WOODPECKER®

UDS - P ULTRASONIC PIEZO SCALER INSTRUCTION MANUAL

Certificated FDA TÜV CE 0197 EN ISO 9001:2000 EN ISO 13485:2003

(Please read this manual before operating)

GUILIN WOODPECKER MEDICAL INSTRUMENT CO.,LTD.

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1.The installation and components of equipment

1.1 Introduction

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 UDS-P ultrasonic piezo scaler has scaling, endo and curing light functions. It contains the following features:

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

2.The handpiece is detachable and can be autoclaved to the high temperature of 135^{0}C and the pressure of 0.22MPa.

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

These features make UDS-P become a new generation product in the world dental market .

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-P is used for the dental calculus elimination and root canal treatment.

1.3 The main technical specifications

a) Power source input: 100V to 240V~ 50Hz/60Hz 1.2A (max)

b) Main unit input: 30VDC 1.3A

c) Output primary tip Vibration excursion:≤100 μm

d) Output half-excursion force:＜2N

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

f） Output power: 3W to 20W

g） Main unit fuse: 250VT 1.6AL

h） Power source fuse: 250VT 2.0AL

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

j） Weight of main unit: 0.68kg

k） Weight of power source: 0.3kg

l) Operating mode: Continuous operation

m) Type of protection against electric shock: Class II

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

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

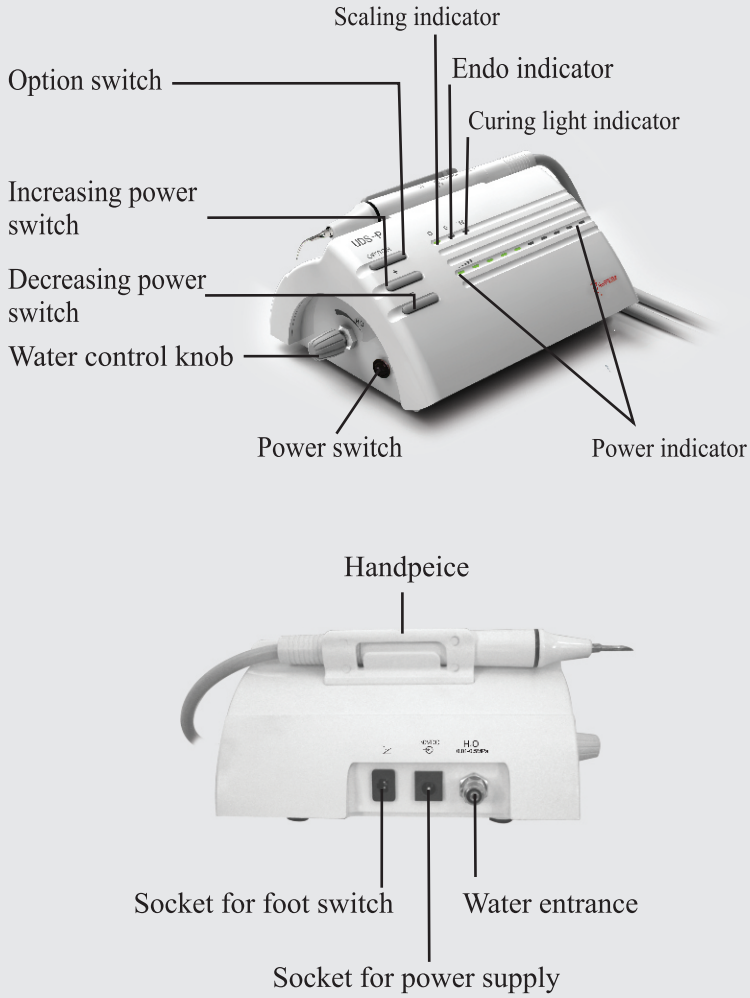
p) Degree of safety of application in the presence of a Flammable Anaesthetic Mixture with air or with Oxygen or Nitrous Oxide:Equipment not suitable for being used in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide

