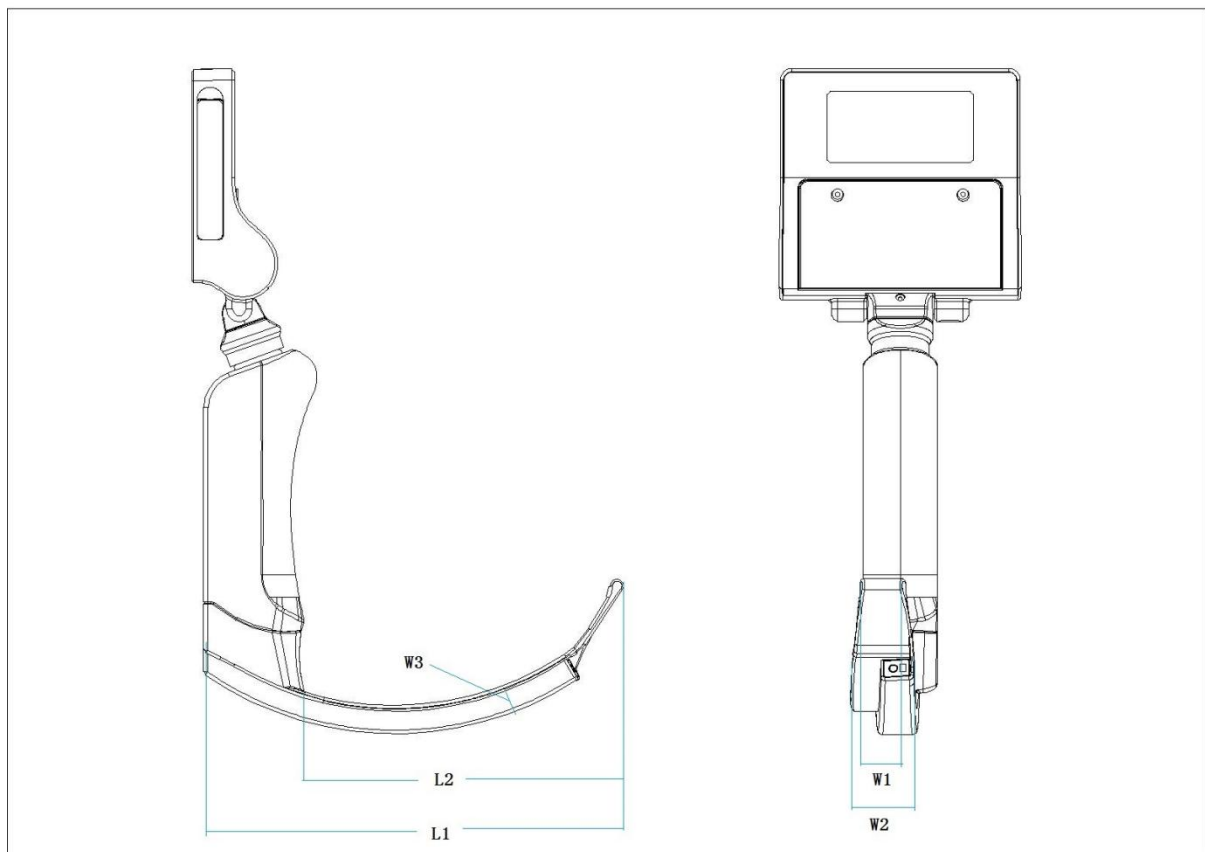
⑩ The device has a signal output or input section;

⑪ Permanent installation equipment or non-permanent installation equipment: Not applicable.

