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Implant-X Dental Implant Unit
Instruction Manual

CE 0197



DTE®

Guilin Woodpecker Medical Instrument Co., Ltd.

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Thank you for purchasing Woodpecker Dental Implant Device Implant-X. In order to guarantee the correct operation, it is recommended to read this instruction manual carefully before operation. For convenient reading, it is recommended to put it where is available at any time.

Device Type

1. Type of protection against electric shock: Class I equipment with internal power supply
2. Degree of protection against electric shock: B type applied part
3. Recommended disinfection method: See section 6 Cleaning, disinfection, and sterilization
4. Waterproof protection is in line with the current version IEC60529: host IPX1,foot pedal IPX6.
5. Degree of safety application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide: Equipment cannot be used in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
6. Operating mode: Continuous operation

Precautions

1. Please read these precautions before operation and operate in correct way.
2. The following icons is for ensuring safe operation, preventing you or others from being hurt. These icons are classified by degree of risk, degree of damage and severity. All indicators should be highly concerned. Please obey the instruction.

Classification	Degree of risk, degree of damage and severity
Dangers	Indicating potential personal injury or bodily injury
Warnings	Indicating potential slight injury or bodily injury
Precautions	Indicating instructions to be observed for ensuring safety

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1. Product introduction

1.1 Precautions

⚠ Danger

1. To prevent electric shock, do not use wet hands to pull the power cord; be sure to prevent the control circuit from water; use a grounded electrical outlet.

2. Keep it away from explosives and combustibles, with special care not to use this machine for patients who use nitrous oxide anesthesia.

3. This equipment may be used only by specialized and suitably trained personnel such as surgeons. The application place of the device is dental clinic or hospital.If correctly used, this equipment does not give rise to side effects. Improper use, on other hand, will give rise to transmission of heat to the tissues.

⚠ Warnings

1. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

2. In the presence of electromagnetic interference environment, the planter may be malfunctioning. Do not install the Dental Implanting Device near equipment that releases magnetic waves. When using ultrasonic vibrating equipment or electrode knife nearby, close the switch on the control panel.

3. Not to position the device to make it difficult to operate the disconnection device.

4. Implant-X requires special precautions for EMC and needs to be installed and put into service according to the EMC environment.

5. Device with electromagnetic launcher will affect the normal operation of Implant-X, do not run both devices at the same time.

6. Implant-X cannot be used in operating rooms containing potentially flammable gas mixtures.

7. To avoid possible injury to human or damage to the device, make sure that the motor handpiece (hereinafter simply referred to as the motor) is completely parked when replacing the planting tool. And the replacement shall be conducted by foot pedal controller.

8. Severe impact, such as dropping, will lead to damage to the implanting device.

9. During the work of peristaltic pump, the water pipe cannot be excessive bending or knotting, otherwise the pipe may fracture.

10. Do not attempt to disassemble the control panel, foot control or motor.

11. Dental handpieces (hereinafter referred to as handpieces) should be cleaned, lubricated and disinfected immediately after use.

12. Do not lubricate the motor. Lubricating oil can cause overheating, resulting in damage to the motor. Control panel and multi-function pedals cannot be disinfected.

13. Do not clean control panel with dissolving solution.

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14. The motor cable cannot be removed from motor.
15. Switch off electrical power after each use.

⚠ Precautions

1. If you need to repair and purchase spare parts, please contact the authorized supplier.
2. It is recommended to use the original pre-disinfection disposable water pipe combination.
3. The accuracy of torque monitoring depends on the accuracy of the handpiece installed on the micro motor. If the handpiece produced by other manufacturers is used, the actual torque value may not be displayed correctly. To ensure that the actual torque matches the displayed torque, please use the matched handpiece.
4. Please read this instruction manual before operation and master parts of functions.
5. Check the operating status of Implant-X before use and confirm that there is no abnormal condition.
6. Test the Implant-X before operation to ensure correct operation.
7. If there is a permanent malfunction (excessive vibrations, noise, heat production, etc.) on the Implant-X, please immediately close it and return it to the authorized dealer.
8. If the frequency of use is very high, please consider storing some spare parts.
9. Please cut off the power before cleaning the control panel with a damp cloth.
10. Dispose water pipe after operation with the method of disposing medical waste.
11. The operation mode of Implant-X is continuous operation mode, i.e., there will be 10 minutes pause after 3 minutes' operation. If there is no system overheating, it will prevent the patients, users or the third party from hurt. The user should be responsible for the use and shutdown of system.

This instruction manual is intended to indicate the safety requirements, installation procedures, proper methods of use and proper maintenance of the equipment. If you encounter any unexpected problems, please contact Service Center of Guilin Woodpecker Medical Instrument Co., Ltd.

