Video Laryngoscope

HYHJ-1320, HYHJ-1330 Ⅰ, HYHJ-1330 Ⅱ, HYHJ-1330 Ⅲ

Technical Instructions for Use

Xi'an Haiye Medical Equipment Co.,Ltd.

Read this manual in detail before using the device

Preface

- Thank you for using our products.
- When you use it, please strictly observe the operating procedures, correct maintenance and carry out maintenance.
- 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.
- Commitment: When dealing with faults, if you need, we promise to provide users with the necessary more detailed technical information.

1.Product Name: Medical video laryngoscope

2.Model and specification: HYHJ-1320、HYHJ-1330 Ⅰ、HYHJ-1330 Ⅱ、HYHJ-1330 Ⅲ

According to whether the camera system and mainframe of the product are detachable and compatible with the size of the laryngoscope blade, different sizes of camera systems and laryngoscope blade are suitable for different populations.

Division / Model	Laryngoscope Blade Material	Is the camera system and host detachable	Can be paired with Laryngoscope Blade
HYHJ-1320	Polycarbonate（PC）	Yes	T1、T2、T3
HYHJ-1330 Ⅰ	Polycarbonate（PC）	No	T1
HYHJ-1330 Ⅱ	Polycarbonate（PC）	No	T2
HYHJ-1330 Ⅲ	Polycarbonate（PC）	No	T3

3.Name, address, and contact information of the registrant:

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

Email：haiyeyiliao@haiyemedical.com

Website：www.haiyemedical.com

National Toll Free: 400 011 0281

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

From the date of sale, this product comes with a 3-year warranty for the main unit and a 2-year warranty for the camera system.

5.The structural composition of the product:

HYHJ-1320 and HYHJ-1330 Type I, II, and III laryngoscopes are mainly composed of display components, laryngoscope blades (made of polycarbonate (PC), disposable sterile supply), camera components, and power adapters.

Main materials: a combination of polycarbonate (PC), ABS plastic, and stainless steel.

Application section: Layngoscope Blade.

6.Product Performance Indicators

6.1 Basic Product Characteristics

① Classified by type of electric shock prevention: internal power supply equipment；

② Classified by the degree of electric shock prevention: BF type application part；

③ According to the classification of liquid ingress protection level specified in GB4208 (display): IPX4；

④ Classified by safety level when used in the presence of flammable anesthetic gases mixed with air or oxygen or nitrous oxide: equipment that cannot be used in the presence of flammable anesthetic gases mixed with air or oxygen or nitrous oxide；

⑤ Classified by operating mode: continuous operation；

⑥ Rated voltage and frequency of the equipment: The internal power supply is lithium-ion battery DC3.6V; The charger is powered by grid power AC 220V, 50Hz；

⑦ Input power of the device: 1.7VA；

⑧ Does the device have application protection against defibrillation discharge effects: Not applicable；

