



Instruction Manual for Dental Implant Unit

(Please read carefully before use)

ZMN-SM-704 V1.3-20231020

Guilin Woodpecker Medical Instrument Co., Ltd.




Thank you for purchasing the dental implant unit with the model of Implant NX/Implant Smart/Implant Air/Implant Pilot produced by Guilin Woodpecker. In order to ensure the correct use of the machine, it is recommended that you carefully read the instructions about installation, operation, maintenance and inspection before use. For your convenience, it is recommended that you keep the instruction manual where it is readily available.

• **Equipment type**

1. Type of protection against electric shock: Class I equipment.
2. Degree of protection against electric shock: Applied part of type B.
3. Manufacturer's recommended sterilization method: see Section 6, Cleaning, Disinfection, Sterilization.
4. The waterproof protection meets the requirements in the current version of IEC60529 IPX0 for the host; IPX6 for the pedal.
5. Safety for use in the presence of flammable narcotic drugs with air, oxygen or nitrous oxide mixtures: this planter is not suitable for use in environments with flammable mixtures of narcotic drugs with air, oxygen and nitrous oxide.
6. Operation mode: intermittent operation.

• **Handling Precautions**

1. Please read the following safety precautions carefully before use and operate this product correctly.
2. The following icons indicate that you can use the product safely and prevent danger from causing harm to you and others. These indicators are classified according to the degree of risk, damage and severity. All indicators should be paid close attention to and must be observed.

Classification	Degree of risk, degree of damage and severity
 DANGER	Indication of possible personal injury or bodily harm
 WARNING	Indication that minor to injury or bodily harm may occur
 ATTENTION	Instructions to follow for safety

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1. Product Introduction

1.1 Precautions before use

DANGER

- (1) Do not unplug the power cord with wet hands to avoid electric shock; be sure to protect the control circuits from water; use a grounded electrical outlet.
- (2) Keep it away from explosives and flammables, and pay special attention not to use this implanter for patients under nitrous oxide anesthesia.
- (3) The device can not be used in MRI environment.


WARNING


- (1) This equipment may fail when used in an environment where electromagnetic wave interference occurs. This equipment cannot be installed near the device that releases the magnetic wave. Turn off the switch on the equipment control panel when there is a super vibrating device or electrode knife in use nearby.
- (2) The Implant NX/Implant Smart/Implant Air/Implant Pilot requires special precautions for EMC and needs to be installed and put into use according to the EMC environment.
- (3) Equipment with electromagnetic emission will affect the normal operation of Implant NX/Implant Smart/Implant Air/Implant Pilot. Do not run these two types of equipment at the same time.
- (4) Cannot be used in operating rooms containing potentially flammable gas mixtures.
- (5) Please make sure the motor handle (hereafter referred to as the motor) is completely stopped when changing the planting tool (and should be replaced by the foot controller) to avoid any possible injury or damage to the equipment.
- (6) Severe impact, such as falling from a high position, will cause damage to the equipment.
- (7) The water delivery pipe should not be excessively bent or knotted during the operation of the peristaltic pump, which may cause the water delivery pipe to break.
- (8) Do not attempt to disassemble the control panel, foot control and motor.
- (9) The dental handpiece (hereinafter referred to as handpiece) should be cleaned, lubricated and disinfected immediately after use.
- (10) Do not lubricate the motor, the lubricating oil will cause overheating and cause damage to the motor. The control panel and multi-function foot pedal cannot be sterilized.
- (11) The control panel cannot be cleaned with a solution with dissolving power.
- (12) The motor wire cannot be removed from the motor.

- (13) Turn off the power switch after each use.
- (14) Any serious incident that has occurred in relation to the device should be reported to manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- (15) Parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient.
- (16) To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.


ATTENTION

- (1) Please contact an authorized supplier for maintenance and purchase of spare parts.
- (2) It is recommended to use the original pre-sterilized disposable water pipe combination.
- (3) The accuracy of torque monitoring depends on the high-precision performance of the handpiece mounted on the micromotor. If a mobile phone of another manufacturer is used, the actual torque value may not be displayed correctly. To ensure that the actual torque matches the displayed torque, please use a matching mobile phone.
- (4) Read this operation manual before use and fully master the functions of each part.
- (5) Check the operation status of planter before use and confirm that there are no anomalies.
- (6) Test planter before use to ensure accurate operation.
- (7) Turn off the planter (excessive vibration, noise, heat production, etc.) immediately and return it to the authorized dealer if there is any permanent failure.
- (8) Consider stocking a small number of spare parts if planter is used frequently.
- (9) Clean the control panel with a wet cloth and cut off the power supply before cleaning.
- (10) Dispose of the water pipes by disposing of medical waste after use.

 The manual aims to make the operator understand the safety requirements, the installation process, the method of correct use and the correct maintenance of the equipment. If you encounter any unexpected problems, please contact the after-sales service center of Guilin Woodpecker Medical Instrument Co., Ltd.

 The manufacturer shall not be liable for personal injury or property loss caused by any user or unauthorized person tampering or altering the equipment.

 The company reserves the right to modify the machine design, product technology or accessories, operating instructions and machine packaging at any time without prior notice, the product pictures shall prevail in kind, and the final interpretation shall be vested in Guilin Woodpecker Medical Instrument Co., Ltd.

 Guilin Woodpecker Medical Instrument Co., Ltd. is committed to continuously updating our products, which brings about changes in equipment components. If there is any difference between your instructions and the instructions on your product, please

contact your dealer or the after-sales service center of Guilin Woodpecker Medical Instrument Co., Ltd. for an explanation.

 This manual is strictly prohibited to be used for purposes other than the installation, use and maintenance of the equipment.

1.2 Product Contraindications and Precautions

- (1) Disabled for patients with hemophilia;
- (2) Disabled for patients or doctors with pacemakers;
- (3) Patients with heart disease and young children should use it with caution.
- (4) Patients with oral and maxillofacial infections, uncured oral mucosal diseases, periapical diseases, gingival diseases, periodontal diseases and oral tumors should use it with caution.
- (5) Disabled for patients with allergic constitution and a history of drug allergy.
- (6) People with mental disorders should use it with caution.
- (7) Patients with severe systemic infectious or systemic diseases, such as heart, liver, kidney, hematopoietic system, digestive system and endocrine system, should use it with caution.
- (8) Pregnant or lactating women, women of childbearing age who have a child-bearing plan in the near future should use it with caution.

