

**COXO**<sup>®</sup>

# USER MANUAL

## Implants UV Activator

UA-1



**Foshan COXO Medical Instrument Co.,Ltd.**

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## **PREFACE**

Thank you very much for choosing our product. To ensure safe and correct use, please read this manual carefully before using this product.

This manual provides detailed information on the safety of the UA-1 and the principles that must be followed with regard to installation, use and maintenance. Please read the following instructions and familiarize yourself with this operational knowledge so that the UA-1 can help you in your clinical practice.

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## 1. Safety

**⚠ Please read the following information carefully before using this device!**

- 1) The device must be used within the scope mentioned in the manual. If the user does not operate according to the instruction or use the device for other purposes, the manufacture will not bear any responsibility.
- 2) Avoid liquids entering the inside of the device to avoid malfunctions.
- 3) Please use original accessories, if the accessories are damaged, please contact the manufacturer or authorized dealer for purchase and replacement.
- 4) Please do not dismantle or modify this device, any modification may cause harm to the medical staff and we are not responsible for the consequences.
- 5) Unstable voltage and exposure to electromagnetic fields can interfere with the normal operation of the device.
- 6) To avoid the risk of electric shock, the device must be connected to a supply network with a protective earth connection.
- 7) When using an external power supply, please confirm whether the voltage is within the voltage range marked by the power adapter, otherwise it may cause injury to the operator or the patient.
- 8) This device is strictly prohibited in high temperature, high humidity, flammable, explosive strong electromagnetic field environment storage or use.
- 9) Device should be used in a well-ventilated environment.
- 10) For the disposal of accessories, please obey local regulations.
- 11) When not in use for a long time, please close the door and disconnect the power supply, the device switch is in the off state.
- 12) The use of this device is only restricted to professional dentists.

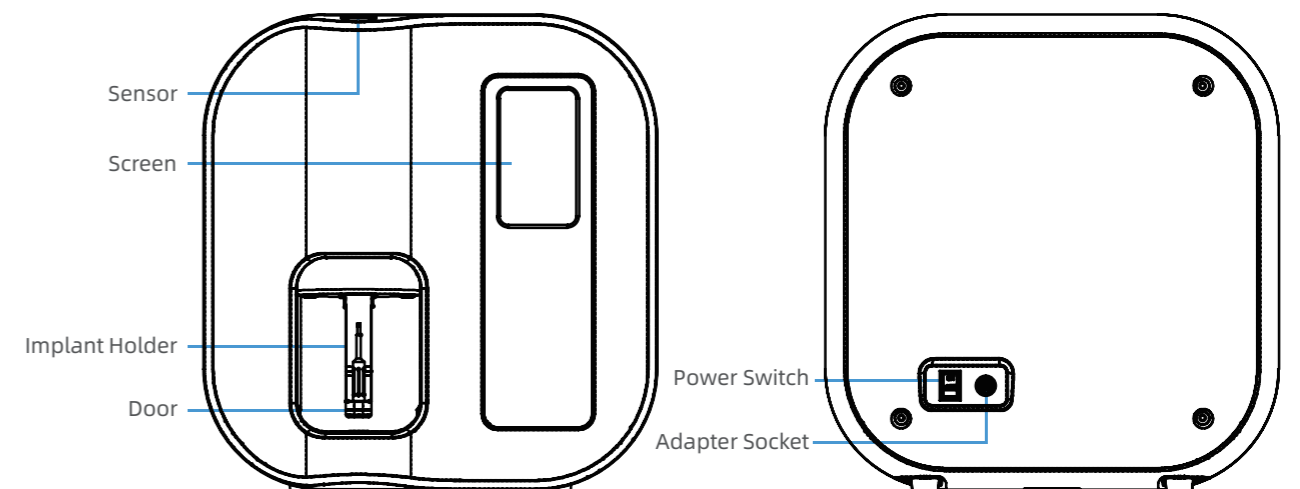
## 2. Applications

Improve osseointegration, improve patient adaptation to implants, reduce implant failure, and reduce the incidence of high marginal bone loss.