1.4 Installation of the main components

1.4.1 Sketch map for installation and connection.

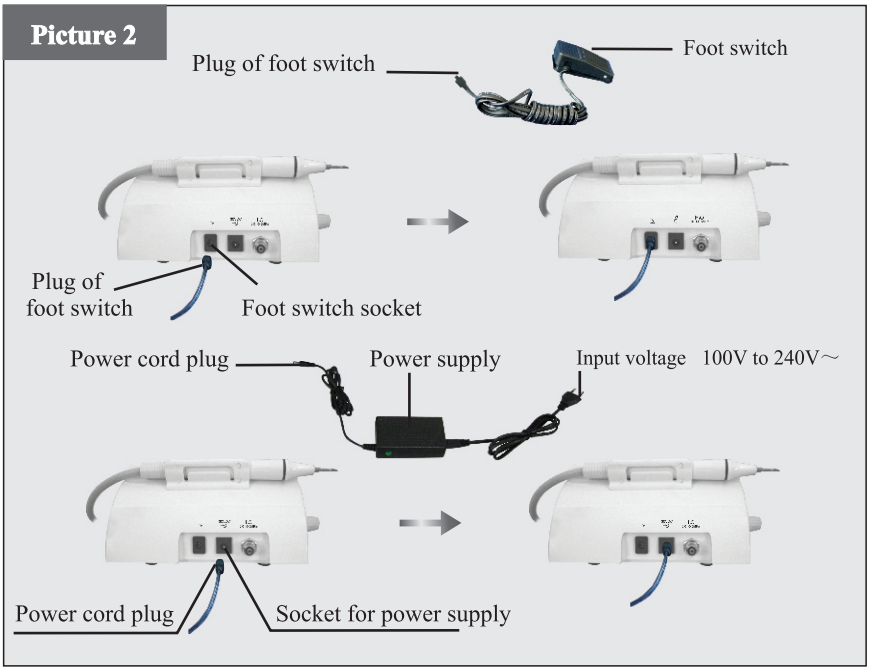
a)The components of the equipment

Picture 1



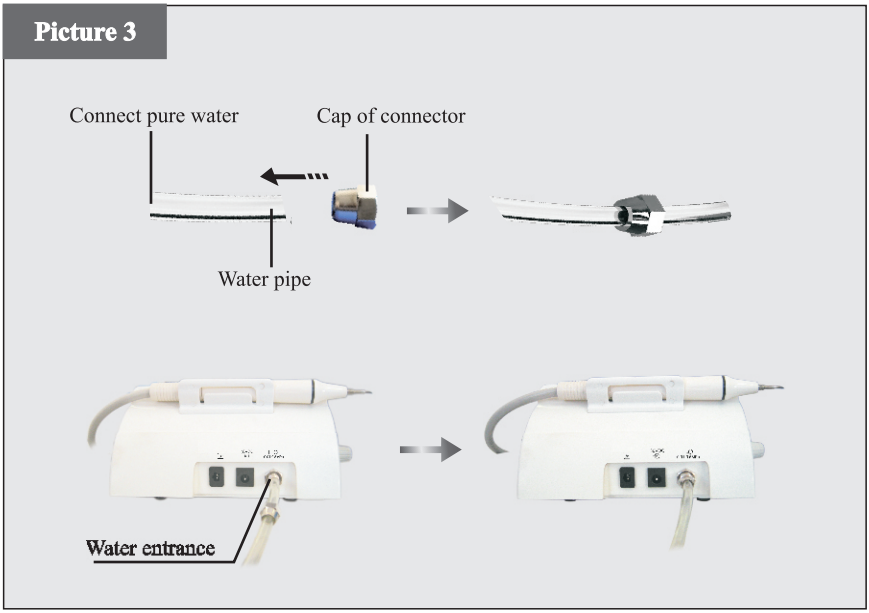
b)Sketch map for connection of foot switch, power supply and main unit

