USER MANUAL

Model :AI Implant Touch

Version : 2204.14.0.0

CONTENTS

WARRANTY

INSTRUCTION

I Period validity:

From the date of purchase, we provide free maintenance for the whole machine three times in two years. (except for Handpiece and Consumable parts.)

II Range of warranty:

During the warranty period, we promise to be responsible for the product quality, such as raw materials or processing defects.

III The following are beyond our warranty:

①.Damage caused by non-compliance with the operation manual or use for abnormal functions.

②.Man made damage caused by improper operation or unauthorized disassembly.

③.Damage caused by improper transportation or storage and lack of maintenance.

④.No signature or seal from the dealer or incomplete warranty filling.

DENTAL IMPLANT UNIT WARRANTY CARD

Customer name	
Detailed address	
Postcode	
Contact Number	
Model	
Master serial number	
Handpiece serial number	
Date of purchase	
Contacts	

Time	Maintenance record	Maintainer

A copy of customer retention

A copy of dealer retention

A copy to the manufacturer

DENTAL IMPLANT UNIT WARRANTY CARD

Customer name	
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SAFETY PRECAUTIONS

1.For the safety of you and patients

This product is a power system used in stomatology, oral surgery and surgery. For safety Please read this manual carefully before operation, otherwise there will be risks.

Please keep this manual in an easy place for easy access.

2.User

Only trained professional dental medical personnel can use this product.Improper use may damage the product and cause damage to patients, users and third parties .

3. Please read and follow the instruction below for safety and avoid damage to users, patients and third parties due to inappropriate usage.

Store the product at room temperature for 24 hours before using it for the first time.

Before each use, check the host, foot switch, bending machine and motor whether damage or components looseness or not,only can be used after confirming that there are no abnormal conditions.

Before each treatment, please check the set parameters and test the operation.

Install the bending machine only when the drive motor is completely stationary.

Do not touch the collet mechanism while the handpiece is still running.

Be sure to ensure correct working conditions and provide sufficient cooling for the treatment site.

This product is intermittent operation equipment: pause for 10 minutes after 3 minutes of operation. If not follow the instruction the equipment will overheated, resulting in damage to patients, users or third parties, the manufacturer shall not responsible for this.

Please use the power socket with ground wire.

Be sure to follow the manufacturer's instructions on the maximum speed, maximum torque and positive and negative rotation of the handpiece operation; Do not overload use.

When the speed is set to 20:1, only the original handpiece of this product can be used, and other handpiece may lead to failure.The manufacturer is not responsible for the damage caused by the deviation between the torque data provided and the speed ratio.

The flushing tube should be approved by the manufacturer (has the medical device registration certificate). Flushing pipe supplied with equipment is only one-time used and must be discarded after each use! Please pay attention to the validity period of the flushing pipe and relevant information waste disposal regulations.

When replacing the fuse, be sure to disconnect the power supply and only use the manufacturer's original fuse (model:F10A250V).When the fuse is scrapped, it shall be handled in accordance with local environmental regulations.

This product is not suitable for use in potentially explosive gas or oxygen enriched gas environment; Can't be free Use in case of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen and nitrous oxide.

Only use the power cord provided by the manufacturer; When not in use for a long time, please unplug the power plug.

In case of overall system failure, do not continue to use the equipment. Ensure that system faults are eliminated and ensure It can be used only after there are no other faults.

INTRODUCTION

Before using this product, please check whether there are implanted medical devices in the patient or user,for example, cardiac pacemaker and ICD (implantable cardioverter defibrillator) ensure that this product is far away from Implanted medical devices.

Medical electrical equipment must pay special attention to EMC (electromagnetic compatibility) precautions, and relevant EMC precautions must be followed for installation and peration. The manufacturer only guarantees that the equipment is in original accessories and spare parts shall meet EMC requirements.If other accessories / spare parts are used,It may lead to the increase of electromagnetic radiation interference or the decline of anti electromagnetic interference ability.

If it is used in the room with electromagnetic wave, it may cause misoperation. In case there is electromagnetic wave please do not use this product near it.

If there is an ultrasonic generator nearby or an electric knife is used, please turn off the power of the equipment.

Do not use any high-frequency portable or mobile communication devices (such as mobile phones) during operation,otherwise, it will affect the medical electrical equipment.

Please install the equipment at the ambient temperature of 0 ~ 40 ℃, humidity of 10 ~ 80% RH,the air pressure is 50 kPa ~ 106 kPa, and the place where frost does not occur inside the master.Installed in places outside this condition may cause equipment failure.

