Endo Radar Pro Endo Motor

INSTRUCTION MANUAL

CE 0197

Please read this manual before operating

www.glwoodpecker.com

GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.

Contents

1 Introduction

1.1 Foreword

Guilin Woodpecker Medical Instrument Co., Ltd. is a high-tech enterprise in researching, developing, and producing dental equipment, and has a perfect quality assurance system, main products including ultrasonic sealer, curing light, Endo motor, apex locator and ultrasurgery, automatic water supply system etc.

1.2 Introduction

Endo Radar Pro is mainly used in Endodontic treatment. It is a cordless endo motor with root canal measurement capability. It can be used as a endo motor for preparation and enlargement of root canals, or device for measuring canal length. It can be used to enlarge the canals while monitoring the position of the file tip inside the canal.

Features:

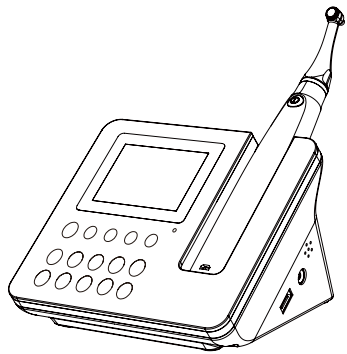
a) Use efficient brushless motor, bringing lower noise and longer service life.

b) Cordless portable endo motor with combined length determination.

c) The built-in high-capacity battery in the base is equipped with a wireless charging system to ensure long enough battery life.

d) The contra-angle can be rotated for 360°.

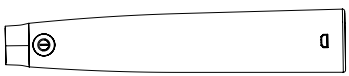
1.3 Product configuration



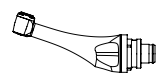
1.3.1 Structure

Endo Radar Pro is composed of Motor handpiece, Contra-angle, measuring wire, USB wire , Power adapter, etc...

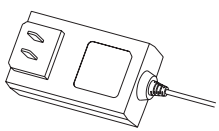
1.3.2 Product accessories



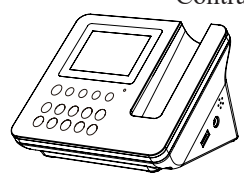
Motor handpiece



Contra-angle

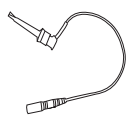


Power adapter

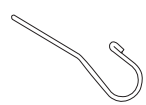


Base

Measuring wire

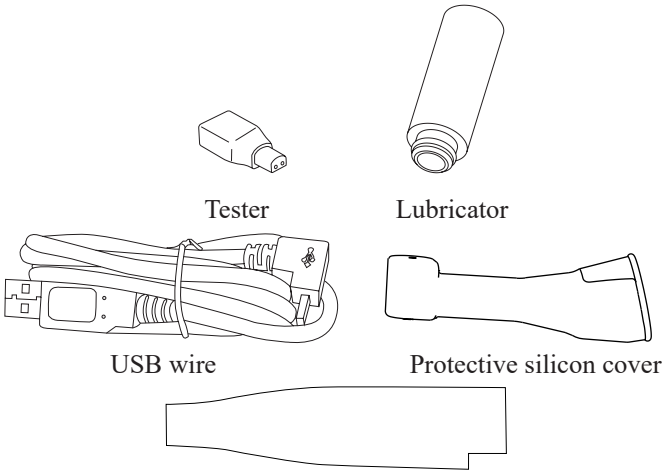


File clip



Lip hook

Touch probe



1.4 Indications for use

Endo Radar Pro is a cordless endo motor with root canal measurement capability. It can be used as a endo motor for preparation and enlargement of root canals, or device for measuring canal length. It can be used to enlarge the canals while monitoring the position of the file tip inside the canal.

1.5 Range of application

1.5.1 The device can be used for preparation and enlargement of root canals, or device for measuring canal length.

1.5.2 The device must be operated in hospital and clinic by the qualified dentists.

1.6 Contraindications

In cases where a patient has been fitted with an implanted heart pacemaker (or other electrical equipment) and has been cautioned against the use of small electrical appliances (such as electric shavers , hair dryers , etc) it is recommended not to use the this device.

1.7 Device safety classification

1.7.1 Type of operation mode:

(1) Motor alone mode and Apex Locator alone mode: Continuous operation

(2) Combined length combination mode:Non-continuous operation(ON:1 minute(Max),OFF:1 minute(Min))

1.7.2 Type of protection against electric shock: Class II equipment with internal power supply

1.7.3 Degree of protection against electric shock: B type applied part

1.7.4 Degree of protection against harmful ingress of water: Ordinary equipment (IPX0)

1.7.5 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.

1.7.6 Applied part: contra-angle, lip hook, file clip, touch probe, protective silicon cover.

1.7.7 The contact duration of applied part: 1 minute.

1.7.8 The temperature of the surface of applied part may reach 45℃.

1.8 Primary technical specifications

1.8.1 Battery:

Lithium battery in base: 11.1V/2600mAh

Lithium battery in motor handpiece: 3.7V/1200mAh

1.8.2 Power adapter:

Input: ~100V-240V 50/60Hz 800mA

Output: DC15V/1.6A

1.8.3 Torque rang: 0.4Ncm~5.0Ncm(4mNm~50mNm)

1.8.4 Speed rang: 100rpm~2500rpm

1.8.5 The contra-angle uses precision gear transmission inside, and the gear ratio is 6:1 (Model: CA161)

1.8.6 First release of software: V1

1.9 Working environment

1.9.1 Environment temperature: +5℃~+35℃

1.9.2 Relative humidity: 30%~75%

1.9.3 Atmosphere pressure: 70kPa~106kPa

1.10 Warnings ⚠

1.10.1 The device must only be used in suitable locations and only by specialized physicians licensed to practice dentistry.

1.10.2 Use the specified battery for this device. Never use any other batteries.

1.10.3 Do not expose the device to direct or indirect sources of heat. Operate and store the device in safe environment.

1.10.4 The device requires special precautions as regards electromagnet compatibility (EMC) and must be installed and

commissioned in strict conformity with the EMC information provided in this instruction manual. Specifically, do not use the device close to fluorescent lamp, radio transmitters and remote controls.

1.10.5 Long time use of the device will lead to overheating of the micro motor, let it cold down that use. If the motor handpiece overheats too persists, contact your distributor.

1.10.6 The USB port of the base must only be connected to USB port of the handpiece through the USB wire. Never use it for other purposes.