The manufacturer will not be responsible for any personal injury or property damage caused by device tampering or modification conducted by unauthorized person.

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Guilin Woodpecker Medical Devices Co., Ltd. will continue to update its products, thus bring changes in device components. If there is any difference between your manual and the description on your product, please contact the authorized distributor or after-sales service center of Guilin Woodpecker Medical Instrument Co., Ltd. for explanation.

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This manual is strictly prohibited from being used in any way other than installation, use and maintenance of the equipment.

1.2 Contraindications and precautions

1.2.1 The hemophilia patient is forbidden to use this equipment.

1.2.2 The patients and doctors with heart pacemaker are forbidden to use this equipment.

1.2.3 Heart disease patients and children should be cautious to use the equipment.

1.2.4 Patients with oral and maxillo-facial infection, oral mucosal diseases, periapical disease, gingivitis, periodontitis, or mouth neoplasm should be cautious to use this equipment.

1.2.5 Patients with allergic constitution and drug allergy history are forbidden to use this equipment.

1.2.6 People with mental disorders should be cautious to use this equipment.

1.2.7 Patients with severe systemic infection or systemic diseases such as the diseases of heart, liver, kidney, hematopoietic system, digestive system and endocrine system should be cautious to use this equipment.

8. Pregnant women, lactating women, and women have a plan of birth should be cautious to use this equipment.

1.3 Scope of use

This product is intended for use in dental surgery, thus other uses are not allowed. There will be potential danger if it is used for other purposes!

1.4 Safety requirement

Guilin Woodpecker Medical Instrument Co., Ltd. will NOT be responsible for any direct or indirect damages and losses under the following conditions:

The equipment is used for any purpose that is not mentioned in the scope of use.

The operator does not follow the steps and requirements in instruction manual to use the device.

The cabling system of the room where the device is used does not meet the appropriate standards and the appropriate requirements.

Assemble, operate and repair the device without authorization of manufacturer.

The environment in which the device is located or stored does not meet the requirements mentioned in technical requirements section of the instruction manual.

2. Accessories description

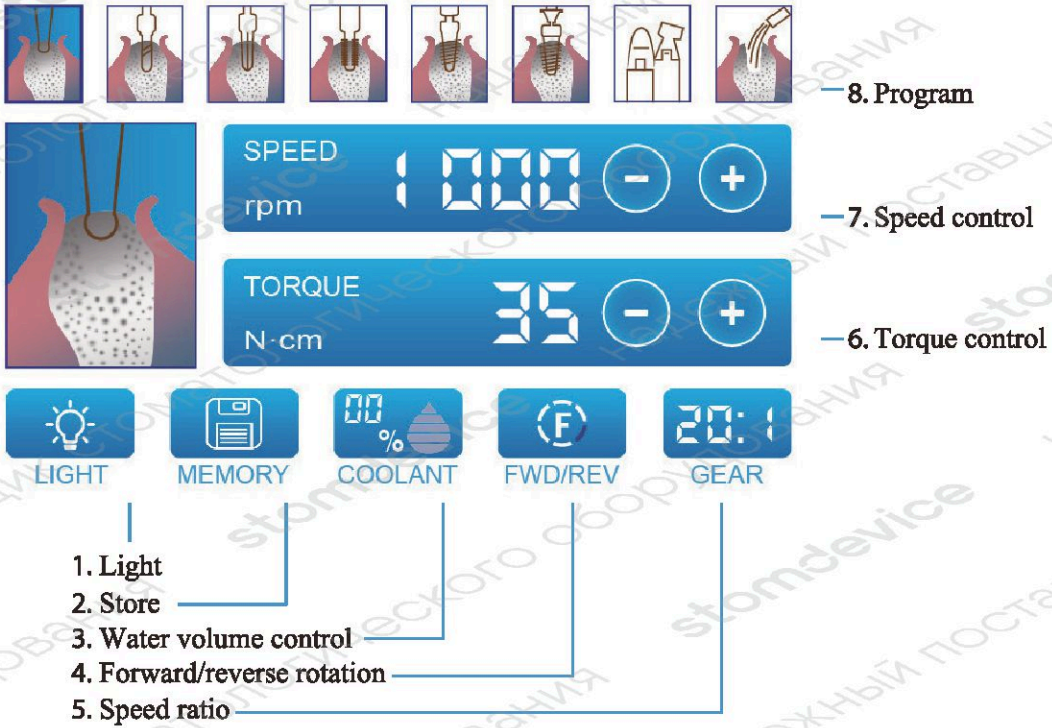
Please refer to packing list for device configuration.

