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ZM N/WI-04-535 2.2 Edition

Please read this manual before operating

DTE®

# D1 ULTRASONIC PIEZO SCALER
# INSTRUCTION MANUAL


FDA CE 0197 www.tuv.com TÜVRheinland ID:0000033514

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

www.glwoodpecker.com

**GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.**

Contents

## 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 is also an indispensable equipment for tooth disease prevention and treatment. The product D1 ultrasonic piezo scaler has scaling, perio functions.

It contains the following features:

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

1.1.2 Singlechip controlled, easy operation and more efficient for scaling.

1.2 Components

1.2.1 The components of the 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 Dl is used for the dental calculus elimination.

1.3 The main technical specifications

1.3.1 Power source Input: 220-240V~ 50Hz/60Hz l50mA

1.3.2 Main unit input: 24V~ l.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: T l.6AL 250V

1.3.8 Power source fuse: T0.5AL 250V

1.3.9 Water pressure: 0.lbar to 5bar (0.01MPa to 0.5MPa)

1.3.10 Weight of main unit: 0.62kg

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 equipment

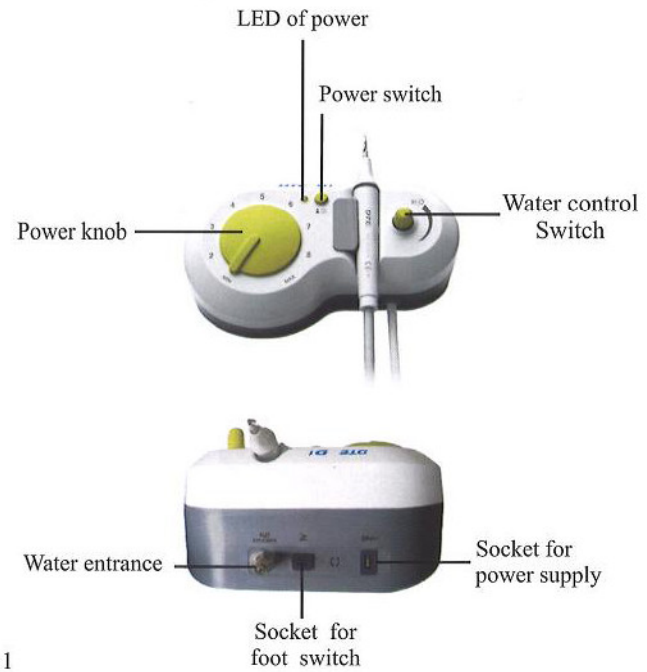
1.3.14 Degree of protection against electric shock: Type BF applied part