1.10.7 Over-heat scorching: the handpiece cannot be used for 10 minutes continuously.

Contra-angle

1.10.8 Only use the original contra-angle. Do not use any other contra-angle or other reduction rate other than original one.

1.10.9 Never press the contra-angle push button when the motor handpiece is running or if it is coming to a stop. This will lead to detachment of the instrument or cause the pushbutton to overheat.

1.10.10 Never remove the contra-angle from the motor handpiece during operation.

1.10.11 Only use undamaged root canal instruments. Please refer to the information provided by the manufacturer.

1.10.12 Only insert the instrument when the contra-angle is stationary.

1.10.13 Never place your fingers on the moving parts of the instrument while it is running or coming to a stop.

1.10.14 Before treatment, check the contra-angle for any damage or loose parts.

Root canal instruments

1.10.15 Before use, make sure the instrument is securely locked in place.

1.10.16 Never use continuous rotary instruments in Safety Glide Path mode.

1.10.17 Never use Safety Glide Path instruments in rotary mode.

1.10.18 Use the torque and speed settings recommended by the instrument manufacturer.

1.10.19 Replacement of lithium batteries by inadequately trained personnel could result in a HAZARD,so please contact local distributors to replace the battery if necessary.

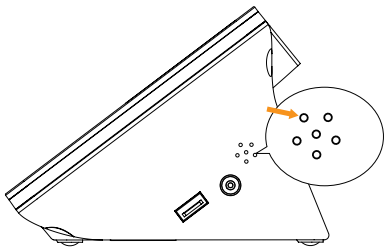
1.10.20 The adapter plug can be used to disconnect from the network

power supply.Don't position the device to make it difficult to operate the disconnection device.

2 Installation and setting

2.1 Reset function

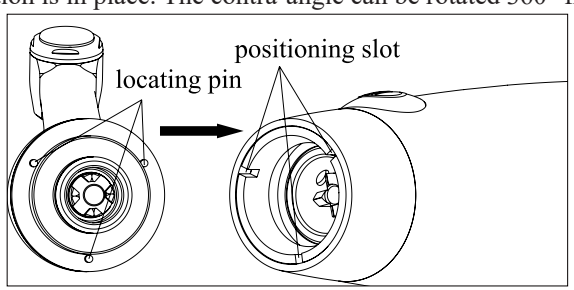
Use the needle to push the internal button for more than 3 seconds to complete the reset by the reset hole indicated by the arrow below, to solve the accidental crash of the base or accidental failure of the touch button.

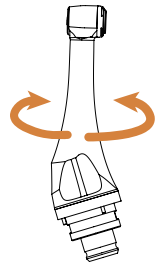


2.2 Installing and removing the contra-angle

2.2.1 Installing

Align any locating pin of the contra-angle with the positioning slot on the motor handpiece and push the contra-angle horizontally. The three locating pins on the contra-angle are inserted into those three positioning holes on the motor handpiece. A “click” sound indicates that the installation is in place. The contra-angle can be rotated 360° freely.



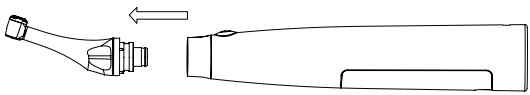


The contra-angle is free to rotate, adapting to the root canal of different positions, and it is convenient to watch the screen when operating.

2.2.2 Removing

When removing the contra-angle, pull it straight out.

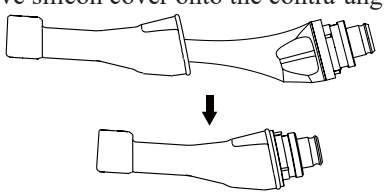
When inserting and removing the contra-angle, turn the motor handpiece power off beforehand.



2.3 Installing and removing the protective silicon cover

2.3.1 Installing

Put the protective silicon cover onto the contra-angle.



2.3.2 Removing

When removing the protective silicon cover, pull it straight out slowly.

2.4 Inserting and removing the file

2.4.1 Inserting

Insert the file into the chuck until it stops.

2.4.2 Removing

Press the push-button and pull out the file.

When inserting and removing the file, turn the motor handpiece power off beforehand.

2.5 Installation and removal of disposable insulation sleeves

2.5.1 Installation

Before each use of the handpiece and after the handpiece is cleaned and disinfected,put on a disposable isolation sleeve. Take the isolation sleeve out of the isolation sleeve box, then insert the isolation sleeve into the motor handpiece from the thin end of the handpiece, and install the isolation sleeve until there is no obvious wrinkle.

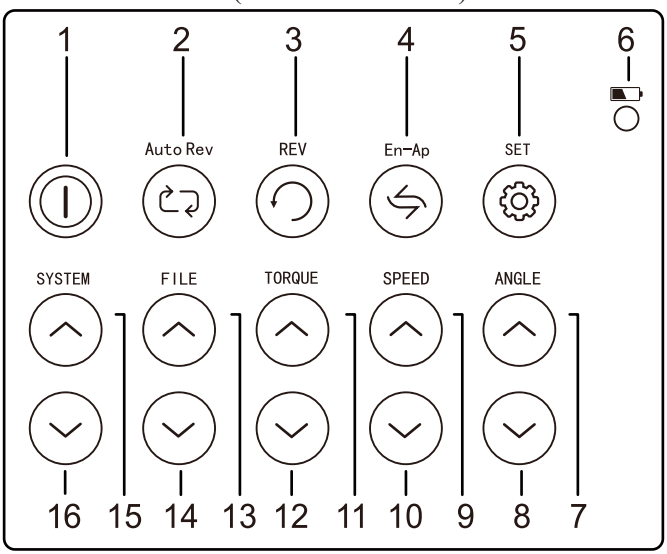
After installing the disposable isolation sleeve, wrap the barrier film around the handpiece surface. After that, clean and disinfect the surface of the handpiece. Refer to Chapter 7.3 for cleaning and disinfection procedures.

2.5.2 Removing

After each use, remove the barrier film and slowly pull the isolation sleeve from the thin end of the handpiece.

⚠ Warming: Isolation sleeves are not reusable.