6.2 Product performance indicators

6.2.1 Laryngoscope Blades Size

Table 1		HYHJ-KC laryngoscope blades part size		Allowance ±5mm	
Model Specification	Total length of blades (L1)	Length of insertable portion (L2)	blades tip width (W1)	Width of blades at camera (W2)	Thickness of insertion section (W3)
HYHJ-KC-T00	158	127	14	21	10
HYHJ-KC-T0	148	112	14	21	10
HYHJ-KC-T1	132	98	14	20	11
HYHJ-KC-T2	115	82	13	21	11
HYHJ-KC-T3	102	70	11	15	10
HYHJ-KC-T4	85	52	10	14	9



HYHJ-KC Dimension Diagram

6.2.2 Basic performance indicators

Specification	Technical Name	Technical Indicators
Machine parameters	Display Resolution	Not less than 960 x 480
	Camera Pixels	≥1 Million
	Field of View	70°±9°
	Effective Depth of Field	Not less than 3-100mm
	Spatial Resolution	≥8lp/mm
	Illuminance (physics)	≥2600lux
	Color Reproduction	Recognizes 24 colors on a standard color palette
	Geometric Distortion	No significant geometric distortion of the image
	Surface Roughness of Throat Lenses	Ra≤0.8um
	Vapor Layer	No blurring of the internal field of the camera after a sudden change from low to high temperatures
	Corrosion Resistance	Laryngoscope blades are corrosion resistant
Internal power supply	Charging Time	≤4h
	Working Time	≥5h
Power Supply Adapter	Charger Input	100-240V, 50/60Hz, 0.5A Max
	Charger Output	5V, 2000mA

(device)		
Working Environment	Environmental Temperature	5℃-40℃
	Relative Humidity	≤80%
	Atmospheric Pressure	860hpa～1060hpa
	Internal Power Supply	DC3.6V
Transportation Storage Environment	Environmental Temperature	-40℃～55℃
	Relative Humidity	≤93%
	Atmospheric Pressure	500hpa～1060hpa

7.Product Applicability

7.1 Intended Purpose:

The video laryngoscope system is indicated to provide visualization and access of the larynx during therapeutic procedures in adult patients and children by professional person in medical facility or hospital. The device is intended for transient use.

7.2 Intended Users

Professional doctor and nurse in hospital.

7.3 Intended patient population and medical condition

- Patients who need to be observed larynx.
- Patients who need ventilation before aid locating correct position trachea's intubation.

7.4 Indications

- Clinical anesthesia or assisted rescue
- Observing larynx.
- Aid locating correct position trachea's intubation.

8. Contraindications: No

9. Cautions and warnings, tips content:

9.1 Clinical Application Considerations:

- ① The operator should read the instructions for use in detail before use, have some experience in intubation, and receive appropriate training and guidance from the manufacturer.
- ② Lubricant should be applied before each use, the lubricant should be in the right amount, so as not to be too little to achieve the effect, too much will result in the Laryngoscope blade in the oral cavity is not easy to fix the position of the Laryngoscope blade.
- ③ In case of unclear vision at the front of the lens due to massive bleeding from the patient's mouth, dirt in the mouth, excessive oral secretions, etc., the laryngoscope should be removed,

the lens gently wiped with a soft gauze, and the patient's mouth should be further treated before using the laryngoscope.

④The laryngoscope should not be inserted too deeply, lest entry of the laryngoscope into the laryngopharynx lift the entire larynx, exposing the esophageal opening rather than the glottis opening.

⑤ In case of difficulty in intubation due to certain conditions in the chest or neck, the laryngoscope can be inserted by further stretching the atlanto-occipital joint and tilting the patient's head back (in case of cervical spine fracture, the head cannot be tilted back excessively, and in this case, the visualization of the laryngoscope application is limited).

⑥If there is difficulty pushing the tracheal tube downward, reduce the force of lifting the laryngoscope upward to return the patient's head to a neutral position, and then push the tracheal tube downward again.

⑦ The appropriate cannula core should be selected to ensure that successful tracheal intubation can be performed.

⑧ When an accident occurs during the correct use of the product, the operator should stop using it and use a spare laryngoscope for intubation; then he/she should contact the Company.

⑨If the product is not operated or maintained and cleaned in accordance with this manual during use, there may be conditions such as no display, poor contact, and unclear display.

⑩If there is strong light causing screen reflection, please adjust the user's viewing angle appropriately.

⑪If any adverse event occurs during the clinical use of the product, please upload it to the National Medical Device Adverse Event Monitoring Information System in a timely manner and contact our company.