1.3 Intended use

This product is intended for use in dental surgery, such as alveolar drilling, reaming and dental implantation.

1.4 Intended user

Professional dentists

1.5 Intended patient

Adult patients in the permanent teeth stage with tooth loss.

1.6 Structure and Composition

It consists of a host, a motor (including the motor tail), a multi-function pedal, etc.

1.7 Security Requirements




Guilin Woodpecker Medical Instrument Co., Ltd. will not be liable for any direct or indirect damage or loss under the following conditions:

- The equipment is used for any purpose outside the scope of use that is not mentioned;
- The operator does not use the equipment in accordance with the steps and requirements described in the instructions;



- The wiring system of the room using the equipment does not meet the appropriate standards and requirements;
- Any assembly, operation or repair of the equipment without the authorization of Woodpecker;
- The environmental conditions in which the equipment is located or stored do not meet the requirements mentioned in the section on technical requirements in the specification.

2. Accessories Description

Please refer to the packing list for the machine configuration.

Number	Accessories	Fig	Remark
1	Motor handpiece		Key functional component
2	Main Unit (Implant NX, Implant Smart, Implant Air, Implant Pilot)		Key functional component
3	Dental contra-angle handpiece (WP-1, WP-1L)		Key functional component

Number	Accessories	Fig	Remark
4	Disposable water pipe		Key functional component
5	Multi-functional foot switch		Key functional component
6	power supply cable		Key functional component
7	spare fuses		Key functional component
8	Holder of transfusion bottle		Key functional component
9	Motor disinfection plug		Real accessory

Number	Accessories	Fig	Remark
10	Handpiece holder		Real accessory
11	Motor cooling pipe clamp		Real accessory

3. Host Interface and Foot Control

3.1 Host Interface

3.1.1 host button control

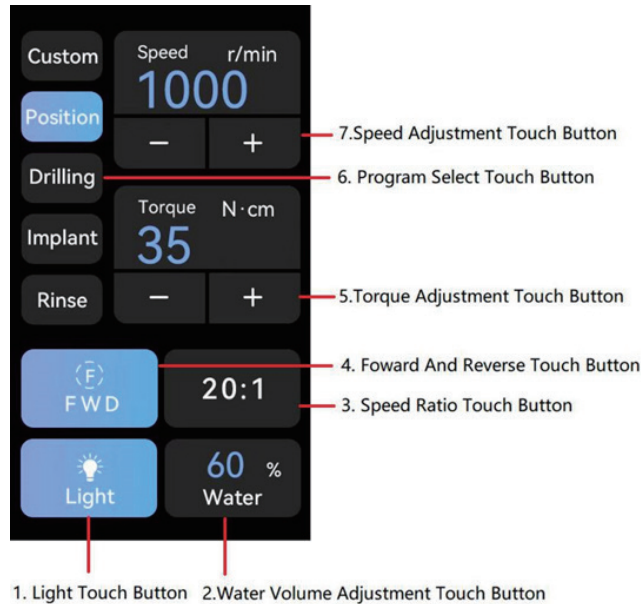


Fig. 1 Main Interface Of Planting Mode

Function Description:

(1) Light touch button

Motor light switch, cycle touch control light on and off.

(2) Water volume adjustment touch button

Click to select the water flow size, there are 6 gears in total, namely anhydrous (00%), 20%, 40%, 60%, 80%, 100% water volume, repeat the button to cycle selection.

(3) Speed ratio touch button

Touch the speed ratio button to automatically enter the gear ratio selection page of the handpiece, and select the correct handpiece gear ratio according to the dental handpiece.

(4) Forward and reverse touch button

Used to select the direction of rotation, each time the direction is changed.

(5) Torque adjustment touch button

Used to set the motor torque range, the button + to increase, the button - to decrease; keep pressing it will accelerate the change.

(6) Program selection touch button

Touch the corresponding icon to select the corresponding program. The function of each program is shown in Section 5.1.

(7) Speed adjustment touch button

Used to set the motor speed, button + to speed up, button - to slow down; keep pressing it will speed up the change.

3.1.2 Restore factory settings interface

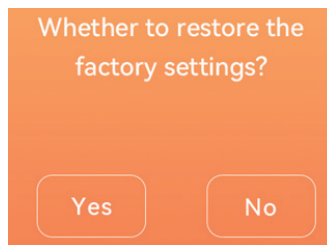


Fig. 2 Restore factory settings interface

Boot while stepping on the foot, the factory reset menu will pop up for confirmation, as shown in Fig. 2. When "Yes" is selected, the saved parameters will be cleared and the original factory setting parameters will be restored. If "No" is selected, the factory settings will not be restored, and it will boot normally.

3.1.3 Error alarm interface

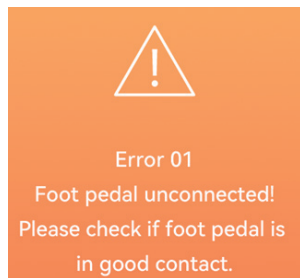


Fig. 3 Error alarm interface

As shown in Fig. 3, Warning 0x indicates the alarm number. For specific numbers and corresponding contents, see Section 7 Error Codes and Solutions.

3.2 Pedal control

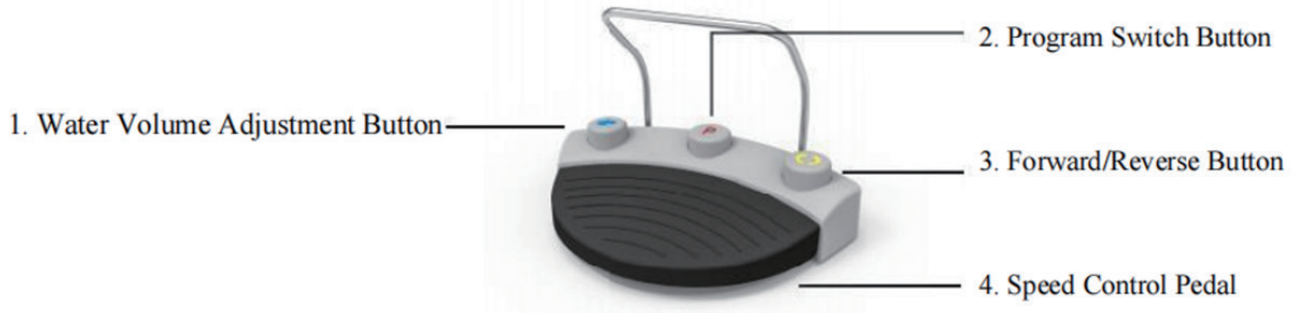


Fig. 4 Multi-Function Pedal

(1) Water Volume Adjustment Button

Used to select six levels of cooling flow; each level is increased each time the button is pressed. If the level is level 6 and the maximum level, then after pressing once, the level cycles back to level 1.