⑨Does the device have a signal output or input section: Not applicable；

⑩Permanent or non permanent installation equipment: Not applicable。

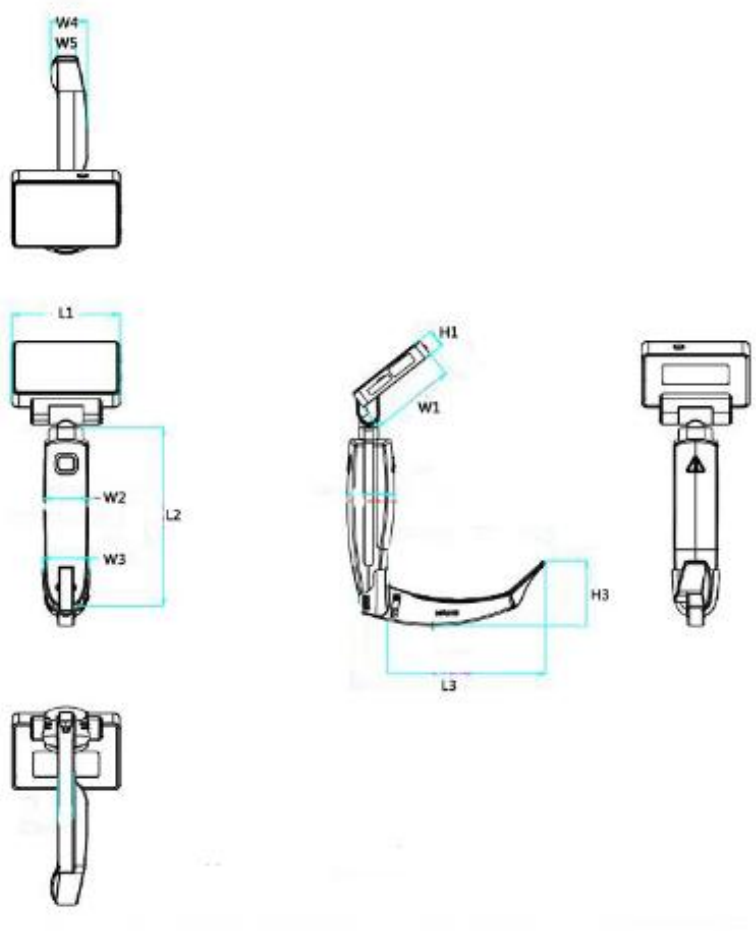
6.2Product performance indicators

6.2.1Laryngoscope Blade Size

HYHJ-1320 and HYHJ-1330 Laryngoscope Blade Partial dimensions Unit: mm

Specification	Laryngoscope Blade Length（L3）	Laryngoscope Blade Width (W3)	Laryngoscope Blade Height (H3)	Insert section Maximum width(W4)	Insert section Minimum width(W5)
T1	119±5	36±5	62±5	22±5	16±5
T2	97±5		44±5	19±5	11±5

T3	80±5		22±5	17±5	10±5



Dimensional schematic diagram of HYHJ-1320 and HYHJ-1330

6.2.2 Performance index:

Item	Name	Specification
Machine parameters	Display screen resolution	Not less than 960×480
	Camera Pixel	≥100 Pixel
	Field angle	70º±9º
	Effective depth of field	Not less than 3-100mm

	Spatial Resolution	≥8lp/mm
	Illuminance	≥2600lux
	Color reproduction ability	Distinguishable 24 colors on the standard color palette
	Geometric distortion	The image has no obvious geometric distortion
	Surface roughness of laryngoscope blade	Ra≤0.8um
	Fog layer	After undergoing a low-temperature to high-temperature mutation test, there is no blurred field of view inside the laryngoscope
Internal power supply	Battery capacity	≥3200mAh
	Charging time	≤4h
	Endurance	≥5h
Charger	Charger input	100-240V, 50/60Hz, 0.5A Max
	Charger output	5V, 2000mA
Work environment	Environmental temperature	5℃-40℃
	Relative humidity	≤80%
	Atmospheric pressure	860hpa～1060hPa
	Internal power supply	DC3.6V
Transportation and 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 observated larynx.

-Patients who need ventilation before aid locating correct position trachea's intubation.

7.4 Indications

-Clinical anesthesia or assisted rescue

-Observating larynx.

-Aid locating correct position trachea's intubation.

8 Contraindication：No

9 Cautions and warnings, tips content:

9.1 Clinical application precautions：

① The operator should read the instructions carefully before use, have some experience in intubation, and receive appropriate training and guidance from the manufacturer.

② Lubricant should be applied before each use, and the lubricant should be in moderation to avoid insufficient effectiveness. Excessive lubricant may cause difficulty in fixing the position of the laryngoscope in the oral cavity.

③ If there is a large amount of bleeding in the patient's mouth, dirt in the mouth, excessive oral secretions and other factors that cause unclear vision at the front end of the lens, the laryngoscope should be removed, the lens should be gently wiped with soft gauze, and the patient's mouth should be further treated before using the laryngoscope.

④ The laryngoscope is inserted too deeply to prevent it from entering the pharynx and lifting the entire

larynx, exposing not the glottis opening but the esophageal opening.

⑤ In case of difficulty in intubation due to certain chest or neck conditions, the patient's head can be further extended and tilted back before inserting a laryngoscope (in the case of cervical fractures, excessive tilting of the head is not allowed, as the use of a visual laryngoscope is limited).

⑥ If it is difficult to push the tracheal tube downwards, the force of the laryngoscope can be reduced to bring the patient's head back to the neutral position, and then the tracheal tube can be pushed downwards.

⑦ Suitable intubation cores should be selected to ensure successful implementation of endotracheal intubation procedures.

⑧ When accidents occur during the correct use of the product, resulting in the loss of basic or partial functions of the laryngoscope, the operator should stop using it and use a spare laryngoscope for intubation; Then you should contact our company.

⑨ If the product is not operated or cleaned according to this manual during use, there may be situations such as non display, poor contact, unclear display, etc.

