Instructions for Use

Flexible Videoscopes For Single Use

CE 0197

Zhejiang UE Medical Corp.

Contents

1 Important Information (please read before use)

Welcome to choose Flexible Videoscopes for Single Use and please read the Instruction carefully before use. The instruction may be updated without further notice. Copies of the current version are available upon request.
The Instructions for Use is applicable to the Flexible Videoscopes for Single Use. As for the detailed info. about UE Display that used together, please refer to the IFU of UE Display.

Notes

The instruction does not explain or discuss clinical procedures, and it only describes the basic operation and precautions related to the operation of the Flexible Videoscopes for Single Use.
Before initial use, it is required for the operator to be fully trained about the use of clinical endoscopes and be familiar with the intended use, indications, warnings, precautions, contraindications, etc. specified in the Instructions for Use.
Maintenance is not necessary as it is a single use device; for storage and transportation conditions, please refer to the descriptions in Section 2.2 'Other Performances'.

1.1 Intended Purpose

The Flexible Videoscopes for Single Use has been designed to be used with the UE Display and endotherapy accessories for endoscopy within the airways and tracheobronchial tree, and it can also be used with an active suction device for suction.

1.2 Indications for Use

It can be used in clinical situations such as Hemoptysis, Foreign body inhalation, Endotracheal intubation, Chest trauma, Pulmonary and bronchial infections.

1.3 Warnings and Precautions

Failure to follow the warnings and precautions may cause injury to patients or damage to the device.

⚠ Warnings

1. The device should not be used in places with fire hazards.
2. The device is disposable and must be handled in a manner consistent with accepted medical practice for such devices.
3. Do not attempt to clean and reuse the device as it is disposable.
4. It is prohibited to use the device in the presence of flammable anesthesia gas mixed with air, or flammable anesthetic gas mixed with oxygen or nitrous oxide, can not be used in oxygen-rich environment to avoid fire or medical accidents.
5. Please do not use the device if the package is broken or function is abnormal.
6. It is prohibited to use the device in a MRI environment.
7. Only to be used by skilled physicians trained in clinical endoscopic techniques and procedures.
8. It is required to watch the real-time images on the UE Display during the operation of inserting, withdrawing and bending. Do not exert excessive force, as it may cause injury to the patient or damage to the device. Directly shinning the light of front end of endoscope into the eyes of patients or other people is prohibited.
9. The device shouldn' t be used for any purpose that goes beyond its intended uses.
10. Heat dissipation from light-emitting part may raise the temperature of the distal tip of the device to over 41℃. Prolonged contact between the head end of the device and mucosa is prohibited, as it may cause mucosa injury.
11. Please make sure that the Tee Cap is closed before suction.
12. Have a alternative endoscope ready to use to ensure continued treatment in the event of the device failure.
13. The outer surface of the tube to be inserted should be checked before each use to ensure that there are no accidental rough surfaces, sharp edges or projections that could cause injury.
14. Before use, carefully check whether the image on the UE display is real-time or recorded, and check whether the direction of the image is as expected.
15. Do not use the active endoscope accessories (such as laser probe and electric surgical equipment) together with this device, otherwise the patient will be injured or the device will be damaged.
16. The device is composed of the parts provided by UE Medical. It can only be replaced with parts that have been authorized by UE Medical. Failure to follow this principle may result in injury to patient.
17. Always make sure that the bending portion is in a straight position when inserting or withdrawing the videoscope accessory in the working channel. Do not operate the deflection control lever and never use excessive force, as this may result in injury to the patient and or damage to the device.
18. When UE Display is in use with the device and other electronic devices are involved, the function in each other may be affected. If it is adjacent to or piled up with other electronic devices, please observe and check whether they can work normally before use. It may be necessary to replacate the device or shield other electronic devices, or shield the room in which they are in, etc. to mitigate interference between them.
19. Always check the compatibility of the endotracheal tube with the double-lumen tube.
20. If failure occurs during the endoscopic surgery, stop the operation immediately and withdraw the device.

