Endo Radar Endo Motor

INSTRUCTION MANUAL

Please read this manual before operating



CE 0197

www.glwoodpecker.com

GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.

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⚠ Note: the description on reciprocating mode is only applicable for the device that has reciprocating mode.

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 Motor products are mainly used in dental root canal preparation, is used for each model pulpitis and pulp necrosis and various root tooth root canal treatment of periarthritis of important equipment.

The equipment has the following characteristic:

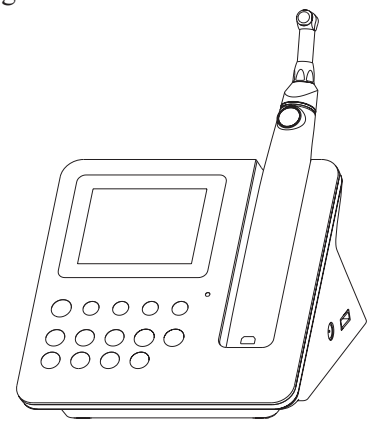
a) Integrates the function of root canal length measurement, can the measurement of single root canal, root canal preparation, also can undertake root canal measurement and preparation at the same time.

b) The precise feedback technology, are sensitive to control the motor output torque, in order to protect the root canal file

c) Cordless handle , operating freely.

d) Large capacity battery equipped with wireless charging system, Ensure long enough use time.

1.3 Product configuration



1.3.1 Structure

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

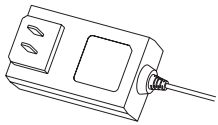
1.3.2 Product accessories



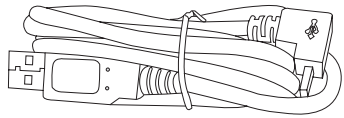
Motor handpiece



Contra-angle



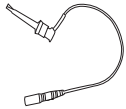
Power adapter



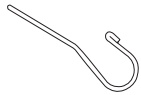
USB wire



Measuring wire



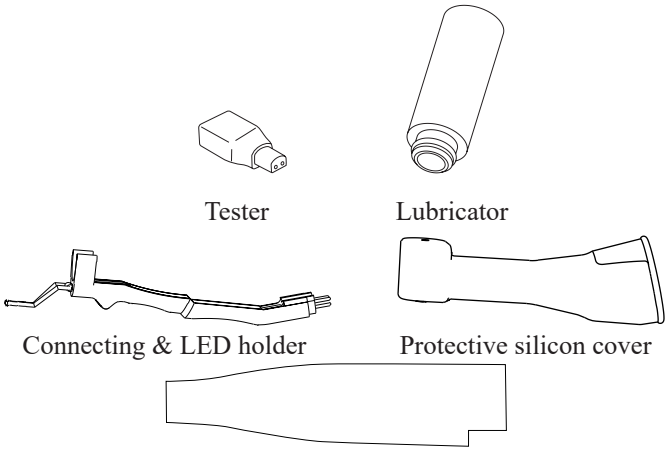
File clip



Lip hook



Touch probe



1.4 Indications for use

Endo Radar is a cordless motor handpiece with torque and speed control used for driving files in both reciprocating and continuous rotary mode during an endodontic procedure.

1.5 Range of application

1.5.1 This product is suitable for various pulpitis and pulp necrosis and various types of periarthritis of root tooth root canal preparation.

1.5.2 The product is only suitable for hospitals, clinics, and must be used by a qualified dentist at the same time.

1.5.3 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.

1.5.4 The classification of the device

Type of protection against electric shock: Class II equipment.

Base and motor handpiece : Internal power device.

Applied part: file clip, lip hook, touch probe, contra-angle.

Type B applied part.

Device not suitable for being used in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

1.5.5 The main technical parameters

Battery: Base 2600mAh, 11.1V

Motor handpiece 750mAh, 3.6V
Power adapter: ~100V-240V 0.8A 50Hz/60Hz
Torque range : 6mNm~40mNm(0.6Ncm~4Ncm)
Rotate speed : 100rpm~650rpm

1.5.6 Working environment
Environment temperature: +5℃~+40℃
Relative humidity: 30%~75%
Atmosphere pressure: 70kPa~106kPa

1.6 Warnings ⚠

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

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

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

1.6.4 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.