(2) Program Switch Button

Used to select the desired program, the increment of the program is that each time the button is pressed and lifted, stepping on program 5 will cycle back to program 1. When you press the Program Switch Button for a short time, the program goes forward, and when you press it for a long time (> 2s), the program goes back.

(3) Forward / Reverse Button

It is used to change the rotation direction of the mobile phone, which can be changed once by pressing it.

(4) Speed Control Pedal

Used to start and stop the motor.

4. Installation

4.1 Safety requirements during installation

⚠️ DANGER: the premise of equipment installation is that the installation must comply with appropriate standards and related

electrical safety requirements.

⚠️ DANGER: the equipment should never be installed in places where there is a risk of explosion and should not be operated in areas where there are flammable gases (anesthetic mixtures, oxygen, etc.).

⚠️ DANGER: the installation site should avoid impact of equipment and splashing of water or other liquids.

⚠️ DANGER: the equipment should not be installed near or above the heat source. It must be installed in a place with adequate air circulation around it, leaving enough space around, especially the exhaust fan and back position.

⚠️ WARNING: parts should not be placed directly under sunlight or ultraviolet light.

⚠️ WARNING: The device is portable, but great care should be taken.

⚠️ WARNING: make sure the connection is dry before connecting the wire to the device. Dry with an air gun if necessary.

4.2 Connection Accessories

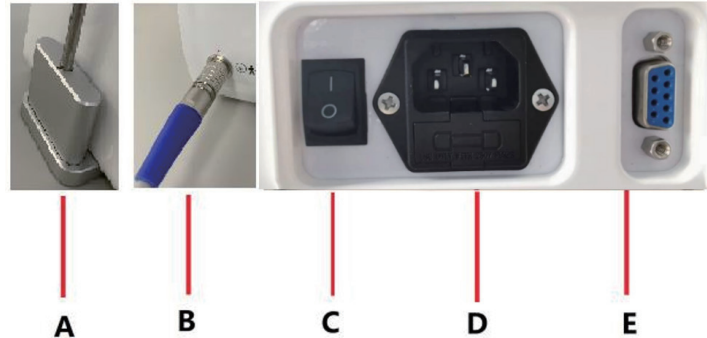


Fig. 5 Accessory Installation

4.2.1 Pedal Installation

Connect the pedal switch plug to the pedal socket and tighten the two retaining screws (Fig. 5 - Reference E).

4.2.2 Power Cord Installation

Plug the power cord output into the power outlet of the device (Fig. 5-reference D).

4.2.3 Infusion Bottle Bracket Installation

Insert the infusion bottle bracket into the retaining hole at the right rear of the housing (Fig. 5 - Reference A).

4.2.4 Infusion Bottle Installation

Hang the infusion bottle (the infusion bottle is purchased saline injection) on the infusion bottle bracket.

4.2.5 Motor Installation.

Insert the motor tail plug into the output socket at the front of the device (note: please aim at the red identification point) (Fig. 5 - Reference B)

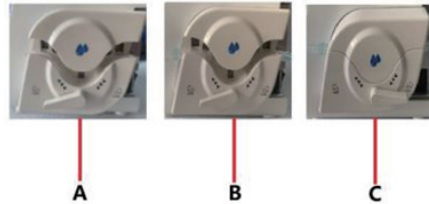


Fig. 6 Disposable Water Pipe Installation

4.2.6 Installation of The Pump Tube On The Peristaltic Pump

(1) Turn the handle of the peristaltic pump counterclockwise (as indicated by the arrow above "CLOSE") to the "OPEN" indication position, and open the pump head (Fig. 6 - Reference A).

(2) Place the pump tubing inside the impeller of the peristaltic pump (Fig. 6 - Reference B).

(3) Turn the handle of the peristaltic pump clockwise (as indicated by the arrow above "OPEN") to the "CLOSE" indication position, and close the pump head (Fig. 6 - Reference C).

4.2.7 The front view of Implant NX/Implant Smart/Implant Air/Implant Pilot after installation is shown in Fig. 7.



Fig. 7 Front view of Implant NX/Implant Smart/Implant Air/Implant Pilot

After all the accessories are installed, turn on the power switch (Fig. 5 - Reference C) and start using the machine after it shows normal.

Make sure to step on the pedal after the rotational speed, torque, water and other parameters are set properly, and the machine starts to work; release the pedal and the machine stops working.

5. Operation

5.1 Procedure

5.1.1 Program selection

Implant NX/Implant Smart/Implant Air/Implant Pilot has 5 program functions. There are two ways to select a program:

- (1) Select by touching the corresponding icon on the screen.
- (2) Switch by pressing the "Program Switch" button on the foot pedal.

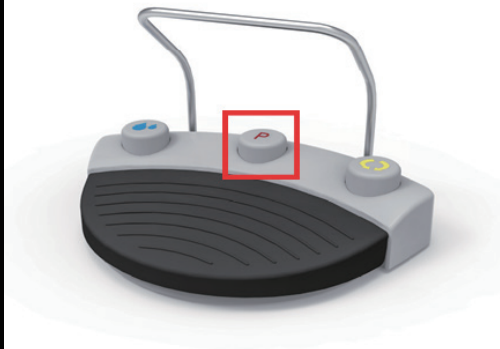


Fig.8 Program Selection

5.1.2 Program Function Description

Icon	Function	Description
Custom	Customization	Match 1:1 straight nose, curved head
Position	Positioning	Use a positioning drill to accurately locate the alveolar bone
Drilling	Planting Pattern Drilling	Determine the direction and depth of the drill hole
Implant	Implant Pattern Placement Of Implants	Implant dental implant into alveolar bone
Rinse	Plant Mode Flush	The motor does not rotate, only water comes out, which is convenient for washing

5.1.3 Factory Settings

When the machine leaves the factory, various parameters have been set according to the actual use, including speed, torque, speed ratio and water output. These parameters can be changed within the range of parameters specified in the current program.