⚠ Precautions

1. Do not exert excessive force when using the device or bend it even at a small angle.
2. The device is provided in sterile. The matched UE Display is provided in non-sterile, and required to be disinfected according to the IFU of UE Display before use.
3. Please confirm that UE Display is fully charged before use.
4. Check the device before use to make sure that the package is intact and the device can run normally after connecting with UE Display.
5. Directly pulling or bending the bending portion by hand is prohibited during operation as it may cause damage to the device. Returning the bending portion to neutral position by deflection control lever is required.
6. Provide patient with a dental pad to avoid injury in using the device.
7. For data or documents processing, please refer to the IFU of UE Display.
8. Keep the device away from any external adverse effects, such as strong electromagnetic radiation or high temperature.
9. The device should be handled carefully to avoid impact, severe vibration and moisture during transportation and use.
10. It is not recommended to apply the device to patient who uses anticoagulant drugs or has blood diseases or coagulopathy.
11. Do not overly tighten any cables.
12. The camera module and LED at the distal tip of the device are easily damaged by external force collision, which may cause image distortion. Please use carefully to avoid collision with other objects.
13. Do not insert a wet cable into display interface, or it may lead to poor video performance or damage to the system.
14. Not compatible with defibrillator.
15. The device is considered contaminated after use and must be disposed of in accordance with local guidelines for the collection of infected medical device with electronic components.
16. Verify the expiration date. Do not use if expired.
17. DO NOT re-use, re-sterilize, and/or reprocess the device.
18. Modification of the device is prohibited.
19. The device is suitable for use in the specified electromagnetic environment and it meets the following immunity test levels. Higher immunity levels may cause the essential performance loss or degradation of the device.
20. Reference label to choose appropriate size.
21. Negative pressure should not exceed 70kPa during suction. If the negative pressure is too high, it may be difficult to interrupt the suction and cause injury.
22. Note: Use suitable water based lubricant to lubricate the insertion section of the device during intubation is also recommended.
23. Cautions: After the use, it is required to confirm the integrity of the device. In case any part is missing, corrective measures must be taken to find the missing parts.

1.4 Contraindications

1. Inadequate intraoperative oxygenation.
2. Malignant arrhythmia.
3. Cardiac instability.
4. Refractory hypoxemia.
5. Coagulopathy.
6. Severe thrombocytopenia.
7. Any other conditions the physician judges unsuitable for use.

1.5 Intended clinical benefits

1. Used with UE display and endotherapy accessories to obtain clear image for inspecting the airways, diagnosing disease, removing inhaled foreign body, and assisting with intubation.
2. Single use application minimises the risk of cross-contamination of the patient.

1.6 Intended user

This device must be used by medical professionals who have been fully trained to operate the clinical endoscopy skillfully and are good at endoscopy-based surgery.

1.7 Intended using environment

The Flexible Videoscopes for Single Use is only designed for use in hospitals.

1.8 Intended patient population

The Flexible Videoscopes for Single Use is designed for use in adults.
Gender: not restrictions;
Weight: no restrictions for weight of the patients;
Health: Patients who need to perform bronchoscopy and treatment, foreign body removal, etc.;
Nationality: multiple.;
Patient state: Patient is not the Operator.

2 Product Description

Flexible Videoscopes for Single Use can be used together with UE Display. For info. on UE Display, please refer to the corresponding Instructions for Use.

2.1 Specifications and models

Models	Outer diameter of hard part at distal end	Outer diameter of insertion tube	Maximum outer diameter of insertion section	Maximum outer diameter of insertion section	Working length
EBS-380C	Φ4.0mm	Φ3.8mm	Φ4.4mm	Φ1.2mm	600mm
EBS-500C	Φ5.0mm	Φ5.0mm	Φ5.5mm	Φ2.2mm	600mm
EBS-600C	Φ5.8mm	Φ5.8mm	Φ6.5mm	Φ2.8mm	600mm

