ALAN
Dental Equipment

VRN®

OPERATION INSTRUCTION

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VRN–A3
VRN–A5

ULTRASONIC SCALER

ALAN Dental Equipment

CONTENT

Copyright and Notice

We congratulate that you become the respected customer of Guilin URIT Medical Electronics Co. Ltd. Welcome to use VRN-A3/VRN-A5 Ultrasonic dental descaler, it will bring you with the new experience and convenience.

This manual is compiled in accordance with the laws and regulations of the People's Republic of China and the specific conditions of VRN-A3/VRN-A5 ultrasonic tooth cleaning machine manufactured by Guilin URIT Medical Electronics Co., Ltd. It is only applicable to VRN-A3/VRN-A5 ultrasonic tooth cleaning machine sold in the People's Republic of China (excluding Taiwan, Hong Kong and Macau).

This specification includes the latest information until printing of the specification. Guilin URIT Medical Electronics Co., Ltd. is solely responsible for the revision and explanation of the simplified Chinese version of the instruction manual, and it reserves the right to change the relevant contents without notice after the instruction manual is printed. Parts of the drawings in this manual are for reference only. If the drawing does not conform to the actual object, the actual object shall prevail.

The use of the product must conform to the relevant operating specifications of the medical department and relevant regulations, and it is restricted to used by trained doctors or technicians only.

Please read this manual carefully before use, and strictly follow the instructions in this manual. Otherwise, Guilin URIT Medical Electronics Co., Ltd shall not be liable for any error or product damage caused by the illegal operation.

Note: Guilin URIT Medical Electronics Co., Ltd. does not promise any particular purpose of the product, nor undertake any implied warranty for merchantability and suitability of any particular purpose.

If you need after-sales service support, please contact Guilin URIT Medical Technology Co., Ltd. or authorized agen ts.

1 Product Overview

1.1 Overview

The VRN-A3/VRN-A5 ultrasonic tooth cleaning machine adopts automatic frequency tracking system to search the best working state automatically, the instrument's performance is more stable, and the handpiece can be sterilized at 135℃high temperature and 0.22MPa high pressure. The Instrument has the built-in computer microprocessor chip, which can control the power of tooth cleaning to make the tooth cleaning become more comfortable.

1.2 Product Structure and Composition

Ultrasonic dental cleaning machine is mainly composed of functional control circuit, fluid circuit, handle, power adapter, working point and pedal switch (wired and/or wireless).

1.3 Product Application scope

It is used to remove calculus, plaque and other tooth stains on the surface of oral teeth, remove the calculus and plaque in the periodontal pocket, clean and swing the root canal of teeth.

1. 4 Product Technical Parameters

- Adaptor Input: 220 V ± 22 V 50/60 Hz
- Host Input: AC24 V
- Primary tip vibration excursion: Minimum, 1 μ m, deviation-50%
  Maximum, 100 μ m, deviation +50%
- Half-excursion force: Minimum, 0.1 N, deviation-50%
  Maximum, 2 N, deviation +50%
- Frequency: 28 kHz ± 3 kHz
- Input power: 40 VA ~60 VA
- Ultrasonic output power: 3 W ~ 20 W
- Fuse: T3AL 250V
- Water pressure: 0.01 MPa ~ 0.5 MPa
- Net weight: 0.5 kg

- Gross weight: 2.0 kg
- Size: 170 mm × 121 mm × 48 mm
- Operation Mode: Continuous Operation
- Type of protection against electric shock: Class Ⅱ Equipment
- Degree of protection against electric shock: Type B applied part
- Degree of protection against liquid inflow: common equipment (IPX0), the pedal switch is the waterproof equipment (IPX1)
- Degree of safety when used with flammable anesthetic gases mixed with air or with oxygen or nitrogen oxide: non-AP, APG type equipment
- Normal operating conditions:

  A) Environment temperature: 5 ℃ ~ 40 ℃

  B) Relative humidity: ≤ 80%

  C) Atmospheric pressure: 70kPa ~ 106kPa

- The Supply voltage's application range: 220 V ± 22 V ~, 50/60 Hz

1.5 Components and Functions

1.5.1 Installation and connection schematics

a)Front and rear diagrams of the main unit

1 main unit
2 power reducing button
3 model adjusting button
4 power increasing button
5 screen
6 water adjusting knob
7 pluggable tail line
8 handpiece
9 working tip
10 liquid circuit interface
11 foot pedal switch interface
12 power input interface
13 power supply switch
14 foot pedal switch
15 power adapter
16 torque wrench

