



New Technology
For Well Being

(Technical) Instructions for Use

Video laryngoscope

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Xinwell

Video laryngoscope



- Welcome to use Video Laryngoscope.
- This product is used in provoking the epiglottis of patients to expose glottis, and guiding medical personnel for correct endotracheal intubation.
- Before using it, please read this IFU carefully.
- After reading, please keep it well for reference at any time.

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Specification Parameters

1. The combination of host and disposable laryngoscope blade

Host	Disposable laryngoscope blade	Operating length (L)	Smallest width of the channel (H)
XY-204-A1	XY-204-A-138	121	13.2
	XY-204-A-126	117	11.2
	XY-204-A-114	102	8.6
XY-204-B1	XY-204-B-087	80	8.6

2. Other parameters

Performance index	Parameter
Appearance	The appearance of the product shall be in a uniform color, with no scratch, no scar, no flange, no burr or other deficiency. The word and sign shall be clear. The appearance of the blades shall be with no security hazard.
Host size	Length x width x height: 212.6 x 83 x 117.2mm
Resolution ratio of the camera	1 million pixels
Display screen	3.0 inch (720x480 pixels)
Battery	3300mAh
Rated voltage	4.2V DC
Input power	≤3.0 VA
Field of view	65°, Accuracy:±15%
Illuminance	L=30mm, ≥500 lx
Depth of the field	20mm~60mm
Anti-water performance	IPX7
Sterility of the blade	EO sterilized and disposable
Ambient environment (temperature and humidity)	0°C~35°C, 30%~75%RH
Valid date of the blade	2 Years
Valid date of the host	5 Years


Attention

Before using, the manufacturer shall train the users, and inform them the operation requirement, performance index and attentions. To use this product safely, and to prevent damage or loss, please pay attention to the following items:

Warning

- 1 Please do not use the blade if the inner package of blade is damaged or it is beyond the valid date.
- 2 Do not plug in or plug out the power adaptor with your wet hands. Otherwise, electric shock might happen.
- 3 Please do not reform, dismantle or fix the machine, or it might hurt human body. Please consult manufacturer if dismantling or repair is needed.
- 4 Please do not approach the fire, which will lead to the distortion, short circuit, and burning of machine.
- 5 Please do not look straight at the camera lamp, which will lead to discomfort in eyes.

Attention

- 6 After charging, please unplug the power adaptor.
- 7 Please use according to the method specified by manufacturer, otherwise defence provided by device might be damaged.
- 8 Please consult manufacturer agent if the components need to be checked or provided.
- 9 Please avoid strong vibration, which will lead to shell fracture or camera and inner component damage.
- 10 Please charge with 100-240V AC supply voltage, or fire and electric shock might happen.
- 11 Please do not use if the package of blade is damaged.
- 12 Blade is disposable, and please do not repeatedly use it. Dispose it according to the relevant regulation about medical waste and industrial waste specified by national and regional authorities.
- 13 Please do not pull the electric wire when unplug it, or it is easy to lead to electric shock because of wire breakage. (Please holds the insulation part of attaching plug when unplug it.)
- 14 If the image is not clear because the blood stains or sputum in patient's mouth pollutes the lens, please insert the machine after removing those.
- 15 If the battery power is less than 10%, the battery image will display , please shut it down at that time and charge the machine.
- 16 Please clean and disinfect the host before and after use, do not scrape the camera lens with hard objects during cleaning, in case that the definition is influenced.
- 17 Please check the insertion part and ensure it is no roughness, sharp edge or projection which may cause damage before use.
- 18 Please check the direction for picking up images is right to get real-time image when turn on the host.

Indication

Range

Products are used in lifting patients epiglottis exposed the glottis, accurately guide staff to endotracheal intubation.

Intended crowd and situation

Video laryngoscope is intended to use for patients with restricted neck movement in operation and first-aid (such as cervical spine injury and atlantoaxial dislocation), with oral maxillo-facial injury, with restricted mouth opening after injury or burn or with difficulty in breathing owing to high-position glottis. Epiglottis will be displayed on the screen, which makes the exposure clear and accurately guides staff to endotracheal intubation. Maneuverability is necessary to enter into hospital or emergency environment, this device is also easy to be applied in ER, ward or ICU.

The intended crowd include the adult and pediatric. XY-204-A1 is for adult and XY-204-B1 is for pediatric. Selection of blades is dependent on the glottis position.