2.6 Touch button of base(Motor alone mode)



1 POWER Power on or power off
2 AUTO REV Automatic protection mode
3 REV Forward or reverse
4 En-Ap The mode button

5 SET Long press to enter the Contra-angle Calibration and Wireless Match interface
In Safety Glide Path mode, switch to choose forward
angle or reverse angle

6 LED Wireless charging LED on the base starts to flash, it means wireless charging

7 In Safety Glide Path Mode, increase the angle

8 In Safety Glide Path Mode, decrease the angle

9 SPEED+ Increase the motor rotation speed

10 SPEED- Decrease the motor rotation speed

11 TORQUE+ Increase the torque

12 TORQUE- Decrease the torque

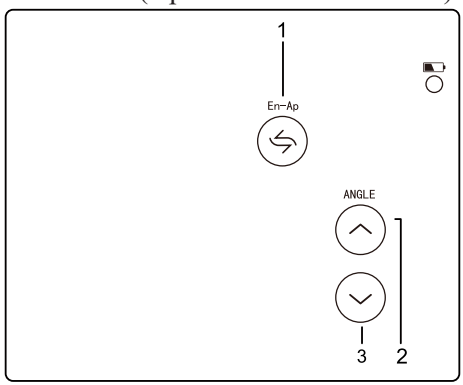
13 FILE+ Positive selection key

14 FILE- Negative selection key

15 SYSTEM+ Select the File system

16 SYSTEM- Select the File system

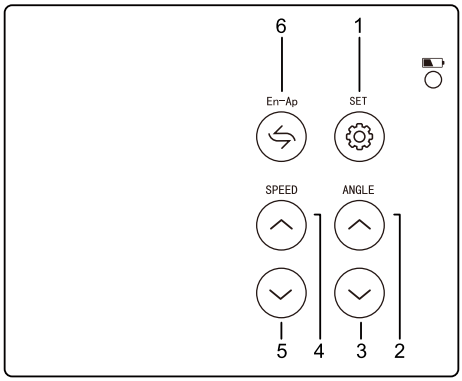
2.7 Touch button of base(Apex locator alone mode)



1 En-Ap The mode button

2 3 ANGLE +- Set the apical point, it can be set anywhere from 1.0mm to apex(0.0mm)

2.8 Touch button of base(Combined length determination mode)



Combined length determination mode parameter setting:

1 SET Touch the button for more than 1 seconds, enter combined length determination mode parameter setting. Touch again, then exit .

2 3 ANGLE +- Set the apical point, it can be set anywhere from 1.0mm to apex(0.0mm)

4 5 SPEED +- Select, "AU.START, AU.STOP, AU.OFF"

"▽SL.D., ▽~~SL.D.~~"

"AP.REV, AP.STOP, AP.OFF"

6 En-Ap Select "AU.START or AU.STOP or AU.OFF", enable or disable "▽SL.D. or ▽~~SL.D.~~", enable or disable "AP.REV or AP.STOP or AP.OFF"

AU.START Enable auto start

The file will start rotating when it is inserted the canal.

AU.STOP Enable auto start and auto stop

The file will start roating when it is inserted the canal, and stop roting when it leaves the canal.

AU.OFF Disable auto start

▽SL.D. Enable apical point slow-down

The file slows down as it approaches the apical point.

▽~~SL.D.~~ Disable apical point slow-down

AP.REV Auto apical point reverse

The file will reverse when the file tip reaches the apical point.

AP.STOP Auto apical point stop

The file will stop when the file tip reaches the apical point.

AP.OFF Disable apical action function

The file rotating as usual even if reach the reference apical point.

2.8.1 The device contains a file library with the preset popular NiTi file systems.

2.8.2 Please follow the file manufacturer's instructions for use .The file system shown on the display must always match the file in use.

2.8.3 Torque and speed values are subject to change by the file manufacturers without notice. Therefore, the preset values in the library must be checked prior to use.

2.8.4 Please use the 8 sets Individual Program to create your own file sequence. This enables you to manage your own series of files.

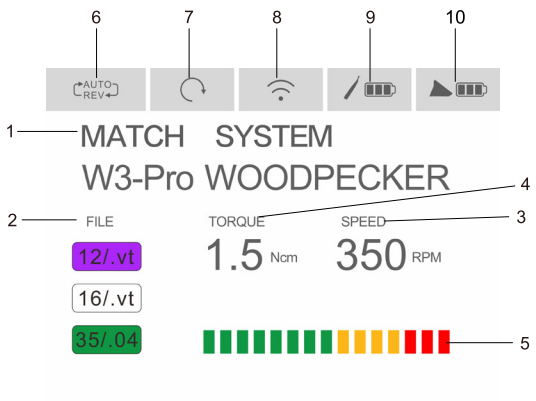
2.8.5 Never use Safety Glide Path files in continuous rotary mode. Never use rotating files in Safety Glide Path mode.

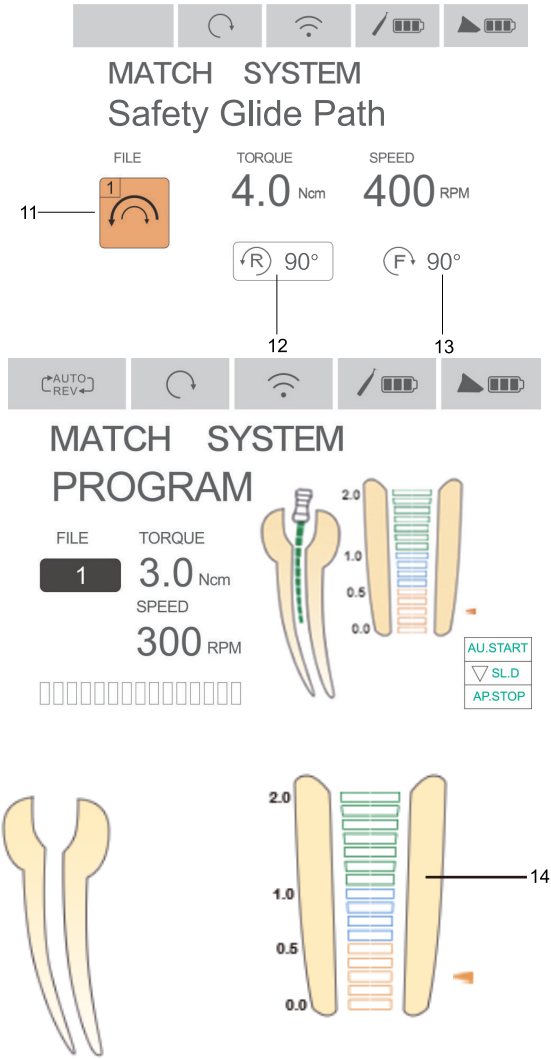
2.8.6 Safety Glide Path mode

Adjustable every 10 degrees, adjustment range: 20º-400º.

The rotation angle is adjustable, but the forward angle must be equal to the reverse angle.