Picture 2



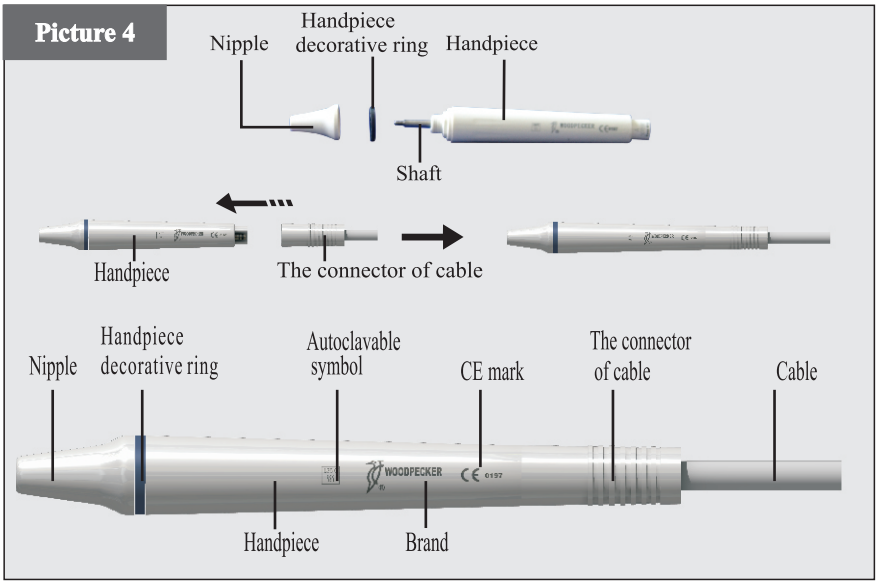
c)Sketch map for connection of water supply system

Picture 3



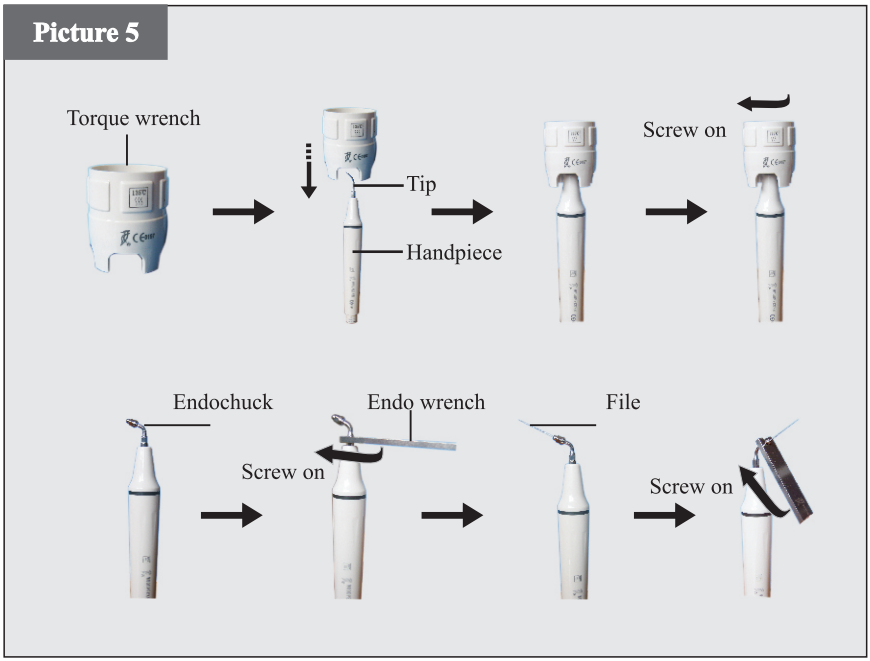
d)Sketch map for connection of detachable handpiece

Picture 4



e)Sketch map for how to install tip and endochuck with wrench

Picture 5



2.Product function and operation

2.1 Scaling function

2.1.1 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 switch to the max based on symbol as shown as 3.5.2[note 1].

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) Select a suitable scaling tip as you need, screw it on the handpiece tightly by the torque wrench(picture 5),then connect the handpiece and the connector of cable correctly.

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

g) Switch on the main unit, then the scaling indicator and the first five lights of power regulator shine.

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

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.

m) After finishing operation, keep the machine working for 30 seconds on the water supply condition in order to clean the handpiece and the scaling tip.

n) Unscrew the scaling tip and pull out handpiece, then sterilize them.

Notice: Don't pull out the handpiece when the machine is working.

2.1.2 Instruction for main components of detachable handpiece（showed in picture 4)· .

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

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

Notice: Keep the connector dry.

2.1.3 Torque wrench instruction (showed in picture 5)

a) The torque wrench's structure is designed in special way which can control the strength of the scaling tip's 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.

b) Operation

① Take the scaling tip into the torque wrench; operate as showed in picture 5.

② Tip installation: Hold the handpiece turn the tip toward direction as showed in picture 5 with the torque wrench. Turn two more circles when the tip stops, then the tip is installed.