1.Purpose

The power system of this product is applicable to the treatment of tooth hard tissue in dental surgery, implantation and maxillofacial surgery.In oral implant treatment, it is used for drilling and tapping of alveolar bone and installation of implant.

2. Dental Implant Medical Device Host

Power supply: AC220V, 50Hz, input power 340va

Type B applied partial devices (not applicable to intracardiac devices)
Intermittent operation equipment: pause for 10 minutes after 3 minutes of operation.

3. Foot Switch

IPX1Internal power supply equipment

Continuous operation equipment

Waterproof grade: IPX1

COMPONENTS LIST

		
Control host	Wired foot switch	Foot switch charger
		
Motor with cable (LED with light optional)	Disposable flushing pipeline	Water bottle bracket
		
20: 1 handpiece (LED with light optional)	Motor bracket	Power cord

1. Needles and Drills for Planting Head

Planting burs and drills are the expected combination devices of this product, but they are not included in the accessories of this product,products with registration certificate configured by users.

2. Disposable Gum Rinser

The disposable flushing pipeline attached to the equipment has been sterilized and is within the validity period.

3. Cooling Water

This product is used in combination with normal saline. Use safe and suitable flushing fluid and operate according to the instructions provided by the manufacturer.

The cooling water bottle (bag) shall be purchased by the user.

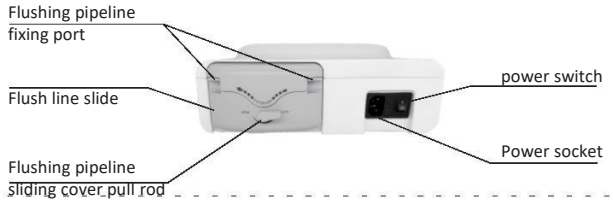
TECHNICAL PARAMETERS

Model	AI Implant Touch
Rated voltage	AC 220 V
Allowable voltage fluctuation	50 Hz
Frequency	±10 %
Maximum power consumption	340 VA
Rated voltage torque range	100～40000 rpm (±10%)
Rated voltage speed range	5～70 N·cm (±10%)
cooling water	0%, 25%, 50%, 75%, 100% 5th gear adjustable
Operation mode	S3 (3 min/10 min)
Size (mm) (W*D*H)	300×280×128
Weight (kg)	5.4

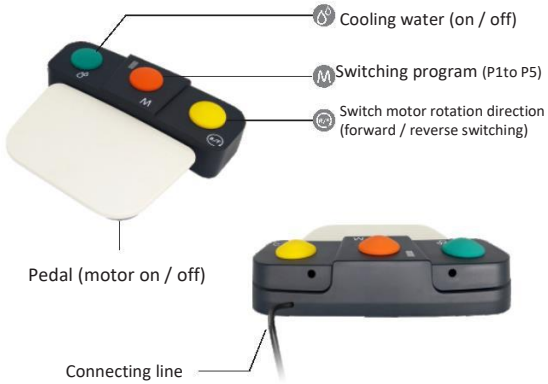
USING INSTRUCTION

1. Front Panel Descripthion

2. Back Plate



3. Foot Padel



4. Motor with Cable

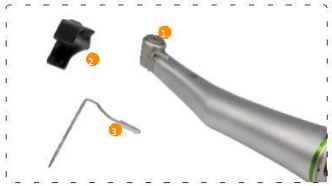
Do not disassemble the motor with cable.
The motor with cable has been lubricated and can be used for a long time.

Please note: when the motor works at low speed, it is difficult to determine whether it is running.

The above figure shows the light outlet of LED motor with cable.

5. Contra-angle Handpiece

Contra-angle handpiece components



1. Button
2. Spray clamp for internal needle cooling system
3. Cooling water pipe for internal needle cooling

Instruction for assembly/disassembly of needle and drill !!!!!!!!!

Only use the turning needle and drill bit in good condition, and pay attention to the rotation direction of the turning needle and drill bit; According to the manufacturer operate according to the operating instructions.

Insert the burs and drills only when the handpiece is stationary.

Do not touch the rotating burs and drills.

Do not press the operation button of the handpiece during use. This can cause the burs, drilsl to fall off and / or handpiece overheat.

6. Installation instructions

Always place the product on a flat surface.

Ensure that the product can be easily disconnected from the power supply.

