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WOODPECKER

Please read this manual before operating

UDS-K LED ULTRASONIC PIEZO SCALER INSTRUCTION MANUAL



FDA CE 0197

- Certified Management System
- EN ISO 9001
- EN ISO 13485

www.glwoodpecker.com

GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.

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1 The installation and components of equipment

1.1 Instruction

Guilin Woodpecker Medical Instrument Co., Ltd. is a professional manufacturer in researching, developing and producing ultrasonic piezo scalers. The product is mainly used for teeth cleaning and also an indispensable equipment for tooth disease prevention and performs treatment. The product UDS-K LED ultrasonic piezo scaler mainly used for tooth disease prevention and treatment. It contains the following features:

1.1.1 Optical handpiece, more convenient for clinical operation.

1.1.2 Automatic frequency tracking ensures that the machine always works on the best frequency and performs more steadily.

1.1.3 The handpiece is detachable and can be autoclaved to the high temperature of 135℃ and pressure of 0.22MPa.

1.1.4 Digitally controlled, easy operation and more efficient for scaling.

1.2 Components

1.2.1 The components of machine are listed in the packing list.

1.2.2 Product performance and structure

Ultrasonic piezo scaler is composed of electrocircuit, water way and ultrasonic transducer.

1.2.3 Scope of application

Ultrasonic piezo scaler UDS-K LED is used for the dental calculus elimination .

1.3 The main technical specifications

1.3.1 Power source input: 220V to 240V~ 50Hz/60Hz 150mA

1.3.2 Main unit input: 24V~ 50Hz/60Hz 1.3A

1.3.3 Output primary tip Vibration excursion: ≤100μm

1.3.4 Output half_excursion force: <2N

1.3.5 Output tip Vibration frequency: 28kHz±3kHz

1.3.6 Output power: 3W to 20W

1.3.7 Main unit fuse: T1.6AL 250V

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1.3.8 Power source fuse: T0.5AL 250V

1.3.9 Water pressure: 0.1bar to 5bar (0.01MPa to 0.5MPa)

1.3.10 Weight of main unit: 0.75kg

1.3.11 Weight of power source: 1.2kg

1.3.12 Operating mode: Continuous operation

1.3.13 Type of protection against electric shock: Class II

1.3.14 Degree of protection against electric shock: Type BF equipment

1.3.15 Degree of protection against harmful ingress of water: Ordinary equipment (IPX0), protection degree against water (used on the foot switch): IPX1

1.3.16 Degree of safety of application in the presence of a Flammable Anaesthetic Mixture with air or with Oxygen or Nitrous Oxide: Equipment not suitable for being used in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide

1.3.17 Working condition:

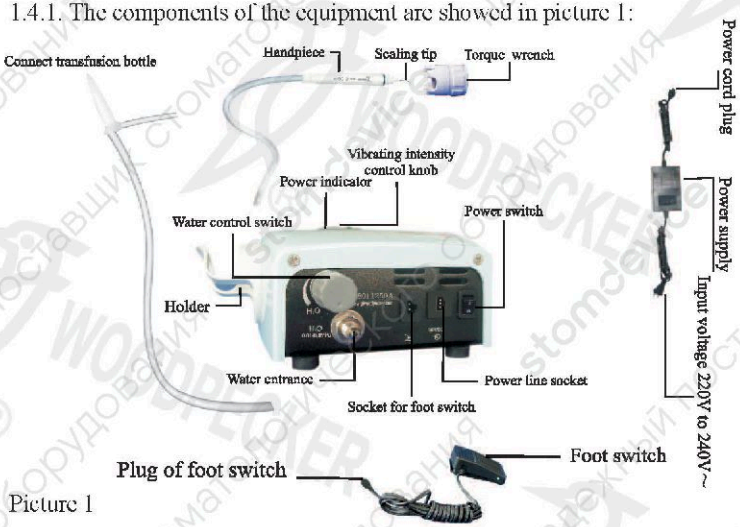
Environment temperature: 5℃ to 40℃

Relative humidity: ≤ 80%

Atmospheric pressure: 70kPa to 106kPa

1.4 Installation of the equipment

1.4.1. The components of the equipment are showed in picture 1:

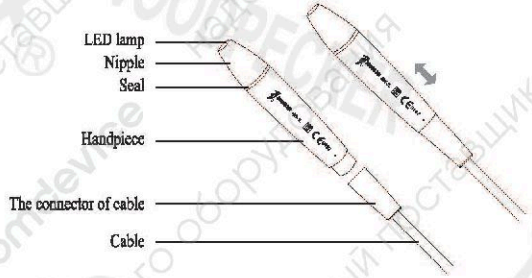


Picture 1

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1.4.2 The components of the detachable handpiece is showed in picture 2:



Picture 2

Instruction for main components of detachable handpiece:

Nipple: the nipple can be removed. You can screw out the nipple and clean the pole with alcohol termly.