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3. Control of host and foot pedal

3.1 Control of host keys

3.1.1 Working interface and control of keys



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1. Light key Motor LED switch; circular touch to control the on/off of LED.
2. Store key Store key; click to store setting specifications.
3. Water control key Click to select water volume. Six water gear, including 00%, 20%, 40%, 60%, 80%, and 100%
4. Forward/reverse rotation

Used to select the direction of rotation; direction changes for each pressing.

5. Speed ratio key

Used to set the gear ratio with handpiece; repeatedly pressing till the LCD correctly displays gear ratio with handpiece.

6. Torque control key

Used to set torque range of motor; "+" for increase, while "-" for decrease. Press and hold to accelerate the speed change.

7. Speed control key

Used to set rotating speed of motor; "+" for speed up, while "-" for slow down. Press and hold to accelerate the speed change.

8. Program key

Touch the icons to choose corresponding programs. Please refer to the Clause 5.1 for the functions of each program.

3.1.2 Interface of restoring the factory settings



Figure 1 Restore factory setting interface

While starting up, press the foot pedal at the same time. The factory reset menu will pop up as shown in the picture. When "YES" is selected, the saved parameters will be cleared and the original factory setting parameters will be restored. When "No" is selected, the factory settings will not be restored and the system will boot normally.

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3.1.3 Error alarm interface

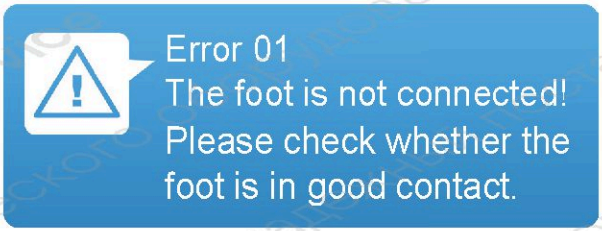


Figure 3 Error alarm interface

As shown in Figure 3, the warning 0x indicates alarm number. Please refer to section 7 Error code and solution for specific number and the corresponding content.

3.2 Foot pedal control



1. Water volume adjustment button

Used for choosing 6 cooling water flow levels. The water level is incremented each time the button is stepped. At the maximum

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level 6, pressing once to loops back to level 1.

2. Program switchover button

Used for choosing needed programs. The program is changed each time the button is stepped. At the Program 8, pressing once to loops back to Program 1.

3. Forward / reverse rotating direction

Used for changing the rotating direction of contra-angle. The direction will change after stepping.

4. Speed control foot pedal

Used to start/stop the motor and control the speed during operation. The operating speed of motor is controlled by the foot of operator. After lifting the foot, the displayed data will change to the maximum setting value.

4. Installation

4.1 Safety requirements during installation

⚠ **Danger**: Equipment is installed on the premise that the installation must meet the appropriate standards and related electrical safety requirements.

⚠ **Danger**: Never install the device in an explosion-hazardous area and the device must not be operated in areas with flammable gases (anesthetic mixture, oxygen, etc.).

⚠ **Danger**: Installation site should be able to protect device from shocks and splashing of water or other liquids.

⚠ **Danger**: Do not install the device near or above a heat source. It must be installed in a well-ventilated area with sufficient space around it, especially the exhaust fan and back.

⚠ **Warning**: Do not directly expose the parts to the sun or UV light source.

⚠ **Warning**: The device is movable. Be careful while handling it.

⚠ **Warning**: Before connecting the cord to the device, make sure the joint is dry. If necessary, dry it with air gun.

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4.2 Accessories connection



Figure 4

4.2.1 Installation of foot pedal:
Connect the foot pedal plug to the foot pedal socket and tighten those two fixing screws (Figure 4 - E)
4.2.2 Power cord installation:
Plug the power cord output into the power supply socket of the device (Figure 4 - D)
4.2.3 Installation of infusion bottle holder:
Insert the infusion bottle holder into the fixing hole on the right rear of the shell; (Figure 4 - A)
4.2.4 Installation of infusion bottle:
Hang the infusion bottle (The infusion bottle contains purchased normal saline injection.) on its holder.
4.2.5 Installation of motor:
Plug the tail cord of motor into the output socket on the front of the device (Note: align the red marking point). (Figure 4 - B)



Figure 5

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4.2.6 Peristaltic pump tube installation:

A. Turn the peristaltic pump knob clockwise to the "OPEN" indicator and open the pump head (Figure 5-A).

B. Place the tube in the impeller of the peristaltic pump (Figure 5 - B).

C. Turn the peristaltic pump knob clockwise to the "CLOSE" position and close the pump head (Figure 5 - D).

4.2.7 Complete machine effect after installations of all accessories: (Figure 6)



Figure 6

4.2.8 Switch on (Figure 4 - C) ; start to use the machine as it display normally:

Step on the pedal after the parameters such as speed, torque and water are set properly. The device starts to work. When the pedal is released, the device stops working.