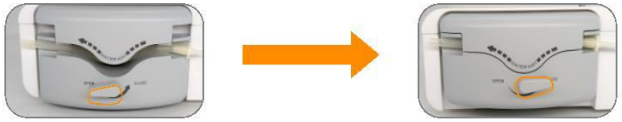
The installation position of the equipment shall ensure easy access to the power switch; In dangerous situations,the power switch or power cord can be used to disconnect the power supply; the power switch can also be used safe stop of equipment.

Control Head Installation

1.Connect the power cord.please pay attention to the wiring position!

2.Plug in the motor cable.please pay attention to the wiring position!

3.Insert the water supply bottle bracket.please note that the maximum bearing capacity is 1.5kg



4. As shown in the picture above, clip the disposable flushing pipeline into the water pipe groove in the sliding cover. Then close the flushing pipeline slide cover.

Test Run

Press the foot pedal to start the motor.

If the motor occurs (such as vibration, abnormal noise, overheating, cooling water failure or leakage, etc.), please release the foot to stop the motor immediately and check whether all components are installed in place. If the fault still cannot be eliminated, please contact the local dealer.

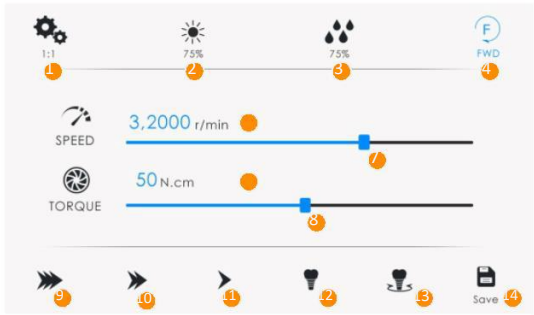
OPERATION INSTRUCTION

1. Ai Implant Touch Operation Interface

Attention

For safety reasons, in the setting data state, stepping on the foot pedal cannot start the motor, so it is necessary to exit the setting state The motor can be started normally.

2. Ai Implant Touch Panel Operation Interface



- Displays the current speed ratio.
- Display the current screen brightness, 0%, 25%, 50%, 75%, 100%, a total of 5 gears
- Display cooling water flow, 0%, 25%, 50%, 75%, 100%, 5 gears in total.
- Display current rotation direction: F / R
- Display real-time speed (r / min)
- Display real-time output torque (0-70n. cm)
- The speed slider can adjust the speed by dragging left and right.
- Torque slider, adjust the torque manually from left to right。
- Pattern1 Pattern2 Pattern3 Pattern4 Pattern5
- Save:

Beep	Function
Ring 1	Clear just set data
Ring 2	Save the data of operation p1-p5
Ring 3	Switch the switch function and speed regulation function of foot control
Ring 4 Ring 5	Restore the factory setting, P1 can realize immediate recovery, and p2-p5 needs to restart the machine calibrate foot control

FACTORY SETTINGS

1. P1-P3 Mode

Speed ratio	1:1	20:1	20:1
Speed(rpm)	35,000	1,200	800
Adjustable speed range(rpm)	100~40,000	5~2,000	5~2,000
Motor rotation direction	Forward	Forward	Forward
Cooling water	Open	Open	Open
Torque(N.cm)	No display	55	55

1. P4-P5 Mode

Speed ratio	20:1	20:1	20:1	20:1
Speed(rpm)	15	30	20	20
Motor rotation direction	Forward	Reverse	Forward	Reverse
Cooling water	Open	Close	Open	Close
Torque(N.cm)	20	20	20	20
Torque range(N.cm)	5~70	5~70	5~60	5~60

TROUBLE SHOOTING

General fault description	Solution
Overheating of electronic devices——Safe shutdown	Turn off the power supply of the equipment and let the equipment cool down for at least 10 minutes,then restart
Electronic device overload	Turn off the power supply of the equipment and let the equipment cool down for at least 10 minutes,Then restart
Foot switch control error——Initializing	Turn off the power of the device and restart it. Do not start foot control when starting the machine.
Foot switch control error	Power off the device., Check the plug connection of the foot control,then restart.
Run time limiter	Power off the device and restart.
system failure	Turn off the power supply of the equipment and allow the motor to cool down for at least 10 minutes,Then restart.
Motor temperature too high	Turn off the power supply of the equipment, check the connection of the plug-in motor and let the motor cool down for at least 10 minutes and restart.

If the product still cannot operate normally after turning off the power of the equipment and turning it on again, please contact the local dealer immediately or call the manufacturer.