2.9 LCD screen





1 SYSTEM Display the selected file system
2 FILE Display the selected file type
3 SPEED Display the rotation speed(applied only to continuous rotation mode)

4 TORQUE Display the limiting value of torque

5 TORQUE BAR Display the limiting value of torque in the bar

6 AUTO REVERSE Display the selected auto reversing protection mode:

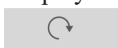
AUTO REVERSING

AUTO STOP

AUTO REVERSE OFF

7 Rotational direction

Display the rotation direction of device


Clockwise continuously rotating


Counterclockwise continuously rotating


Safety Glide Path motion mode

8 Wireless communication connection status indication


The motor handpiece is connected to the base wirelessly


Wireless communication has been disconnected or the motor handpiece is not turned on to establish a wireless communication

9 Display the current remaining battery power of the motor handpiece


Fully charged


The remaining battery power is about 70%


The remaining battery power is about 30%


The battery is very low, please charge in time

10 Display the current remaining battery power of the base

Fully charged

The remaining battery power is about 70%

The remaining battery power is about 30%

The battery is very low, please charge in time

11 Display the current Safety Glide Path mode file system number

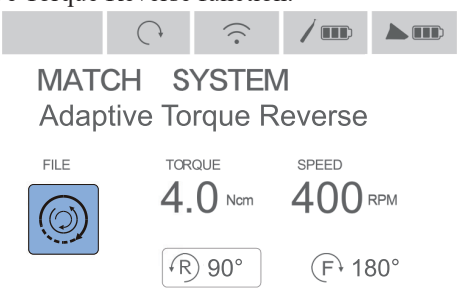
12 Reverse angle, adjustable from 20° to 400°

13 Forward angle, adjustable from 20° to 400°

14 Apex bar Display apex bar

2.10 ATR Mode

ATR: Adaptive Torque Reverse function.



Normal continuous forward rotation, the forward angle can be stepped by 10°, the angle is set between 20°-400°, and the reverse angle defaults to 90°. When the load of the file is greater than the set torque limit, the file will start to rotate alternately at the set angle.

Trigger torque: 0.4Ncm-4Ncm

Speed: 100rpm-500rpm

2.11 Standby mode

If the device is not used for 3 minutes, the motor handpiece will automatically shut down. In shutdown mode, press the handle button, you can boot instantly.

⚠ **Note: the description on Safety Glide Path mode is only applicable for the device that has Safety Glide Path mode.**

3 Motor alone mode

3.1 Base start and stop

3.1.1 starting: If power off, press and hold the POWER button for several second, welcome screen will appear.

3.1.2 shutdown: When power on, press and hold the POWER button for 1 second, the screen slowly get dark, and the device shutdown.

3.2 Starting and stop of motor handpiece

3.2.1 When the motor handpiece is power off, press the ON/OFF button, if the LED of motor handpiece button is blue, indicating that the motor handpiece in power-on state.

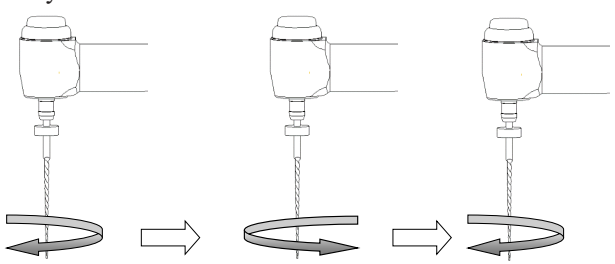
3.2.2 After the base is powered on, in the power-on state of handpiece, if the base wireless communication connection icon is lit, the motor handpiece had established wireless communication with the base. When the ON/OFF button is pressed, the motor handpiece would enter the working state according to the current mode set in the base.

3.2.3 Long press the ON/OFF button, and the handpiece will turn off.

3.3 Auto reversing protection mode

3.3.1 AUTO REVERSING

During operation, if the load exceeds a preset value, the needle rotation mode file automatically becomes reverse mode. When the load again lower than the preset value, the file returns to the needle rotationally forward mode.

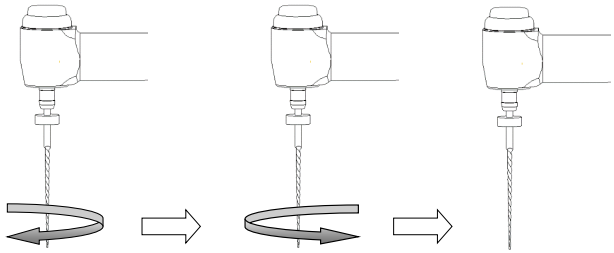


AUTO REVERSING mode is only effective continuous forward

3.3.2 AUTO REV AUTO STOP:

During operation, if the load exceeds a preset value, The motor reverse automatically and the base alarms .if the load lower the preset value, The motor stops.

Push the handpiece button twice to restart the handpiece.



3.3.3 AUTO REVERSE OFF

If the load lower the preset value, The motor stops.

Push the handpiece button twice to restart the handpiece.

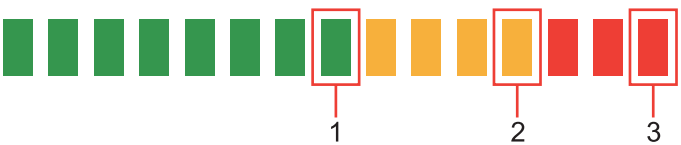
3.4 The display of the torque

Instructions

a)when it shows location 1 in the picture, The current load is 50% of the preset load.

b) when it shows location 2 in the picture, The current load is 80% of the preset load.

c) when it shows location 2 in the picture, The current load is 100% of the preset load and the motor stops.



3.5 File choosing system

Touch the SYSTEM button to select the different system.Touch the FILE button to select the different type of file from the system.

3.6 Changing the speed and torque

When desired continuous rotary file is selected,press SPEED key to select the desired speed setting.(Speed range: 100-2500rpm)

Press the TORQUE key to select the desired torque setting.(Torque

range: 0.4-5.0Ncm)

3.7 User-defined system

PROGRAM Mode: 8 sets of User-defined continuous rotary system speed and torque parameters can be set, and the user defined file system number (File system number: 1-8) can be switched by the button.

Safety Glide Path Mode: 3 sets of User-defined Safety Glide Path system speed, torque, forward angle and reverse angle parameters can be set. In the Safety Glide Path mode, press the SET button to switch between the forward and reverse angles. Press the ANGLE "+"button to increase the angle, press the ANGLE "-" button to decrease the angle. The adjusting range of angle is 20°-400°, with 10 ° interval for each adjustment.