9.2 Warning:

①This product must not be used in places where there is a risk of fire.

②*This product should not be used in the presence of a mixture of flammable anesthetic gas and air or a mixture of nitrous oxide.

③*The internal part of this product is a special device, users are not allowed to disassemble it by themselves.

- ④ This product may not be used for purposes other than those for which it is intended.
- ⑤ Modification of this equipment is not authorized.
- ⑥ This product is a direct plug-in adapter as a disconnecting device when charging, so do not place the device in a position that is difficult to operate.
- ⑦ This product in the highest ambient operating temperature Laryngoscope blade outlet maximum temperature may exceed 41 °C, the laryngoscope blades insertion surface maximum temperature may exceed 41 °C; the use of the patient's oral cavity needs to be a healthy oral cavity, no mucosal breakage, no relevant medication, etc., for a period of time of no more than 1 min. the highest ambient operating temperature can not be used for infants, to avoid causing scalding of the oral mucosa.
- ⑧ Before each use of this product, the outer surface of the laryngoscope blade that enters the patient should be inspected to ensure that there are no rough surfaces, sharp edges, or protrusions that could cause injury.
- ⑨ Before each use or after changing the observation settings, the operator should check to make sure that the observed image is a real-time image and that the image orientation is correct, otherwise the diagnosis or treatment may be affected.
- ⑩ Do not look directly at the light emitted from this product, as this may cause some eye damage.

Do not use other equipment that has a BF-type application section or CF-type application section in the application configuration of this product.

9.3 Safety advice:











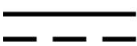








- ① This product must be protected from any adverse external influences such as strong electromagnetic radiation or high temperatures.
- ② The product should be carefully and gently placed during transportation and use to prevent shock, severe vibration and moisture.
- ③ This product can only be serviced by our authorized professionals.
- ④ This product can only be charged with the power adapter provided by our company.
- ⑤ Please contact our customer service department in case of any malfunction of this product.

⚠ 9.4 Notes:

- ① Do not use it with excessive force.
- ② The monitor parts of this product are not waterproof, so please pay attention to waterproof when cleaning.

- ③ Please charge it first time you use it.
- ④ When the product is not used for a long time, it needs to be charged once in 2-3 months.
- ⑤ If you need to replace the battery, please contact the manufacturer.
- ⑥ Use with caution in patients with severe oral mucosal breakdown.
- ⑦ When the product is scrapped or reaches the end of its useful life, it should be categorized and disposed of in accordance with medical solid waste so as not to cause harm to the environment.
- ⑧ This product cannot be operated in the charging state and is not intended for use as a medical device.

10. Explanation of Graphics and Symbols Used in Medical Devices.

	BF-type Equipment		Manufacture Date
	Logo		Validity Period
	Power Switch		Internal Power Supply, Do Not Disassemble
	Battery Level		Memory Card Normal
	General warning sign		Refer to instruction manual/booklet
	Direct Current		Photo and Video Buttons
	Model number		Authorised representatives in the European Union
	Serial number		Medical equipment labelling
	Separate collection symbol for waste electrical and electronic equipment (please comply with local laws and regulations).		CE mark
	Manufacturer		

11. Instructions for installation and use:

11.1 Assembly and disassembly instructions:

Instructions for assembly and disassembly of HYHJ-KC type:



1. Align the mounting points and slots of the main unit and the camera system, and clamp them tightly with mutual force.



2. Check whether the card position is secure, no abnormality that assembly is complete.



3. In the off state, hold the handle with one hand, hold the main unit with the other hand and pull the clamp ring, and separate it in two directions along the clamp slot.



Note: When disassembling, need to lift and pull the ring to disassemble easily, do not pull it directly.



4. Press the sterilizing cap onto the fillet hole of the camera system.



5. After disassembling the main unit and camera system, sterilize them and put them into the box in order.

• If you encounter a crash during use, press the small round hole next to the SD port with a crankpin to restore it.