Once the user disassembles and repairs by himself, he cannot enjoy the free warranty service within the warranty period。

CLEANING STERILIZATION MAINTENANCE&STORAGE

Clean, disinfect or sterilize according to the regulations, standards and principles of your country (region).

1. Control host and foot switch

The master is not allowed to carry out mechanical cleaning (thermal cleaning sterilizer) and sterilization.Do not immerse the master in water or flush it with water

Manual cleaning and sterillization

The front panel of the control host is sealed and can be cleaned by wiping.

The foot switch is an internal power supply device, which is a closed device without anti-seepage protection. The waterproof grade is ipx1 and should be clean by wiping.

Disinfect with disinfectant. Wipe disinfection is recommended.

Only disinfectants that do not contain chlorine and are certified by a formal certification body should be used.
Please pay attention to the manufacturer's detailed instructions on the use of disinfectants.

Storage

Please unplug the power cord of the master when it is not used for a long time.

Please keep the equipment in a place free of dust, sulfuric acid and salt water, and the ambient temperature is 0 ~60 ℃, the humidity is 10 ~ 85% RH, and the atmospheric pressure is 50kPa ~ 106kpa.

2. Motor with Cable

Do not twist or wind the motor cable!

Do not wind the cable too tightly!
Do not place the motor with cable in liquid disinfectant or ultrasonic cleaner.

Manual Cleaning

Wash with softened (< 38"C/< 100*F) by brush.
Remove any liquid residues (use absorbent cloth and blow until dry with compressed air)

Manual Sterillization

Disinfect with disinfectant, and wipe disinfection is recommended.

Only disinfectants that do not contain chlorine and are certified by a formal certification body should be used。

After manual cleaning and disinfection, the last sterilization must be carried out in class B or S steam sterilizer.(in closed state, according to GB / t30690-2014 standard)。

Cleaning and Sterillization

Hot cleaning sterilizer can be used to clean and disinfect the motor with cable.

Follow the sterilizer manufacturer's recommendations for equipment about cleaning and flushing.After hot cleaning and disinfection, ensure that the inside and outside of the motor with cable are kept completely dry.

Sterillization and Storage

It is recommended to use class B disinfection furnace conforming to GB / T30690-2014 for sterilization, other methods may be reduce the service life of the motor
Follow the manufacturer's recommendations clean and disinfect before sterilization.

Must be in accordance with YY / t0698 5-2009 standard, use bacteria free packaging materials to pack the motors and accessories properly.

Store the disinfected articles in a dry and dust-free place.
It is recommended that you overhaul the motor with cable regularly every year.

3. 20:1 Contra-angle Handpiece

After the treatment, please clean, disinfect and refuel the handpiece immediately, and then sterilize it.

Manual Cleaning

If the pollution is serious, please clean it with sterile paper towel first.

Only disinfectants without protein stabilizing effect can be used

Internal and external manual cleaning

Rinse with demineralized water (38 ℃)。

Remove any liquid residue (use a water absorbent cloth and blow dry with compressed air).

Do not place the handpiece in liquid disinfectant or ultrasonic cleaner.。

Cleaning and disinfection

After each treatment, the handpiece shall be cleaned and disinfected, and the infiltrated liquid (such as blood or saliva) shall be washed and cleaned prevent residue on internal components.

After manual cleaning, disinfection and adding lubricating oil, it must be at grade B or S-class sterilizer (according to GB / T30690-2014 standard) last sterilization (closed).

The handpiece can be cleaned and disinfected with a hot cleaning sterilizer.

The operation shall be carried out in accordance with the manufacturer's specifications for equipment, detergent and abstergent.

Maintenance

After hot cleaning and disinfection, ensure that the inside and outside of the handpiece are kept completely dry. Use compressed air to remove liquid residues. After each hot cleaning and disinfection add oil to lubricate the dry handpiece immediately.
Please be sure to add oil before each sterilization

Daily oiling

Use special handpiece lubricating oil.
Follow the instructions on the fuel injection tank and package.

Test Run After Oiling

Place the end of the handpiece downward.

Start the handpiece for about 30 seconds to remove excess oil.
Start at the minimum speed and gradually increase to the maximum speed in 5 to 10 seconds. Once you see any dirt the whole disinfection and cleaning steps shall be repeated.
Wipe the handpiece with gauze or soft cloth.

It is recommended to use class B disinfection furnace conforming to GB / T30690-2014 for sterilization.

Follow the device manufacturer's instructions.