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

⑪ If any adverse events occur during clinical use, please upload them to the National Medical Device Adverse Event Monitoring Information System in a timely manner and contact our company.

9.2 Warning:

① This product cannot be used in areas with fire hazards.

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

③ The internal components of this product are special devices, and users are not allowed to disassemble them by themselves.

④ This product cannot be used for any other purposes beyond its scope of application.

⑤ It is not allowed to modify this equipment.

⑥ Before each use of this product, the outer surface of the laryngoscope that enters the patient's body should be checked to ensure that there are no rough surfaces, sharp edges, or protrusions that could cause harm.

⑦ Before each use or after changing the observation settings, the operator should check to ensure that the

observed images are real-time and the image orientation is correct, otherwise it will affect diagnosis or treatment.

⑧ During the use of laryngoscopes, the front camera of the laryngoscope may generate some heat. Operators are advised not to touch the camera with the patient without the laryngoscope lens.

⑨ Do not look directly at the light emitted from this product, as it may cause eye damage.

9.3 Safety advice：

① This product must avoid any adverse external effects, such as strong electromagnetic radiation or high temperature。

② This product should be handled with care during transportation and use to prevent impact, severe vibration, and moisture。

③ This product can only be repaired by professionals authorized by our company。

④ This product can only be charged using the power charger provided by our company。

⑤ If there is any malfunction with this product, please contact our customer service department in a timely manner。

⚠ **9.4 Note：**

① Do not use too much force during use。

② The display components of this product are not waterproof. Please pay attention to waterproofing when cleaning。

③ Please charge it before using it for the first time. This product cannot be operated while charging and is not intended for use as a medical device。

④ When the product is not used for a long time, it needs to be charged every 2-3 months. If you need to replace the battery, please contact the manufacturer。

⑤ Use with caution in patients with severe oral mucosal damage。

⑥ When a product is scrapped or reaches its service life, it should be classified and treated according to medical solid waste to avoid harm to the environment。

9.5 Factors affecting usage：

① Not reading the instruction manual in detail or lacking experience in intubation operation。

② Insufficient lubrication of laryngoscope blade.

③ Unreasonable insertion position and depth of the laryngoscope blade.

10.Explanation of graphics and symbols used in medical devices

Graphics and symbols	Description	Graphics and symbols	Description
	BF type equipment		Date of manufacture
	Company logo		Validity Period
	Power switch		Warning (notification)
	General waring sign		Refer to instruction manual/booklet
	Direct current		Photo and video button
#	Model number	EC REP	Authorised representatives in the European Union
SN	Serial number	MD	Medical equipment labelling
	Separate collection symbol for waste electrical and electronic equipment (please comply with local laws and regulations).	CE 0197	CE mark
	Manufacturer		

11.Instructions for installation and use:

11.1Assembly and disassembly instructions:

HYHJ-1320 assembly and disassembly instructions:

Assembly parts

1.Take out the host and any camera systems.

2. Align the steel ball of the camera system with the groove of the host and put it in.

3.Pull the camera system down along the groove of the host until the camera system is locked into the bearing of the host.

Assembly parts

4. Gently move the camera system in the direction of the arrow to ensure that the contacts of the camera system and the host are in full contact.

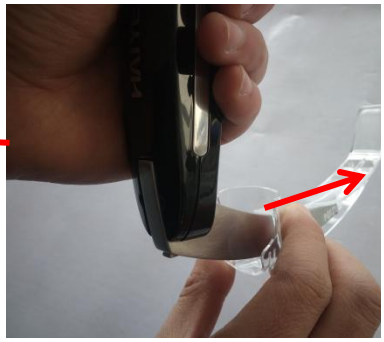
5. Take out the disposable laryngoscope blade that matches the camera system and insert it into the camera system.

6. Push the laryngoscope blade to the top locking point of the camera system and lock it tightly without any looseness.

7. Assembly is complete.

Disassembly part

1.Use your fingers to pinch the two sides of the end of the laryngoscope blade to remove the laryngoscope blade from the stuck position.



2. Remove the laryngoscope blade from the camera system.

3.Gently push the camera system in the direction of the arrow to return its steel ball to the groove position of the main unit.

4. Move the camera system upwards along the groove of the main unit to remove it.

5.The disassembled host and camera system are placed in the box in order.

Note: Connect the camera system first and then turn on the machine. To replace the camera system, the machine must be turned off. The above pictures are for reference only. Please refer to the actual product.