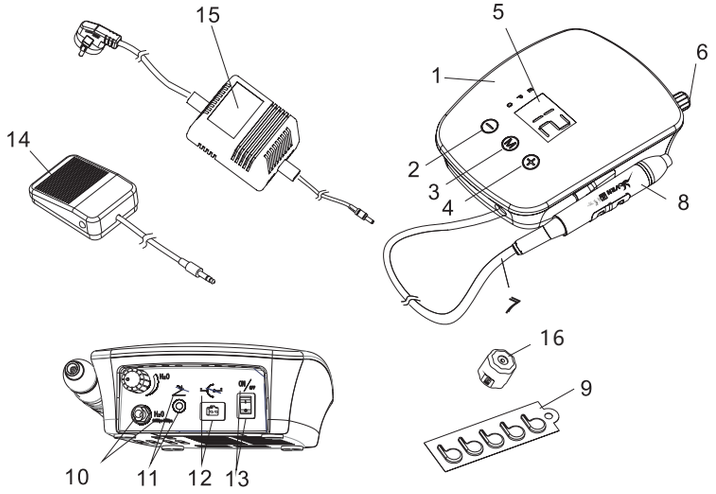

Figure 1

b)Line connections

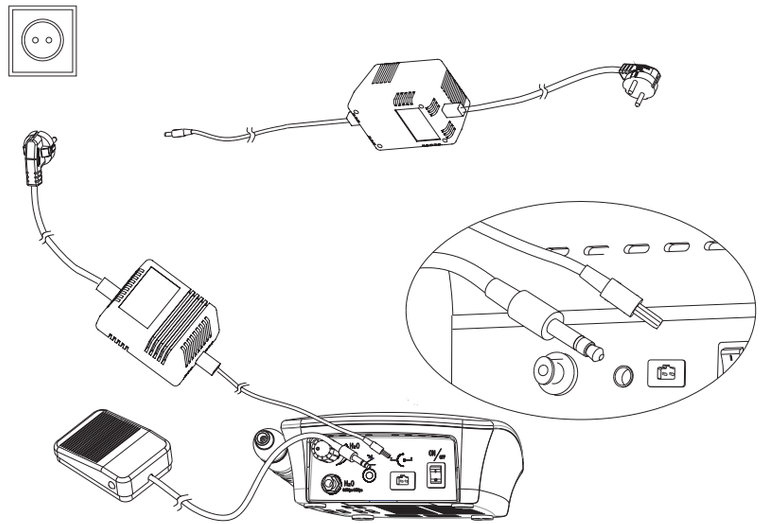

Figure 2

c)Liquid circuit connections

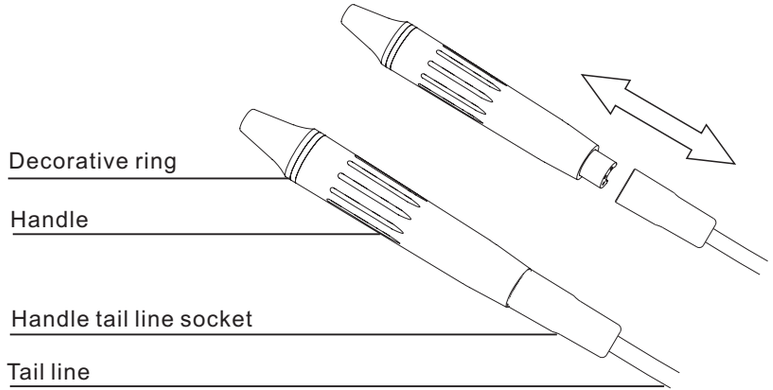

Figure 3

d) Connection Schematic Diagram of Detachable Handpiece

Normal detachable handpiece

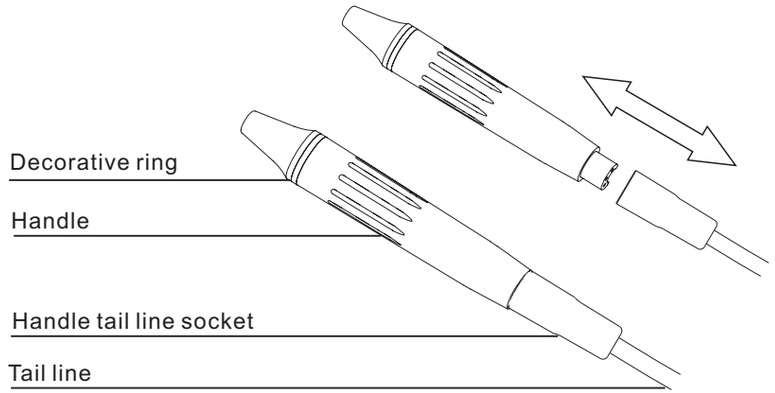

Figure 4

LED Detachable Handpiece

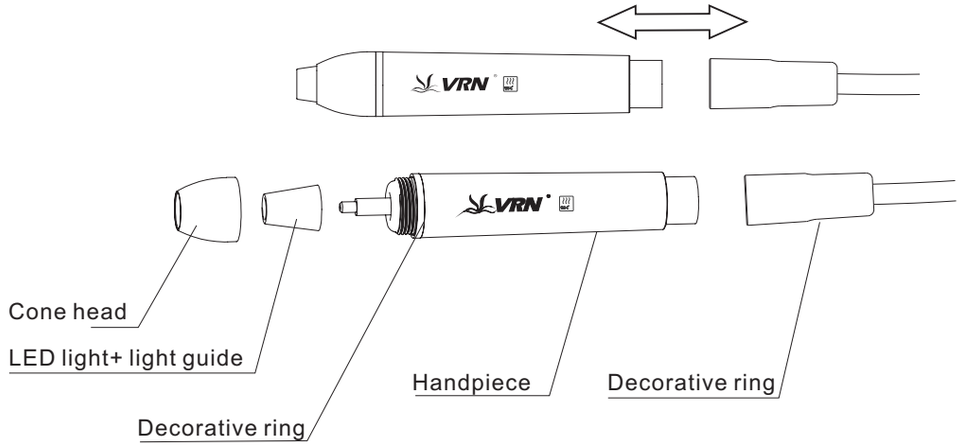