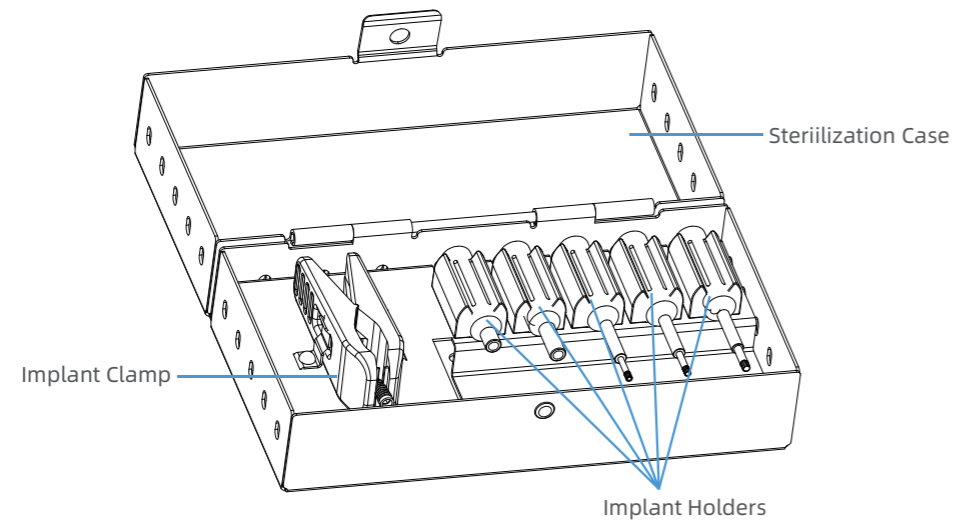
## 3. Contraindications

Prohibited for dentists with pacemakers.

## 4. Description

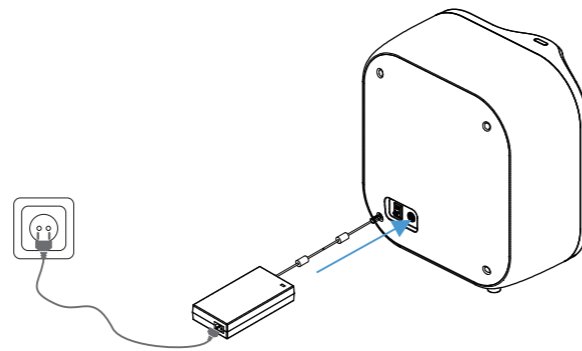


## 5. Accessories



## 6. Power

Connect adapter to the adapter socket, connect it to the power cord.  
Connect the power cord socket to the socket.

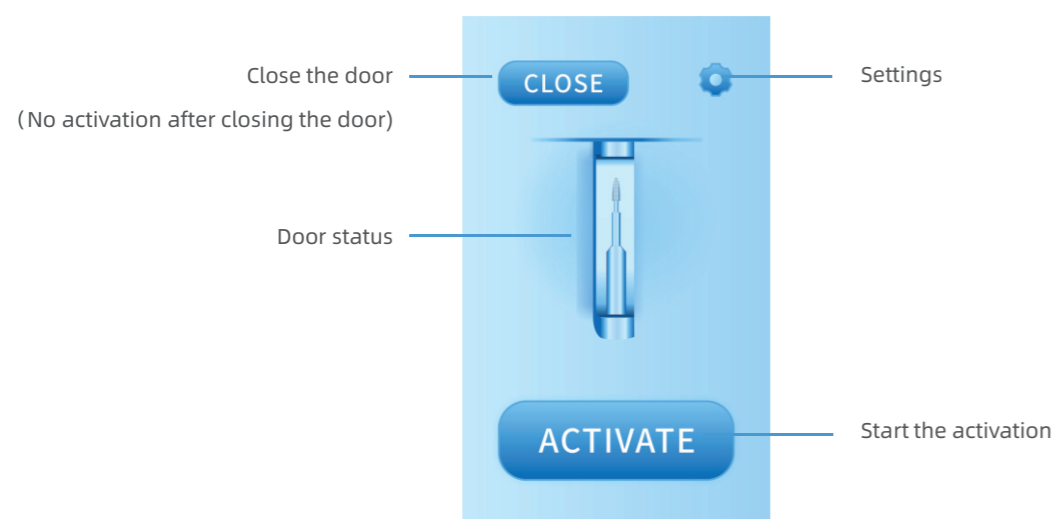


## 7. Operation

### 7.1. Turn on/off

Turn on/off the power switch to turn on/off.