HYHJ-1330 Ⅰ, Ⅱ, Ⅲ type assembly and disassembly instructions:

1. Take out the disposable laryngoscope blade that matches the video laryngoscope;

2. Push the laryngoscope blade along the camera to the locking position at the bottom of the host, lock it tightly without loosening, and turn it on for use;

3. Use your fingers to pinch the two sides of the end of the laryngoscope blade to make the laryngoscope blade exit the locking position, and then remove the laryngoscope blade along the camera.

11.2 Instructions for use:

Power on: Press and hold the power button for 1-3 seconds to power on, and press and hold the power button for 1-3 seconds to power off.

Freeze: Press the power button once to freeze the picture, and press it again to return to the working state.

Photographing and recording: Press the camera button once to automatically take pictures and store them; press and hold the camera button to start recording, and press the camera button again to stop recording and store them.

Normal operation: The green light is on, and the display can display images normally.

Charging: Please use the original charger. The blue light is on to indicate that it is charging, and the green light is on to indicate that it is fully charged. When the device is powered on, the blue light flashes, and charging is required.

Battery maintenance: Please use the original charger. The charging time should not exceed 6 hours at a time. If it is not used for a long time, charge it at least once every 2-3 months.

Screen rotation: The display can rotate forward and backward within 0°~155°, and the left and right rotation angle is within 0°~275°.

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

HYHJ-1320 Specifications and Instructions:

Large camera systems should use T1 blades,

Medium camera systems should use T2 blades,

Small camera systems should use T3 blades,

Medical staff should choose the appropriate size of camera system and laryngoscope blade according to the patient's body shape and personal usage habits.

HYHJ-1330Ⅰ, Ⅱ, Ⅲ specifications instructions:

HYHJ-1330 Ⅰ should use T1 laryngoscope blade,

HYHJ-1330 Ⅱ should use T2 laryngoscope blade,

HYHJ-1330 Ⅲ should use T3 laryngoscope blade,

Medical staff should choose medical video laryngoscope and laryngoscope blade of appropriate size according to the patient's body shape and personal usage habits.

Interference: Please keep a proper distance when using electronic equipment that is sensitive to electromagnetic interference with this product at the same time.

11.3 Instructions:

① Connect the video laryngoscope according to the assembly instructions, turn on the power switch, the green indicator light is on, the camera light source is 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 entering.

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.

⑧After using the laryngoscope, turn off the power switch, put the main unit and camera system into the box, and dispose of the disposable laryngoscope blade as medical waste.

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

12.1Maintenance, cleaning and disinfection：

①The handle and display screen of the video laryngoscope can be wiped with medical alcohol. When not in use, they should be placed in the packaging box according to the instructions to avoid unnecessary damage.

②The 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.

③The disposable laryngoscope blades of HYHJ-1320, HYHJ-1330Ⅰ, Ⅱ, and Ⅲ are sterilized by ethylene oxide and are provided as disposable sterile products. They cannot be disinfected and reused. If the packaging of the disposable laryngoscope blade is damaged, it cannot be used.

④When 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
The image is not clear	The blade is dirty or the anti-fog function is lost	Replace the blade or remove dirt
Image not showing	The camera system is not connected properly	Check the camera system connection port
Cannot boot	Dead battery	Please charge

12.3 Transportation and storage conditions

During transportation, avoid rain and snow, heavy pressure, and strong collision; the packaging should be able to protect against slight moisture, heavy pressure, and collision.

Storage environment: temperature -40℃～+55℃, humidity: ≤93%, no external biological invasion, good ventilation.

12.4 Accessories List

Serial	Name	HYHJ-1320 Model	HYHJ-1330Ⅰ,Ⅱ,Ⅲ Model

number		Quantity	quantity
1	Display Parts	1 set	1 set
2	Camera system	3 sets	——
3	Disposable blades	3 pcs	1 pcs
5	Power adapter	1 pcs	1 pcs
6	Data cable	1 pcs	1 pcs

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

14.Instruction Manual Revision Date： June 13, 2024

15.Product production date： See product back label

16.Product Expiration Date： See product back label

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

<table>
<tr><td colspan="3">Guidance and manufacturer's declaration – Electromagnetic emissions</td></tr>
<tr><td colspan="3">The video laryngoscope is intended to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in such an electromagnetic environment:</td></tr>
<tr><td>Launch test</td><td>Compliance</td><td>Electromagnetic Environment - Guide</td></tr>
<tr><td>RF Transmission GB 4824</td><td>1 group</td><td>The video laryngoscope uses RF energy only for its internal function. Therefore, its RF emissions are low and are unlikely to cause any interference to nearby electronic equipment.</td></tr>
<tr><td>RF Transmission GB 4824</td><td>Category A</td><td rowspan="3">The video laryngoscope is suitable for use in all establishments other than domestic and not directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emission GB