1.6.5 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.

1.6.6 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.

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

1.6.8 If the handpiece works for 10 minutes continnously, the temperature of the surface of the handpiece and contra-angle may reach 56℃.

Contra-angle

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

1.6.10 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.

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

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

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

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

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

Root canal instruments

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

1.6.17 Never use continuous rotary instruments in reciprocating mode.

1.6.18 Never use reciprocating instruments in rotary mode.

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

1.6.20 The device cannot be used on the patient during maintenance.

1.6.21 Not to position equipment to make it difficult to operate the disconnection device.

2 Installation and setting



2.1 Please remove the “Switch label” before first time usage.

2.2 Through the tail restart hole can be directly cut off the base power supply circuit, when there was a crash phenomenon such as the base, can use a needle inserted with hole, when the base shutdown can be pulled out, then open the base again, then to restart the base operation.

2.3 Installing and removing the contra-angle

2.3.1 Installing

Position the projecting tip of the contra-angle opposite the motor handpiece slot, push the projecting tip of the contra-angle into the slot without forcing until it “clicks in”.

The contra-angle can be install at 6 adjustable head positions.



2.3.2 Removing

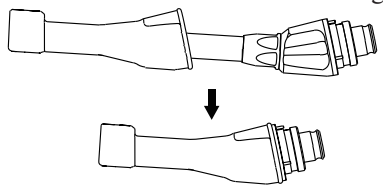
When removing the contra-angle, pull it straight out.

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

2.4 Installing and removing the protective silicon cover

2.4.1 Installing

Put the protective silicon cover onto the contra-angle.



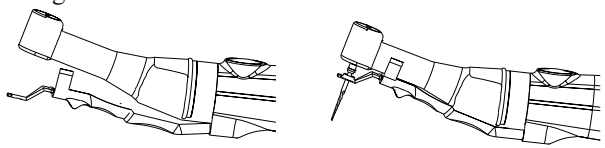
2.4.2 Removing

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

2.5 Installing and removing the Connecting & LED holder

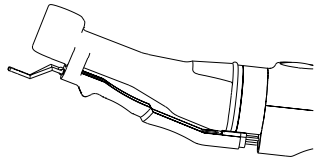
2.5.1 Installing

Install the Connecting & LED holder into the motor handpiece, clamp the contra-angle and file.



2.5.2 Removing

Sliding it in the direction of the socket of motor handpiece and then removed with contra-angle. Otherwise it will be damaged.



2.6 Inserting and removing the file

2.6.1 Inserting

Insert the file into the chuck until it stops.

2.6.2 Removing

Press the push-button and pull out the file.

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

2.7 Installation and removal of disposable insulation sleeves

2.7.1 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.

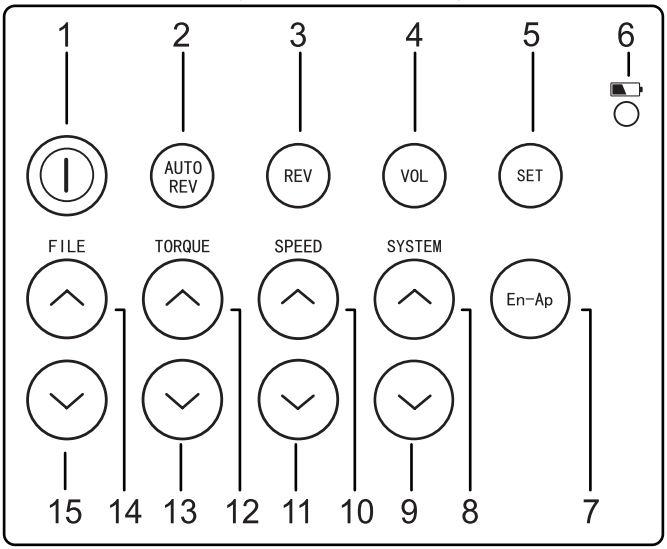
After installing the disposable isolation sleeve, wrap the barrier film around the handpiece surface. After that, clean and disinfect the surface of the handpiece. Refer to Chapter 7.3 for cleaning and disinfection procedures.