### 7.2. Main interface description



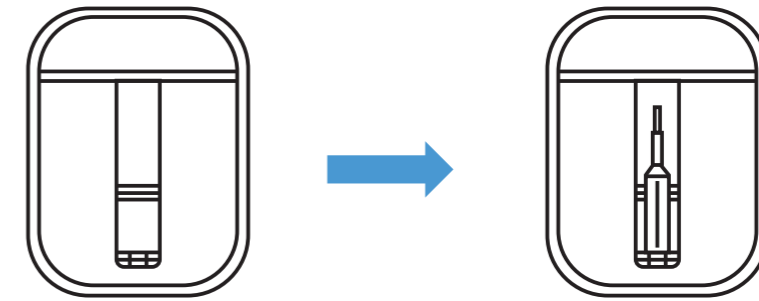
## 7.3. Installation the implant holder



Note:

- Control unit and adapter shall not be serviced or maintenance during normal treatment.
- Please use the clamp when fitting the implant.

Select the desired implant holder, attach the implant to the holder and place the holder on the door.



## 7.4. Activation

This device has two modes to activate: Button Mode and Sensor Mode.

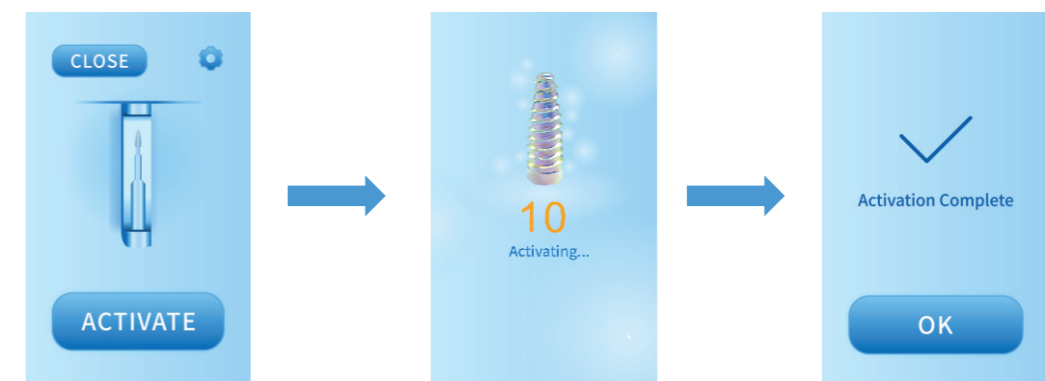


Note:

- Do not place obstacles in the working area of the door during activation.

### ◆ Button Mode

Press **ACTIVATE** to start activation, after the countdown, activation is complete:



Tip:  
After starting the activation, press **STOP** or place your hand over the sensor within 5 seconds to stop the activation, and cannot be stopped afterwards:



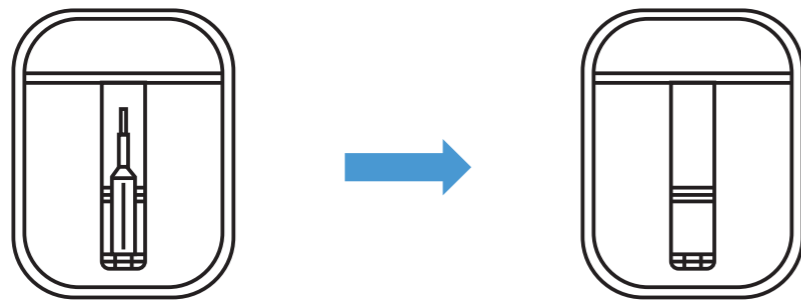
#### ◆ Sensor Mode

Place your hand over the sensor, when the hand leaves, activation starts.