Contraindications

1. Severe airway trauma or obstruction that does not permit safe passage of ETT.
2. Cervical spine injury, in which the need for complete immobilization of the cervical spine makes endotracheal intubation difficult.

Working principle

The image of epiglottis will be captured by camera in hook-on fitting, and the LED will provide light and contrast ratio. Products are used in lifting patients epiglottis exposed the glottis, accurately guide staff to endotracheal intubation.

Primary composition

The video laryngoscope is composed of the host, disposable laryngoscope blade (hereafter abbreviated as blade), power adaptor and USB charging line, etc. The host is composed of display fitting, handle fitting and hook-on fitting. The details are shown in **Fig.1** and **Fig.2**.

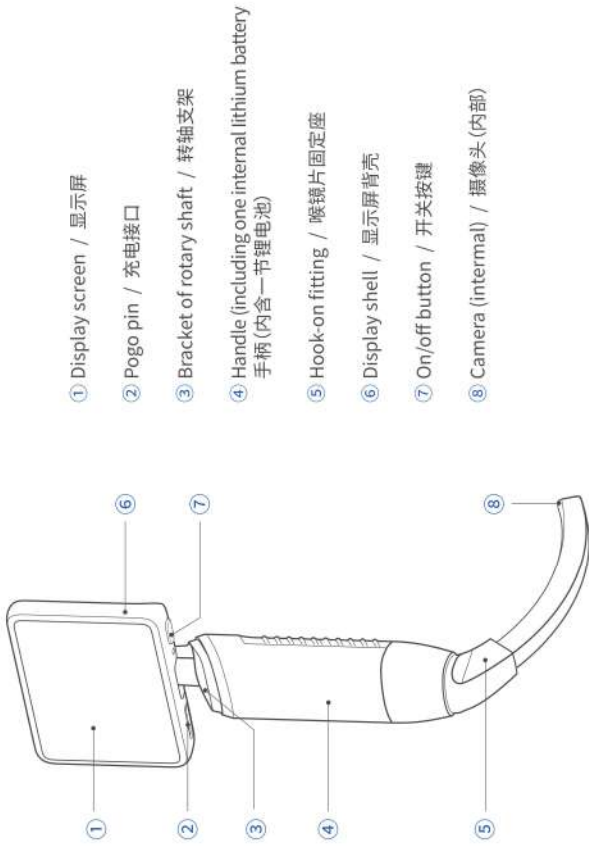


Fig. 1 Schematic drawing of the Video Laryngoscope

图一 麻醉视频喉镜产品结构图

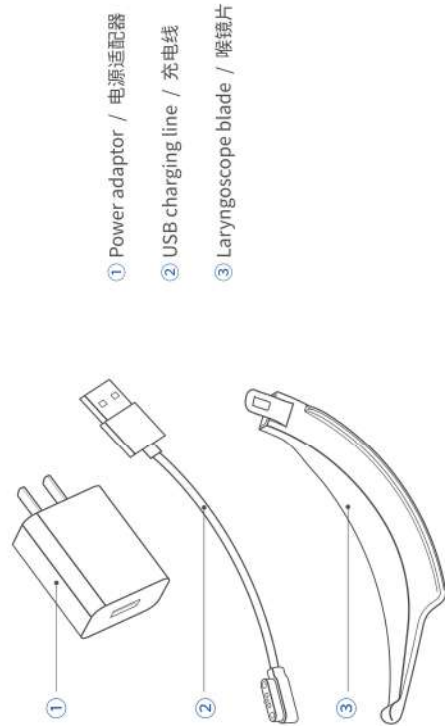


Fig. 2 Accessory drawing of the Video Laryngoscope

图二 麻醉视频喉镜配件图

Operation

Acceptance guidance

The product has been tested rigorously according to the technical requirements before leaving factory and packed cautiously to avoid to damage occurs in transportation and unwrapping. Please perform the following steps after receiving the product:

Check whether there is crack, dent or other damage in outer carton caused by transportation. If there is, please contact with our company timely.

Open the Lid and base box, check the accessories according to the Accessory List and whether there is damage in host and blade package. If there is, please contact with our company timely.