Figure 5

e) Installation diagram of the Endo chuck and the working tip

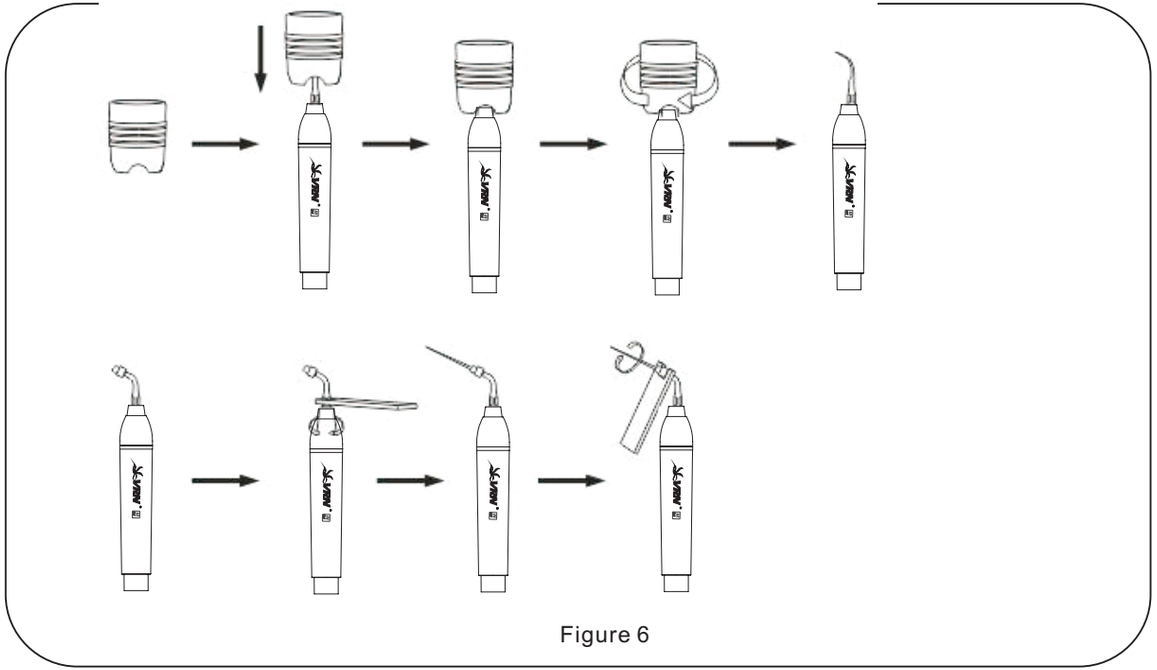

Figure 6

2 Product function and usage

2.1 Tooth cleaning function

2.1. 1 Operation

1) Open the package and check whether the accessories of the product are complete according to the packing list. Remove the main unit from the packing box and place the main unit facing the operator on a stable flat.

