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Please read this manual before operating

UDS-N2 LED ULTRASONIC SCALER

INSTRUCTION MANUAL



FDA CE 0197

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 scalers. The product is mainly used for teeth cleaning and also an indisensable equipment for tooth disease prevention and treatment.

The built-in ultrasonic scaler UDS-N2 LED is used along with dental unit for teeth cleaning. They are also indispensable equipments for tooth disease prevention and treatment.

1.2 Components

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

1.2.2 Components and scope of application

a) Ultrasonic scaler is composed of elect circuit, water way and ultrasonic transducer.

b) This model is used for the dental calculus elimination and root canal treatment.

1.3 The main technical specifications

1.3.1 Technical specifications of ultrasonic scaler

a) Power input:

With transformer 220-240V~ 50Hz/60Hz 150mA

Without transformer 24V~ 50Hz/60Hz 1.3A

b) Output primary tip Vibration excursion: ≤100μm

c) Output half-excursion force: <2N

d) Output tip Vibration frequency: 28kHz±3kHz

e) Output power: 3W to 20W

f) Water pressure: 0.01MPa to 0.5MPa

g) Weight of main unit: 0.2kg

h) Weight of transformer: 1kg (optional)

i) Operating mode: Continuous operation

j) Type of protection against electric shock: Class II

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k) Degree of protection against electric shock: Type BF applied part

l) Applied part of the equipment: handpiece and tip

m) Degree of protection against harmful ingress of water: Ordinary equipment

n) Degree of protection against harmful ingress of water: protection degree against water (used on foot switch):IPX1

o) Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide: Equipment can not be used in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide

1.3.2 Working condition

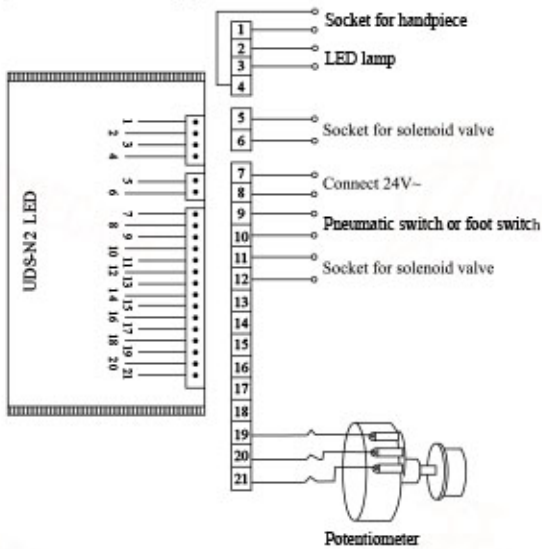
a) Environment temperature: 5℃ to 40℃

b) Relative humidity: ≤80%

c) Atmospheric pressure: 70kPa to 106kPa

1.4 Installation the equipment

The main components of this equipment and installation are showed as picture 1:



picture 1

Notice:

a) Please connect power supply and pneumatic switch (or foot switch) showed as picture 1.

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b) The No.7 lead and No.8 lead should be connected with 24V~, and this circuit isn't allowed to act as switch circuit.

c) The No.9 lead and No.10 lead should be connected with pneumatic switch (or foot switch) directly, and this circuit isn't allowed to do the short circuit.

d) The followings should be noticed during installation.

① Pneumatic power switch, pneumatic penstock and pneumatic foot switch are equipped by manufacturers of the dental unit or the end-users.

② The manufacturers of dental unit, the dealers or end-users of the equipment need to dig holes in salver of dental unit so as to fix potentiometer and fetch out the silica gel pipe of handpiece pipe.

③ Keep enough space for dispersing heat of ultrasonic generator.

④ Built-in ultrasonic scaler without transformer occupies a little space, and works with current 24V~, power ≥20W.

⑤ Before turning on the scaler, turn the potentiometer knob to the minimum and the water control switch to the maximum.

⑥ The frequency of ultrasonic scaler is extremely high. Under normal water supply, a light touch and a certain to-and-fro motion will eliminate the tartar without obvious heat. Overexertion and longtime lingering are forbidden.