③ Tip uninstallation: Hold the handpiece, turn the wrench toward anti-clockwise direction.

④ Sterilize it in sterilizer after each treatment.

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

⑥ Keep the torque wrench in a cool, dry and ventilated place and keep it clean.

c) Precaution

The following sterilizing methods are forbidden.

① Braise in liquor;

② Dip in iodine, alcohol or glutaraldehyde;

③ Torrefy in oven or microwave oven.

Notice: we are not responsible for any damage of the torque wrench directlyor indirectly made by any way in the above items.

2.2 Endo function

a) Usage process

① Fix endochuck to handpiece by endo wrench.

② Unscrew the screw cap on the endochuck.

③ Put the ultrasonic file into the hole in the front of endochuck.

④ Screw down the screw cap with endo wrench to tight up the ultrasonic file.

⑤ Press option key, turn to endo function.

⑥ When ultrasonic scaler turns into endo function, only the first lead light is on and the power is at first grade. Put the ultrasonic file into the patient's root canal slowly, step on the foot switch, then make endo treatment. During the treatment, turn up the power gradually according to the needs.

b) Notice

① **When fixing endochuck, it must be screwed down.**

② **The screw cap on the endochuck must be screwed down.**

③ **Don't press it too hard when the ultrasonic file is in the root canal.**

④ **Don't step on the foot switch until the ultrasonic file is in the root canal.**

⑤ **The power range is supposed from 1st to 5th grade.**

3.Sterilization and maintenance

3.1 Sterilization of detachable handpiece

3.1.1 Autoclaved to high temperature/pressure:

a) 121°C/1bar（0.1MPa）

b) 135°C/2.2bar（0.22MPa）

c) Pull out the handpiece and unscrew the scaling tip and endochuck after each operation.

d) Pack the handpiece with sterile gauze or sterile bag before sterilizing.

e) Reuse handpiece after it cools naturally in case of scalding hand.

3.1.2 Notice

a) Clear the cleaning liquid on the handpiece with 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 notice whether the outer of the handpiece is 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 handpiece. Please lubricate them with dental lube frequently, as sterilization and repeated pulling and inserting will reduce their life-span. 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 disinfectors such as iodine, alcohol and glutaraldehyde.

③ Put handpiece into oven or microwave oven for baking.

3.2 Sterilization of scaling tips and endochuck

All the scaling tips and endochuck can be autoclaved to 135℃.

3.3 Sterilization of torque wrench and endo wrench

a)The torque wrench and endo wrench can be sterilized in high temperature and pressure.

b) The following sterilization ways for torque wrench are forbidden:

① Braise in liquor.

② Dip in iodine, alcohol or glutaraldehyde.

③Torrefy 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, endochuck,torque wrench and endo wrench .

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

3.5 Troubleshooting and notes

3.5.1 Troubleshooting

Fault	Possible cause	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 connect	Connect the power plug well
	The foot switch is in loose	Insert the foot switch to its socket tightly
	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	Screw the tip on the handpiece tightly (picture 5)
	The connect plug of the handpiece with the circuit board is in loose connect	Contact our dealers or us
	Something wrong with the handpiece	Send it to our company to repair
	Something wrong with the cable	Contact our dealers or us

Fault	Possible cause	Solutions
The scaling tip vibrates but there is no spray when stepping on the foot 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 pipe by multi-function syringe【note2】
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 】
The amount of spouting water is too little	The water pressure is not high enough	Make the water pressure higher
	The water pipe is blocked	Clean the water pipe by multi-function syringe【note2】
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 because of vibration	Screw on the tip tightly (as showed in picture 5)
	The coupling between the handpiece and the cable isn't dry	Dry it by the hot air
	The tip is damaged【note3】	Change a new one
There is water seeping from the coupling between the handpiece and the cable	The waterproof "O " ring is damaged	Change a new "O " ring
The u-file doesn't vibrate	The screw cap is loose	Tighten it
	Endochuck is damaged	Change a new one
There is noise coming from the endochuck	The screw cap is loose	Tighten it

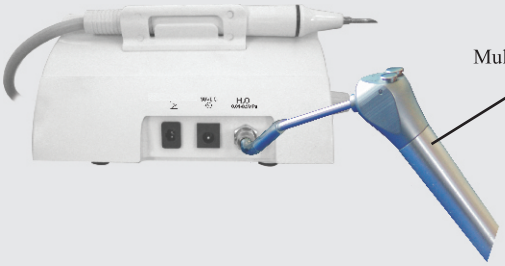
If the problem still can't be solved, please contact with local dealer or manufacturer.