The range and factory settings of each parameter are shown in the following table:

Icon	Function	Speed (r/min)	Torque (N.cm)	Speed Ratio	Water Volume /%
Custom	Customization (Implant NX)	10-205000 1200(D)	5-80 45(D)/Max	1:1, 1:2, 1:2.7, 1:3, 1:4.2, 1:5, 16:1, 20:1, 27:1 20:1(D)	80
Custom	Customization (Implant Smart)	10-207500 1200(D)	5-80 45(D)/Max	1:1, 1:2, 1:2.7, 1:3, 1:4.2, 1:5, 16:1, 20:1, 27:1 20:1(D)	80
Custom	Customization (Implant Air)	10-210000 1200(D)	5-80 45(D)/Max	1:1, 1:2, 1:2.7, 1:3, 1:4.2, 1:5, 16:1, 20:1, 27:1 20:1(D)	80

Icon	Function	Speed (r/min)	Torque (N.cm)	Speed Ratio	Water Volume /%
Custom	Customization (Implant Pilot)	10-212500 1200(D)	5-80 45(D)/Max	1:1, 1:2, 1:2.7, 1:3, 1:4.2, 1:5, 16:1, 20:1, 27:1 20:1(D)	80
Position	Positioning	45-2500 1000(D)	5-80 35(D)	16:1, 20:1, 27:1, 20:1(D)	60
Drilling	Planting Pattern Drilling	45-2500 800(D)	5-80 35(D)	16:1, 20:1, 27:1, 20:1(D)	60
Implant	Implant Pattern Placement Of Implants	10-100 20(D)	5-80 35(D)	16:1, 20:1, 27:1, 20:1(D)	0
Rinse	Plant Mode Flush	-	-	-	80

Note: "D" in the table refers to the default value.

5.2 Adjust the default parameters

Within the specified range, the following parameters can be adjusted:

1. Maximum Speed
2. Torque Upper Limit
3. Water Volume
4. Speed Ratio
- 5.2.1 Adjust the maximum speed

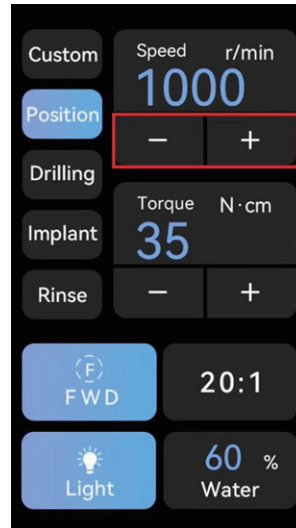


Fig. 9 Adjusting the maximum speed

Adjust the motor speed by pressing the "speed" (+, -) button, each time the speed button is pressed, the speed changes once, keep pressing, the speed setting value will change faster.

5.2.2 Adjusting the upper limit of torque



Fig. 10 Adjusting the upper limit of torque

Adjust the maximum output torque of the motor by pressing the "torque" (+, -) button, and the torque changes every time you touch the torque button. Press and hold all the time, and the torque setting will accelerate the change.

5.2.3 Adjusting the amount of water



Fig. 11 Adjusting the amount of water

Adjust a total of 6 gears by touching the "water" button on the panel, and adjust one gear each time you touch it. Adjust through the blue "water" button on the foot.

5.2.4 Adjust the speed ratio

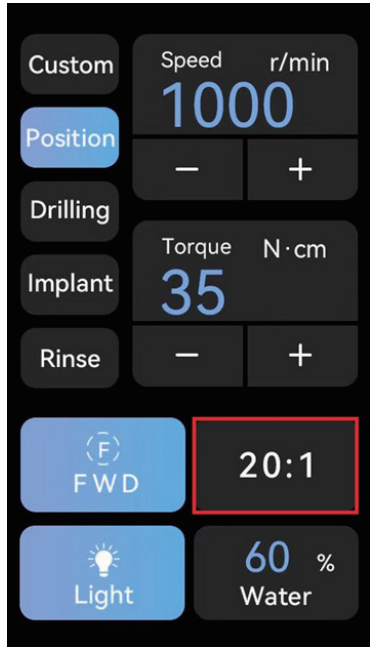


Fig. 12 Adjust the speed ratio

Adjust by pressing the "speed ratio" button to correspond to the gear ratio of the phone you want to use.

Gear ratio	Maximum speed			
	Implant NX	Implant Smart	Implant Air	Implant Pilot
27:1	1500	1500	1500	1500
20:1	2000	2000	2000	2000
16:1	2500	2500	2500	2500
1:5	205000	207500	210000	212500
1:4.2	172200	174300	176400	178500

1:3	123000	124500	126000	127500
1:2.7	110700	112050	113400	114750
1:2	82000	83000	84000	85000
1:1	41000	41500	42000	42500

5.3 Adjust the rotation direction of the motor



Fig. 13 Adjust the direction of rotation

Touch the forward and reverse button to change the rotation direction of the motor.

Pressing the "forward/reverse" button on the foot during treatment can also change the rotation direction of the motor.

5.4 Adjust the motor light



Fig. 14 Adjust the motor light

Through the "lamp" button, set the light on and off when stepping on the foot, and toggle the light off state each time you press.

5.5 Save parameters



Fig. 15 Save parameters

After completing the above steps, the above parameters such as rotational speed, torque, water volume, After completing the above steps, the above parameters such as rotational speed, torque, water volume, and speed ratio will be automatically saved.

5.6 Peak torque display

In the Implanting mode, the foot was stepped down and the implant began to rotate. The resistance encountered by the implant during rotation was shown by the peak torque, and the displayed value represented the most resistance encountered by the implant during rotation. When lifting the foot, keep the peak torque display, until the next step on the foot peak torque will be zero.

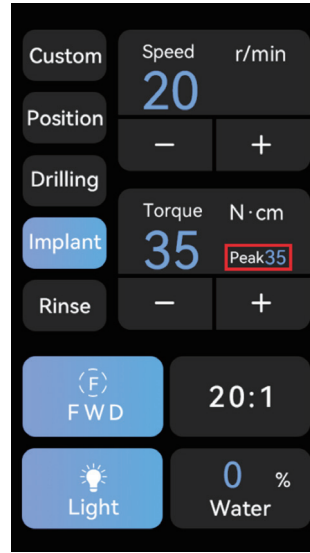


Fig. 16 Peak torque display

5.7 Max torque display

In custom mode, when the user selects the speed ratio 1:1, 1:2, 1:2.7, 1:3:3, 1:4.2, 1:5, the torque always displays Max, and the torque cannot be adjusted. When the user selects the speed ratio 16:1, 20:1, 27:1, the torque can be adjusted.