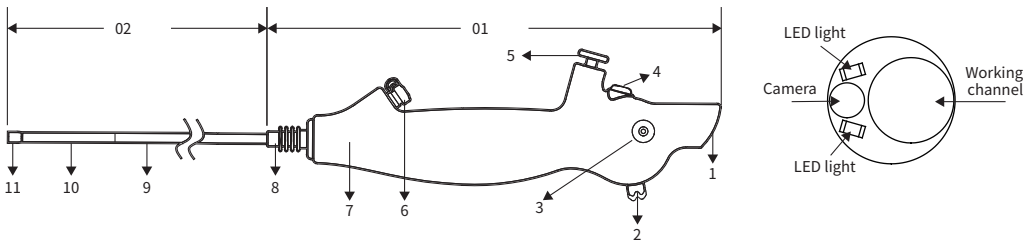
Comments:
Specifications and models (full name):
EBS-380C: Flexible Videoscopes for Single Use Slim 3.8/1.2
EBS-500C: Flexible Videoscopes for Single Use Regular 5.0/2.2
EBS-600C: Flexible Videoscopes for Single Use Large 5.8/2.8

2.2 Other Performances

Other Performances		EBS-380C	EBS-500C	EBS-600C
Optical System	Field of view (°)	90		
	Depth of field (mm)	6–50		
	Illumination (lux)	⩾700		
Storage and Transportation	Transportation temperature (℃)	-35~60		
	Recommended storage temperature (℃)	-20~40		
	Relative humidity (%)	30~93		
	Atmospheric pressure (hPa)	500~1060		
Operating Environment	Temperature (℃)	5~40		
	Relative humidity (%)	30~85		
	Atmospheric pressure (hPa)	860~1060		
Sterilization	Sterilization Method	EO		
Bending angle	Upward bending angle (°)	180	180	180
	Downward bending angle (°)	180	180	180
Operation mode		Non-continuous, reference UE Display		

2.3 Structure and Performance

The flexible videoscope for single use consists of operating section and insertion section.



S/N	Name	Function
01	Operating section	Control deflection control lever, suction button and camera button to complete the operation of bending, suction, picture taking/video recording, etc.
02	Insertion section	The part inserted into patients, namely applied part.
1	Display interface	Connecting UE Display.
2	Deflection control lever	Control the direction of the bending angle.
3	Suction interface	Connect with the negative-pressure device.
4	Camera button	Single-click to picture taking, long press the button to video recording.
5	Suction button	Press to suction.
6	Tee cap	Close the Tee cap during suction and keep it open during liquid delivery.
7	Handle	Suitable for holding in left and right hands.
8	Tube connection	Used for fixing ETT in advance.
9	Insertion tube	Used for bendable insertion.
10	Bending portion	Achieve the bending directions.
11	Distal tip	Includes camera, LED light and working channel.

2.4 Compatible Devices

2.4.1 Display device
UE Display
2.4.2 Other compatible devices
It has been evaluated for the following endotracheal tubes (ETT), double lumen tubes (DLT) and endoscopic accessories (EA) sizes:

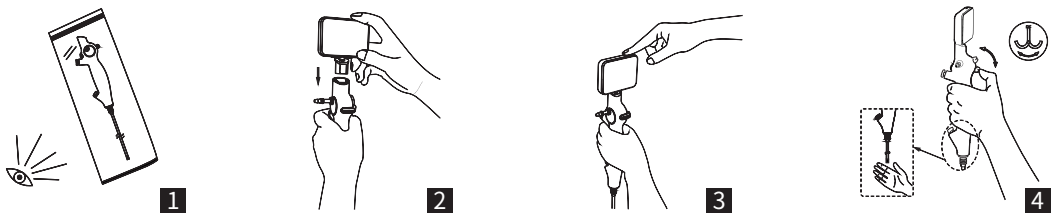
Models	Minimum ETT inner diameter	Minimum DLT size	EA maximum working channel width
EBS-380C	5.0mm	35 Fr	Up to 1.2mm
EBS-500C	6.0mm	N/A	Up to 2.2mm
EBS-600C	7.0mm	N/A	Up to 2.8mm

Notes:
1. The insertion part of the equipment must be lubricated before use;
2. There is no guarantee that instruments selected solely using this working channel size will be compatible in combination. Compatibility of selected instruments should be tested before the procedure.