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

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

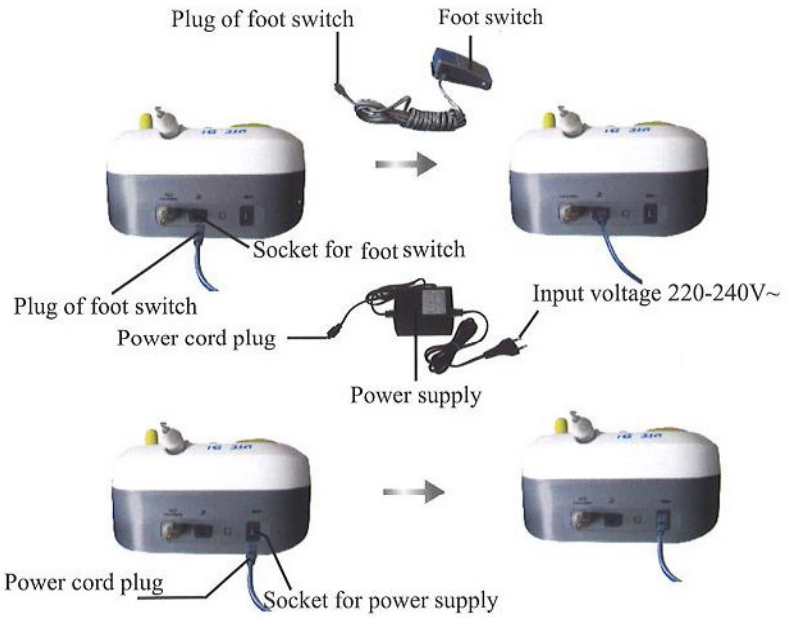
1.4 Installation of the main components

1.4.1 The front and back map of the main unit



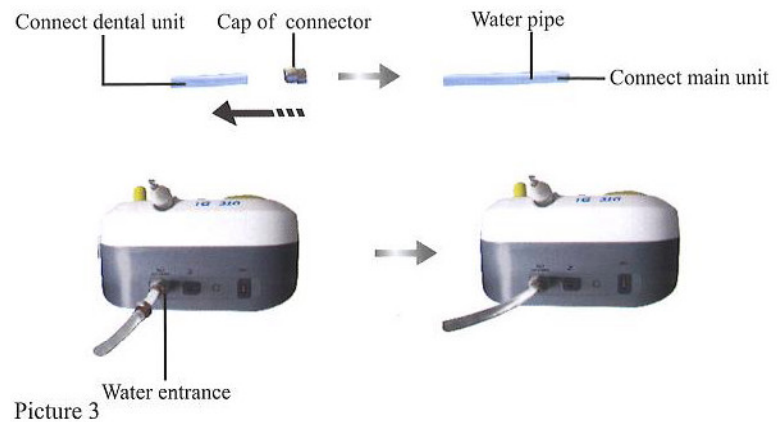

Picture 1

1.4.2 Sketch map for connection of foot switch,adapter and main unit



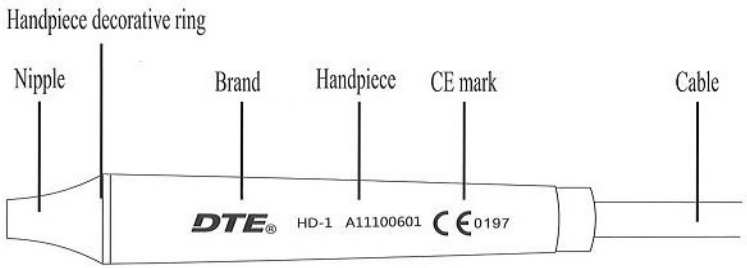

Picture 2

1.4.3 Sketch map for connection of water supply system



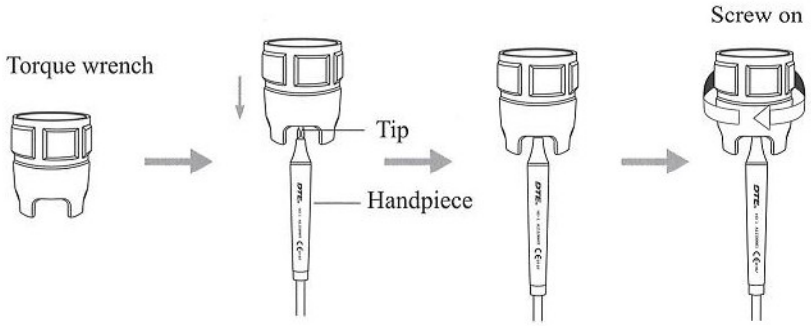

Picture 3

1.4.4 Sketch map for handpiece




Picture 4

1.4.5 Sketch map for how to install tip with wrench




Picture 5

## 2. Product function and operation

2.1 Scaling function

2.l.1 Operation

a) Open the packing box, make sure that all the parts and accessories are complete according to the packing list. Take the main unit out of the box and put it on a stable plane.

b) Turn the water control knob to the max based on symbol as shown in 3.5.2 [note l].

c) Insert the plug of the foot switch to its socket ( picture 2).

d) Connect one end of the water pipe to the water entrance , and the other end to the pure water source (picture 3).

e) Insert the plug of the power source to its socket , then get through to the power (picture 2).

f) Switch on the main unit, then the power indicator shines.

g) Select a suitable scaling tip as you need, screw it on the handpiece tightly by the torque wrench(picture5).

h)The normal frequency is extremely high. Under the normal working state of scaling tips, a light touch and a certain to-and-fro motion will eliminate the tartar without heating. Overexertion and long-time lingering are forbidden .

i)Vibrating intensity: Adjust the vibration intensity as you need, generally turn the knob to the middle grade. According to patients' different sensitivity and the rigidity of the gingival tartar, adjust the vibration intensity during the clinical treatment.

j) Water volume adjust: Step on the foot switch, and the tip begins to vibrate, then turn the water control switch to form fine spray to cool down the handpiece and clean the teeth.