Fig. 17 Max torque display

5.8 Standard operation

(1) After installing the corresponding accessories, power supply, turn on the power switch, after boot, the system defaults to the first program (positioning mode).



Fig. 18 Boot Operation

(2) Touch the screen to select the desired program, or select by pressing the "Program Switch" button on the foot.



Fig. 19 Program Switch

- (3) Confirm that the corresponding parameters of the program, such as rotational speed, torque, water flow, forward and reverse, rotational speed ratio, etc., meet the requirements.
- (4) Step on the pedal motor and start to turn.
- (5) The torque protection function is turned on when the torque reaches the preset value, when the motor stops and maintains the set torque output to prevent excessive torque. Release the pedal, remove the torque protection function, and when you step on it again, the motor will continue to rotate below the preset limit.
- (6) Release the pedal and the motor stops.

6. Cleaning, Disinfection and Sterilization

If there is blood or salt residue on the main unit and foot controller, unplug the power cord, wipe it off with a damp cloth, and wipe with a soft cloth dampened with alcohol. The contra-angle handpiece and the motor hanpiece can be disinfected with heat sterilizers. Plug in motor disinfection stopper before disinfection the motor hanpiece!

Warning:

Never place the main unit and foot controller in a washer-disinfector, autoclave or ultrasonic bath.

Warning:

If you use a disinfectant in the form of a spray, never spray the devices and accessories directly.

Warning:

Only use surface disinfectants that are certified by officially recognized institutes, do not contain chlorine and have been declared aldehyde-free.

Warning:

Clean and disinfect the main unit and foot controller regularly. When subjecting the main unit and foot controller to cleaning and disinfection ensure that the charging cable is not connected and that the charging socket is closed.

Warning:

Only the following parts can be sterilized:

Contra-angle handpiece and its kit, motor hanpiece, handpiece holder, motor disinfection stopper, pipe clamp, O-ring.

The cleaning, disinfection and sterilization of the contra-angle handpiece and the motor hanpiece are as follow.

Unless otherwise stated, they will be hereinafter referred to as “products”.

Warnings:

The use of strong detergent and disinfectant (alkaline pH>9 or acid pH <5) will reduce the life span of products. And in such cases, the manufacturer takes no responsibility.

The products may not be exposed to temperature above 138°C.

6.1 Processing limit:

The products have been designed for a large number of sterilization cycles. The materials used in manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. The maximum number of sterilizations for motor handpiece is 250 times. The allowed maximum times of sterilization for contra-angle handpiece is 600 times.

6.2 Initial processing:

Processing principles:

It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for cleaning/disinfection and sterilization, and that the validated parameters are adhered to during every cycle.

Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or

clinic, especially with regard to the additional requirements for the inactivation of prions.

6.3 Post-operative treatment:

The post-operative treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows:

1. Wipe all visible surfaces of the device with a disposable soft cloth, including motor handpiece, water bottle hooks, pedals, and cables. And then dry them after washing;
2. Wipe all visible surfaces of the device including motor handpiece, water bottle hooks, pedals and cables with a disposable soft cloth dampened with disinfectant to ensure that all surfaces are wet. Let the disinfectant work during a specified period of time and then dry the surface;
3. Dry all the cleaned and disinfected parts thoroughly in the air indoors.

Cautions:

- (1) Do not automatically clean the main unit.
- (2) Do not use metal brushes.

6.4 Preparation before cleaning:

Steps:

Tools: tray, a disposable soft cloth, a disposable soft cloth dampened with disinfectant, motor disinfection stopper

1. Remove the motor handpiece from the main engine and put the motor handpiece into a clean tray.
2. Please plug the motor disinfection stopper in the motor handpiece.

6.5 Cleaning:

The cleaning should be performed no later than 24 hours after the operation.

The cleaning can be divided into automated cleaning and manual cleaning. Automated cleaning is preferred if conditions permit.

Automated cleaning:

The parts that can be cleaned automatically are as follow: contra-angle handpiece.

- The cleaner is proved to be valid by CE certification in accordance with EN ISO 15883.
- There should be a flushing connector connected to the inner cavity of the product.
- The cleaning procedure is suitable for the product, and the irrigating period is sufficient.
- Do not clean the product with ultrasound.

It is recommended to use a washer-disinfector in accordance with EN ISO 15883. For the specific procedure, please refer to the automated disinfection section in the next section "Disinfection".

Manual cleaning:

The parts that need to be cleaned Manually are as follow: motor handpiece.

Manual cleaning steps:

1. Wet the soft cloth completely with distilled water or deionized water, and then wipe all the surfaces of the handpiece and main unit until the surface of them is not stained.
2. Wipe the surface of the handpiece and main unit with a dry soft nap-free cloth.
3. Repeat the above steps at least 3 times.

Notes: Use distilled water or deionized water for cleaning at room temperature.

Precautions:

- (1) The cleaning agent does not have to be pure water. It can be distilled water, deionized water or multi-enzyme. But please ensure that the selected cleaning agent is compatible with the product.
- (2) In washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it would be difficult to remove.
- (3) After cleaning, the chemical residue should be less than 10mg / L.

6.6 Disinfection:

Disinfection must be performed no later than 2 hours after the cleaning phase. Automated disinfection is preferred if conditions permit.

Automated disinfection-Washer-disinfector:

The parts that can be disinfected automatically are as follow: contra-angle handpice.

- The washer-disinfector is proved to be valid by CE certification in accordance with EN ISO 15883.
- Use high temperature disinfection function. The temperature does not exceed 134 ° C, and the disinfection under the temperature cannot exceed 20 minutes.
- The disinfection cycle is in accordance with the disinfection cycle in EN ISO 15883.