2. Product function and usage

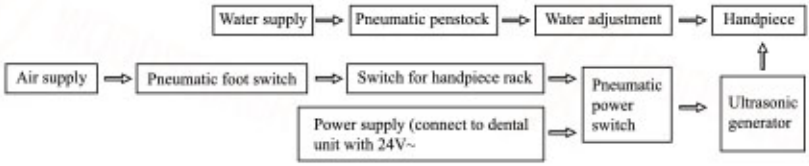
2.1 Working principle

2.1.1 Summarization: the built-in ultrasonic scaler is consist of ultrasonic generator (circuit), cable, handpiece (energy-transformed instrument), scaling tip, pneumatic switch (the power switch of pneumatic penstock and the circuit's commutating and filtering, is controlled by pneumatic foot pedal of dental unit and switch for handpiece rack of ultrasonic scaler at the same time) and switch for handpiece rack (it controls the air supply which gets through pneumatic penstock and pneumatic power switch. And the air supply is off when handpiece is in the rack and on when handpiece is out).

2.1.2 Chart of working principle:

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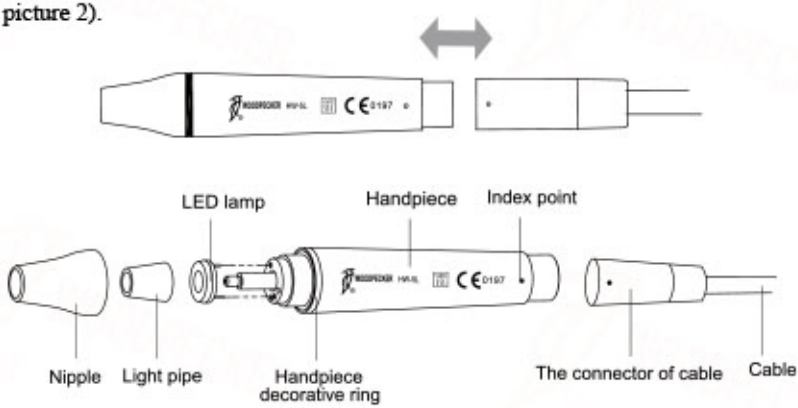
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The air supply is on when the handpiece is out from the rack. Step on the foot switch, pneumatic power switch, pneumatic penstock, ultrasonic generator, handpiece and scaling tip all start working at the same time, and water supply is opens, the LED lamp on the top of the handpiece shines.

2.2 Scaling function

2.2.1 Instruction for main components of detachable handpiece (showed in picture 2).



Picture 2

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

b) Handpiece decorative ring: The seal can be removed and cleaned with alcohol termly.

c) Handpiece: The main part of the whole handpiece, can be autoclaved under the high temperature and pressure.

d) Symbol: Autoclaved (135℃, 0.22MPa)

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e) The connector of the cable: Connect the handpiece with the water source and power supply of the main unit.

f) LED lamp、Light pipe: Clean them with purified water and sterilize them under the high temperature of 135℃ and high pressure of 0.22Mpa.

2.2.3 Instruction for using torque wrench (showed in picture 3)

a) 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.

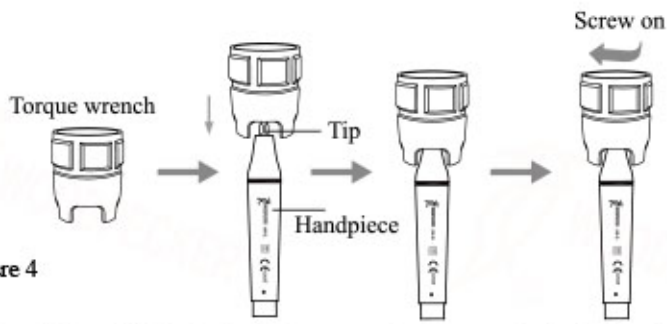


Picture 3

b) Operation

① Take the tip into the torque wrench as picture 4 showed.

② Install and uninstall the scaling tip as picture 4 showed.



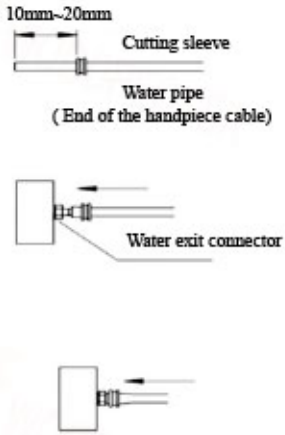
Picture 4

Ⅰ Installation: Hold the handpiece turn the tip toward clockwise direction with the torque wrench. Turn one more circles when the tip stops, then the tip is installed.

Ⅱ Uninstallation: Hold the handpiece, turn the wrench toward anti-clockwise direction.