Seal: the seal can be disassembled and cleaned with alcohol regularly.

Handpiece: the main part of ultrasonic scaler, can be autoclaved under the high temperature and pressure.

Symbol: autoclaved (135℃, 0.22MPa)

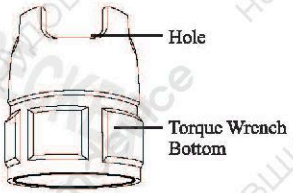
The connetor of the cable: connect the handpiece with the water source and power supply of the main unit.

Note: Keep the connector dry.

1.4.3. Torque Wrench Instruction

a) Brief introduction and illustration (see picture 3)

The torque wrench's structure is designed in special way which can control the strength of the scaling tip installation properly and correctly .It also can guarantee the operator screw or unscrew the scaling tip effectively and keep their hands away from being scratched.



Picture 3

b) Sterilization condition

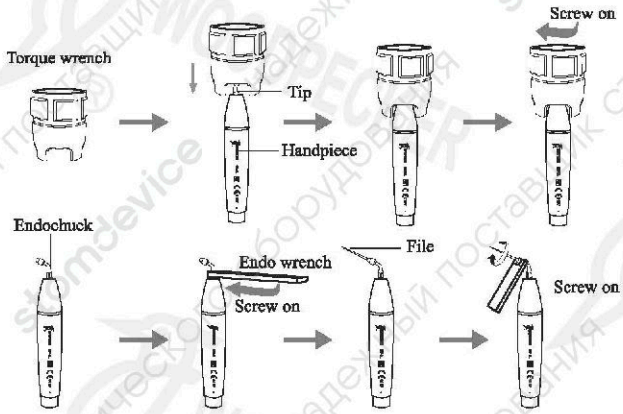
Sterilize in steam with temperature 135℃ and pressure 0.22MPa

c) Operation

①Take the wrench as showed in picture 4;

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Picture 4

②Tip installation: Hold the handpiece,turn the tip toward clockwise direction with the torque wrench .Turn two more circles after the tip stops , then the tip is installed ;

③Uninstall: Hold the handpiece , turn torque wrench toward counter-clockwise direction;

④Sterilize after each operation;

⑤The torque wrench must be cooled naturally after sterilization to avoid scalding when using next time ;

⑥Keep in a cool ,dry and ventilative place and keep it clean .

d) Notice

Forbidden sterilization way as following:

①Braise in liquor;

②Dip in iodine, alcohol or glutaraldehyde;

③Torrefy in oven or micro-wave oven.

Notice:We are not responsible for the damage of the torque wrench for any cases listed in above.

2. Product function and operation

2.1 Operation

2.1.1 Open the packing box, make sure that all the parts and accessories are complete according to the packing list.

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2.1.2 Take the main unit out of the box and put it on a stable plane.

2.1.3 Turn the water control knob towards clockwise direction to the max and turn the vibrating intensity control knob towards clockwise direction to a suitable position.

2.1.4 Insert the plug of the foot switch to its socket.

2.1.5 Connect one end of the water pipe to the water entrance, and the other end to the pure water source.

2.1.6 Connect the handpiece: screw on the scaling tip to the handpiece by the torque wrench, then insert the connector of the cable to the handpiece correctly.

2.1.7 Get through to the power.

2.1.8 Press the power switch of the main unit, then the power indicator shines.

2.2 Operation method and function instruction

2.2.1 Make the scaler straight to the operator. Before turning on, please turn the vibrating intensity control knob to the minimum and water control switch to the maximum.(turn three circles towards clockwise direction from the minimum to the maximum)

2.2.2 The normal frequency is as high as 28kHz+ 3kHz. Under normal working condition light touch and a certain to-and-fro motion will eliminate the tartar without obvious heating. Overexertion and overstay are forbidden.