The adjusting range of speed is 100-500rpm, the adjusting range of torque is 2.0-5.0Ncm. (File System No.: 1-3)

3.8 Calibration

This function is to decrease fluctuation in the rotation speed of the motor handpiece and the difference in torque by the contra-angle.

Calibration is recommended when using a new/other contra-angle or after an extended period of operation, as the running properties can change with usage, cleaning and sterilization.

a. Install the contra-angle to the motor handpiece.

b. Touch the "En-Ap" button to select the Motor alone mode.

c. Touch the "SET" button for more than 1 seconds to enter setting interface.

d. Touch the "SYSTEM" button to select "Contra-angle Calibration" , then touch the "En-Ap" button to enter the calibration.

e. Power on the motor handpiece to start calibration.

f. The screen display "Calibration Successed", then the display return to its original state.

3.9 Battery charging

3.9.1 Base charging

The base has a built-in energy storage lithium battery.

When the battery power sign  display on the base screen, please do not continue to use, and immediately connect the power adapter plug to the power socket of the base. When charging, the screen display panel power icon will scroll display, when the battery power sign no longer scroll display, indicating that the battery was fully charged.

After charging, pull out the power adapter.

3.9.2 Motor handpiece charging

The motor handpiece has a built-in energy storage lithium battery and is equipped with wireless inductive charging.

When the base is in the power-on state, put the motor handpiece correctly in the motor handpiece slot of the base, the wireless charging indicator on the base starts to flash, and the base can start wireless induction charging of the motor handpiece. After the motor handpiece is fully charged, the wireless charging indicator would be off.

⚠ WARNNING

a. Do not open the device ,or change the battery. That may cause a short-circuit.

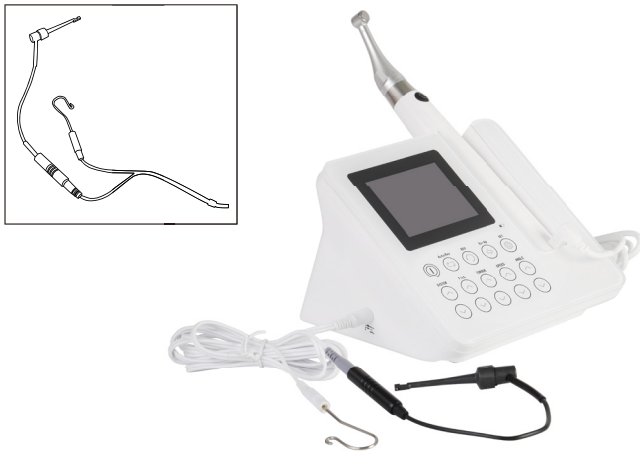
b. If the battery leakages, please stop using immediately, and deliver the machine to the authorized service center for repairing.

c. Please do not use other USB cable to charging, otherwise will cause damage to the machine.

4 Apex locator alone mode

4.1 Insert the measuring wire

4.1.1 Insert the plug of the measuring wire into the left side socket of the unit.(as the picture)



Picture 1

Attention:

a. Please be careful to use the device, keep it stable and avoid hit. Incautious use will lead to the damage or the failure of the machine.

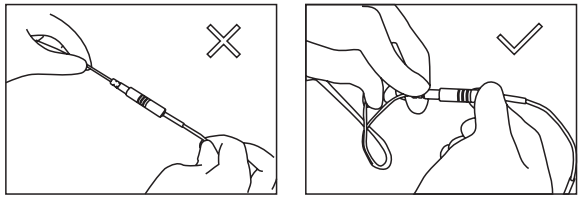
b. Measurement cannot be proceeded without the complete insertion of the plug.

c. Be sure not to hit the plug. Keep the device away.

4.1.2 Insert the file clip and lip hook respectively into the two sockets of the measuring wire. [Picture 1]

Attention:

Be sure not to pull the wire when inserting or pulling out the measuring wire and the file clip. [Picture 2(a)]



Picture 2(a) Picture 2(b)

Correct operation showed as in picture 2(b).

4.2 Test the wire connectting (Test before each use)

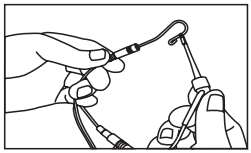
a. Press the power button .When the machine is starting up, you can press the En-Ap button. And you can enter into the apex measure

module.

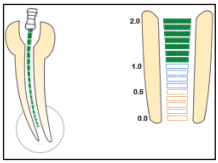
b. Make sure if the plug of the measuring wire is inserted into the socket correctly.

c) Make sure if the file clip and lip hook are connected well to the measuring wire.

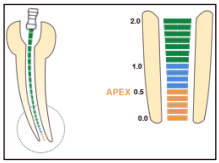
d) Make the lip hook touch the bent wire of the file clip [as showed in picture 3] to confirm all the instruction bars are displayed on the LCD screen and static display the word "OVER", otherwise , it means that the file clip or the measuring wire is damaged, should be replaced.



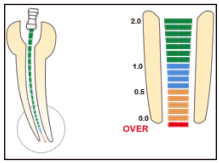
Picture 3



Picture 4(a)



Picture 4(b)



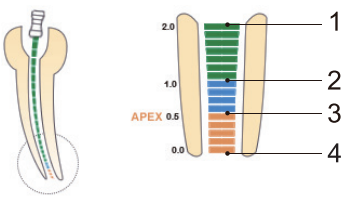
Picture 4(c)

4.3 Explanations on the interfaces displayed

a) The screen displays the front region of the apical foramen by instruction bars. Please refer to the green region as showed. [Picture 4(a)]

b) The file has gone to the position near by the apical foramen when it comes to the orange bars. [Picture 4(b)]

c) The file has exceeded the apical foramen when the red bars displayed.A continuous beep sound will be generated at the same time [Picture 4(c)]



1) Approx 2mm to apical foramen
2) Approx 1mm to apical foramen
3) Approx 0.5mm to apical foramen
4) Apex (apical foramen)

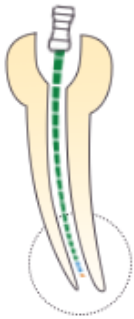
4.4 Testing the device by tester. (Two weeks test again)

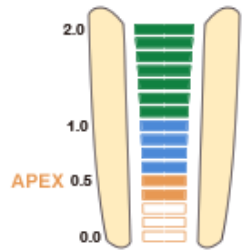
User can use the tester to check if the device work properly, specific operation is as follows:

a. Pulling out the measure wire and turn off the device.

b. Insert the tester

c. Turn on the device and press the En-Ap button. Then you can enter into apex measure module. If the indicating bar indicates within ±3 bars away from the dial 0.5, it means the machine is fine.