2.7.2 Removing

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

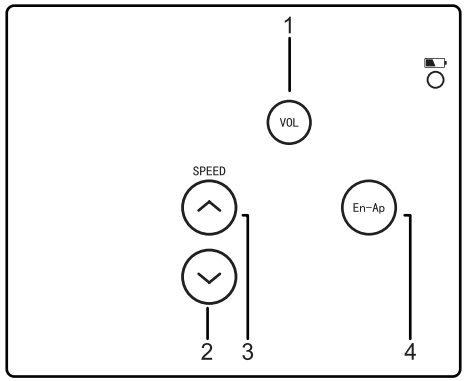
⚠ Warming: Isolation sleeves are not reusable.

2.8 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 VOL Adjust the volume
5 SET Parameters calibration
6 LED If continuously with green LED, it means wireless charging
7 EN-Ap The mode switch
8 SYSTEM+ Select the File system
9 SYSTEM- Select the File system
10 SPEED+ Increase the motor rotation speed
11 SPEED- Decrease the motor rotation speed
12 TORQUE+ Increase the torque
13 TORQUE- Decrease the torque
14 FILE+ Positive selection key
15 FILE- Negative selection key

2.9 Touch button of base(Apex locator alone mode)

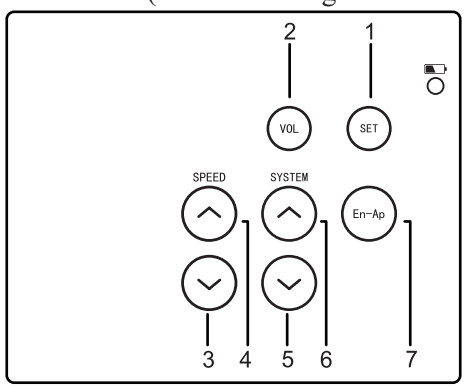


1 VOL Adjust the volume

2 3 SPEED +- Set the apical point, it can be set anywhere from 10 to apex(00)

4 En-Ap The mode switch

2.10 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 VOL Adjust the volume

3 4 SPEED +- Set the apical point, it can be set anywhere from 10 to apex(00)

5 6 SYSTEM+- Select “AP.REV/AP.STOP”, “AUTO”,

▽SL.D.”

7 En-Ap Select “AP.REV” or “AP.STOP”, enable or disable “↻AUTO”, enable or disable “▽SL.D.”

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.

Enable auto start

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

↻~~AUTO~~ 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

File Library

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

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

2.10.3 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.