Caveats:

1. Connect the camera system first and then turn on the power, replace the camera system, must be done in the off state.
2. The disinfection cap must be installed tightly before disinfecting the device after use.
3. The display can be rotated up to 180° to the left and up to 90° to the right; if there is resistance, please do not rotate it hard.

The above illustrations are for reference only, and the actual product shall prevail.

11.2 Instructions for use:

Power on: long press the power button for 1-3 seconds to turn on, long press the power button for 1-3 seconds to turn off.

Framing: press the power button once in the power-on state, the picture will be framed, then press it again to return to the working state.

Photo and video: press the photo and video button once, the picture will be taken and saved automatically; long press the photo and video button to start the video recording, press the photo and video button again, the video recording will stop and be saved automatically.

Normal work: green light is on, the display can show the image normally.

Charging: Please use the original charger, the blue light indicates that it is charging, the green light indicates that it is fully charged. Blue light blinks in power-on state, need to charge.

Battery maintenance: please use the original factory equipped charger, a charging time should not be more than 6 hours, when not in use for a long time, at least 2-3 months to charge.

Screen Rotation: The maximum rotation angle of the display is $170^{\circ}\pm 10^{\circ}$ for front and back, and $270^{\circ}\pm 10^{\circ}$ for left and right.

Storage function: Maximum 64G memory card can be inserted, with the function of storing photos and videos.

HYHJ-KC specification usage instructions:

This host can be equipped with six different sizes of reusable laryngoscope blades, healthcare professionals should choose the right size of laryngeal lenses according to the patient's body type and personal use habits.

Interference: electronic equipment that is sensitive to electromagnetic interference, please maintain an appropriate distance when using with this product at the same time.

11.3 Operation Instructions:

- ① Connect the video laryngoscope according to the assembly instructions, turn on the power switch, the green indicator light will be on, the camera light source will be on, and the display screen can normally display the scene seen by the high-definition camera.
- ② Insert the intubation core into the appropriate position in the tracheal tube, and apply lubricant to the catheter balloon.
- ③ Put the patient in a supine position, the operator stands in front of the patient's head, opens the patient's mouth with fingers, and slowly puts the laryngoscope blade into the mouth along the midline of the tongue, observing the display screen while inserting.
- ④ After seeing the epiglottis, place the front end of the laryngoscope blade on the laryngeal

surface of the epiglottis, gently lift the epiglottis, and clearly expose the glottis.

⑤ Insert the tracheal tube into the patient's mouth along the right side of the laryngoscope blade, observe from the screen, when the front end of the tracheal tube appears in the field of vision, align the front end of the tracheal tube with the glottis and insert it to the appropriate depth under the glottis.

⑥ Keep the position of the laryngoscope and tracheal tube unchanged and pull out the intubation core. The operator fixes the tracheal tube with his right hand and withdraws the laryngoscope from the mouth with his left hand.

⑦ Inflate the tracheal tube cuff and the intubation is completed.

⑧ After using the laryngoscope, turn off the power switch, clean and disinfect the main unit and camera system, and then put them into the box.

12. Product maintenance and care methods, storage and transportation conditions:

12.1 Maintenance, cleaning and disinfection:

12.1.1 The display part of the video laryngoscope can be wiped with medical alcohol. When not in use, it should be placed in the packaging box according to the instructions to avoid unnecessary damage.

12.1.2 The video laryngoscope can be used normally within two months when fully charged and not turned on. It is recommended to charge it at least once every 2-3 months when not in use for a long time.

12.1.3 Cleaning and disinfection of laryngoscope blades:

① After using the laryngoscope blades, remove them, install the disinfection cap on the handle, and immediately clean them thoroughly with running water to remove residual substances such as blood and mucus, and wipe them dry with sterile gauze;

② After wiping dry, the laryngoscope blades can be disinfected or sterilized by the following methods: immerse in 2% alkaline glutaraldehyde solution for at least 20 minutes for disinfection, and immerse for 10 hours for sterilization (pay attention to protecting the contacts and camera).

③ After taking out, rinse with sterile water, wipe dry with sterile gauze, and store in a sterile bag;

④ When using the video laryngoscope for the first time, the laryngoscope blade should be cleaned and disinfected.