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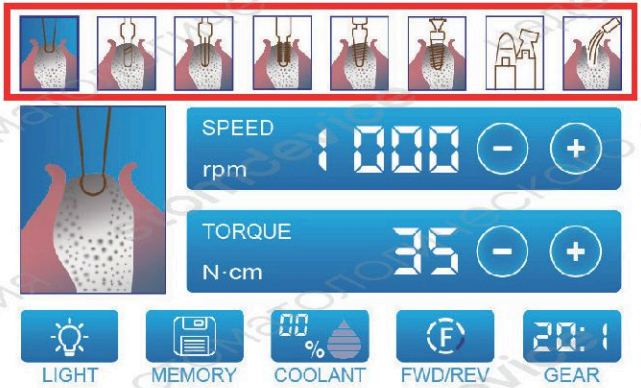
5. Operation

5.1 Program

5.1.1 Choice of programs

Implant-X owns 8 programs. There are two ways to choose program:

1. Touch the corresponding icons on the screen.
2. Step on the “Program switchover” button on the foot pedal.





5.1.2 Function description of programs

The function of each program is as shown as follow:

Icon	Function	Description
	Positioning	Accurate positioning on the alveolar bone by using a positioning drill.

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	Hole-drilling	Determine the direction and depth of hole-drilling.
	Hole-broadening	Determine the diameter of the hole.
	Tapping	Make a thread on the hole to match the implant.
	Implanting	Implant dental implants into alveolar bone.
	Lock the abutment screw	Screw the nut onto the dental implant.
	User defined mode	Change straight handpiece, contra-angle with different speed ratios for different dental procedures.
	Cleaning	Water discharging without motor rotation is convenient for flushing.

5.1.3 Factory Settings

Before delivery, several parameters mainly including speed, torque, speed ratio and water output have been set according to the actual application. These parameters can be changed within the range of parameters specified in the current program.

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The range of different parameters and their factory settings are as shown in the table below:

Icon	Function	Speed/ rpm	Torque/ N·cm	Speed ratio	Water output/%
	Positioning	200-2500 1000(D)	5-80 35(D)	16:1,20:1, 27:1,20:1(D)	40
	Hole-drilling	200-2500 800(D)	5-80 35(D)	16:1,20:1, 27:1,20:1(D)	40
	Hole-broadening	200-2500 600(D)	5-80 35(D)	16:1,20:1,27:1,20:1(D)	40
	Tapping	15-100 20(D)	5-80 35(D)	16:1,20:1, 27:1,20:1(D)	40
	Implanting	15-100 20(D)	5-80 35(D)	16:1,20:1, 27:1,20:1(D)	0
	Lock the abutment screw	15-100 20(D)	5-15 10(D)	16:1,20:1, 27:1,20:1(D)	0
	User defined mode	15-40000 1200(D)	5-80 45(D)	1:1,1:2,1:3, 1:5,16:1, 20:1,27:1, 20:1(D)	40
	Cleaning	——	——	——	80

Note: the letter "D" stands for default value.

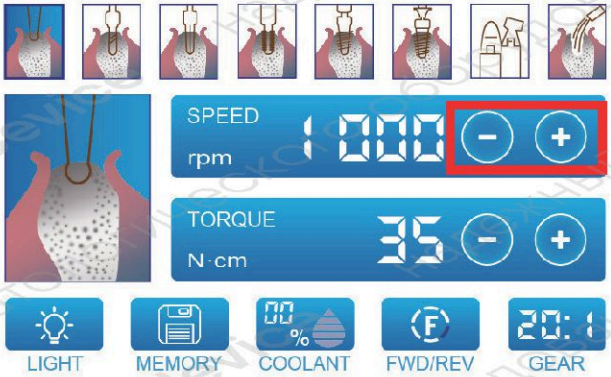
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5.2 Default parameter adjustment

Within specified range, the adjustable parameters are as follow:

1. Maximum speed
2. Maximum torque
3. Water output
4. Speed ratio

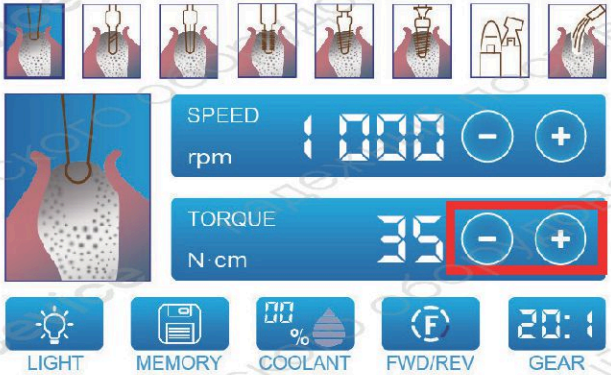
5.2.1 Maximum speed adjustment



Touch the “Speed” (+, -) key to adjust motor speed. The speed will change each time after touching the “Speed” key. Long press the “Speed” key to accelerate the change of speed setting value.