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

l) During the clinical treatment, be sure not to make the end of tip touch the teeth vertically and not to make the tip overexert on the surface of the teeth in case of hurting the teeth and damaging the tip.

## 3. Sterilization and maintenance

3.1 Sterilization of handpiece

Handpiece can be sterilized by any neutral sterilized liquid for cleaning and sterilizing. Do not sterilize under the high temperature and pressure.

3.2 Sterilization of scaling tips

All the scaling tips can be autoclaved to 135℃ .

3.3 Sterilization of torque wrench

3.3.1 The torque wrench can be sterilized under high temperature and pressure.

3.3.2 The following sterilization ways for torque wrench are forbidden:

a) Braise in liquor.

b) Dip in iodine, alcohol or glutaraldehyde.

c) Torrefy in oven or microwave oven.

**Notice: We are not responsible for any damage of the torque wrench directly or indirectly made by any way in the above items.**

3.4 Cleaning of tips and torque wrench

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

3.5 Troubleshooting and notes

3.5.1 Troubleshooting

| Fault | Possible causes | Solutions |
|---|---|---|
| The scaling tip doesn't vibrate 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 (picture5 |
| | The connect plug between the handpiece and the circuit board is in loose contact | Contact our dealers or us |
| | Problem of handpiece | Contact our dealers or us |
| The scaling tip vibrates but there is no spay when stepping on the switch. | The water control switch is not on | Turn on the water control switch [note 1] |
| | There is impurity in the electric-magnetic valve | Contact our dealers or us |
| | The water system is blocked | Clean the water line by multi-function syringe [note 2] |
| There is still water flowing out after the power is off. | There is impurity in the electric-magnetic valve | Contact our dealers or us |
| The handpiece generates heat. | The water control switch is in a low setting | Turn the water control switch to a higher grade [note 2] |



| Fault | Possible causes | Solutions |
|---|---|---|
| The amount of spouting water is too little. | The water pressure is not high enough | Make the water pressure higher |
| The vibration of the tip becomes weak. | The tip hasn't been screwed on to the handpiece tightly | Screw the tip on the handpiece tightly (as showed in picture 5) |
| | The tip is loose by because of vibration | Screw on the tip tightly (as showed in picture 5) |
| | The tip is damaged [ note3 ] | Change a new one |

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

3.5.2 Notes

[Note 1] The water control knob can adjust the water volume according to the symbol

[Note 2] Clean the water pipe with the multi-function syringe of the dental unit (as showed in picture 6):


Picture 6

① Cut the water pipe at a distance of 10cm t020cm from the water entrance

② Turn on the electricity and get through to the electricity.

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

④Disassemble the tip or handpiece.

⑤Step on the foot switch.

⑥Turn on the switch of the Multi-function syringe, press the water into the machine and the impurity blocked in the water pipe can be eliminated.

[Note 3] If the scaling tip has been screwed on tightly and there is fine spray too, the following phenomena show that the scaling tip is damaged:

①The vibrating intensity and the water atomization degree become weak obviously.

②During treatment, it produces the sound like "buzz" from the scaling tip

## 4. Precaution

4.1 Notice when using equipment

4.1.1 Keep the scaler clean before and after operation.

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

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

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

4.1.5 Change a new one when the tip and ultrasonic file are damaged or worn excessively.

4.1.6 Don't twist the tip or rub them.

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

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

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

4.1.10 Don't knock or rub the handpiece.

4.1.11 Please put the power plug into the socket easy to pull out, to make sure it can be pull out in emergency.

4.1.12 This device can only be equipped with the special power supply of Guilin Woodpecker Medical Instrument Co., Ltd.

4.1.13 The power supply is NOT waterproof. Please keep it dry and away from the water.

4.1.14 After operating, turn off power, then pull out the plug.



4.1.15 We are only responsible for the safety on the following conditions:

a) The maintenance, repair and modification are made by the manufacturer of the authorized dealer.

b) The changed components are original of "DTE" and operated according to instruction manual.