2) Turn the water adjustment knob to the maximum as shown (see 3.5. 2【Note 1】).

3) Insert the foot switch plug into the foot switch socket (as shown in Figure 2)

4) Connect one end of the water pipe to the water inlet and the other end to the purified water source (as shown in Figure 3).

5) Fasten that working tip to the handpiece with a working tip wrench, and then properly socket the handpiece with the handpiece tail socket. Before installing the handle, dry the handle connecting end and the tail socket thoroughly.

6) keep the main unit power switch in the off state, then connect the power supply output terminal to the main unit, and then connect the power supply input terminal to the electric supply (as shown in Fig. 2).

7) Turn on the main unit power switch, and the power indicator will be lighted up.

8)The frequency of the product is fast during normal operation, in the case of ensuring normal water outlet of the machine, dental calculus can be eliminated only through light contact and reciprocating movement at a certain speed, and the working tip has no obvious fever feeling; excessive force or long time stay on the local part should be avoided during dental cleaning.

9) Vibration intensity: the vibration intensity can be adjusted according to the requirement. Generally, it will be ok if it is adjusted to the medium vibration intensity. It can also be adjusted according to the patient's sensitivity and hardness of dental calculus at any time during the clinical process.

10) Water regulation: press the foot switch, the working tip will generate vibration, and rotate the water regulation knob to form water mist to cool the handpiece and clean the tooth surface.

11) Generally the posture of holding a pen is used to hold the handpiece.

12) During clinical scaling, do not make the tip of the working tip contact with the tooth vertically, and do not apply heavy pressure to avoid damaging the tooth body and the working tip.

13) After completing the clinical scaling, keep working for 30 seconds on the condition of ensuring water supply to clean the handpiece and tip.

14)Remove the working tip and take down the handle for sterilization.

Notes:

1)Do not pull out the handpiece when the foot switch is pressed and the product vibrates.

2)Do not press the pedal switch to allow the dental cleanser to operate without properly installing the handpiece or working tip.

2. 1. 2 Main companents and handpiece usage (see Figure 4, e.g. 5)

Decorative rings: can be washed with alcohol.

Handpiece: the important part of the whole machine, which can be sterilized under high temperature and high pressure.

Tail socket: it is used to connect waterways and circuits between the handle and the mainframe.

Note: Keep the handpiece dry when connecting it to the tail socket.

2.1.3 Force-limiting wrench usage (see Figure 6)

The force-limiting wrench adopts a special structure design, which can ensure that the user can load and unload the working tip effectively and protect the hand of the user in the process of using, and the user will not be scratched by the working tip in the process of loading and unloading.

Usage Steps:

1) Place the working tip into the force limiting wrench.

2) Install the working tip: grasp the handpiece, rotate the working tip clockwise with a force-limiting wrench until the working tip can no longer be rotated, and then the installation of working tip is finished.

3)Unload that working tip: grasp the handlpiece, and rotate the force-limiting wrench counterclockwise to remove the working tip.

4) After each use, please disinfect and sterilize the force-limiting wrench.

5) After sterilization,because the surface temperature of the force-limiting wrench is very high, the force-limiting wrench can be used again after cooling to avoid scalding.

6) When the force limiting wrench is not used, place it in a ventilated and dry place and keep it clean.

2.2 Root canal washing function

Usage Steps:

1) Fix the root canal file holder to the handpiece with a root canal wrench.

2) Unscrew the nut of the root canal file holder.

3) Insert that ultrasonic root canal file into the hole which is in the front of the root canal file holder.

4) Use a root canal wrench to tighten the nut of the root canal file.

5) Press function key M to select The Endo mode mode.