Accessory list

1. Accessory list of XY-204-A1

Component name	Quantity	Note
Video laryngoscope	1	
Disposable laryngoscope blade(114)	1	
Disposable laryngoscope blade(126)	1	
Disposable laryngoscope blade(138)	1	
Power adaptor	1	
Magnetic USB charging line	1	
Instruction for use(IFU)	1	

2. Accessory list of XY-204-B1

Component name	Quantity	Note
Video laryngoscope	1	
Disposable laryngoscope blade(087)	3	
Power adaptor	1	
Magnetic USB charging line	1	
Instruction for use(IFU)	1	

Operating environment

Atmosphere range: 86kPa~106kPa

Keep away from electromagnetic interference

Operation

- Charging the battery**
 - Video Laryngoscope uses Li-ion battery arranged in the handle and power adapter randomly equipped. Battery charger is the only power adapter for Video Laryngoscope, just for charging.

Attention: Please charge the product with power adaptor complying with the electrical safety requirements.

Attention: Li-ion battery is not fully charged leaving the factory. Please fully charge the adapter in your first use.

Attention: The action of plugging and unplugging shall be smooth with no interference by other substances, and please unplug the power adaptor when the charging completes.

 - Full charging the battery needs 5 hours. There will be a charging icon displayed on the screen when it is being charged. The screen will go out after standing still for 1 minute, but the charging will go on until it's fully charged.

Attention: If power on and the USB is plugged for charging, the screen is locked to display relevant charging interface.
- Connection with blade**
 - Select the blades depending on the glottis position.
 - Take out the disposable blade from its package (coated paper and PE bag).
 - Insert the connector of handle into the connecting set of blade.

Attention: Insert the handle connector into the connecting set of blade. Please make sure the clip is clamped well. If it is not clamped well, the product may malfunction or hurt human body. (as is shown in Fig.3)

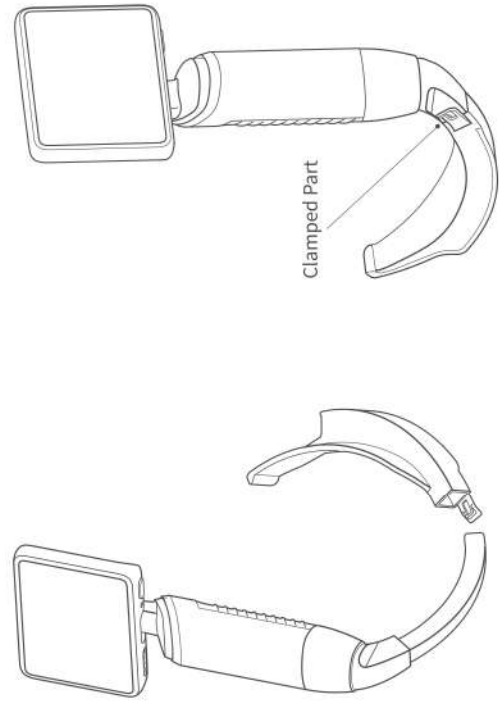



Fig. 3 Connection with blade

Power on

- Press the power button “” for 3 seconds. Image should be on the display screen, and white LED is automatically open.
 - Patients lie on their heads, and Doctors lift their necks up, letting their oropharynx and trachea overlapping in one axis, which is the standard operation of intubation. Doctors stand besides patients' heads, pushing their lower lip and jaw off, bracing the incisors with index fingers.
 - When mouth is open entirely, hold the laryngoscope with left hand, making the pick-up head is in right angle with larynx. At that time, observe the display screen. Until there is an edge of glottis on the screen, push the blade gently. After the glottis is totally exposed, endotracheal intubation should begin according to the guidance of display screen.
- Attention:** If the image is not clear because the blood stains or sputum in patient's mouth pollutes the lens, please insert the machine after removing those.
- During use, the rotary angle of display screen could be adjusted (the biggest rotary angle is 85°) to adapt different use, environment and angle. (as is shown in Fig. 4)

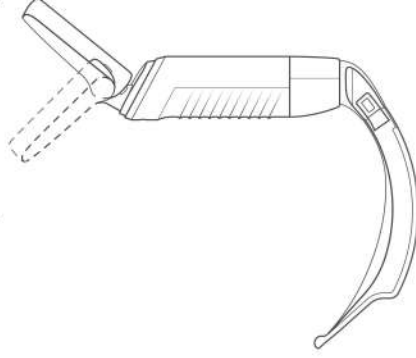



Fig.4 Rotary angle of display screen

- After use, press the power button “” for about 3 seconds. Release the button after confirming there is no display on the screen, indicating the host is closed. The white LED will be closed automatically after power off. Then you should take the blade off, destroy it according to the regulation, and wipe the hook-on fitting and handle with 75% medical alcohol.
- After wiping, put the host into the package, dry them, then keep it in the clean and dry environment.