4.1.16 The internal screw thread of the scaling tips produced by some manufacturers maybe coarse, rusty and collapsed. This will damage the external screw thread of the handpiece irretrievably. Please use "DTE" brand scaling tips.

4.2 Contraindication

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

4.2.2 The patients or doctors with heart pacemaker are 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 kept in a cool, dry and ventilated place.

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

4.3.3 This equipment should be stored in a room where the relative humidity is ≤80%, atmospheric pressure is 50kPa to 106kPa, and the temperature is –l0℃ to +50℃.

4.3.4 If the machine is not used for a long time, please make it get through the power and water once per month for five minutes.

4.4 Transportation

4.4.1 Excessive impact and shake should be prevented in transportation. Lay it carefully and lightly and don't invert it.

4.4.2 Don't put it together with dangerous goods during transportation.

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

4.5 Working condition

a) Environment temperature: 5℃to 40℃

b) Relative humidity: ≤80%

c) Atmosphere pressure: 70kPa to 106kPa

## 5. After service

We offer one year's 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 non-professional person.

## 6. Symbol instruction

DTE® Trademark

 Consult the accompanying documents

 Date of manufacture

 Manufacturer

 Class II equipment

 Type BF applied part

 Used indoor only

 Appliance compliance WEEE directive

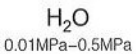
 Alternating current

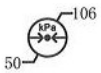
24V~ 24VAC power supply socket

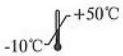
 Socker for the foot switch

 Adjustment for the water flow

 Power switch

 Water entrance pressure 0.01MPa-0.5MPa

 Atmospheric pressure for storage

 Temperature limitation

 Humidity limitation

 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

## 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

| Guidance and manufacturer's declaration - electromagnetic emissions | | |
|---|---|---|
| The model D1 is intended for use in the electromagnetic environment specified below. The customer or the user of the model D1 should assure that it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment - guidance** |
| RF emissions CISPR 11 | Group 1 | The model D1 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 D1 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 D1 is intended for use in the electromagnetic environment specified below. The customer or the user of the models D1 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<br>±8 kV air | ±6 kV contact<br>±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<br>±1 kV for Input/output lines | ±2kV for power supply lines<br>±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<br>±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<br>40 % $U_T$ (60% dip in $U_T$) for 5 cycles<br>70% $U_T$ (30% dip in $U_T$) for 25 cycles<br><5% $U_T$ (>95 % dip in $U_T$) for 5 sec | <5 % $U_T$ (>95% dip in $U_T$.) for 0.5 cycle<br>40 % $U_T$ (60% dip in $U_T$) for 5 cycles<br>70% $U_T$ (30% dip in $U_T$) for 25 cycles<br><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 D1 require continued operation during power mains interruptions, it is recommended that the models D1 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. | | | |

**Guidance & Declaration - Electromagnetic immunity**

The models D1 is intended for use in.the electromagnetic environment specified below. The customer or the user of the models D1 should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
|---|---|---|---|
| Conducted RF<br>IEC 61000-4-6<br>Radiated RF<br>IEC 61000-4-3 | 3 Vrms<br>150 kHz to 80 MHz<br>3 V/m<br>80 MHz to 2.5 GHz | *3V*<br><br>*3 V/m* | Portable and mobile RF communications equipment should be used no closer to any part of the models D1 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>**Recommended separation distance**<br><br>3V<br><br>$d=1.2\times P^{1/2}$ 80 MHz to 800 MHz<br><br>$d=2.3\times P^{1/2}$ 800 MHz to 2.5 GHz<br><br>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).<br><br>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]<br><br>Interference may occur In the vicinity of equipment marked with the following symbol:<br><br>  |

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 D1 is used exceeds the applicable RF compliance level above, the model D1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models D1.

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

**Recommended separation distances between portable and mobile RF communications equipment and the models** D1

The models D1 is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models D1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models D1 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.