Cleaning and disinfecting steps by using Washer-disinfector:

1. Carefully place the product into the disinfection basket. Fixation of product is needed only when the product is removable in the device. The products are not allowed to contact each other.
2. Use a suitable rinsing adaptor, and connect the internal water lines to the rinsing connection of the washer-disinfector.
3. Start the program.
4. After the program is finished, remove the product from the washer-disinfector, inspect (refer to section "Inspection and Maintenance") and packaging (refer to chapter "Packaging"). Dry the product repeatedly if necessary (refer to section "Drying").

Precautions:

(1) Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.

(2) With this equipment, cleaning, disinfection and drying will be carried out together.

(3) Cleaning:

(a) The cleaning procedure should be suitable for the product to be treated. The flushing period should be sufficient (5-10 minutes). Pre-wash for 3 minutes, wash for another 5 minutes, and rinse it for twice with each rinse lasting for 1 minute.

(b) In the washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it is difficult to remove.

(c) The solution used can be pure water, distilled water, deionized water or multi-enzyme solution, etc., and only freshly prepared solutions can be used.

(d) During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed. The used cleaner is neodisher MediZym(Dr.Weigert).

(4) Disinfection:

(a) Direct use after disinfection: temperature ≥ 90 ° C, time ≥ 5 min or $A0 \geq 3000$;

Sterilize it after disinfection and use: temperature ≥ 90 ° C, time ≥ 1 min or $A0 \geq 600$

(b) For the disinfection here, the temperature is 93 ° C, the time is 2.5 min, and $A0 > 3000$

(5) Only distilled or deionized water with a small amount of microorganisms (<10 cfu/ml) can be used for all rinsing steps. (For example, pure water that is in accordance with the European Pharmacopoeia or the United States Pharmacopoeia).

(6) After cleaning, the chemical residue should be less than 10mg / L.

(7) The air used for drying must be filtered by HEPA.

(8) Regularly repair and inspect the disinfectant.

Manual disinfection:

The parts that need to be disinfected Manually are as follow: motor handpiece.

Manual disinfection steps:

1. Soak the dry soft cloth with 75% alcohol.

2. Wipe all the surfaces of the motor handpiece with a wet soft cloth for at least 3 minutes.

3. Wipe the surface of motor handpiece with a dry soft nap-free cloth.

Notes:

a) The cleaning and disinfection must be performed within 10min before use.

b) The disinfectant used must be used immediately, no foaming is allowed.

c) In addition to 75% alcohol, you can use non-residue disinfectants such as Oxytech from Germany, but you must respect the concentration, temperature and time specified by the disinfectant manufacturer.

6.7 Drying:

If your cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.

Methods:

1. Spread a clean white paper (white cloth) on the flat table, point the product against the white paper (white cloth), and then dry the product with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the product drying is completed.
2. It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80°C ~ 120°C and the time should be 15 ~ 40 minutes.

Precautions:

- (1) The drying of product must be performed in a clean place;
- (2) The drying temperature should not exceed 138 °C;
- (3) The equipment used should be inspected and maintained regularly.

6.8 Inspection and maintenance:

In this chapter, we only check the appearance of the product. Make sure the inspection is correct.

1. Check the product. If there is still visible stain on the product after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.
2. Check the product. If it is obviously damaged, smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used.
3. Check the product. If the accessories are found to be damaged, please replace it before use. And the new accessories for replacement must be cleaned, disinfected and dried.
4. If the service time (number of times) of the product reaches the specified service life (number of times), please replace it in time.

6.9 Packaging:

The disinfected and dried product quickly package in a medical sterilization bag (or special holder, sterile box).

Precautions:

- (1) The package used conforms to ISO 11607;
- (2) It can withstand high temperature of 138 °C and has sufficient steam permeability;
- (3) The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of

contaminants;

(4) Avoid contact with parts of different metals when packaging.

6.10 Sterilization:

Use only the following steam sterilization procedures (fractional pre-vacuum procedure*) for sterilization, and other sterilization procedures are prohibited:

1. The steam sterilizer complies with EN13060 or is certified according to EN 285 to comply with EN ISO 17665;
2. The highest sterilization temperature is 138 ° C;
3. The sterilization time is at least 4 minutes at a temperature of 132 ° C / 134 ° C and a pressure of 2.0 bar ~ 2.3 bars.
4. Allow a maximum sterilization time of 20 minutes at 134 °C.

Verification of the fundamental suitability of the products for effective steam sterilization was provided by a verified testing laboratory.

Precautions:

- (1) Only products that have been effectively cleaned and disinfected are allowed to be sterilized;
- (2) Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.
- (3) Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;
- (4) Please use the recommended sterilization procedures for sterilization. It is not recommended to sterilize with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended. If you use the sterilization procedures that have not been recommended, please adhere to related effective standards and verify the suitability and effectiveness.

* Fractional pre-vacuum procedure = steam sterilization with repetitive pre-vacuum. The procedure used here is to perform steam sterilization through three pre-vacuums.

6.11 Storage:

1. Store in a clean, dry, ventilated, non-corrosive atmosphere with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20 °C to +55 °C;
2. After sterilization, the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

Precautions:

- (1) The storage environment should be clean and must be disinfected regularly;

(2) Product storage must be batched and marked and recorded.

6.12 Transportation:

1. Prevent excessive shock and vibration during transportation, and handle with care;
2. It should not be mixed with dangerous goods during transportation;
3. Avoid exposure to sun or rain or snow during transportation.

The cleaning and disinfection of main unit are as follows.

- Before each use, wipe the surface of the machine and the tail cord of the motor handpiece with a soft cloth or paper towel soaked in 75% medical alcohol. Repeat the wipe for at least 3 times.
- After each use, wipe the surface of the device and the tail cord of the motor handpiece with a soft cloth soaked in clean water (distilled or deionized water) or a clean disposable wipe. Repeat the wipe for at least 3 times.

7. Error Prompt Code And Solution (Error Alarm Interface)

When there is a problem with the operation, the display will provide an error code for diagnosing the problem. Specifically, switch to the error prompt interface to provide an explanation of the problem and how to handle it:

Error Code	Error Description	Treatment Measures
Error 01	The pedal is not connected	Make sure the pedals are connected. If the alarm is not eliminated, please contact the local distributor or Woodpecker.
Error 02	Abnormal motor voltage	The power supply voltage is unstable to ensure that the network voltage is stable. If the alarm is not eliminated, please contact the local distributor or Woodpecker.
Error 03	Boot Failure	When starting up, the motor handle is not connected, make sure that the motor handle and the host are connected normally, and then power on again. If the alarm is not eliminated, please contact the local distributor or Woodpecker.
Error 04	Handle not connected	Please check that the handle is in good contact. If the alarm is not eliminated, please contact the local distributor or Woodpecker.
Error 05	Abnormal signal line	Please contact our local distributor or us.