Note:  
Sensor is not available during activation.

### 7.5. Removal of the implant holder

◆ After using, disassemble the implant holder.



Tip:  
If you need to continue activation, please repeat 7.3-7.4.

### 7.6. Open/Close the door

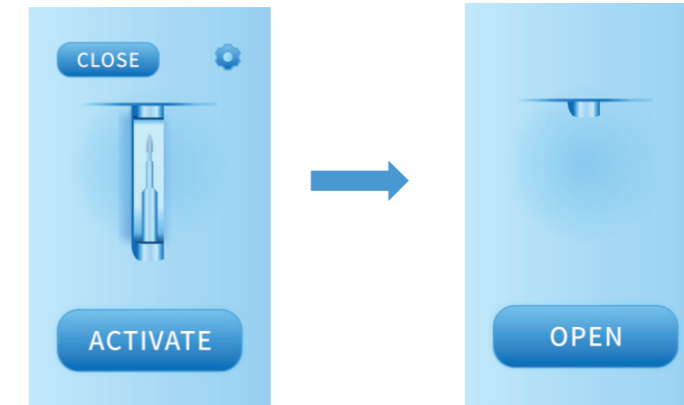
This device has two modes to open/close the door: Button Mode and Sensor Mode.

Note:

- Do not place obstacles in the working area of the door during activation.
- No activation after closing.

#### ◆ Button Mode

Press **OPEN** to open the door, press **CLOSE** to close the door.



#### ◆ Sensor Mode

When the door opens/closes, place your hand over the sensor for 2s and the door will close/open automatically.

## 8. Settings

Note:  
Sensor is not available when setting.

Press to enter the setting and press to exit.

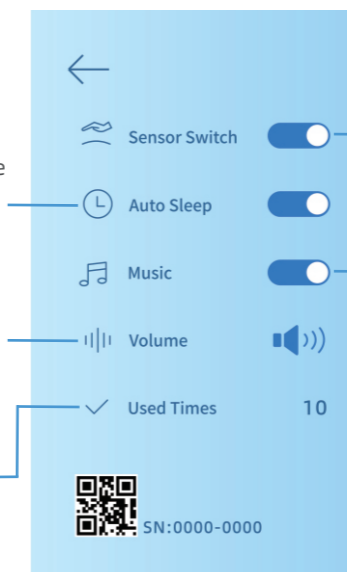
#### Auto Sleep:

Turn on/off auto sleep.  
\*When auto sleep is on, if it is not operated within 10min, the device will automatically turn off the screen and close the door.

#### Volume:

Turn up/down the volume of beeps, warning tones and music.

Used Times : Shows the number of activations completed.



#### Sensor Switch:

turn on/off the sensor switch.  
\*If sensor switch is off, the door can only be opened/closed and activated using the button.

#### Music:

Turn on/off music in the process of activation.  
\*If music is off, no music during activation.