17625.1</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuation/flicker emission GB 17625.2</td><td>Not applicable</td></tr>
</table>

Table 2

Guidance and manufacturer's declaration - Electromagnetic immunity			
The video laryngoscope is intended to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in such an electromagnetic environment:			
Immunity test	IEC 60601Test level	Comply with level	Electromagnetic environment - Guidance
Electrostatic Discharge GB/T 17626.2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be wood, concrete or tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient Burst GB/T 17626.4	±2 kV for power lines	±2 kV for power lines	Mains power quality should be that of a typical commercial or hospital environment.
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	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on the power input line GB/T 17626.11	＜5% U_T，lasts 0.5 cycles （On UT, >95% of the sag） 40% UT for 5 cycles (60% dip in UT) 70% UT for 25 cycles (30% dip in UT) <5% UT for 5s (>95% dip in UT)	<5% UT for 0.5 cycle (>95% dip in UT) 40% UT for 5 cycles (60% dip in UT) 70% UT for 25 cycles (30% dip in UT) <5% UT for 5s (>95% dip in UT)	The mains power quality should be that of a typical commercial or hospital environment. If the user of the video laryngoscope requires continued operation during mains power interruptions, it is recommended that the video laryngoscope be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field（50 Hz/60 Hz） GB/T 17626.8	3 A/m	3 A/m	Power frequency magnetic fields should be characteristic of levels found in a typical location in a typical commercial or hospital environment.
Notes： U_T Refers to the AC mains voltage before the test voltage is applied.			

Table 4

<table>
<tr><td colspan="4">Guidance and manufacturer's declaration - Electromagnetic immunity</td></tr>
<tr><td colspan="4">The video laryngoscope is intended to be used in the electromagnetic environment specified below. The purchaser or user should ensure that it is used in such an electromagnetic environment:</td></tr>
<tr><td>Immunity test</td><td>IEC 60601Test level</td><td>Comply with level</td><td>Electromagnetic environment - Guidance</td></tr>
<tr><td>Radio Frequency Conduction GB/T 17626.6</td><td>3 V （ Effective value） 150 kHz～80 MHz</td><td>3 V（Effective value）</td><td rowspan="2">Portable and mobile RF communications equipment should not be used closer to any part of the video laryngoscope, including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter.
Recommended isolation distance
$d = 1.2\sqrt{P}$
$d = 1.2\sqrt{P}$ 80 MHz～800 MHz
$d = 2.3\sqrt{P}$ 800 MHz～2.5 GHz
Where:
P—The maximum rated output power of the transmitter provided by the transmitter manufacturer, in watts (W);
d—The recommended isolation distance, in meters (m).
The field strength of fixed RF transmitters is determined by an electromagnetic site survey a and should be lower than the compliance level in each frequency range b.
Interference may occur in the vicinity of equipment marked with the following sy  l.</td></tr>
<tr><td>Radio Frequency Radiation GB/T 17626.3</td><td>3 V/m 80 MHz～2.5 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">Note 1: At 80 MHz and 800 MHz, the formula for the higher frequency band applies.
Note 2: These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">[a] 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 video laryngoscope is used exceeds the applicable RF compliance level above, the video laryngoscope should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the video laryngoscope.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Table 6

Recommended distance between portable and mobile radio frequency communication equipment and video laryngoscope			
The video laryngoscope is expected to be used in a controlled electromagnetic environment with radio frequency radiation disturbance. Communications equipment based on maximum rated power output, the purchaser or the user can through the following recommended by maintaining a portable and mobile radio communication equipment (transmitter) and the minimum distance between video laryngoscope to prevent electromagnetic interference.			
Maximum rated output power of transmitter W	The isolation distance corresponding to different frequencies of the transmitter/m		
	150 kHz～80 MHz $d = 1.2\sqrt{P}$	80 MHz～800 MHz $d = 1.2\sqrt{P}$	800 MHz～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
For not listed above transmitter maximum rated power output and the recommended separation distance d, in meters (m), a formula to determine the available transmitter frequency corresponding column, P here is provided by the transmitter manufacturers transmitter maximum rated output power, in watts (W) as the unit. Note 1: at 80mhz and 800mhz frequency points, the formula of higher frequency range is adopted. Note 2: these guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and humans.			