2.2.3 Select a suitable scaling tip according to your request, screw it on to the handpiece tightly by the torque wrench.(as showed in the picture 4)

2.2.4 Step on the foot switch, the tip begins to vibrate, and the LED lamp on the top of the handpiece shines. Release the foot switch, the LED lamp keep shining for 10 seconds.

2.2.5 Vibrating intensity: Adjust the vibrating intensity as you need, generally turn the knob to the middle grade. Because different patients has different sensitivity and the rigidity of the gingival tartar is not alike too, the vibrating intensity should be adjusted during the clinical treatment.

2.2.6 Water adjustment: Step on the foot swtich, the tip begins to vibrate, then turn the water control switch to form fine spray to cool down the handpiece and clean the teeth.

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2.2.7 The handpiece can be handled in the same gesture as a pen in hand.

2.2.8 Make the tip touch the surface of the teeth lightly, don't use too much pressure, or else the teeth will be hurt and the scaling tip will be damaged.

2.2.9 After finishing operation, keep the machine working for 30 seconds with the wate supply, so that the handpiece and the scaling tips can be cleaned.

2.2.10 Pull out the handpiece and unscrew the scaling tip, make them be sterilized.

Notice: Don't pull out the handpiece when the foot switch is stepped on and the machine is working.

3. Sterilization and maintenance

3.1 Sterilization of handpiece

3.1.1 The optional autoclave temperature/pressure:

a) Sterilization at 121°C/1 bar (0.1MPa).

b) Sterilization at 135°C/2.2 bar (0.22MPa).

3.1.2 Pull out the handpiece and unscrew the scaling tip after every operation.

3.1.3 Pack the handpiece with sterile gauze or bag.

3.1.4 Reuse the handpiece after it cools naturally, in case of scalding hand.

3.1.5 Notice:

a) Clear the cleaning liquid in the handpiece by compressed air before sterilization.

b) Be sure that the scaling tip has been unscrewed from the handpiece, and it can not be sterilized with others.

c) Please pay attention that whether the outer of the handpieces damaged during the treatment or sterilization, don't smear any protective oil on the surface of handpiece.

d) There are two waterproof "O" rings at the end of the handpiece. Please lubricate them with dental lube frequently, as sterilization and repeating pulling and inserting will reduce their life-span. Once they are damaged or worn excessively, please change new ones.

e) The following sterilizing methods are forbidden:

① Put the handpiece into any liquid for boiling.

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② Put the handpiece in disinfectors such as alcohol, iodine or glutaraldehyde.
③ Put the handpiece in oven or micro-wave oven for baking.

3.2 Sterilization of the scaling tip and endochuck
All the scaling tips can be autoclaved to 135℃.

3.3 The sterilization of the torque wrench
The wrench can be sterilized under high temperature and pressure.

3.4 The cleaning of the torque wrench and scaling tip
Both of them can be cleaned with an ultrasonic cleaner.

3.5 Troubleshooting and notes

Fault	Possible causes	Solutions
The scaling tip doesn't vibrate and there is no water flowing out when stepping on the foot switch.	The power pipe plug is in loose contact.	Make the plug insert to the socket well.
	The foot switch is in loose contact.	Insert the foot switch to its socket tightly.
	The fuse of transformer is broken.	Contact our dealers or us.
	The fuse in the main unit is broken.	Contact our dealers or us.
The scaling tip doesn't vibrate but there is water flowing out when stepping on the foot switch.	The tip is in loose contact.	Screw the tip on the handpiece tightly (picture 4).
	The connect plug between the handpiece and the circuit board is in loose contact.	Contact our dealers or us.

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Fault	Possible causes	Solutions
The scaling tip doesn't vibrate but there is water flowing out when stepping on the foot switch.	Something wrong with the handpiece.	Send it to our company to repair.
	Something wrong with the cable.	Contact our dealers or us.
The scaling tip vibrates but there is no water flowing out when stepping on the switch.	The water control switch is turned off.	Turn on the water control switch [note 1].
	There is impurity in the solenoid valve.	Contact our dealers or us.
	The solenoid valve is abnormal.	Percuss the solenoid valve by some hard things [note 2].
There is still water flowing out after the power is off.	There is impurity in the solenoid valve.	Contact our dealers or us.
The handpiece generates heat.	The water control switch is in a low grade.	Turn the water control switch to a higher grade [note 1].
The amount of spouting water is too little.	The water control switch is in a low grade.	Turn the water control switch to a higher grade [note 1].
	The water pressure is not high enough.	Make the water pressure higher.
	The water pipe is blocked.	Clean the water line by multi-function syringe [note2].