2.2.3 Cutting sleeve use instruction (showed as picture 5)

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Picture 5

a) Put the cutting sleeve through the water pipe, keep it 10mm to 20mm away from the entrance.

b) Put the water pipe in the middle of the water exit connector(about 3mm), then push the cutting sleeve forward to the front edge of the water exit connector.

c) Pinch the cutting sleeve and the water pipe with your fingers, push them forward at the same time until they are wrapped into the water exit connector fully. Then the cutting sleeve is in the middle of the water exit connector.

Notice:

Cut off the forepart of the water pipe about 6mm if repeat the above operation.

3. Sterilization and maintenance

3.1 Sterilization of detachable handpiece

3.1.1 Autoclaved to the high temperature/pressure:

a) 121℃/1bar (0.1MPa)

b) 135℃/2.2bar (0.22MPa)

3.1.2 Pull out the handpiece and unscrew the tip and endochuck after operation.

3.1.3 Pack the handpiece with steriled gauze or steriled bag before sterilization.

3.1.4 Reuse handpiece after it cools naturally in case of burning hand.

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3.1.5 **Notice:**

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

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

c) Please notice whether the outer of the handpiece is damaged during the treatment and 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 repeated pulling and inserting will reduce their using life. Change a new one once it is damaged or worn excessively.

e) The following sterilizing methods are forbidden:

① Put handpiece into any liquid for boiling.

② Dip handpiece in disinfector such as iodine, alcohol and glutaraldehyde.

③ Put handpiece into oven or microwave oven for baking.

3.2 Sterilization of scaling tips

All the scaling tips can be sterilized with alcohol cotton or disifected cloth. It's also ok to sterilized them by ultrasonic cleaner.

3.3 Sterilization of torque wrench

3.3.1 The torque wrench can be sterilized by neutral non-corrosive disinfector for cleaning and sterilizing, or be sterilized in high temperature and pressure.

3.3.2 The following sterilizing ways for torque wrench are forbidden:

a) Boiled in liquor.

b) Dip in iodine, alcohol and glutaraldehyde.

c) Torrefy in oven or microwave oven.

Notice: We are not responsible for any damage caused in the above items.

3.4 Cleaning of tips the torque wrench

The scaling tip the torque wrench can be cleaned by ultrasonic cleaner.

3.5 Sterilization and cleaning of LED lamp and Light pipe

Clean the LED lamp and Light pipe with purified water and sterilize them under high temperature and high pressure after every operation.

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4. Contraindication

4.1 The hemophilia patient is forbidden to use this equipment.

4.2 The patients or doctors with heart pacemaker are forbidden to use this equipment.

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

5. Troubleshooting

Fault	Possible causes	Solutions
The scaling tip doesn't vibrate when stepping on the foot switch.	The plug is in loose or wrong contact.	Connect as picture 1 showed.
	Handpiece and the connector of cable connect irrelevantly.	Pull out handpiece and insert it again.
	Scaling tip is loose.	Screw it on tightly with torque wrench.
	There is some water between the handpiece and the connector of cable.	Dry the connect point.
	There is something wrong with detachable handpiece.	Send it to our company to repair.
The scaling tip vibrates, but there is no water flowing out.	Water supply of dental unit is off.	Check the water supply of the dental unit.
	There is no water coming out from the cable.	Clean the water pipe of the cable with multi-function syringes.
	There is no water coming out from the handpiece.	Clean the water pipe of the handpiece with multi-function syringes.
The handpiece generates heat.	The amount of spouting water is too little.	Turn the water control switch to a higher grade.

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Fault	Possible causes	Solutions
The amount of spouting water is too little.	The water pipe of dental unit is jammed.	Clean the water pipe.
	The water pipe of cable is jammed.	Clean the water pipe of the cable with multi-function syringe.
	The water pipe of handpiec is jammed.	Clean the water pipe of the handpiece with multi-function syringe.
	The water pressure is not high enough.	Enhance the water pressure.
The vibration of the tip becomes weak.	The tip hasn't been screwed tightly.	Screw down the scaling tip.
	The tip vibrates loose.	Screw down the scaling tip.
	The tip is damaged.	Change a new one.
There is water seeping from the coupling between the handpiece and cable.	The waterproof "O" ring is damaged.	Change a new "O" ring.
LED light don't work	Poor contact	Contact tightly
	Something wrong with LED light	Change a new one
	LED lamp installed backwards	Please install the "+" of the LED lamp to the "+" of the handpiece
The potentiometer is failure.	The potentiometer is damaged.	Change a new one.

If the problem still can't be solved, please contact with local dealer or manufacturer.