## 9. Cleaning, Disinfection and Sterilization

<b>Instrument</b>	Implant Holders, Implant Clamp and Sterilization Case. The procedure for cleaning, disinfection and sterilization applies only to Implant Holders, Implant Clamp and Sterilization Case.
<b>Advice</b>	Reprocessing procedures have only limited implications to a surgical instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the instrument. There is no limit of maximum allowable reprocessing cycles. The instrument should no longer be reused in case of signs of material degradation. In case of damage the instrument should be reprocessed before sending back to the manufacturer for repair.
<b>Reprocessing Instructions</b>	
<b>Preparation at the Point of Use</b>	Remove the implant holder. Remove gross soiling of the instrument with cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process. Store the instruments in a humid surrounding.
<b>Transportation</b>	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
<b>Preparation for Decontamination</b>	The instruments must be reprocessed in a disassembled state. Only Implant Holders, Implant Clamp and Sterilization Case can be cleaned and disinfected with automated methods and sterilized with steam sterilization process. Do not sterilize control unit. The control unit cannot be cleaned and disinfected in a washer/disinfector. For these parts, only general wipe decontamination is possible!
<b>Decontamination of other parts than Implant Holders, Implant Clamp and Sterilization Case</b>	After operation, take out control unit on the workbench. Soak a soft cloth completely with distilled water or deionized water, Decontamination and wipe all the surfaces of these components, until the surface of the parts the components are visually clean. For decontamination, soak a dry soft cloth with 75% alcohol Wipe all surfaces of control unit with the wet soft cloth for about 3 minutes. Please follow the instructions of manufacturer of disinfectant swipe the surface of the component with a dry soft lint-free cloth.
<b>Pre-Cleaning</b>	Following instruction is only relevant for Implant Holders, Implant Clamp and Sterilization Case. Not use automated cleaning, disinfection and sterilization for other parts than implant holders, Implant clamp and Sterilization Case in this system! Do a manual pre-cleaning, until the instruments are visually clean. Clean the surface with a soft Bristol brush.
<b>Cleaning</b>	Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing

	potential and industrial safety. Automated Cleaning: Use a washer-disinfector meeting the requirements of the ISO 15883 series. Put the instrument into the machine on a tray. Connect the instrument with the WD by using suitable adapter and start the program: <ul style="list-style-type: none"> <li>• 4 min pre-washing with cold water (&lt;40°C) emptying</li> <li>• 5 min washing with a mild alkaline cleaner at 55°C</li> <li>• emptying</li> <li>• 3 min neutralizing with warm water (&gt;40°C)</li> <li>• emptying</li> <li>• 5 min intermediate rinsing with warm water (&gt;40°C)</li> <li>• Emptying</li> </ul> If manual repetitive processing methods must be used, please verify before use.
<b>Disinfection</b>	Automated Disinfection: Automated Thermal Disinfection in washer/ disinfector under consideration of national requirements in regards to A0-Value (see EN 15883). A disinfection cycle of 5 min disinfection at 93 °C has been validated for the instrument to achieve an A0 value of 3000.
<b>Drying</b>	Automated Drying: Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel.
<b>Functional Testing, Maintenance</b>	Visual inspection for cleanliness of the instruments and reassembling. Functional testing according to instructions of use. If necessary, perform reprocessing process again until instrument is visibly clean. Defective accessories should be immediately discarded. The defects include: plastic deformation and corrosion maintenance is not required. Instruments oil must not be used.
<b>Packaging</b>	Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to GB/T19633.
<b>Sterilization</b>	Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 13060) under consideration of the respective country requirements. Minimal requirements: 3 min at 134 °C. In EU, 5 min at 134 °C is required. Maximal sterilization temperature: 137°C. Sterilisable times: 100.
<b>Storage</b>	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures refer to label and instructions for use.
<b>Reprocessing validation study information</b>	The above-mentioned reprocessing process (cleaning, disinfection sterilization) has been successfully validated.
<b>Additional Instructions:</b> None	
It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.	

## 10. Operating, transport and storage environment

### Operation environment

Operation temperature	+5°C - +40°C
Operation humidity	20%RH - 80%RH
Atmospheric pressure	86kPa - 106kPa

### Transport and storage environment

Storage temperature	-10°C - +55°C
Storage humidity	≤93%RH
Atmospheric pressure	50kPa - 106kPa

## 11. Technical Specifications

Adapter	Input: 100-240V~ 50/60Hz 6.5A Max
	Output: 24.0V 9.2A
Input power	250VA
Operating mode	Short operation
Ozone production	< 0.02ppm
Activation time	10s
UV wavelength	172nm
Degree of Protection(IEC 60529)	Control unit (IPX1)
Pollution degree	Level 2
Overvoltage category	Class II
Classification of protection against electric shock	Class II (Adapter)
Protection against electric shock	Type B
Product size (mm)	L316×W187×H331
Product weight	5.5kg

\* Error range of the above measured values: ±10%

## 12. Maintenance

- Please store in a dry and cool place.
- When the device is not used for a long time, please unplug the power plug and save it to prolong its service life.