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Fault	Possible causes	Solutions
The vibration of the tip becomes weak.	The tip hasn't been screwed on to the handpiece tightly.	Screw on the tip to the handpiece tightly (as showed in picture 4).
	The tip is loose by because of vibration.	Screw on the tip tightly (as shown in picture 4).
	The coupling between the handpiece and the cable isn't dry.	Dry it by the heated wind.
	The tip is damaged [note3].	Change a new one.
The vibration is too strong and the vibrating intensity control knob is malfunction.	The vibrating intensity control knob is damaged.	Contact our dealers or us.
There is water seeping from the coupling between the handpiece and the cable.	The waterproof "O" ring was damaged.	Change a new "O" ring.

If the problem still can't be solved yet, please contact the local distributors or our company.

[Note1] The water control knob can adjust the water volume according to the symbol.

[Note2] To clean the water pipe with the multi-function syringe of the dental unit. (as showed in the picture 5) :



Picture 5

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① Snip the water pipe with scissors at a distance of 10cm-15cm from the water entrance

② Turn on the power switch, get through to the power.

③ Connect the multi-function syringe of dental unit to the water pipe.

④ Step on the foot switch.

⑤ Turn on the switch of the multi-function syringe, press the air or water into the water line in the machine, then the impurity blocked in the water line can be eliminated.

[Note3] If the scaling tip has been screwed on tightly and there is fine spray too, the following phenomena show that the scaling tip was damaged:

The vibrating intensity and the water atomization degree become weak obviously.

When operating , there is some buzz when the scaling tip is working.

4. Precaution

4.1 Notice when using equipment

4.1.1 Keep the scaler clean before and after opreation.

4.1.2 The handpiece, scaling tip and torque wrench must be sterilized before every treatment.

4.1.3 Don't screw the scaling tip when stepping on the foot switch.

4.1.4 The scaling tip must be fastened and there must be fine spray coming out from the tip when operating.

the tip or rub the tip.

4.1.5 Change a new one when the tip is damaged or worn excessively.

4.1.6 Don't make the tip twist or rub it.

4.1.7 Don't use impure water source. Never replace the distilled water with physidogical saline.

4.1.8 If use water source without hydraulic pressure, the water surface should be one meter higher than the head of the patient.

4.1.9 Be sure that the connecting end of handpiece and the socket of the connector of cable are complete dried before handpiece installation.

4.1.10 Don't pull the cable emphatically in operating.

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4.1.11 Please don't rub or knock the handpiece.

4.1.12 After operation, turn off the power, then pull out the plug.

4.1.13 As a professional company producing medical instruments' we are responsible for the safety only when maintenance' repair and change are done by "Woodpecker" company or our authorized distributors the replacing spare parts belong to ours and operating by the manual.

4.1.14 The screw thread of the scaling tips that produced by some other manufacturers may be coarse, rusty and collapsed , this will damage the screw thread of the handpiece irretrievably. Please use "Woodpecker"brand scaling tip.

4.2. Contraindication

4.2.1 The patient who has hemophilia is not allowed to use this equipment.

4.2.2 The patient or doctor who uses heart pacemaker is forbidden to use this equipment.

4.2.3 The heart disease patient, pregnant woman and children should be cautious to use the equipment.

4.3. Storage and maintenance

4.3.1 The equipment should be handled carefully and lightly, be sure that it is far from the vibration, and is installed or keep it in a cool , dry and ventilated place.

4.3.2 Don't put the machine together with the articles that is combustible poisonous,caustic, or explosive.

4.3.3 This equipment should be reserved in a room where the relative humidity is ≤80%, atmospheric pressure is 50kPa to 106kPa, the temperature is -10℃ to +50℃.

4.3.4 Please turn off the power switch and pull out the power line plug when the equipment is not used. If the machine is not used for a long time, please make it get through to the power and water once per month for five minutes.