Before sterilization, clean, disinfect and lubricate the handpiece.

Must be in accordance with YY / T0698 according to standard 5-2009, the handpiece shall be properly packed with bacteria free packaging materials.

Store the handpiece in a dry place.

When using the handpiece of the manufacturer, it is recommended that you overhaul it regularly every year.

4. Sterilization Method

Sterilizer shall be used for class B steam sterilization according to GB / t30690-2014.
The sterilization time shall last for at least 15 minutes at 134 ℃ and 0.21mpa.

INSPECTION, GUARANTEE SECONDARY TRANSPORTAION & RESERVED RIGHTS

1.Inspection

Be sure to check the product function and safety regularly. The inspection must be carried out by the manufacturer or authorized by the manufacturer, and the following procedures must be included:

1) Visually check whether the appearance of the instrument is damaged;
2) Measure whether the equipment has leakage current；
3)Visually check whether the components have safety problems;
4) Carry out functional test to check whether the requirements can be met;
5) In case of failure, be sure to return the whole set of equipment.。

2. Guarantee

Warranty libility

Warranty period: two years. (three free repairs, excluding handpiece and vulnerable parts.) During the warranty period, the manufacturer is only responsible for the problems caused by product quality, such as raw materials or processing defects.

Warranty Terms

The warranty is valid only if all instructions for use are followed.

When electrical installation is carried out in the place of use, it must comply with GB16895 .24 (indoor safety of medical electrical equipment) relevant regulations on installation).

All assembly, modification or maintenance must be carried out by the manufacturer or a third party authorized by the manufacturer.

The manufacturer shall not be responsible for any damage caused by improper disposal or repair by a third party not authorized by the manufacturer .

If the equipment is opened without permission, all warranty requirements and any other requirements during the warranty period will be invalid.

The final right of interpretation belongs to the manufacturer.

3. Re-transportation

After the user transports the equipment for the second time (it is clear that the product has been used and can work normally) the original packaging of the manufacturer must be used during transportation. If the original packaging is not used, it will cause damage during transportation the manufacturer assumes no responsibility.

Transportation Environment

Transportation temperature: - 40 ℃ ～ 70 ℃
Transportation humidity: 10 ～ 85% RH
Transport atmospheric pressure: 50kPa ～ 106kpa

4. Reserved Rights

The company reserves the following rights:

1) Have the right to adjust the product design without prior notice.

2) Do not make any inaccuracies in product related manuals, packaging inserts or printing errors caused by configuration changes assumed liabilities.

3) If the product configuration due to product upgrade or other reasons is inconsistent with the product picture, product data, etc without prior notice to customers.

SYMBOL DESCRIPTION

1.Symbol description on controller

Class II equipment

Foot switch

On / off

Fuse

Type B instrument (not applicable to intracardiac instruments

2.Description of symbols on the package

This side is up

Avoid moisture

Fragile, handle with care

Electromagnetic compatibility information

●(dental implant machine) meets the electromagnetic compatibility standards of YY0505-2012 and YY0836-2011 relevant requirements.

●The user shall install and use according to the electromagnetic compatibility information provided in the accompanying documents.

●Portable and mobile RF communication equipment may affect the performance of (dental implant machine) when using avoid strong electromagnetic interference, such as close to mobile phones, microwave ovens, etc.

●The guidelines and manufacturer's statement are detailed in the annex.

●Dental implant machines should not be used close to or stacked with other equipment, if they must be close to or stacked, observe and verify that it can operate normally under the configuration it is used.

●Except for dental implants sold as spare parts of internal components by the manufacturer of dental implants, the use of accessories and cables outside the regulations may increase the emission of equipment or system or reduce the immunity.

●The use of accessories and cables outside the regulations together with equipment and systems may increase the emission of equipment or systems or reduce the immunity

Serial number	Name	Cable length(m)	Is it shielded
1	power cord	2m	No
2	Motor cable	1.85mm	No

Annexes

Guidelines and manufacturer's statements - electromagnetic emissions		
(Implant) is expected to be used in the electromagnetic environment specified below, The purchaser or user of (Implant) should ensure that it is used in this electromagnetic environment		
Launch test	Compliance	Electromagnetic environment - Guidelines
GB4824 RF launch	Group 1	(Implant) uses RF energy only for its internal function. so its RF emission is very low and may not be harmful to nearby electronic equipment any interference.
GB4824 RF launch		(Dental implant machine) suitable for use in all facilities, including household use and directly connected to the residential public low-voltage power supply network for household use.
GB17625.1 Harmonic emission		
GB17625.2 Voltage fluctuation / flicker emission		