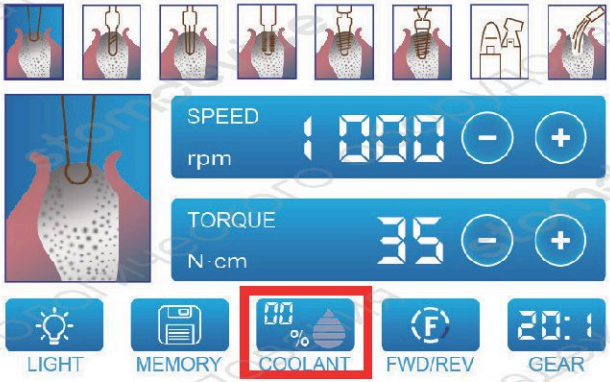
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5.2.2 Maximum torque adjustment



Touch the “Torque” (+, -) key to adjust maximum torque output of motor. The torque will change each time after touching the “Torque” key. Long press the “Torque” key to accelerate the change of torque setting value.

5.2.3 Water output adjustment



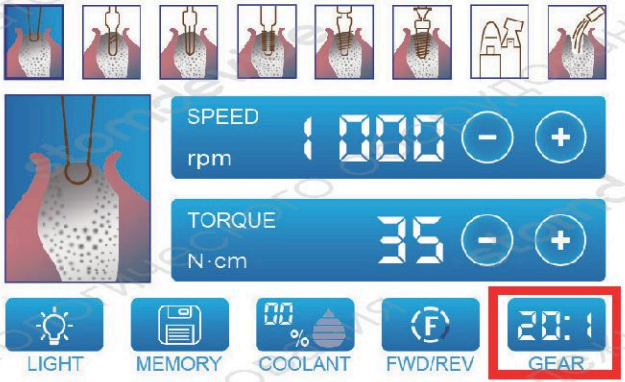
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Touch the “Water volume” key on the screen to adjust. There are 6 water levels. The water level will change to the next level after each touch.



Step on the blue “Water volume adjustment” button to adjust water volume.

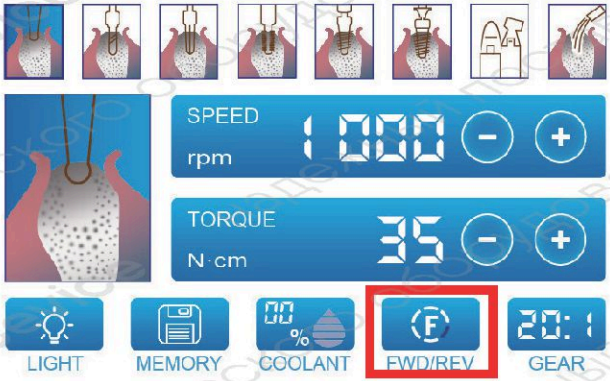
5.2.4 Speed ratio adjustment



Adjust by pressing the "Speed Ratio" button to match the gear ratio of the handpiece to be used.

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5.3 Motor rotating direction adjustment



Touch the key shown above to change the rotating direction of motor.



Step on the “Forward/reverse rotation” during operation to change the rotating direction of motor.

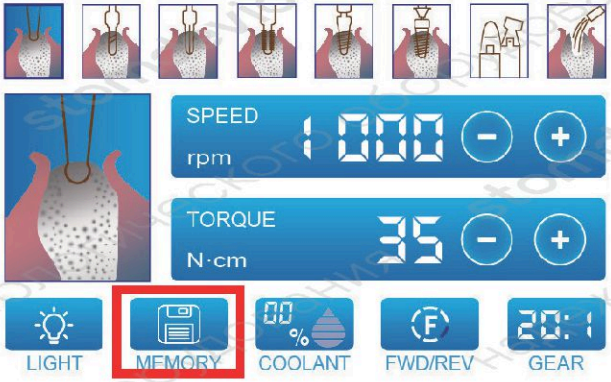
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5.4 Motor LED adjustment



Touch the “LED” button to for setting to determine the on or off state of LED while stepping on foot pedal. The state of LED will change once after each touch. Only the device with LED owns this function.