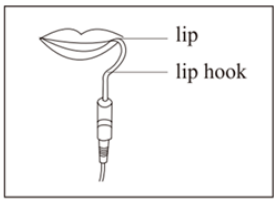
4.5 Operation instruction

4.5.1 Please let the measure wire insert the base. Then staring up the power button. Next press the “En-Ap” button. And you can enter into the apex mode.

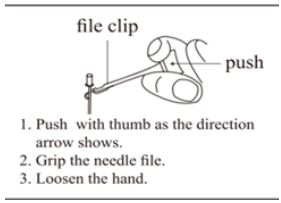
4.5.2 When the device is starting up, you can press the power button again. And the machine can turn off.

4.5.3 Hang the lip hook on the lip, make sure it contact the oral mucosa as a reference electrode [Picture 5].

4.5.4 Clip the file with file clip, approach to the apex, then there will be continuous alarm when the distance is less than 2mm [Picture 6].



Picture 5



Picture 6

Attention:

a. When grip the root canal with a needle file, please grip the upper

of the metal part(near the root canal at the needle handle). If you grip the lower part (bladeor moving part),it will wear the metal part of the file folder and the resin part. [Picture 7]

b. When measuring the length of root canal, please don't use the metal needle file.

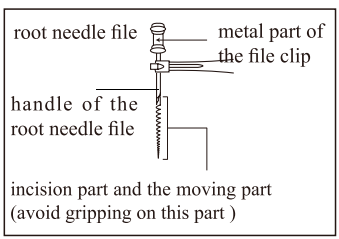
If you operate the device without the dentistry glove,it will cause leakage and the result of measurement will be inaccurate.Therefore, please use the resin needle file and remember don't touch the metal part with finger.

c. Please don't use the worn file clip, and it will make the result of measurement inaccurate.

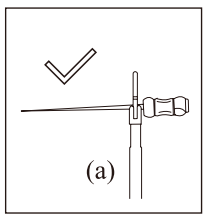
d. Please reference the [Picture 8(a)] to grip the needle file. If as [Picture 8(b)], it can't.

4.5.5 When the file reaches the apex, adjust the rubber piece set on the endo file to the reference point (incision edge or fossa edge), then pull out the endo file, measure the length between the top of the file and the rubber piece, and this is the working length of the tooth. It also can be used with the touch probe instead of file clip, when it is inconvenient to measure the back teeth. [Picture 9]

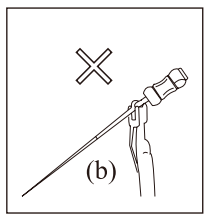
4.6 The components that touch body must be autoclaved under high temperature and high pressure. The shell and measuring wire should be cleaned by 75% alcohol.



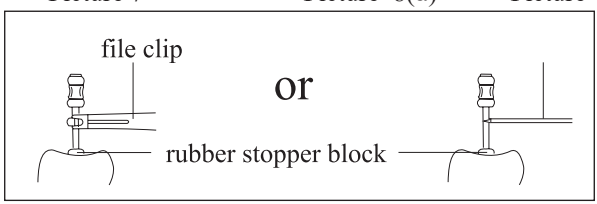
Picture 7



Picture 8(a)



Picture 8(b)



Picture 9

4.7 Cleaning and disinfection

4.7.1 You can use the alcohol or the soap clean the machine and the measuring wire.

4.7.2 Don’t use the chemical reagent.

4.7.3 The lip hook, file clip, touch probe and the contra-angle must be cleaned, disinfected before you start the treatment.

⚠ WARNNING

Measuring wire cannot be clean by high temperature and high pressure.

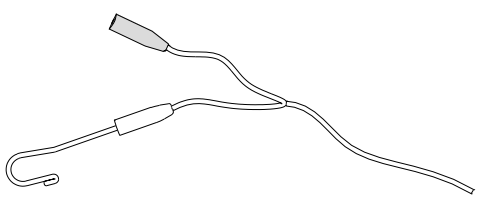
5 Combined length determination mode

For a combined length determination

5.1 Base installing

5.1.1 Insert the measuring wire into the left side female socket of the base.

5.1.2 Insert the lip hook into the white female socket of measuring wire.



5.1.3 Insert the USB wire’s male plug (big) into the right side USB’s female socket of the base.

5.2 Contra-angle & Motor handpiece installing

5.2.1 Put the protective silicon cover onto the contra-angle.

5.2.2 Install the contra-angle into the motor handpiece.

5.2.3 Install the file into the contra-angle, clamp the file.

5.2.4 Insert the USB wire's male plug (small) into the upper side female socket of the motor handpiece.

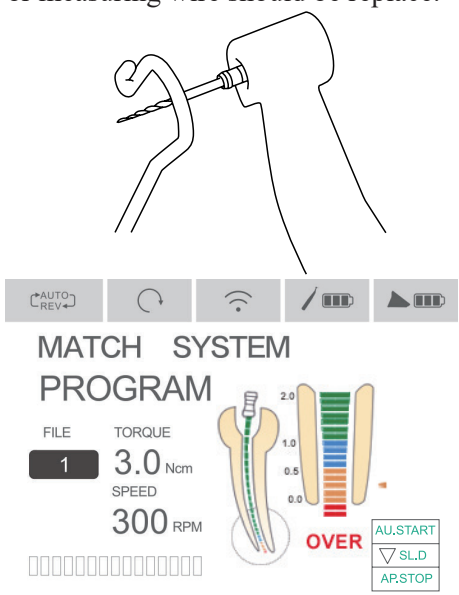
5.3 Base setting

5.3.1 Touch the "En-Ap" button to select the Combined length determination mode.

5.3.2 Select file system.

5.3.3 Combined length determination mode parameter setting (See 2.7).

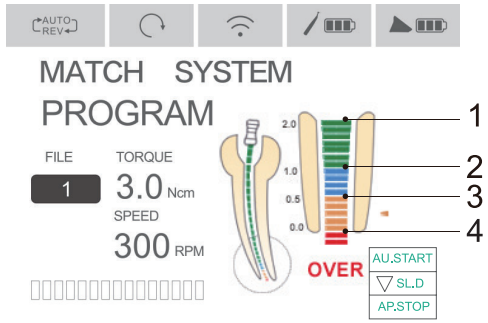
5.4 Connection testing(Test every time before using): touch the file with the lip hook, if it show "OVER", it works well, otherwise, the USB wire or measuring wire should be replace.