6) When The Endo mode is selected,only E-mode letters and power numbers are displayed on the screen, insert the ultrasonic root canal file into the root canal of the patient slowly, step on the foot switch, and start root canal washing, and the power of root canal washing can be adjusted according to different requirement.

Notes:

1) The root canal file holder must be tightened when installing.

2) Tighten the nuts when installing them.

3)When that root canal of the tooth are washed , no heavy pressure can be exerted on the root canal.

4) Do not press the foot switch when the ultrasonic root canal file is not inserted into the root canal.

5) When using the root canal washing function, it is recommended that the power should be slowly increased from 1st grade to 7th grade.

3 Sterilization and Maintenance

3.1 Handle disinfection can refer to cleaning,disnfecting and sterilizing instructions, please read the instructions before disinfection, and operate according to the instructions.

3.1.1 Handle disinfection can refer to cleaning,disnfecting and sterilizing instructions.

3.1. 2 Sterilization in High Temperature and High Pressure Environment

1) When sterilize with a sterilizer, it should be set at 135℃, 2.2 bar (0.22 MPa), 15 min.

2) Pull out the handpiece and remove the working tip or the root canal grip slipper after each use.

3) Wrap the handpiece with a disinfectant towel or bag.

4) After sterilization, the handpiece should naturally cool down before being reused to avoid scalding.

Notes:

1) Before sterilization, blow off the cleaning liquid remaining in the handle with the compressed air.

2) When sterilizing, the working tip must be removed from the handpiece, and it should not be mixed with other instruments to sterilize.

3) Please pay attention to the external damage of the handpiece in the process of disinfection at any time. Do not wipe any protective oil on the surface of the handpiece.

4) There are two waterproof O-rings at the end of the handpiece. In order to prolong the service life, the O-rings should be lubricated with dental lubricants frequently due to repeated sterilization and plugging. In case of breakage or excessive wear, the waterproof O-rings should be replaced in time.

5) The disinfectant parts can be sterilized at least 250 times.

6) It is strictly forbidden to sterilize the handpiece in the following ways:

- Digest the handpiece in the liquor
- Soak the handpiece in disinfectant such as iodine, alcohol, glutaraldehyde, etc
- Bake it in an oven or microwave oven with high-temperature

3.2 Sterilization of working tip and root canal file holder

The working tip and root canal file holder can be sterilized under high temperature and high pressure.

3.3 Sterilization of force-limiting wrenches and root canal wrenches

1) The force limiting wrench and root canal wrench can be sterilized under high temperature and high pressure.

2) It is strictly forbidden to sterilize them with the following methods

- Digest the handpiece in the liquor
- Soak the handpiece in disinfectant such as iodine, alcohol, glutaraldehyde, etc
- Bake it in an oven or microwave oven with high-temperature

Notes:

We shall not be responsible for any damage to the force limiting wrenches or root canal wrenches caused directly or indirectly by the above-mentioned improper using ways.

4 Packing list

No.	Name	Specification Model
1	Motherboard	/
2	Control panel	/
3	Detachable handpiece	A3:HP-2 A5:PH-1
4	Tips	A3:5 tips A5:8 tips
5	Wrench	/
6	Endo wrench	/
7	Handpiece seal	/
8	Waterproof O-ring	3.5mm×1.5mm
9	Multi-function syringe	/
10	Water pipe	4mm×6mm
11	Power adapter	24VAC
12	Electric-magnetic valve	/
13	Wired foot switch	/
14	LED	/

Note： This instruction manual did not detail the specification parts of ultrasonic scaler; please check the promotion documents and "packing list" along with the packing.

5 Symbol instruction

VRN®	Manufacturer's logo		Caution! Read the operation instruction		Class Ⅱ equipment		Applied part, type BF
	Disposal		Manufacturer		Used indoor only	SN	Serial number
135℃	Autoclavable	%	Storage Humidity		Storage Temp		Keep dry
	Fragile		Refer to instruction manual / booklet	EC REP	Authorised representative in the European community	CE 0123	CE marking:refers to directive 93/42 EEC,including EN60601-1 and EN60601-1-2
- +	Electrical Outlet		Foot switch connection	H_2O 0.01Mpa-0.5Mpa	Water supply		up
IPX4	Waterproof grade is splash proof	IPX6	Waterproof rating of water resistance		Production date		

6 Storage and transportation

1) Do not shake.Keep in a cool, dry and ventilated place.