5.5 Save the parameters



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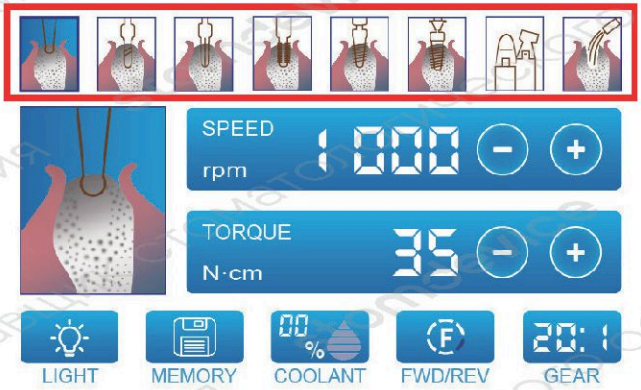
After finishing the above steps, press “Store” key. You will hear a beep if the parameters are saved.

5.6 Standard operation

1. After installation of corresponding accessories, connect to the power supply, and turn on the power supply. After booting, the displayed interface is default to be Program 1.



2. Touching screen or stepping on the “Program switchover” button on the foot pedal to choose the program.

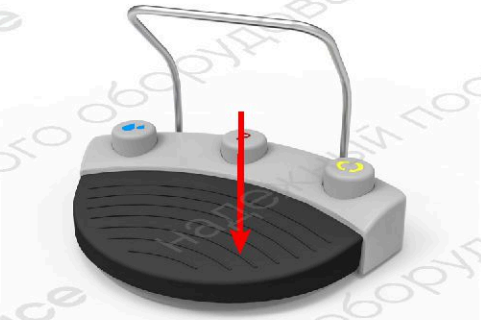




3. Confirm that the speed, torque, water flow, forward/reverse rotation, speed ratio and other parameters of corresponding program meet the requirements.

4. Step on the foot pedal, and then motor starts to rotate. Deep step to accelerate; the maximum speed value is the current program speed setting value; light step to reduce the speed; the minimum trigger speed is15 rpm (Gear ratio of handpiece: 20:1). After fully release, the speed restore to the set value speed.

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5. Torque protection will start as the torque reaches preset value. Meanwhile, the motor slows down to stop, preventing from generating excessive torque. Release foot pedal to remove torque protection. Step again, and the motor will rotate under preset torque value.

6. Release foot pedal, and the motor stop rotating.

6. Clean, 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. Handpiece and motors can be disinfected with heat sterilizers. Plug in motor disinfection stopper before disinfection of motor!

Before the first use, it is recommended to let it be autoclaved under 134 °Cand (0.20 ~ 0.23) MPa for not less than 4 minutes.

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.

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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:

Handpiece, motor and its tail cable, holder of silicone handpiece, motor disinfection stopper, motor cable-cooling pipe clamp, and lubricant nozzle.

Concrete steps:

Step	Manual method	Automatic method	Warning
Cleaning	Separate the main unit and foot controller from the charging base. Thoroughly wipe all visible surfaces of the device with a disposable soft cloth, including water bottle hooks, pedals, and cables. And then dry them after washing.	Parts that can be cleaned automatically are motor holders, motors and motor tail cables. It is recommended to use a cleaning machine in accordance with ISO 15883-1 and refer to the instructions of the cleaning machine.	Do not automatically clean the main unit.
Disinfection	After any pre-cleaning, wipe all visible surfaces of the device including water bottle hooks, pedals and cables with a disposable soft cloth dampened with disinfectant(at least 30 s) to ensure that all surfaces are wet. and allow to act (contact time > 30 minutes). If large surfaces have to be treated, use more than one wipe where necessary.	Parts that can be disinfected automatically are motor holders, motors and motor tail cables. It is recommended to use a thermal disinfector in accordance with ISO 15883-1 and refer to the instructions of the thermal disinfector.	Before disinfection, please plug the motor disinfection stopper in the motor.
Drying	Dry all the cleaned and disinfected parts thoroughly in the air indoors.	Drying is generally a part of cleaning and disinfection process. Please operate as per the Instruction of washers and disinfectors.	Disposable water pipes are for single use only and should not be disinfected and sterilized, and have no need of drying.

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Packaging	Seal the motor, motor tail cord and motor holder in the sterilization bag.	——	Sterilization bag should be in accordance to applicable sterilization standard, and is suitable for sterilization.
Sterilization	——	Put the sterilization bags into the autoclave sterilizer. It is recommended to be sterilized under 134 ° C (273 ° F), (0.2-0.23) MPa for not less than 4 minutes. Dry them after sterilization.	The sterilized items should cool down to room temperature before next operation.