Battery power display

Battery power icon is on the upper right of the screen with a battery shape. If battery is full, there will be 5 white blanks displayed. If the icon changes to , it is a lower power alarm, and the product shall be charged timely.

Battery change

The use habit will have significant influence on battery. Bad habit, such as excessive charging, over discharging, placement in high temperature, will do irreversible harm to battery, which lead to battery capacity decline. When the battery capacity couldn't meet the normal operation requirements, please contact with our company to change the battery.

Consumable

The blade is the consumable of the product. The change method of it can be seen in section Connection with blade and Power on in this IFU.

Decommissioning and disposal

The video laryngoscope is primarily composed of host and disposable laryngoscope blade. The valid date of video laryngoscope is 5 years. When beyond valid date, if the engineer of the manufacturer validates that the safety and effectiveness have no influence on product, the host can be in delayed use. Otherwise, the product shall be disposed according to the relevant regulation about medical waste and industrial waste specified by national and regional authorities.

The valid date of the blade is 2 years when complying with the specified transport, storage and use method. The blade beyond valid date is forbidden to use.

▲ Attention: The blade is EO sterilized, it is forbidden to use blade beyond valid date or damaged package. The used blade shall be disposed according to the relevant regulation about medical waste and industrial waste specified by national and regional authorities.

Maintenance

Daily maintenance

- 1 The handle surfaces shall be wiped with dry or 75% alcohol dust-free soft cloth and for safekeeping after use.
 - a Do not scrape the glass plate of lens with hard objects, to prevent influencing the definition.
 - b Blades after EO sterilization are disposable products. Repeated use is strictly forbidden.
- 2 Please contact with the manufacturer timely if the product can't be charged.
- 3 Please put the product with package in a dry and clean place.
- 4 Please do not dismantle or repair the product, to prevent damaging it.
- 5 Please dispose the host according to the relevant regulation about electrical equipment waste specified regional authorities when it is beyond valid date.

Cleaning Method

- 1 Before use, please wipe the product with dry or 75% alcohol dust-free soft cloth.
- 2 Blades are solely packaged after EO sterilization. It is disposable, repeated use and blade with damaged package is strictly forbidden.

- 3 After use, please unload and destroy the blades. And please clean the host machine and handle with dry or 75% alcohol dust-free soft cloth.

Malfunction Analysis and Exclusion

When any adverse event in the following table appears, users can take action to cope according to the Ways of Coping in the following table.

Table 1 Malfunction information table

NO.	Adverse Events of Operation	Ways of Coping
1.	Cannot turn it on.	If the battery power is not sufficient, charge for 5 minutes, then remove the USB, and turn it on. If it still can't be turned on, there may be damage in internal components. Please contact the after-sales for repair.
2.	Blur Image	Check if there is foreign matter on the blade surface.
3.	Battery cannot be charged normally.	Please affirm if the plug is totally inserted in the socket. Please insert other machine's plug into the socket to affirm if the socket is electrified. If it still cannot be charged normally, please contact with after-sales in time.

Transport and storage condition

Transport condition

Use general means of transport, avoid violate impact, rain and sunlight exposure

Storage condition

Store indoors with good ventilation and no corrosive gas where the temperature is from -20°C to +55°C, relative humidity is no more than 80%.

Production date and Valid date

Production date

Shown on the label.

Valid date

The host is valid for 5 years, which follow the regulation of regular maintenance, consumable change, component repair.

The blade after EO sterilization is valid for two years, which follow the regulation of storage, transport and use method. The expiry date can be seen on package sealing.

Warnings and Symbols Explanation

All warnings and symbols included in the product shall not be covered or torn off. If the warnings and symbols detach or are vague, please inform the technical department of XINWELL to change.