Guidelines and manufacturer's statements - Electromagnetic Immunity			
Implant) is expected to be used in the electromagnetic environment specified below, The purchaser or user of (Implant) should ensure that it is used in this electromagnetic environment.			
Anti-interference measurement	IEC 60601 test level	Coincidence level	Electromagnetic environment - Guidelines
electrostatic discharge（ESD） GB/T 17626.2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	The floor should be made of wood, concrete or ceramic tiles. if the floor is covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transient burst GB/T 17626.4	±2kV Pair the power cord	±2kV Pair the power cord	The network power supply shall have the quality used in typical commercial or hospital environment
surge GB/T 17626.5	±1 kVLine to line ±2 kVLine to ground	±1 kVline to line ±2 kVline to ground	The network power supply shall have the quality used in typical commercial or hospital environment

Power input line Users with voltage sag and short time (60% sag on UT) are interrupted in power supply Interruption and voltage variation drop) 70% u, continuous GB / T 17626.11 25 weeks (on u, 30%)	< 5% u for 0.5 weeks ((on u, > 95% sag) 40% u for 5 weeks < 5% for 5S Continue for 5S (on u, > 95% sag)	70% u for 25 weeks (on u, 30% sag) (on u, > 95% sag)	The network power supply shall have the quality used in typical commercial or hospital environment. If continuous operation is required during dental implant, uninterruptible power supply or battery power supply is recommended.
Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m,50Hz/60Hz	The power frequency magnetic field shall have the horizontal characteristics of power frequency magnetic field in typical places in typical commercial or hospital
Note: UT refers to the AC network voltage before the test voltage is applied			
Rf conduction GB/T 17625.6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communication equipment should not be used closer to any part (dental implant) than the recommended isolation distance, including cables. The distance shall be calculated by the formula corresponding to the transmitter frequency Recommended isolation distance d = 1.2√P d = 1.2√P 80 MHz to 800 MHz d = 2.3√P 800 MHz to 2,5 GHz Where p is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (W), and D is the recommended isolation distance, in meters (m). The field strength of the fixed RF transmitter is determined by surveying the electromagnetic site a, and each frequency range B shall be lower than the coincidence level. Interference may occur near equipment marked with the following symbols
Rf radiation GB/T 17626.3	3 V/m 80 MHz to 2,5 GHz	3 Vm	
Note 1: for 80MHz and 800MHz frequencies, the formula of higher frequency band is adopted. Note 2: these guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human body			

a. The field strength of fixed transmitting airports, such as base stations of wireless (cellular / cordless) telephone and ground mobile radio, amateur radio, am (amplitude modulation) and FM (frequency modulation) radio broadcasting and television broadcasting, cannot be predicted accurately in theory Yes. In order to evaluate the electromagnetic environment of fixed RF transmitter, the survey of electromagnetic site should be considered. If the measured field strength of the place where (dental implant) is located is higher than the RF compliance level of the above application, observe (dental implant) to verify its normal operation that 's ok. If abnormal performance is observed, supplementary measures may be necessary, such as reorientation or positioning

b. In the whole frequency range of 150kHz ~ 80MHz, the field strength should be less than 3 V / m.

Recommended isolation distance between portable and mobile RF communication equipment and (dental implant)

(implant) is expected to be used in an electromagnetic environment with controlled radiated RF disturbance. According to the maximum output power of communication equipment, The purchaser or user of (implant) can maintain portable and mobile RF communication equipment through the following recommended methods
Minimum distance between (transmitter) and (implant) to prevent electromagnetic interference

Rated maximum output power of transmitter/W	Isolation distance corresponding to different frequencies of transmitter/m		
	150 kHz ～ 80 MHz $d = 1.2\sqrt{}$ P	80 MHz ～ 800 MHz $d = 1.2\sqrt{}$ P	800 MHz ～ 2.5GHz $d = 2.3\sqrt{}$ P
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 the rated maximum output power of the transmitter not listed in the above table, the recommended isolation distance D, in meters (m), can be determined by the formula in the corresponding transmitter frequency column. Here P is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (W).
Note 1: at 80 MHz and 800 MHz frequencies, the formula of higher frequency range is adopted
Note 2: these guidelines may not be suitable for all situations. Electromagnetic propagation is affected by the absorption and reflection of buildings, objects and human body.