8. Storage and Maintenance

8.1 This equipment should be handled with care, away from the source, installed or stored in a cool, dry and ventilated place.

8.2 Do not mix with any toxic, corrosive, flammable and explosive items during storage.

8.3 The equipment should be stored in an environment where the relative humidity does not exceed 10%~93%, the atmospheric pressure is 70kPa~106kPa, and the temperature is -20°C~+55°C.

8.4 When the equipment is not in use, the power switch should be turned off and the power plug should be unplugged; when not in use for a long time, electricity and water should be turned on once a month for five minutes each time.

8.5 Check the integrity of the cable frequently. If it is damaged, please replace it with the original parts.

8.6 Replacement of fuses
















Be sure to turn off the power supply (see Fig. 18 - Reference B) to turn off the device and disconnect the power cord from the main power supply when doing the following.



Fig. 20 Fuse replacement

9. Symbols

	Fragile items, handle with care		CE marked product
	Use indoor only		Follow instructions
	Foot switch interface		Alternating current
	Manufacturer		Date of manufacture
IPX0	Ordinary equipment		Authorised Representative in the EUROPEAN COMMUNITY

	Type B applied part		Autoclavable up to the specified temperature
	Serial number		Humidity limit for storage: 10%~93%
	Atmospheric pressure for storage: 70kPa~106kPa		Temperature limit for storage: -20°C~+55°C
	Appliance complies with WEEE directive	IPX6	Anti strong spray
	Protective earthing		Fuse
	On (Power)		Off (Power)
	There is a waterway in the component.		Water flow direction
	Position of the knob when the peristaltic pump is on and the direction in which the knob can be rotated in the current state		
	Position of the knob when the peristaltic pump is off and the direction in which the knob can be rotated in the current state		

10. Specifications

10.1 Host Specifications

Host Model	Implant NX	Implant Smart	Implant Air	Implant Pilot
Power Input	AC 100-240V 50Hz/60Hz			
Host Size	155mm×167mm×227mm			

Size of fuse	5.2 mm×20mm			
No-Load Speed (r/min)	300 ~ 41000	300 ~ 41500	300 ~ 42000	300 ~ 42500
Motor Model	SPM58L, SPM58NL, SPM58LS, SPM58, SPM45L, SPM45NL, SMP60L, SMP60NL			
Input Power	180VA			
Software Version	V1			
Ambient Temperature Range	+5 ~ 40°C			
Relative Humidity Range	30% ~ 75%			
Atmospheric Pressure Range	70kPa ~ 106kPa			
Handpiece Gear Ratios	Output speed (r/min)			
	Implant NX	Implant Smart	Implant Air	Implant Pilot
16: 1	20 ~ 2500	20 ~ 2500	20 ~ 2500	20 ~ 2500
20: 1	15 ~ 2000	15 ~ 2000	15 ~ 2000	15 ~ 2000
27: 1	10 ~ 1500	10 ~ 1500	10 ~ 1500	10 ~ 1500
1: 1	300 ~ 41000	300 ~ 41500	300 ~ 42000	300 ~ 42500
1: 2	600 ~ 82000	600 ~ 83000	600 ~ 84000	600 ~ 85000
1: 2.7	810 ~ 110700	810 ~ 112050	810 ~ 113400	810 ~ 114750
1: 3	900 ~ 123000	900 ~ 124500	900 ~ 126000	900 ~ 127500
1: 4.2	1260 ~ 172200	1260 ~ 174300	1260 ~ 176400	1260 ~ 178500
1: 5	1500 ~ 205000	1500 ~ 207500	1500 ~ 210000	1500 ~ 212500

10.2 Specifications of multi-function pedals

Model: MF4;

Tail line length: 2.8m;

11. After-sales Service

After sale, if the equipment cannot work properly due to quality problems, it can be repaired by our company with the warranty card. For details, please refer to the warranty instructions in the warranty card. Irreparable equipment damage caused by non-

designated professional maintenance personnel does not fall within the scope of free warranty.

12. Environmental Protection

This product is a medical device and is not allowed to be arbitrarily discarded. Comply with your national regulations, guidelines and requirements for the disposal of end-of-life device.

Please remove the power cord and internal circuit board and discard them as electronic product waste according to local regulations. Prior to disassembly and disposal the motor, motor tail and the surface of main unit must not be contaminated and must have been completely reprocessed (Cleaning/Disinfection/Sterilization) according to section 6. Then discard them as universal product waste according to local regulations.

Part Name	Toxic and Hazardous Substances or Elements					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent chrome (Cr6+)	Polybrominated biphenyls (PBB)	Polybrominated diphenyl ethers (PBDE)
Host	○	○	○	○	○	○
Motor Handle	○	○	○	○	○	○
Dental Contra-Angle	○	○	○	○	○	○
Multifunctional Pedal	○	○	○	○	○	○
Mechanical Components, Including Screws, Nuts, Washers, etc.	○	○	○	○	○	○

○: Indicates that the content of the toxic substance in all homogeneous materials of the component is below the limit specified in SJ/T-11363-2006 Limit Requirements for Toxic and Hazardous Substances in Electronic Information Products.

×: Indicates that the content of the toxic substance in at least one homogeneous material of the part exceeds the limit requirement specified in SJ/T-11363-2006.

(This product meets the EU RoHS environmental protection requirements; at present, there is no mature technology in the world to replace or reduce the content of lead in electronic ceramics, optical glass, steel and copper alloys.)

According to the Administrative Measures for the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products, Regulations on the Administration of the Recycling and Disposal of Waste Electrical and Electronic Products and relevant standards, please observe the safety and precautions of the product, and recycle or dispose of the product in an appropriate way according to local laws and regulations after the product is used.

13. Warranty

13.1 Before being put on the market, all Woodpecker equipment is fully inspected to ensure that it can be used properly.

13.2 Warranty

During the warranty period, the Woodpecker is responsible for repairing or replacing the damaged parts of the equipment free of charge, and the complete replacement of Woodpecker products is not included.