2) Do not mix with toxic, corrosive, flammable goods.

3) The product should be stored in an environment where the relative humidity does not exceed 90%, the atmospheric pressure is 75 kPa to 106 kPa, and the temperature is -20 ° C to 55 ° C.

4) Should be protected from excessive shake and vibration during transport.

5) Avoiding the sun or rain and snow.

7 EMC Declaration

Guidance and manufacturer's declaration--electromagnetic emissions		
The models VRN-A8 Dental Ultrasonic SandBlasting Scaler are intended for use in the electromagnetic environment specified below. The customer or the user of the VRN-A8 Dental Ultrasonic SandBlasting Scaler should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic emissions-guidance
Radiated Emission EN 60601-1-2: 2015 EN55011:2016+A1:2017	Class B	The models VRN-A8 Dental Ultrasonic SandBlasting Scaler 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.
Conducted Emissions EN 60601-1-2: 2015 EN55011:2016+A1:2017	Class B	The models VRN-A8 Ultrasonic Periodontal Therapy System are suitable for used in domestic establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic Current EN 60601-1-2: 2015 EN 61000-3-2:2014	Test configuration and procedure see clause 7.1 of standard EN 61000-3-2:2014	
Voltage Fluctuations/ Flicker Emissions EN 60601-1-2: 2015 EN 61000-3-3:2014	Test configuration and procedure see clause 5 of standard EN 61000-3-3:2013	

Guidance and manufacturer's declaration--electromagnetic immunity		
The models VRN-A8 Ultrasonic Periodontal Therapy System are intended for use in the electromagnetic environment specified below. The customer or the user of the VRN-A8 Ultrasonic Periodontal Therapy System should assure that it is used in such an environment.		
Immunity Test	Compliance	Electromagnetic emissions-guidance
Electrostatic Discharge EN60601-1-2:2015 EN61000-4-2:2009	±15kV for air discharge ±8kV contact discharge	Floors should be wood, concrete or ceramic tile. If floors are covers with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst	±2kV a.c pwoer lines	Main power quality should be that of a typical commercial or hospital environment.
Surge Test EN60601-1-2:2015 EN61000-4-5:2014	±1kV a.c pwoer line(s) to line(s)	Main power quality should be that of a typical commercial or hospital environment.

Immunity Test	Compliance	Electromagnetic emissions-guidance
Conducted Disturbance Snducedby Radio-frequeng Fields	comply with the requirments of clanse 8.9 of EN60601-1-1-2: 2015 at immunity test levels of 3Vrms and 6Vrms over the frequency range beginning at the start frequency and extending to 80MHz	For AC power input lines: EUT is placed on an insulating support of 0.1m high above a ground re-rerence plane.It must be 0.3m away the CDN(coupling and decoupling network)of whtich the bottom is made of metaillic mtaerial and placed above the ground reference plane shall be between 30 and 50mm(where possible).The disturbance signal amplifiled by amplifieris injected to EUT through CDN. For Signal Line and Control Line: EUT is placed on an insulating support above a ground reference plane .The EM camp is directly placed on the ground reference plane with its metallic bottom contacting the plane. Gables between EUT and auxiliary equipment are put through the EM clamp.The disturbance signal amplified by amplifier is injected to EUT through EM clamp. Record any perfomance degradation of the EUT during the testand judge the test result according to performance criterion.
Voltage Dips and Interruptiongs	100%/10ms,20ms 30%/500 ms	EUT is connected to the simulator according to the test photo.When conducting this,the power supply shall be set at the minimum and maximum rated input voltages and test voltage changes shall be step changes at the phaseangle of 0°,45°,90°,135°,180°,225°,270°and315°.

Immunity Test	Compliance	Electromagnetic emissions-guidance
Radiated,Radio-frequ ency,electromagnetic field	comply with the requiments of clanse 8.9of EN60601-1-2:2015 at immunity test levels	EUT and its auxiliary instrument are placed on a turntable which is 0.8 meter above ground.Transmitting antenna mounted on an antenna mast is set 3 meter away from the EUT.During the test,each of the four sides of EUT will face the transmissing antenna with the turntable cycled.Both horizontal and vertical polarization of the antenna areset on testand measured individually. In order to judge the performance of the EUT,a set of monitor system is used.Record any performance degradation of the EUT during the test and judge the test result according to performance criterion.