5.5 Hook the lip hook in the corner of the patient's mouth.

5.6 Power on the motor handpiece to operate.

5.7 The display of root hole magnified area display in combined length determination mode:



1) Approx 2mm to apical foramen
2) Approx 1mm to apical foramen
3) Approx 0.5mm to apical foramen
4) Apex (apical foramen)

⚠ WARNNING

In the combined length determination mode,If the running time reaches 1 minute, please allow the device to cool down for 1 minute and start again the motor handpiece.

6 Trouble shooting

When trouble is found, check the following points before contacting your distributor. If none of these are applicable or the trouble is not remedied even after action has been taken, the product may have failed. Contact your distributor.

Problem	Cause	Solution
After the motor handpiece is activated, if the wireless communication connection status indication is “  ”, the wireless connection between the motor handpiece and the base fails.	1. The wireless connection has failed 2. Handpiece far from the base.	1.Press the handpiece “ON/OFF” button more than 5 seconds to power off and power on again. 2. Place the handpiece near the base and power on.
The contra-angle cannot be calibrated.	The calibration procedure may have been interrupted by increased resistance in the contra-angle.	If calibration has been interrupted, calibrate the motor handpiece again to rule out the possibility of a motor fault. 2.Clean and lubricate the contra-angle. 3.Start the calibration procedure again.
Motor handpiece is getting hot.	Run time is too long with Safety Glide Path mode	Allow the device to cool down and start again the motor handpiece.
Continuous rotary file blocks in the root canal	Wrong file setting. Too much pressure on the instrument.	Change the rotational direction by pressing the REV key. Start the handpiece and pull out the file carefully.
Safety Glide Path file blocks in the root canal.	Too much pressure on the instrument. File not frequently clened.	Try to remove the file with a pair of pliers by pulling out and rotating the file gently clockwise.

7 Cleaning, Disinfection and Sterilization

7.1 Foreword

For hygiene and sanitary safety purposes, the contra-angle, the lip hook, the file clip,the protective silicon cover and the touch probe must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use, as well as all subsequent uses.

7.2 General recommendations

7.2.1 Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA and Health Canada approval) and in accordance with the DFU of the disinfecting solution manufacturer.

7.2.2 Do not place the contra-angle in a disinfectant solution or in an ultrasonic bath.

Do not use chloride detergent materials.

7.2.3 Do not use bleach or chloride disinfectant materials.

7.2.4 For your own safety, please wear personal protective equipment (gloves, glasses, mask).

7.2.5 The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments where applicable after sterility.

7.2.6 The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.

7.2.7 To sterilize the endodontic files, refer to the manufacturer's instructions for use.

7.2.8 The contra-angle needs to be lubricated after cleaning and disinfection, but before sterilization.

7.3 Cleaning and disinfection steps for the motor handpiece, the AC adapter and the base.

Before and After each use, all the objects that were in contact with infectious agents should be cleaned using towels impregnated with a disinfecting and detergent solution (a bactericidal, fungicidal and aldehyde free solution) approved by VAH/DGHM-listing, CE marking, FDA and Health Canada.

⚠ Warning: Do not sterilize the motor handpiece, the AC adapter and the base.

7.3.1 Pre-Op processing

Before each use, the handpiece, charger, and base must be cleaned and disinfected. The specific steps are as follows:

⚠ Warning: The handpiece, charger, and base cannot be cleaned and disinfected with automatic equipment. Manual cleaning and disinfection is required.

7.3.1.1 Manual cleaning steps:

1. Take out the handpiece, charger, and base on the workbench.

2. Wet the soft cloth completely with distilled water or deionized water, and then wipe all the surfaces of the components such as the handpiece, charger, base, etc. until the surface of the component is not stained.

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

4. Repeat the above steps at least 3 times.

Note:

a)Use distilled water or deionized water for cleaning at room temperature.

7.3.2.1 Manual disinfection steps:

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

2. Wipe all surfaces of headpiece, charger, base and other components with a wet soft cloth for at least 3 minutes.

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

Note:

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.

d) After cleaning and disinfecting the handpiece, you must install a disposable isolation sleeve before use and repeat steps 1, 2 and 3 to clean the disposable isolation sleeve(For detailed installation steps, see section 2.5).

7.3.2 Post-Op processing

After each use, clean and disinfect the handpiece, charger, and base within 30 minutes. The specific steps are as follows:

Tools: Nap-free soft cloth, tray

1. Remove the contra-angle from the handpiece, place it in a clean tray, and then remove the disposable isolation sleeve from the handpiece.

2. Soak the nap-free soft cloth with distilled water or deionized water, and then wipe all the surfaces of the components such as the handpiece, charger, base, etc. until the surface of the component is not stained.

3. Wet the dry soft cloth with 75% alcohol, and then wipe all surfaces of the handpiece, charger, base and other components for 3 minutes.

4. Put the handpiece, charger, base and other components back into the clean storage area.

Note:

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.

7.4 The cleaning, disinfection and sterilization of contra-angle,lip hook, file clip,protective silicon cover,touch probeare 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℃.

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 products is 250 times.

7.4.1 Initial processing

7.4.1.1 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.

7.4.1.2Post-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. Remove the products from the base, and rinse away the dirt on the surface of handpiece with pure water (or distilled water/deionized water);

2. Dry the products with a clean, soft cloth and place it in a clean tray.

Notes:

a) The water used here must be pure water, distilled water or deionized water.

7.4.2 Preparation before cleaning

Steps:

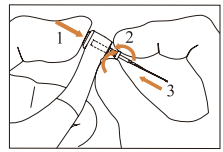
Tools: tray, soft brush, clean and dry soft cloth.

1. Remove the shanks/files.

2. Remove the file clip, isolation sleeve,Contra-angle and connecting wire from the handpiece in sequence, and then put them into a clean tray;

3. Use a clean soft brush to carefully brush lip hook, file clip,protective silicon cover,touch probe, head and back cover of the contra-angle until the dirt on surface is not visible. Then use soft cloth to dry the products and put them into a clean tray. The cleaning agent can be pure water, distilled water or deionized water.