13.3 Woodpeckers will not be liable for any direct or indirect damage or loss under the following conditions:

- (1) The equipment is used for any purpose outside the scope of use mentioned.
- (2) The operator does not use the equipment in accordance with the steps and requirements written in the instruction manual.
- (3) The wiring system of the room where the equipment is used does not meet the appropriate standards and requirements.
- (4) The equipment is assembled, operated and repaired by a person not authorized by the Woodpecker.
- (5) The environmental conditions in which the equipment is located or stored do not meet the requirements mentioned in the section on technical requirements in the specification.

13.4 Transportation, incorrect use and negligent damage will be excluded from the policy. If the part has been tampered with by an unauthorized person, the policy will no longer take effect.

13.5 Warning

The policy is only if the policy is sealed with the product and returned to us in full; if allowed, send it to your Woodpecker seller within 20 days of the purchase date, along with a notice and invoice certificate from the seller or purchaser. In order to benefit from the policy, the purchaser must return the product to be repaired to the seller / importer at the place of purchase at his own expense.

13.6 Parts shall be properly packed and returned (or as originally packed).

13.7 All parts must have the following information.

- (1) Details of the buyer, including telephone number, etc.;
- (2) Details of the seller or importer;
- (3) Photocopy of the photo of the goods, date of purchase, parts problem, part name and serial number; and
- (4) Description of the problem.

13.8 Any damage caused in the course of transportation is not included in the insurance policy; in the event of a free accident or an accident caused by improper use, the repair of Woodpecker products will be charged according to the true cost.

14. Electromagnetic Compatibility Statement

Instructions for use

The ME EQUIPMENT or ME SYSTEM is suitable for Professional healthcare facility environment and so on. Dental Implant Device do not contains magnetically sensitive electronic components and circuitry.

⚠ Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

⚠ Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

⚠ Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Dental Implant Device (model name: Implant NX/ Implant Smart/Implant Air/Implant Pilot), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

If any: a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any: the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term “ESSENTIAL PERFORMANCE” need not be used).

14.1 Cable installation requirements

No.	Cable Name	Length	Shield
1	Power Cable	1.5m	No
2	Pedal Line	2.8m	No
3	Handle Tail	1.8 m	No

14.2 Guidance and manufacturer’s declaration - electromagnetic emissions

Guidance and manufacturer’s declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

14.3 Guidance and manufacturer’s declaration -electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ±2 kV input/output lines: ±1 kV 100 kHz repetition frequency	Power supply lines: ±2 kV input/output lines: ±1 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	line(s) to line(s): ±0.5, ±1 kV line(s) to earth: ±0.5, ±1, ±2 kV	line(s) to line(s): ±0.5, ±1 kV line(s) to earth: ±0.5, ±1, ±2 kV
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM bands) 80% Am at 1kHz	150KHz to 80MHz: 3Vrms 6Vrms (in ISM bands) 80% Am at 1kHz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity magnetic fields IEC 61000-4-39	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m	Not application

NOTE U_T is the a.c. mains voltage prior to application of the test level.

14.4 Guidance and manufacturer's declaration -electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic Immunity								
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power(W)	Distance (m)	IEC 60601-1-2 Test level (V/m)	Compliance level (V/m)
	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27	27
	450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9	9
	745							
	780							
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	0,2	0,3	28	28
	870							
	930							
	1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	0,2	0,3	28	28
	1845							
	1970							
	5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9	9
	5500							
5785								

14.5 Recommended separation distances between portable and mobile RF communications equipment and the model Implant NX/Implant Smart/Implant Air/Implant Pilot Dental Implant Device

Guidance and manufacturer's declaration - electromagnetic Immunity		
Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz	CW	8

Guidance and manufacturer's declaration - electromagnetic Immunity		
Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
134,2 kHz	Pulse modulation ^a 2,1 kHz	65 ^b
13,56 MHz	Pulse modulation ^a 50 kHz	7,5 ^b
a) The carrier shall be modulated using a 50% duty cycle square wave signal. b) r.m.s., before modulation is applied.		

15. Special Instructions

See the product packaging label for the production date of the product; service life: 10 years.

Scan and Login website
for more information



Guilin Woodpecker Medical Instrument Co.,Ltd.

Information Industrial Park, Guilin National High-Tech

Zone, Guilin, Guangxi, 541004 P. R. China

Sales Dept.: +86-773-5873196/2350599

After-sales Service Dept.: 0773-5827898

E-mail: woodpecker4@glwoodpecker.com

Website: <http://www.glwoodpecker.com>



MedNet EC-Rep GmbH
Borkstrasse 10 · 48163 Muenster · Germany

Dental Implant Unit Warranty Card

Name of Customer		(I) For Distributor
Address Details		
Postal Code		
Tel		
Model		
Main Unit No.		
Handpiece No.		
Contra-angle No.		
Purchase Date		
Contact Person		
Date	Maintenance Record	Repairer



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 After-sales Service Dept.: 0773-5827898
 E-mail: woodpecker4@glwoodpecker.com
 Website: http://www.glwoodpecker.com

Distributor:	Seal
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Dental Implant Unit Warranty Card

Name of Customer		(II) Return to Manufacturer
Address Details		
Postal Code		
Tel		
Model		
Main Unit No.		
Handpiece No.		
Contra-angle No.		
Purchase Date		
Contact Person		
Date	Maintenance Record	Repairer



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 E-mail: woodpecker4@glwoodpecker.com
 Website: http://www.glwoodpecker.com

Distributor:	Seal
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Cut along the dashed line

Warranty Instruction

I Period validity:

Within one year from the date of sale, the main unit, handpiece, foot pedal, and contra-angle can be repaired for free by providing warranty card.

II Range of warranty:

Within the warranty period of validity, we are responsible for any troubles caused by quality problems or products technique and structure.

III The following are beyond our warranty:

1. The damage caused by disobeying the operation instruction or lack of the needed condition.
2. The damage caused by unsuitable operation or disassembly without authorization.
3. The damage caused by unadvisable transportation or preservation.
4. There isn't the seal of distributor or the warranty card isn't filled in completed.

Warranty Instruction

I Period validity:

Within one year from the date of sale, the main unit, handpiece, foot pedal, and contra-angle can be repaired for free by providing warranty card.

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3. The damage caused by unadvisable transportation or preservation.
4. There isn't the seal of distributor or the warranty card isn't filled in completed.