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

2.10.5 Never use reciprocating files in continuous rotary mode. Never use rotating files in reciprocating mode.

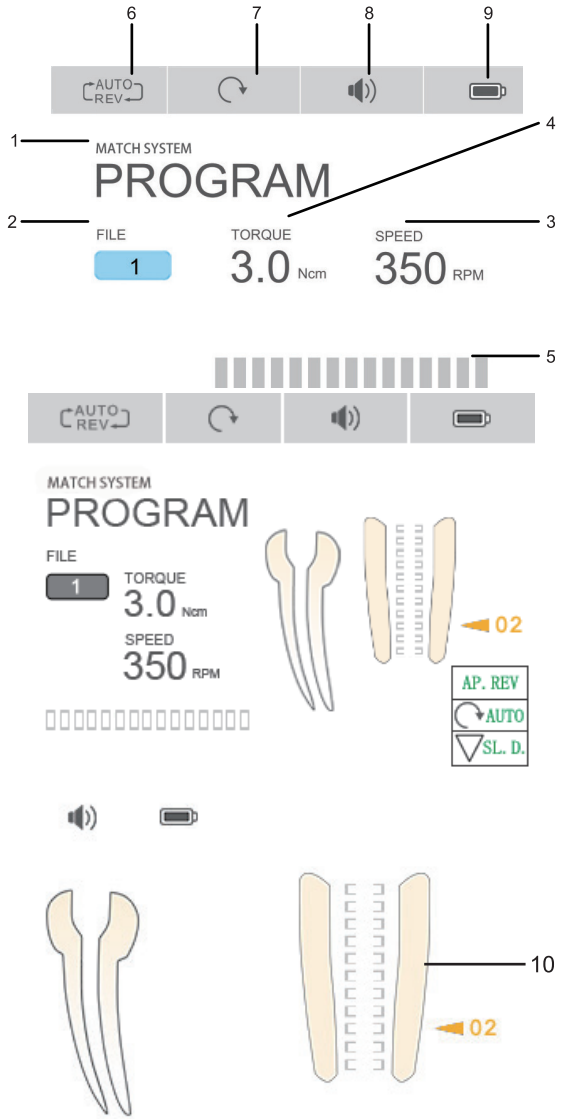
2.10.6 Reciprocating mode

a.Speed and torque cannot be adjusted at WAVE ONE/RECIPROC system

b. Three reciprocating angles are available at RECIPROCATING system.

c. If the maximum torque is achieved , the motor will auto reverse. If this occurs, remove the file from the root canal and clean the flutes.

2.11 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

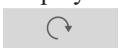


AUTO STOP

AUTO REVERSE OFF

7 ROTATIONAL DIRECTION

Display the rotation direction of device


clockwise continuously rotating


counterclockwise continuously rotating


Reciprocating motion mode

8 BATTERY

Display the remaining power of base:


Full state of charge


15%-80% of electricity


Prompt charging is needed due to the very low power

9 VOLUME

Display the volume of main unit


high volume

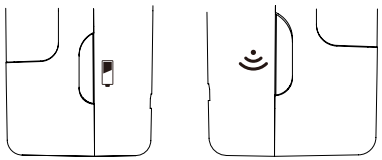
low volume

on silent mode

10 APEX BAR

Display apex bar

2.12 Introduction of LED and button on handpiece



2.12.1 The state of battery:

a) more than 30% electricity remained

b) less than 30% electricity remained, the battery need to be charged

2.12.2 Wireless connecting state:

a) (green) wireless communication connected

b) (light off)Disconnected and long press the button, to restart the handpiece

2.13 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.

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 Handpiece

3.2.1 When the handpiece is off, press the ON / OFF button, if the LED is green , indicating that the handpiece is ready for work.

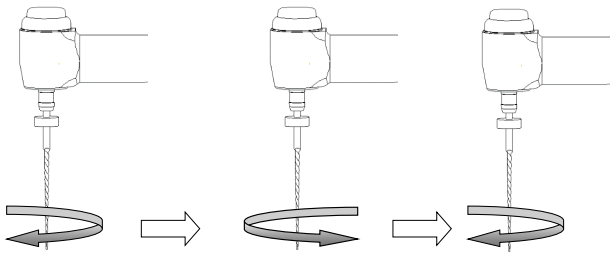
3.2.2 The handpiece is ready for work, if the LED is green, the handpiece will work as the set program.

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.

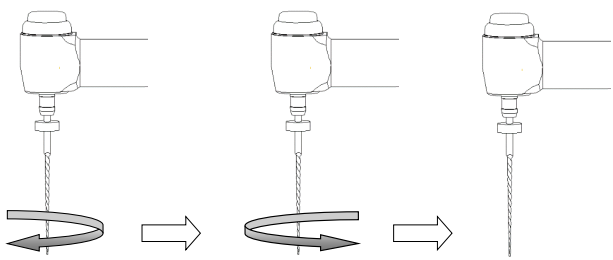


AUTO REVERSING mode is only effective continuous forward

3.3.2 AUTO 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.

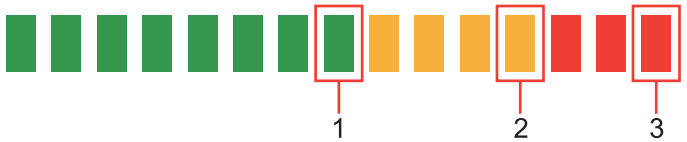
3.4 The display of the torque

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 User defined system

The device is delivered with 8 programs with default values of torque and speed.

Specific operation as follows

a.Push SYSTEM button to change to PROGRAM mode

b.Push FILE button to the subsystem ,which is not be setted

c.Push SPEED button and TOPQUE button to set user's parameters

3.7 Changing the speed and torque

When desired continuous rotary file is selected,press SPEED key to select the desired speed setting.