3 Instructions for Use

3.1 Check and Preparation

1. Check whether the paper-plastic bag is intact.①
2. Open the package and take out the Flexible Videoscopes for Single Use.
3. Hold Flexible Videoscopes for Single Use with one hand, hold UE Display with the other hand and connect it to the Display interface on Flexible Videoscopes for Single Use, then press the switch button on UE Display and confirm whether the screen displays normally and at right direction. When necessary, adjust image settings on UE Display, refer to IFU of UE Display for specifics.②③
4. Use thumb to gently pull the swing arm up and down to confirm whether the bending angle is normal, and use index finger to control the suction button and camera button to see if they function normally.④



3.2 Insertion ⑤

Before insertion, please apply medical-grade water-soluble lubricant on the insertion section of Flexible Videoscopes for Single Use, watch the real-time image on the UE Display and insert it into oral or nasal cavity of patient. If the image on screen is blurred, gently rub the tip of head end against mucosa wall or withdraw the device and clean the camera with sterile gauze. When inserting the endoscope orally, it is recommended to use a mouth pad to protect the endoscope from being damaged.

3.3 Liquid Injection ⑥

Open the Tee cap, completely insert the head of the syringe into the Tee port and push the syringe piston to inject the liquid via the working channel of the device, during which suction operation is not allowed as it will direct the liquid into the suction collection system. Flush the passage with 2ml of air to make sure that all liquid has left the channel.

3.4 Suction ⑦

Connect the negative-pressure system to the suction interface on Flexible Videoscopes for Single Use, hold the suction button by index finger to start suction. Please keep the working channel of the device unblocked and the Tee cap is closed.

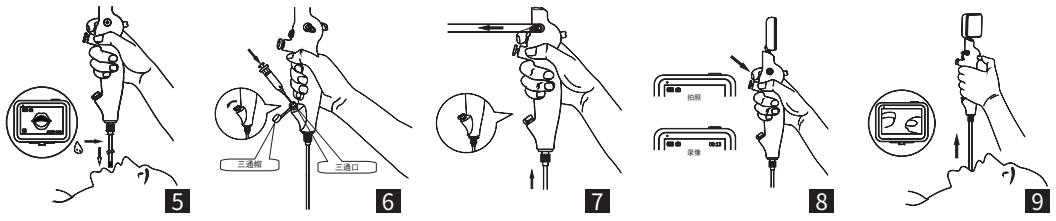
3.5 Photo Shooting and Video Recording ⑧

Photo shooting: short press the camera button, picture was successfully taken if a photo shooting icon flicked on the upper left corner of UE Display.

Video recording: long press the camera button for 1 - 2 seconds, the device is recording if video recording symbol appears with a flicking red spot on the upper left corner and timing starts on the upper right corner. Double press the camera button to end and complete the recording.

3.6 Device Removal ⑨

After operation, watch UE Display and control the deflection control lever by thumb to withdraw the insertion tube slowly, do not pull it out violently; Then long press the switch button on UE Display to turn the display off, and pull the UE Display out from the Flexible Videoscopes for Single Use.



3.7 Disposal after Use

Visual Inspection:

Are there any parts missing from the bending portion, lens, or insertion tube? If any part is missing, please take corrective action to find it. Are there any signs of damage to the bending portion, lens, or insertion tube? If so, please check the integrity of the device and determine if there are any missing parts. Are there cracks, holes, sharp edges, loose, swelling, or other abnormalities in the bending portion, lens, or insertion tube? If so, please check if the parts of the videoscope are fell off.

The Flexible Videoscopes for Single Use is a disposable medical device and is not suitable for traditional cleaning and disinfection. The device is considered contaminated after use and must be disposed in accordance with local guidelines for collection of infected medical devices with electronic components. Reuse the device after disinfection is prohibited, otherwise it will cause cross infection.

4 Product Technical Specifications

The Flexible Videoscopes for Single Use comply with the following standards:

–IEC 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance.

–IEC 60601-1-2 Medical Electrical Equipment - General Requirements for Basic Safety and Essential Performance, Collateral Standard, Electromagnetic Disturbances, Requirements and Tests.