3.5.2 Notes

a) The water control knob can adjust water volume according to the symbol.

b) [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 to 20cm from the water entrance.

② Turn on the electricity and get through the electricity.

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

④ Disassemble the tip or handpiece.

⑤ Step on the foot switch.

⑥ Turn 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.

c) [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:

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

② During 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, endo wrench and endochuck must be sterilized before every treatment.

4.1.3 Don't screw the handpiece, scaling tip and endochuck 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 or rub the tip and endochuck.

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 Keep the connector of handpiece and the socket of the cable dry before installing the handpiece.

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

4.1.11 Don't knock or rub the handpiece.

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

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

Ⅰ The maintenance, repair and modification are made by the manufacturer or the authorized dealer.

Ⅱ The changed components are original of "Woodpecker" and operated according to instruction manual.

4.1.14 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 ″Woodpecker″ brand scaling tips.

4.1.15 This model is only matched the adapter of our company.

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 70kPa to 106kPa, and the temperat ure is −10℃ 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 minute s.

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^{0}C to 40^{0}C

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

WOODPECKER	Trademark		Caution, consult accompanying documents
	Class II equipment		Use indoor only
	Type BF applied part	135℃	Can be autoclaved
	Alternating current	30V DC	30VDC power supply socket
	Socket for the foot switch	H_2O 0.01MPa~0.5MPa	Water entrance pressure 0.01MPa to 0.5MPa
H_2O	Adjustment for the water flow	FDA	FDA marked product
CE 0197	CE marked product		Appliance compliance WEEE directive
-10℃ +50℃	Temperature limitation	50 kPa 106	Atmospheric pressure for stroage
0% 80%	Humidity limitation		Manufacturer
	Date of manufacture	EC REP	Authorised Representative in the EUROPEAN COMMUNITY

ISO 9001:2000 Certificated by international quality control system of ISO

ISO 13485:2003 Certificated by medical instrument manufacturer quality control system of ISO

7.Environmental protection

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

8.Manufacturer's rights

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 conformity the following standards:

EN 60601-1:1990+A1:1993+A2:1995+A13:1996

EN 60601-1-2:2001/EN 60601-1-4:2001

EN 61205:1994/EN ISO 22374:2005

EN ISO 14971:2000+A1:2003

EN 980:2003/ISO 9687:1993/EN 1041:1998

EN ISO 17664:2004/EN ISO 17665-1:2006

EN ISO 10993-1:2003/EN ISO 10993-5:1999/EN ISO 10993-10:2003+A1:2003

10.2 EMC - Declaration of conformity

Guidance and manufacturer's declaration – electromagnetic emissions		
The model UDS-P is intended for using in the electromagnetic environment specified below. The customer or the user of the model UDS-P 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-P 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-P 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	Not applicable	

Guidance & Declaration — electromagnetic immunity			
The model UDS-P is intended for using in the electromagnetic environment specified below. The customer or the user of the model UDS-P 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	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±2 kV common mode	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 % UT (>95% dip in UT) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	<5 % UT (>95% dip in UT.) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model UDS-P requires continued operation during power mains interruptions, it is recommended that the model UDS-P should be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity

The model UDS-P is intended for using in. the electromagnetic environment specified below. The customer or the user of the model UDS-P 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	3V	Portable and mobile RF communications equipment should be used no closer to any part of the model UDS-P, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\times P^{1/2}$
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, should be less than the compliance level in each frequency range. Interference may occur In the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz. the higher frequency range applies.
NOTE 2 These guidelines may not be applied 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 model UDS-P is used exceeds the applicable RF compliance level above, the model UDS-P should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model UDS-P.

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 model UDS-P

The model UDS-P is intended for using in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model UDS-P can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model UDS-P 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×P1/2	80MHz to 800MHz d=1.2×P1/2	800MHz to 2.5GHz d=2.3×P1/2
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 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 1 At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not be applied 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.

GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.
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2nd Edition