7. Error code and solution (error alarm interface)

When there is a problem with the operation, the display will provide the error code of the problem diagnosis: Specifically, switch to the error prompt interface for explanation and solution to the problem:

Error code	Error description	Solution
Error 01	Foot pedal is not connected	Make sure that the foot pedal is connected. If the problem cannot be solved, please contact local distributors or manufacturer.
Error 02	Motor over-current	Please contact local distributors or manufacturer.
Error 03	Motor overheat	Please contact local distributors or manufacturer.
Error 04	Motor phase default	Please contact local distributors or manufacturer.
Error 05	Motor light abnormality	Please contact local distributors or manufacturer.
Error 06	Peristaltic pump abnormality	Open and close peristaltic pump, if the alert is not dismissed, please contact local distributors or manufacturer.
Error 07	Motor voltage abnormality	Power supply voltage is not stable. Make sure the grid electricity voltage is stable. If the alert is not dismissed, please contact local distributors or manufacturer.

8. Storage and maintenance

8.1 The device should be handled carefully and lightly. Be sure that it is far from the vibration, and installed or kept in a cool, dry, and ventilated place.

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8.2 Do not store the machine together with articles that is poisonous, combustible, caustic, or explosive.

8.3 This device should be stored in a room where the relative humidity is not more than 10%~93%, atmospheric pressure is 70kPa~106kPa, and the temperature is-20℃ ~ +55℃.

8.4 Turned off power switch and unplug the power plug when the device is not in use. If it is not used for a long time, please get through to power supply and water for five minutes once per month.

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

8.6 After each operation, the contra-angle shall be cleaned, applied oil, and disinfected as per requirements. If it is not used for a period, please clean it, apply oil to it, and disinfect is at least once a week.

Replacement of fuse

Power supply shall be cut off while intending to conduct the following operations. And disconnect power supply cable and main power supply. (See Figure 7 - Refer to B)

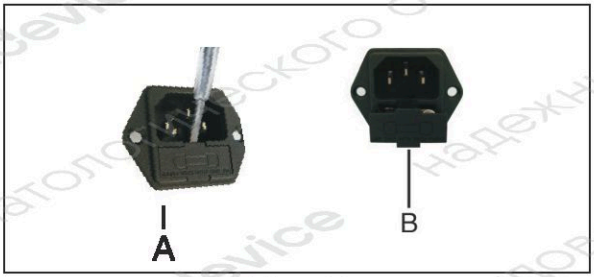


Figure 7

1. Danger: Switch off the apparatus.

2. Insert a flat-blade screwdriver to the groove under the power supply hole, and then pry it out (Figure 7 - ref. A);

3. Pull out the fuse compartment (see Figure 7 - Ref. B) and select the appropriate fuse for replacement by following the label on the bottom of the power supply socket.

8.7 The maintenance personnel appointed by the manufacturer can obtain the equipment maintenance-related data (such as circuit diagrams, component lists, etc.) from the manufacturer.

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9. Symbols

DTE.	Mark		Follow Instructions for Use
	Use indoor only	~	Alternating current
	Socket for the foot switch		Caution mechanical injury
	Manufacturer		Date of manufacture
IPX1	Drip-proof	IPX6	Strong water spraying experiment
	Type B applied part	134°C	Can be autoclaved
	Caution		Protective earthing
SN	Serial number		Humidity limit for storage
	Atmospheric pressure for storage	-20°C +55°C	Temperature limit for storage
	Appliance complies with WEEE directive	CE 0197	CE marked product
EC REP	Authorised Representative in the EUROPEAN COMMUNITY		

Note:Please refer to product packaging label for production date.

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10. Specifications

10.1 Host specifications

Model: Implant-X
Device for intermittent operation: 3 min ON,10 min OFF
Power supply voltage: 200-240V~
Power supply frequency: 50/60Hz
Software version: Implant-V1.0.0
Input power: 150VA
Fuses: 2×T1.6AL 250V
Applied parts: Contra-angle handpiece
Maximum Temperature: 41.8℃
Maximum water volume: 110ml/min
Dimension: 265mm*263mm*119mm
Operation environment:
Environment temperature: +5~40℃
Relative humidity: 30%~75%
Atmosphere pressure:70kPa~106kPa
Device case material: PC+ABS
Handpiece material: brass

10.2 Motor specifications:

Model: SPM58L, SPM58NL, SPM58, SPM58LS
Rotating speed range: 300-40,000 rpm
Torque range: 5-80 Ncm(ratio: 20:1)
Input voltage: DC27V
Dimension: Maximum diameter 21.5 mm, Length 110 mm
Tail cord length: 1.8m

10.3 Foot pedal controller specifications

Model: MF4

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Tail cord length: 2m

11. After-sales service

Since the date of sale, the device enjoys one year of free warranty, and our company is responsible for the lifetime maintenance.

Irreparable damage to device caused by non-designated professional maintenance personnel does not belong to the scope of free warranty.

12. Environment protection

The device does not contain any harmful ingredients. It can be handled or destroyed in accordance with the relevant local regulations.