–IEC 60601-2-18 Medical Electrical Equipment, Part 2 - 18: Particular Requirements for the Basic Safety and Essential Performance of Endoscopic Equipment.

–ISO 8600-1 Endoscopes — Medical Endoscopes and Endotherapy Devices — Part 1: General Requirements.

–ISO 11135:2014 Sterilization of Health-care Products — Ethylene Oxide — Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices.

5 Troubleshooting

Problem	Possible cause	Recommended action
Unclear image	Blood, saliva or other dirt on the camera	Withdraw the Flexible Videoscope for Single Use and wipe the camera with sterile gauze
Absent or reduced suction capability	Blocked channel	Rinse the working channel with sterile saline by a syringe.
	Suction pump is not turned on or not connected to negative-pressure pump.	Turn on the pump on and check the suction tube connection.
	The swing arm is not at the neutral position	Return the swing arm to the neutral position
No image on the UE Display	The Flexible Videoscope For Single Use is not connected to the UE Display	Connect to the UE Display. (If any resistance is found, do not operate violently to avoid further damage to the device)
	The Flexible Videoscope For Single Use is damaged	Replace the endoscope with a new one.
The LED light is off	The Flexible Videoscope For Single Use is damaged	Replace the endoscope with a new one.
	The Flexible Videoscope For Single Use is not connected to the UE Display	Connect the UE Display. (If any resistance is found, do not operate violently to avoid further damage to the device)

6 Description on Marks

Mark		UDI			
Description	TYPE BF APPLIED PART	Unique Device Identifier	Temperature limit (-35°C ~60°C)	Humidity limitation (30%~93%)	Atmospheric pressure limitation (500hpa~1060hpa)
Mark					
Description	Fragile, handle with care	This Way Up	Keep away from sunlight	Keep dry	Stacking limit by 5
Mark		CN			LOT
Description	Do not use if package is damaged	Date of manufacture, Country of manufacture	Use-by date	Manufacturer	Batch code
Mark	MD			90°	IPX7
Description	Medical device	Caution	Do not re-use	Field of view	IP Code (Insertion section)
Mark	CE 0197			60cm / 23.6"	
Description	CE marking of conformity, and Notified Body Code			Working length of the insertion portion	
Mark		STERILE EO			
Description	Refer to instruction manual/booklet	Sterilized using ethylene oxide, Single sterile barrier system			

7 Date of manufacture and service life

The Flexible Videoscopes for Single Use is disposable,and valid for 3 years after sterilization.

Date of manufacture: see product label for details. Use-by date: see product label for details.

Date of Compilation (Revision) of Instruction Manual: April, 2023

8 Customer service

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation (EU) 2017/745 on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website: https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

For additional information, contact your Zhejiang UE Medical Corp. Sales Representative or Customer Service.

No electronic version of the IFU provided.

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Appendixes: EMC Performance Index

Basic Performance of the Device (Table 1)

Mode	Description
Work Mode	The real-time pictures captured by camera can be showed on UE Display in any situation.

The special precautionary measures related to the electromagnetic compatibility (EMC) shall be adopted for the device, and the installation and use shall be conducted in accordance with the information on the electromagnetic compatibility stipulated in the instructions. Portable and mobile radio-frequency communication equipment may affect the device.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The following cable shall be used to meet the requirements on the aspect of the electromagnetic emission and anti-interference performance. (Table 2)

Cable Name	Type-C data line	Connection line
Length	1.5m	2.0m

In addition to the cables (transducers) sold as the spare parts of the internal components, the accessories and cables (transducers) which are not stipulated may increase the emission of the device or system or reduce the noise immunity.

The device or system shall not be near to or stacked up with other equipment for the use, and if the device or system needs to be near to or stacked up with other equipment, the observation and verification shall be conducted for ensuring that the normal operation can be achieved under its used configuration.

PORTABLE RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME QUIPMENT or ME SYSTEM], including cables specified by the MANUFACTURER. Otherwise, degradation of the performance of this equipment could result.