Symbol	Meaning	Symbol	Meaning
	KEEP DRY		KEEP AWAY FROM SUNLIGHT
	FRAGILE. HANDLE WITH CARE		THIS WAY UP
	CAUTION		DO NOT RE-USE
	STERILIZED USING ETHYLENE OXIDE		CONSULT INSTRUCTIONS FOR USE
	SERIAL NUMBER		DO NOT USE IF PACKAGE IS DAMAGED
	ON/OFF BUTTON		DO NOT RESTERILIZE
	CLASS 7 ANTI-WATER		TYPE BF
	BATTERY INDICATION		ABANDONED ELECTRIC EQUIPMENT SIGN (PLEASE OBSERVE THE LOCAL REGULATION)
	CLASS II EQUIPMENT		LOW BATTERY
	MANUFACTURER		DIRECT CURRENT
	BATCH CODE		DATE OF MANUFACTURE
	USE BY		CATALOGUE NUMBER
	THE PRODUCT HAS PASSED CE CERTIFICATION		AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	TEMPERATURE LIMIT		

EMC

EMC information

Special prevention measures related to EMC are required. Install and use it according to EMC information specified in IFU.

Portable and mobile RF communication equipment may influence this product.

Besides the cables (transducer) sold as spare parts of internal components, the accessories and cables (transducer) out of provision may lead to the increase of emission of equipment and system or the decrease of noise immunity.


Equipment or system should not be close to or in stacking use with other equipment. If it has to, please observe and verify that it can be operated normally with the used configuration.

Cable information		
Cable name	Model&Spec.	Length
Magnetic USB charging line	/	0.9m

Basic performance	
Name	Description
Charging performance	When the charging performance is normal, the LED displays green light during charging, and the green light will keep if it's fully charged
Image performance	The image can be captured clearly

Guidance and Manufacturer Declaration ----- EME		
Equipment is expected to be used in the following regulated EM environment. Purchaser or user should assure it is used in this environment:		
Emission Test	Conformity	EM environment ----- guidance
RF emission GB 4824 (CISPR 11)	1 group	Equipment uses RF energy for its internal function. In hence, its RF emission is quite low. And it influences the electric equipment around in a quite low possibility.
RF emission GB 4824 (CISPR 11)	Class A	Equipment is applicable to all non-domestic equipment and equipment not directly connecting to the low-voltage power supply network of residence.
Harmonic radiation GB 17625.1	Not applicable	
Voltage fluctuation/ flash emission GB 17625.2 (IEC61000-3-3)	Not applicable	

Guidance and Manufacturer Declaration ----- EMI			
Equipment is expected to be used in the following regulated EM environment. Purchaser or user should assure it is used in this environment:			
Immunity Test	IEC60601 Test Voltage	Conforming Voltage	EM environment --- Guidance
Electrostatic Discharge (ESD) GB/T 17626.2 (IEC61000-4-2)	<ul style="list-style-type: none"> ±8kV Contact Discharge ± 15kV Air Discharge 	<ul style="list-style-type: none"> ±8kV Contact ±15kV Air 	The floor should be made of wood, concrete or ceramic tile. If the floor is made of composite material, the relative humidity should be at least 30%.
EFT GB/T 17626.4 (IEC61000-4-4)	<ul style="list-style-type: none"> ±2kV On the power cord ±1kV On the input/output line 	<ul style="list-style-type: none"> ±2kV is not applicable to power cord 	Net power should have the quality used in typical business or hospital.
Surge GB/T 17626.5 (IEC61000-4-5)	<ul style="list-style-type: none"> ±1kV Line to line ±2kV Line to ground 	<ul style="list-style-type: none"> ±1kV Line to line Is not applicable 	Net power should have the quality used in typical business or hospital.
Voltage dip, short disruption and voltage change on the power input line GB/T 17626.11 (IEC61000-4-11)	<ul style="list-style-type: none"> 5% UT, sustaining 0.5 circle (on the UT, > 95% sagging) 40% UT, sustaining 5 circles (on the UT, 60% sagging) 70% UT, sustaining 25 circles (on the UT, 30% sagging) < 5% UT, sustaining 5s (on the UT, > 95% sagging) 	<ul style="list-style-type: none"> < 5% UT, sustaining 0.5 circle (on the UT, > 95% sagging) 40% UT, sustaining 5 circles (on the UT, 60% sagging) 70% UT, sustaining 25 circles (on the UT, 30% sagging) < 5% UT, sustaining 5s (on the UT, > 95% sagging) 	Net power should have the quality used in typical business or hospital. If users need successive operation of equipment during power off, UP or battery operation is recommended.
PFMF (50/60Hz) GB/T 17626.8 (IEC61000-4-8)	3 A/m	3 A/m	PFMF should have the PFMF level property in typical business or hospital.