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6. Precaution

Notice when using equipment

6.1 Keep the scaler clean before and after operation.

6.2 The handpiece, scaling tip, torque wrench, endo wrench and endochuck must be sterilized before each treatment.

6.3 Don't screw or unscrew the scaling tip when stepping on the foot pedal.

6.4 The scaling tip and endochuck must be fastened and there must be fine spray or drip coming from the tip when operating.

6.5 Change a new one when the tip is damaged or worn excessively. Don't twist the tip or rub the tip.

6.6 While scaler working ,the heat of scaling tip will become higher if there is no water flowing out.Please keep the water flow smoothly.

6.7 Don't use impurity water source and be sure not use normal brine instead of pure water source.

6.8 Ensure the connector of handpiece and the socket of the cable dry before installing the handpiece.

6.9 Don't pull the cable forcibly in case of the handpiece falling off the cable.

6.10 The internal screw threat of the scaling tips produced by some other manufactures, may be coarse, rusty and collapsed. This will damage the external screw threat of the handpiece irretrievably. Please use "DTE" brand scaling tips.

6.11 Before connecting the built-in ultrasonic scaler without transformer to power supply, please check the output voltage is 24V~, in case of connecting to wrong power supply and that may break the unit.

6.12 Manufacturers of dental unit or the end-user aren't allowed to disconnect the built-in ultrasonic scaler, in case of affecting the function of scaler. If you have any special request, please contact with us.

① WARNING: No modification of this equipment is allowed.

② WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

7. Storage and maintenance

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7.1 The equipment should be handled carefully and lightly. Be sure that it is far from the vibration, and installed or kept in a cool, dry and ventilated place.
7.2 Don't store the machine together with the articles that is combustible, poisonous, caustic, or explosive.
7.3 This equipment should be stored in a room where the relative humidity is ≤80%, atmospheric pressure 50kPa to 106kPa, and the temperature -10℃~+50℃.
7.4 Please turn off the electrical source if not be use it, if not use for a long time, please make the machine get through to the power and water once per month for five minutes.

8. Transportation

8.1 Excessive impact and shake should be prevented in the transportation. Lay it carefully and lightly and don't invert it.
8.2 Don't put it together with dangerous goods during transportation.
8.3 Avoid solarization and get wet in rain or snow during transportation.

9. After-service

We offer two year free repair to the equipment according to the warranty card.
The repair of the equipment should be carried out by our professional technician.
We are not responsible for any irretrievable damage caused by the not professional person.

10. Environmental Protection

There is not any harm factor in our product. You can deal with it based on the local law.

11. For technical data, please contact

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

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12. Manufacturer's right

We reserve the rights 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.

13. Symbol instruction

WOODPECKER Trademark	Used indoor only
Date of manufacture	Alternating current
Manufacturer	135℃ Can be autoclaved
Class II equipment	CE 0197 CE marked product
Type BF applied part	FDA marked product
106 50 Atmospheric pressure for storage	Recovery
+50℃ -10℃ Temperature limitation	Keep dry
80% 0% Humidity limitation	Handle with care
Consult the accompanying documents	
Appliance compliance WEEE directive	
EC REP Authorised Representative in the EUROPEAN COMMUNITY	

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

14. Declaration of conformity

14.1 Product conformity 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

14.2 EMC - Declaration of conformity

Guidance and manufacturer's declaration - electromagnetic emissions		
The model UDS-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 LED are intended for use in the electromagnetic environment specified below. The customer or the user of the model UDS-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 LED should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The models UDS-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 LED 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 modesl UDS-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 LED are 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	

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Guidance & Declaration — electromagnetic immunity			
The models UDS-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 LED are intended for use in the electromagnetic environment specified below. The customer or the user of the models UDS-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 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-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 LED require continued operation during power mains interruptions, it is recommended that the models UDS-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 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-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 LED are intended for use in.the electromagnetic environment specified below. The customer or the user of the models UDS-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 LED 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	*3V* *3 V/m*	Portable and mobile RF communications equipment should be used no closer to any part of the models UDS-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 LED, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** 3V $d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=2.3\times P$ 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-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 LED are used exceeds the applicable RF compliance level above, the model UDS-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 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-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 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-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 LED

The model UDS-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 LED is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models UDS-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 LED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models UDS-N1, UDS-N2, UDS-N3, UDS-N2 LED, UDS-N3 LED, V1, V2, V3, V2 LED, V3 LED are 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.

15. 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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