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guideline and Statement of the Manufacturer – Electromagnetic Emission (Table 3)

Guideline and Statement of the Manufacturer – Electromagnetic Emission		
The Flexible Videoscope for Single Use is estimated to be used in the following stipulated electromagnetic environment, and the purchasers or users shall guarantee that it is used in such electromagnetic environment.		
Emission Experiment	Conformity	Electromagnetic Environment – Guideline
CISPR 11:2015+A1+A2 Conducted and radiated RF emissions	Group 1, class A	The device only uses the radio-frequency energy for the internal functions. Therefore, its radio-frequency emission is very low, and has very low possibility for producing the disturbance for the nearby electric equipment.

Guideline and Statement of the Manufacturer – Electromagnetic Immunity (Table 4)

Guideline and Statement of the Manufacturer – Electromagnetic Immunity			
The device is estimated to be used in the following stipulated electromagnetic environment, and the purchasers or users shall guarantee that it is used in the electromagnetic environment.			
Immunity Test	60601 Test Level	Conformity Level	Electromagnetic Environment – Guideline
IEC 61000-4-2:2008 Electrostatic Discharge	± 8kV contact ± 2kV, ± 4kV, ± 8kV, ± 15kV air	± 8kV contact ± 2kV, ± 4kV, ± 8kV, ± 15kV air	The ground shall be wood, concrete or tile, and if the ground is covered by the synthetic material, the relative humidity shall be 30% at least.
Radiated RF EM fields IEC 61000-4-3:200 6+A1+A2	3V/m 80MHz-2.7GHz 80%AM at 1kHz	3V/m 80MHz-2.7GHz 80%AM at 1kHz	-
Proximity fields from RF wireless communications equipment IEC 61000-4-3:2006+A1+A2	IEC 61000-4-3 See the RF wireless communication equipment table in "Recommended minimum separation distances".	IEC 61000-4-3 See the RF wireless communication equipment table in "Recommended minimum separation distances".	-
IEC 61000-4-4:2012 Electrical Fast Transient Burst	±2kV for Power Supply Line ±1kV for Input/Output Line	±2kV for Power Supply Line ±1kV for Input/Output Line	The network power supply shall be equipped with the quality used in the classic commercial or medical environment.
IEC 61000-4-5:2014 Surge	Line to line:±0.5kV, ±1kV Line to earth:±0.5kV, ±1kV, ±2kV	Line to line: ±0.5kV,±1kV Not Applicable	The network power supply shall be equipped with the quality used in the classic commercial or medical environment.
IEC 61000-4-11:2004 Voltage dips and Voltage interruptions	0% U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% U_T; 1 cycle and 70% U_T; 25/30 cycles; Single phase: at 0° 0% U_T ; 250/300 cycle	0% U_T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% U_T; 1 cycle and 70% U_T; 25/30 cycles; Single phase: at 0° 0% U_T ; 250/300 cycle	The network power supply shall be equipped with the quality used in the classic commercial or medical environment. If the continuous operation needs to be conducted by the user for the use of The device during the interruption period of the power supply, it is recommended to adopt the uninterruptible power supply or battery for the Flexible Videoscopes for single use the power supply.
IEC 61000-4-8:2009 Power Frequency Magnetic Field (50Hz/60Hz)	30 A/m	30 A/m	The power frequency magnetic field shall be equipped with the level characteristics of the power frequency magnetic field of the classic locations of the classic commercial or hospital environment.
IEC 61000-4-6:2013 Conducted disturbances induced by RF fields	Input a.c. power PORT, Input d.c. power PORT, PATIENT coupling PORT, Signal input/output parts PORT 3V in 0.15MHz - 80MHz 6V in ISM and/or amateur radio bands between 0.15MHz and 80MHz 80% AM at 1kHz	Input a.c. power PORT, Signal input/output parts PORT 3V in 0.15MHz - 80MHz 6V in ISM and/or amateur radio bands between 0.15 MHz and 80MHz 80% AM at 1kHz	-
Note: U_T refers to the voltage of the AC network before the implementation and test of voltage.			

Guideline and Statement of the Manufacturer – Electromagnetic Immunity (Table 5)

Recommended minimum separation distances

Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. The flexible videoscope has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and this flexible videoscope as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Distance (m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ±5kHz deviation 1kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						