RF conduct GB/T 17262.6 (IEC61000-4-6)	3 V (effective value) 150kHz - 80MHz	3 V (effective value)	<ul style="list-style-type: none"> Portable and mobile RF communication equipment should not use any parts closer to equipment compared with the recommended isolation distance, including cables. This distance should be calculated by the relative formulas. Recommended isolation distance $d = 1.2 \sqrt{P}$ 150kHz-80MHz $d = 1.2 \sqrt{P}$ 80MHz-800MHz $d = 2.3 \sqrt{P}$ 800MHz-2.5GHz In formulas: P—According to the biggest rated power output of transmitter provided by transmitter manufacturer, the unit is Watt (W); d—Recommended isolation distance. Its unit is meter (m). Field intensity of fixed RF transmitter should be assured through the survey to EMF. Every frequency range should be lower than conforming voltage. Disturbance may appear around the equipment marked in the following symbol. 
RF radiation GB/T 17262.3 (IEC61000-4-3)	3 V/m 80MHz - 2.5GHz	3 V/m	
<p>Note 1: UT points AC voltage before exerting experimental voltage.</p> <p>Note 2: Use high frequency formulas on the 80MHz and 800MHz frequency.</p> <p>Note 3: The guidance may be not applicable to all situations. Electromagnetic propagation is influenced by uptake and reflects of buildings, objects, and human body.</p>			
<p>A. Fixed transmitter, such as: wireless phone (honeycomb/cordless), land mobile radio base station, amateur radio, FM, AM, and telecast, etc. Their field intensity cannot be predicted accurately in theory. To evaluate the EME of fixed RF transmitter, survey of electromagnetic fields should be considered. If the field intensity where equipment placed in is higher than the above RF conforming level, observe the equipment to verify if it can operate normally. If abnormal performance is observed, supplemental measures are required, such as adjusting the direction or position of equipment again.</p> <p>B. Under the frequency range of 150kHz-80MHz, field intensity should be lower than 3V/ M.</p>			

Authorized representative in European community



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Effective Date: 2020-05-13 Ver. No.: 1.0

Recommended Isolation Distance between Portable and Mobile RF Communication Equipment and this equipment																		
Recommended Isolation Distance between Portable and Mobile RF Communication Equipment and this equipment This equipment is expected to be used in the EME where RF radiation disturb is controlled. According to the biggest rated power output of communication equipment, the purchaser or user could prevent electromagnetic interference through the following recommended minimum distance between portable and mobile RF communication equipment (transmitter) and this equipment.																		
Biggest Rated Output Power of Transmitter W	Isolation distance for different frequency of transmitter/m																	
	<table border="1"> <thead> <tr> <th>150kHz - 80MHz $d = 1.2 \sqrt{(p)}$</th> <th>80MHz - 800MHz $d = 1.2 \sqrt{(p)}$</th> <th>800MHz - 2.5GHz $d = 2.3 \sqrt{(p)}$</th> </tr> </thead> <tbody> <tr> <td>0.01</td> <td>0.12</td> <td>0.12</td> </tr> <tr> <td>0.1</td> <td>0.38</td> <td>0.38</td> </tr> <tr> <td>1</td> <td>1.2</td> <td>1.2</td> </tr> <tr> <td>10</td> <td>3.8</td> <td>3.8</td> </tr> <tr> <td>100</td> <td>12</td> <td>12</td> </tr> </tbody> </table>	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	0.1	0.38	0.38	1	1.2	1.2	10	3.8	3.8	100	12
150kHz - 80MHz $d = 1.2 \sqrt{(p)}$	80MHz - 800MHz $d = 1.2 \sqrt{(p)}$	800MHz - 2.5GHz $d = 2.3 \sqrt{(p)}$																
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0.1	0.38	0.38																
1	1.2	1.2																
10	3.8	3.8																
100	12	12																
For the biggest rated output power of transmitter not listed above, recommend isolation distance (d) could be affirmed by corresponding formulas in transmitter frequency column, with the unit of meter (m). P represents the biggest rated output power of transmitter provided by transmitter manufacturer. Its unit is Watt (W).																		
<p>Note 1: When the frequency is 80MHz and 800MHz, use the high frequency formulas.</p> <p>Note 2: The guidance may be not applicable to all situations. Electromagnetic propagation is influenced by uptake and reflects of buildings, objects, human body.</p>																		