12.1.4 When a patient is using it, the handle of the video laryngoscope cannot be cleaned and disinfected, and the video laryngoscope cannot be charged.

12.2 Troubleshooting:

Fault	Reason	Exclusions
Unclear image	The blade is dirty or the anti-fog function is lost	Replace laryngoscope blade or remove dirt
No image displayed	The camera system is not connected properly	Check camera system connection port
Cannot start the device	The battery is dead	Please charge
Distorted screen, freeze	The system is stuck	Press reset button

12.3 Transportation, storage conditions

During transportation, avoid rain and snow soaking, heavy pressure and intensity collision; its packaging should be able to play a protective role against slight moisture, heavy pressure and collision.

Storage environment: temperature $-40^{\circ}\text{C} \sim 55^{\circ}\text{C}$, humidity: $\leq 93\%$, no external biological aggression, good ventilation.

12.4 List of accessories

S/n.	Accessory Name	Quantity	Remarks
1	Display Parts	1 unit	
2	Camera system	1pcs	Integral with laryngoscope blade
3	Power adapter	1 set	
4	Data cable	1 pcs	1 pcs

13. Date of preparation of instructions: October 10, 2022

14. Date of revision of instructions: Oct.23, 2024

15. Product production date: See the label on the back of the product

16. Product use period: 5 years

17. EMC Information

Note:

1. The purchaser or user of the video laryngoscope should use the video laryngoscope in the electromagnetic environment specified in Tables 1, 2, 4, and 6, otherwise the video laryngoscope may not work properly.

2. Portable and mobile radio frequency communication equipment may affect the normal use of the video laryngoscope. Please use the video laryngoscope in the recommended electromagnetic environment.

Warning:

1. In addition to the accessories and cables provided by the manufacturer of the video laryngoscope, the use of accessories and cables other than those specified may cause the video laryngoscope to increase its emission or reduce its immunity.

2. The video laryngoscope 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 the configuration in which it is used.

Table 1

Guidelines and Manufacturer's Declarations - Electromagnetic Emissions		
The video laryngoscope is intended to be used in the electromagnetic environment specified below, and the purchaser or user shall ensure that it is used in such electromagnetic environment:		
Launch test	Conformance	Electromagnetic Environment - Guidelines
Radio Frequency Emission GB 4824	1 group	The video laryngoscope uses RF energy only for its internal functions. As a result, it has very low RF emissions and has little potential to interfere with nearby electronic devices
Radio Frequency Emission GB 4824	Category A	
Harmonic emission GB 17625.1	Inapplicable	
Voltage fluctuation/flicker emission GB 17625.2	Inapplicable	Video laryngoscopes are suitable for use in all installations not intended for domestic use and not directly connected to the public low-voltage supply network of domestic dwellings.

Table 2


Guidelines and Manufacturer's Declarations - Electromagnetic Immunity
The visual laryngoscope is intended for use in the electromagnetic environment specified below, and the purchaser

or user shall ensure that it is used in such electromagnetic environment:			
Immunity Test	IEC 60601 Test Level	Level of Compliance	Electromagnetic Environment - Guidelines
Electrostatic Discharge GB/T 17626.2	±6 kV Contact Discharge ±8 kV Air Discharge	±6 kV contact discharge ±8 kV air discharge	The floor should be wood, concrete or tile, or at least 30% relative humidity if the floor is covered with a synthetic material
Electrical Fast Transient Pulse Group GB/T 17626.4	±2 kV The Power Code	±2 kV The Power Code	Grid power should be of a quality typically used in commercial or hospital environments
(Electrical) Surge GB/T 17626.5	±1 kV Line to Line ±2 kV Line to Ground	±1 kV line to line ±2 kV line to ground	Grid power should be of a quality typically used in commercial or hospital environments
Voltage Dips, short interruptions and voltage variations on the power input line GB/T 17626.11	<5% U_T , for 0.5 cycles (>95% Transient rop on U_T) 40% U_T for 5 cycles (60% transient drop on U_T) 70% U_T for 25 cycles (30% holdover on U_T) <5% U_T for 5s (>95% transient drop on U_T)	<5% U_T , for 0.5 cycles (>95% transient drop on U_T) 40% U_T for 5 cycles (60% transient drop on U_T) 70% U_T for 25 cycles (30% holdover on U_T) <5% U_T for 5s (>95% transient drop on U_T)	The net power supply should be of a quality typically used in a commercial or hospital environment. If users of visual laryngoscopes require continuous operation during power interruptions, an uninterruptible power supply (UPS) or battery power is recommended for visual laryngoscopes
Work frequency magnetic field (50 Hz/60 Hz)	3 A/m	3 A/m	The IF magnetic field shall be characterized by IF magnetic field levels typical of sites in a typical