4.4 Transportation

4.4.1 Excessive impact and shake should be forbidden in transportation. Lay it

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carefully and lightly and don't invert it.

4.4.2 Don t put it together with dangerous goods.

4.4.3 Avoid solarization and getting wet in rain and snow during transportation.

5. After service

From the date this equipment has been sold, base on the warranty card , we will repair this equipment free of charge if it has quality problems , please refer to the warranty card for the warranty period.

6. Symbol instruction



Trademark


Consult the accompanying documents


Date of manufacture


Manufacturer


Class II equipment


Type BF applied part

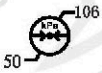
IPX0 Ordinary equipment


Used indoor only

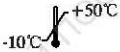

Appliance compliance WEEE directive


Alternating current

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Atmospheric pressure for storage



Temperature limitation



Humidity limitation



Can be autoclaved



CE marked product


FDA marked product



Authorised Representative in the EUROPEAN COMMUNITY



Got the quality management system certification and CE certification issued by TüV Rheinland

7. Environmental protection

There are no harmful factors in our product. You can deal with it based on the local law.

8. Manufacturer's right

We reserve the right to change the design of the equipment, the technique, fittings, the instruction manual and the content of the original packing list at any time without notice. If there are some differences between blueprint and real equipment, take the real equipment as the norm.

9. For technical data, please contact

EC REP Wellkang Ltd (www.CE-Marking.eu)
29 Harley St.,LONDON,W1G 9QR,UK

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10. Declaration of conformity

10.1 Product conforms to the following standards

EN 60601-1:2006
EN 60601-1-2:2007
EN 61000-3-2:2006
EN 61000-3-3:2008
EN 60601-1-4:1996
EN 60601-1-6:2007
EN 61205:1994
EN ISO 22374:2005
EN 62304:2006
EN 980:2008
EN ISO 9687:1995
EN 1041:2008
EN ISO 14971:2009
EN ISO 7405:2008
EN ISO 17664:2004
EN ISO 17665-1:2006
EN ISO 10993-1:2009
EN ISO 10993-5:2009
EN ISO 10993-10:2010

10.2 EMC - Declaration of conformity

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Guidance and manufacturer's declaration - electromagnetic emissions		
The model UDS-K LED is intended for use in the electromagnetic environment specified below. The customer or the user of the model UDS-K LED should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The model UDS-K LED uses 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 model UDS-K LED 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 & Declaration — electromagnetic immunity			
The models UDS-K LED is intended for use in the electromagnetic environment specified below. The customer or the user of the models UDS-K LED 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors 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 ±1kV for interconnecting cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±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_T (>95% dip in U_T) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95% dip in U_T) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models UDS-K LED require continued operation during power mains interruptions, it is recommended that the models UDS-K LED be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

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Guidance & Declaration - Electromagnetic immunity

The models UDS-K LED is intended for use in.the electromagnetic environment specified below. The customer or the user of the models UDS-K LED should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the models UDS-K LED including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	*3V*	3V
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	*3 V/m*	$d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=2.3\times P^{1/2}$ 800 MHz to 2.5 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,[a] should be less than the compliance level in each frequency range.[b] Interference may occur In the vicinity of equipment marked with the following symbol:

NOTE I At 80 MHz end 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.

[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 models UDS-K LED is used exceeds the applicable RF compliance level above, the model UDS-K LED should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models UDS-K LED.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

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Recommended separation distances between portable and mobile RF communications equipment and the models UDS-K LED

The models UDS-K LED is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models UDS-K LED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models UDS-K LED 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 m		
	150kHz to 80MHz $d=1.2\times P^{1/2}$	80MHz to 800MHz $d=1.2\times P^{1/2}$	800MHz to 2,5GHz $d=2.3\times P^{1/2}$
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) accordable to the transmitter manufacturer.

NOTE I At 80 MHz and 800 MHz. the separation distance for 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.

The device has been tested and homologated in accordance with EN 60601-1-2 for EMC. This does not guarantee in any way that this device will not be effected by electromagnetic interference.Avoid using the device in high electromagnetic environment.

11. Statement

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD. The industrial design, inner structure, etc. have claimed for several patents by WOODPECKER, any copy or fake product must take legal responsibilities.

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