Press the TORQUE key to select the desired torque setting.

The speed and torque cannot changed for reciprocating systems.

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 battery,when the LED twinkle and turn red , please do not use anymore.then connect the charger

3.9.2 Handpiece charging

The handpiece has wired charging and wireless charging function.

a. Wireless charging: during the main unit is working, put the handpiece in to the main unit, the LED will be turn light.

b. Wired charging : connect the USBwire between the handpiece and the main unit, when it needs to be recharged during operation (as the picture)



⚠ 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.

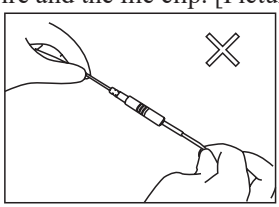
b. Measurement cannot be proceeded without the complete insertion of the plug.

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

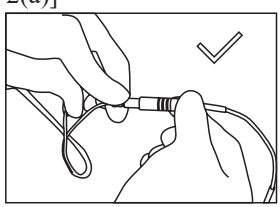
4.1.2 Insert the file clip and lip hook respectively into the two sockets of the measuring wire. [Picture 1]

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).

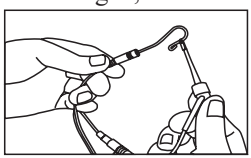
4.2 Test the wire connectting (Test before each use)

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.

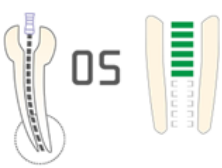
b. Make sure if the plug of the measuring wire is inserted into the socket correctly.

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

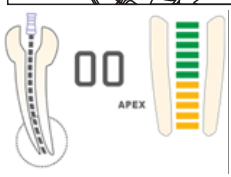
d) Make the lip hook touch the bent wire of the file clip [as showed in picture 3] to confirm all the instruction bars are displayed on the LCD screen and static display the digital '-3', otherwise , it means that the file clip or the measuring wire is damaged, should be replaced.



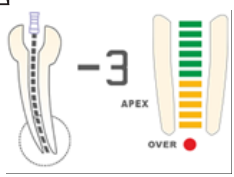
Picture 3



Picture 4(a)



Picture 4(b)



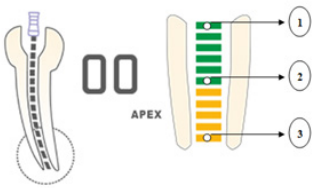
Picture 4(c)

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 0.6mm to apical foramen
3) Apex(apical foramen)

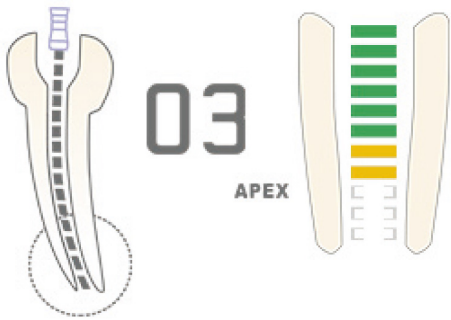
4.4 Testing the device by tester. (Two weeks test again)

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. The screen shows “01” “02”or ”03” or”04”. It means the machine is fine.



4.5 Operation instruction

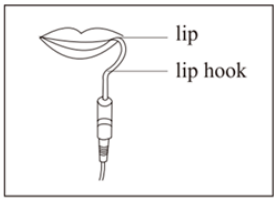
4.5.1 Please let the measure wire insert the base. Then staring up the power button. Next press the “En-Ap” button. And you can enter into the apex mode.

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

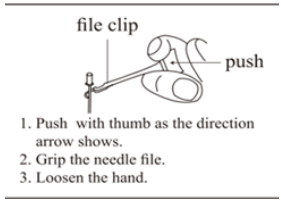
4.5.3 If you press the“ VOL” button, you can turn up the voice.

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

4.5.5 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.