GB/T 17626.8			commercial or hospital environment.
Note: U _T refers to the AC network voltage before applying the test voltage.			

Table 4

Guidelines and Manufacturer's Declarations - Electromagnetic Immunity			
The video laryngoscope is intended to be used in the electromagnetic environment specified below, and the purchaser or user shall ensure that it is used in such electromagnetic environment:			
Immunity Test	IEC 60601 Test Level	Level of Compliance	Electromagnetic Environment - Guidelines
Radio-Frequency Conduction (RFCC) GB/T 17626.6	3 V (RMS) 150 kHz to 80 MHz	3 V (RMS)	<p>Portable and mobile RF communications equipment should not be used closer to any part of the visual laryngoscope, including cables, than the recommended isolation distance. This distance shall be calculated by a formula corresponding to the frequency of the transmitter.</p> <p>Recommended isolation distances</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Style:</p> <p>P-Maximum rated output power of the transmitter in watts (W) according to the transmitter manufacturer;</p> <p>d-Recommended isolation distance in meters (m).</p> <p>The field strength of a fixed RF transmitter is determined by surveying the electromagnetic field house^a and should be lower than the compliance level</p>
Radio-Frequency Radiation GB/T 17626.3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

			<p>in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment  marked with the following symbols.</p>
--	--	--	---

Note 1: At the 80 MHz and 800 MHz frequency points, the formulas for the higher bands are used.

Note 2: These guidelines may not be appropriate in all cases, and electromagnetic propagation is affected by absorption and reflection from buildings, objects and the human body.

^a Fixed transmitters, such as: base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radio, AM and FM radio broadcasting, and television broadcasting, have field strengths that are not accurately predictable in theory. In order to assess the electromagnetic environment of a fixed RF transmitter, a survey of the electromagnetic field should be considered. If the field strength of the site where the visual laryngoscope is located is measured to be higher than the applicable RF compliance level described above, the visual laryngoscope should be observed to verify that it can function properly. If abnormal performance is observed, additional measures may be necessary, such as reorienting or repositioning the visual laryngoscope.

^b The field strength shall be less than 3 V/m over the entire frequency range of 150 kHz to 80 MHz.

Table 6

Recommended isolation distances between portable and mobile radio frequency communication equipment and video laryngoscopes			
<p>Video laryngoscopes are intended for use in electromagnetic environments where radio frequency radiation disturbances are controlled. Based on the maximum rated output power of the communications equipment, the purchaser or user may protect against electromagnetic interference by maintaining a minimum distance between portable and mobile radio frequency communications equipment (transmitters) and visual laryngoscopes as recommended below.</p>			
Maximum rated output power of the transmitter W	Isolation distance for different frequencies of the corresponding transmitter/m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
<p>For transmitter maximum output power ratings not listed in the table above, the recommended isolation distance d, in meters (m), can be determined by using the formula in the frequency column of the corresponding transmitter, where P is the maximum output power rating of the transmitter, in watts (W), as supplied by the transmitter manufacturer.</p> <p>Note 1: At the 80 MHz and 800 MHz frequency points, the formula for the higher frequency range is used.</p> <p>Note 2: These guidelines may not be appropriate in all cases, and electromagnetic propagation is affected by absorption and reflection from buildings, objects and the human body.</p>			