## 13. Troubleshooting

If the device is not working properly, please check the following table before calling our sales service center.


Malfunction	Cause	Solution
Device not responding	The power switch is off	Turn on the power switch
	Incorrectly connected power adapter	Check that the adapter is connected correctly
Touch screen does not respond	The screen is wet or dirty	Clean the screen
	Program crash	Restarting the device
	The screen is damaged	Contact the dealer or the manufacture
Sensing failure	The way to use is wrong	Do the command within 5cm of the sensor
The screen displays "Communication failures"	Screen and motherboard communication failure	Restarting the device
The screen displays "Activated silo failure"	There are some foreign matter on the activated silo	Manually pull down the door to remove foreign objects
	The activated silo is damaged	Restarting the device
The screen displays "The illuminant is damaged"	The illuminant is damaged	Contact the dealer or the manufacture
The screen displays "The suction is abnormal"	The suction is abnormal	Restarting the device
The screen displays "Ozone leakage"	Ozone concentration is too high	Turn off and ventilate the device
The screen displays "Door operating failures"	There are some foreign matter on the door	Press "OPEN" "CLOSE" or manually pull down the door to remove foreign objects
	The door is damaged	Restarting the device

## 14. Guarantee











The products and technical services are the responsibility of our company, and the technical department will provide you with technical support in case of problems.

The warranty period of the device is 12 months from the date of purchase, the adapter is guaranteed for 6 months, and the rest of the accessories are not guaranteed.

## 15. Recycling and Disposal

 Disposal of waste instrument must comply with national regulations and standards. Ensure that all components do not produce pollution during the disposal process.

## 16. Symbols

	Note		Refer to the instructions for use		This way up
	Tip		Serial number		Keep dry
	Fragile, handle with care		Special disposal of waste electronic equipment		CE Marking
	Caution! Federal law restricts this device to sale by or on the order of a dentist, physician, veterinarian or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.				

## 17. Guidance and manufacture's declaration -- EMC

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this device can be affected by portable and mobile RF communications equipment.



### NOTE:


- Do not use a mobile phone or other unit that emit electromagnetic fields, near this device. This may result in incorrect operation of the device.
- This device has been thoroughly tested and inspected to assure proper performance and operation!
- This device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this device should be observed to verify normal operation in the configuration in which it will be used.

## Guidance and Manufacture's Declaration - Electromagnetic Emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR11	Group 1	The device use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The device is suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance & Manufacture's Declaration - Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/output lines	±2kV for power supply lines	Mains power quality should be that of atypical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2kV line to ground	±0.5 kV, ±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U <sub>T</sub> ( > 95% dip in U <sub>T</sub> .) for 0.5 cycle < 5% U <sub>T</sub> ( > 95% dip in U <sub>T</sub> .) for 1 cycle 70 % U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25/30 cycles < 5% U <sub>T</sub> ( > 95% dip in U <sub>T</sub> .) for 5 sec	< 5% U <sub>T</sub> ( > 95% dip in U <sub>T</sub> .) for 0.5 cycle < 5% U <sub>T</sub> ( > 95% dip in U <sub>T</sub> .) for 1 cycle 70 % U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25/30 cycles < 5% U <sub>T</sub> ( > 95% dip in U <sub>T</sub> .) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U <sub>T</sub> is the a.c. mains voltage prior to application of the test level.			

Guidance & Manufacture's Declaration - Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands 3 V/m, 10V/m 80 MHz to 2.7 GHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands 3 V/m, 10V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = [3,5/V_i] \times \sqrt{P}$ $d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site Survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	385MHz- 5785MHz Test specifications for ENCLOSURE REPORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1: 2020)	385MHz- 5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014+A1 : 2020)	
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<sup>a</sup> 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.			
<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

**Recommended separation distances between portable and mobile RF communications equipment and the device**

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According To Frequency of Transmitter		
	150 kHz to 80 MHz $d=1.2\times\sqrt{P}$	80 MHz to 800 MHz $d=1.2\times\sqrt{P}$	150 kHz to 80 MHz $d=1.2\times\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.