Disassembling steps



(a)

(b)

(c)

a) Press the push-button and pull out the shank/file.

b) When removing the protective silicon cover, pull it straight out slowly.

c) When inserting and removing the contra-angle, turn thehandpiece power off beforehand.

7.4.3 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.

7.4.3.1Automated cleaning

•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.

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".

Notes:

a) 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.

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

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

7.4.4 Disinfection

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

7.4.4.1Automated disinfection-Washer-disinfector

·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 neededonly 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 theproductfrom the washer-disinfector, inspect (refer to section "Inspection and Maintenance") and packaging (refer to chapter "Packaging"). Dry the productrepeatedly if necessary (refer to section "Drying").

Notes:

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

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

c) Cleaning: (c1) 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. (c2) In the washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it is difficult to remove. (c3) The solution used can be pure water, distilled water, deionized water or multi-enzyme

solution, etc., and only freshly prepared solutions can be used. (c4) During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed. The used cleaner is neodisher MediZym (Dr. Weigert).

d) Disinfection: (d1) Direct use after disinfection: temperature ≥ 90 ° C, time ≥ 5 min or A0 ≥ 3000;

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

(d2) For the disinfection here,the temperature is 93 ° C, the time is 2.5 min, and A0>3000

e) 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).

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

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

h) Regularly repair and inspect the disinfector.

7.4.5 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 productdrying is completed.

2. It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80℃~120℃ and the time should be 15~40 minutes.

Notes:

a) The drying of product must be performed in a clean place.

b) The drying temperature should not exceed 138 °C;

c) The equipment used should be inspected and maintained regularly.

7.4.6 Inspection and maintenance

7.4.6.1 Inspection

In this chapter, we only check the appearance of the product.

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.

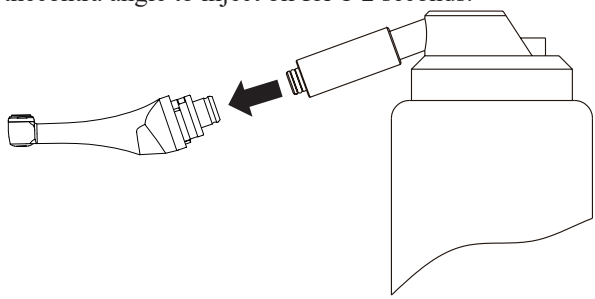
3. Check the product. If the accessories are found to be damaged, please replace it before use. And the new accessories for replacement must be cleaned, disinfected and dried.

4. If the service time (number of times) of the product reaches the specified service life (number of times), please replace it in time.

7.4.6.2Maintenance

Oil lubrication of sterilized and dried products.

The nozzle of cleaning lubricant is aligned with the air intake hole at the end of thecontra angle to inject oil for 1-2 seconds.



7.4.7 Packaging

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

Notes:

a) The package used conforms to ISO 11607;

b) It can withstand high temperature of 138 °C and has sufficient steam permeability;

c) The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants;

d) Avoid contact with parts of different metals when packaging.

7.4.8 Sterilization

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

·The steam sterilizer complies with EN13060 or is certified according to EN 285 to comply with EN ISO 17665;

·The highest sterilization temperature is 138 ° C;

·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.

·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.

Notes:

a) Only products that have been effectively cleaned and disinfected are allowed to be sterilized;

b) Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.

c) Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;

d) 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.

7.4.9 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.

Notes:

a) The storage environment should be clean and must be disinfected regularly;

b) Product storage must be batched and marked and recorded.

7.4.10 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.

8 Storage, maintenance and transportation

8.1 Storage

8.1.1 This equipment should be stored in a room where the relative humidity is 10% ~ 93%, atmospheric pressure is 70kPa to106kPa, and the temperature is -20°C ~ +55°C.

8.1.2 Avoid the storage in a too hot condition. High temperature will shorten the life of electronic components, damage battery, reshape or melt some plastic.

8.1.3 Avoid the storage in a too cold condition. Otherwise, when the temperature of the equipment increases to a normal level, there will be dew that will possibly damage PCB board.

8.2 Maintenance

8.2.1 This device do not include accessories for repair usage, the repair should be carried out by authorized person or authorized after service center.

8.2.2 Keep the equipment in a dry storage condition.

8.2.3 Do not throw, beat or shock the equipment.

8.2.4 Do not smear the equipment with pigments.

8.3 Transportation

8.3.1 Excessive impact and shake should be prevented in transportation. Lay it carefully and lightly and don't invert it.

8.3.2 Don't put it together with dangerous goods during transportation.

8.3.3 Avoid solarization and getting wet in rain and snow during transportation.

9 Environmental protection

Please dispose according to the local laws.

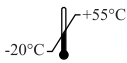
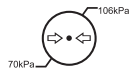
10 After service

From the date this equipment has been sold, based on the warranty card, we will repair this equipment free of charge if there are quality problems. Please refer to the warranty card for the warranty period.

11 European authorized representative

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

12 Symbol instruction

	Date of manufacture	SN	serial number
	Type B applied part		Manufacturer
IPX0	Ordinary equipment		Class II equipment
	Used indoor only		Recovery
	Handle with care		Keep dry
	Power ON / OFF		Temperature limitation
	Humidity limitation		Atmospheric pressure for storage
	Follow Instructions for Use	CE 0197	CE marked product
	Appliance compliance WEEE directive		
EC REP	Authorised Representative in the EUROPEAN COMMUNITY		

13 Statement

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD. The industrial design, inner structure, etc, have claimed for several patents by WOODPECKER, any copy or fake product must undertake legal responsibilities.

14 EMC-Declaration of conformity

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 Endo Radar Pro is intended for use in the electromagnetic environment specified below. The customer or the user of the model Endo Radar Pro should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model Endo Radar Pro 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 Endo Radar Pro 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 Endo Radar Pro is intended for use in the electromagnetic environment specified below. The customer or the user of the model Endo Radar Pro 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 IEC 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.
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 Endo Radar Pro requires continued operation during power mains interruptions, it is recommended that the models Endo Radar Pro 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 Endo Radar Pro is intended for use in.the electromagnetic environment specified below. The customer or the user of the models Endo Radar Pro should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
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 Endo Radar Pro, 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 Endo Radar Pro is used exceeds the applicable RF compliance level above, the model Endo Radar Pro should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model Endo Radar Pro.
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 Endo Radar Pro

Recommended separation distances between portable and mobile RF communications equipment and the model Endo Radar Pro			
The model Endo Radar Pro is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model Endo Radar Pro can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model Endo Radar Pro 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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for more information

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