13. Statement

Woodpecker reserves the right to change the design of the equipment, the technique, fittings, instruction manual and the content of the original packing list at any time without further notice. The pictures are only for reference. The final interpretation rights belong to Guilin Woodpecker Medical Instrument Co., Ltd.

14. Guarantee

14.1Before being put into market, all woodpeckers device should be thoroughly inspected to ensure proper use.

14.2Woodpecker promised that for any new products purchased from authorized distributors or importers of Woodpeckers, if ill function is resulted from the quality problem, you are entitled to free replacement during the warranty period:

- One year since the date of purchasing equipment;
- One year since the date of purchasing motor and tail cord.

14.3 During the warranty period, Woodpecker will repair or replace the damaged parts of the device for free.

14.4 Woodpeckers will not be responsible for any direct or indirect damage and loss if:

14.4.1 The equipment is used for any purpose other than the mentioned scope of use.

14.4.2 The operator does not follow the steps and requirements stipulated in the instruction manual to use the device.

14.4.3 The cabling system of the room where the equipment is used does not meet the appropriate standards and the appropriate requirements.

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14.4.4 The device is installed, operated, or repaired by the unauthorized personnel.

14.4.5 The environment where the device is used and stored does not meet the requirements stipulated in relevant section of instruction manual.

14.5 Damage caused by transportation, incorrect use, or negligence will be excluded from the warranty. And if the parts are tempered by unauthorized, the warranty card losses effect.

14.6 Warnings

To request a warranty, please send your device, warranty card, and invoice for the device to your Woodpecker distributor / importer within the warranty period. In order to be repaired during the warranty period, the purchaser shall return the repaired product to the distributor / importer at their expense.

14.7 Parts must be properly packaged (or in original packaging) while being sent back.

14.8 All parts must be accompanied by the following information

14.8.1 Buyer information, including phone numbers, etc.;

14.8.2 Distributor or importer information;

14.8.3 A copy of the photo of the goods, date of purchase, problem of part, part name and serial number;

14.8.4 Description of the problem.

14.9Any damage caused during transportation is not under warranty. If the problem is caused by incorrect use, the repair fee should be undertaken by the users.

15. EMC-Declaration of comformity

The device has been tested and homologated in accordance with EN 60601-1-2 for EMC. This does not guarantee in any way that this device will not be effected by electromagnetic interference Avoid using the device in high electromagnetic environment.

Technical Description Concerning Electromagnetic Emission

Table 1: Declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions
The model Implant-X is intended for use in the electromagnetic environment specified below. The customer or the user of the model Implant-X should assure that it is used in such an environment.

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Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model Implant-X uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The model Implant-X is suitable for used in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions lEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions lEC 61000-3-3	Complies	

Technical Description Concerning Electromagnetic Immunity

Table 2: Guidance & Declaration - electromagnetic immunity

Guidance & Declaration — electromagnetic immunity			
The model Implant-X is intended for use in the electromagnetic environment specified below. The customer or the user of the model Implant-X should assure that It is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) lEC 61000-4-2	±8kV contact ±2, ±4, ±8, ±15kV air	±8kV contact ±2, ±4, ±8, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst lEC 61000-4-4	±2kV for power supply lines ±1kV for Input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge lEC 61000-4-5	±0.5, ±1kV line to line ±0.5, ±1, ±2kV line to earth	±0.5, ±1kV line to line ±0.5, ±1, ±2kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.

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Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT.) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 250 cycles	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT.) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models Implant-X requires continued operation during power mains interruptions, it is recommended that the models Implant-X be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field lEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 3: Guidance & Declaration - electromagnetic immunity concerning Conducted RF & Radiated RF

Guidance & Declaration - Electromagnetic immunity			
The model Implant-X is intended for use in.the electromagnetic environment specified below. The customer or the user of the models Implant-X should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

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Conducted RF lEC 61000-4-6 Conducted RF lEC 61000-4-6 Radiated RF lEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM frequency band 3 V/m 80 MHz to 2.7 GHz	3V 6V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the models Implant-X, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2×P1/2 d=2×P1/2 d=1.2×P1/2 80 MHz to 800 MHz d=2.3×P1/2 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacturer and d Is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur In the vicinity of equipment marked with the following symbol:
NOTE I At 80 MHz end 800 MHz. the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model Implant-X is used exceeds the applicable RF compliance level above, the model Implant-X should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model Implant-X. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the model Implant-X

Recommended separation distances between portable and mobile RF communications equipment and the model Implant-X

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The model Implant-X is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model Implant-X can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model Implant-X as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz d=1.2×P1/2	80MHz to 800MHz d=1.2×P1/2	800MHz to 2,7GHz d=2.3×P1/2
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.

NOTE I At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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