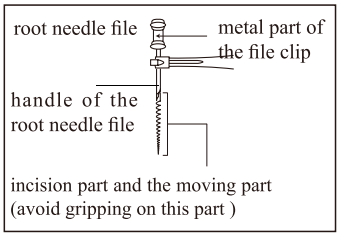
If you operate the device without the dentistry glove,it will cause leakage and the result of measurement will be inaccurate.Therefore, please use the resin needle file and remember don't touch the metal part with finger.

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

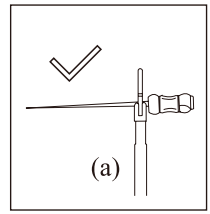
d. Please reference the [Picture 8(a)] to grip the needle file. If as [Picture 8(b)], it can't.

4.5.6 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]

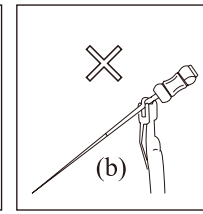
4.6 The components that touch body must be autoclaved under high temperature and high pressure. The shell and measuring wire should be cleaned by 75% alcohol.



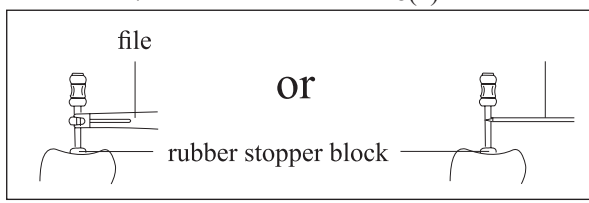
Picture 7



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 hip hook,filp 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

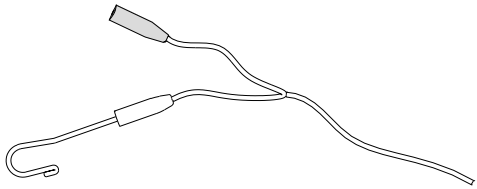


For a combined length determination

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 Connecting & LED holder into the motor handpiece, clamp the contra-angle.

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

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

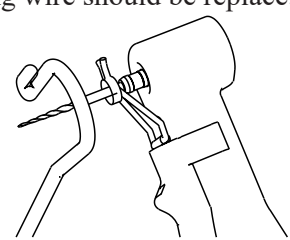
5.3 Base setting

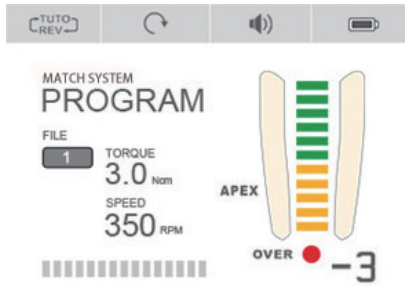
5.3.1 Touch the "En-Ap" button to select the Combined length determination mode.

5.3.2 Select file system.

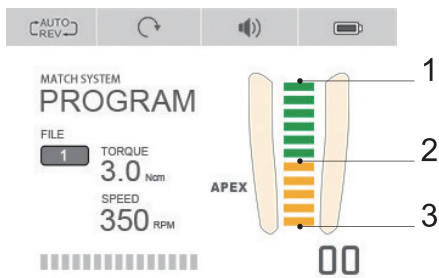
5.3.3 Combined length determination mode parameter setting (See 2.9).

5.4 Connection testing(Test every time before using): touch the file with the lip hook, if it show"-3", 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 0.6mm to apical foramen
3 Apex(apical foramen)

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
The handpiece cannot be connected to the base	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 reciprocating 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.
Reciprocating 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 connecting & LED holder, 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.

7.3.1.2 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 2.7).

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 connecting & LED holder,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:

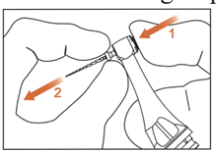
Tools: tray, soft brush, clean and dry soft cloth.

1. Remove the shanks/files.

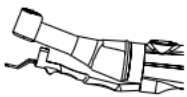
2. Remove the file clip, isolation sleeve,Contra-angle and connecting wire from the handpiece in sequence, and then put them into a clean tray;

3. Use a clean soft brush to carefully brush connecting & LED holder, 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)



(d)

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

b) Sliding it in the direction of the socket of handpiece and then removed with contra-angle. Otherwise it will be damaged.

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

d) 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.

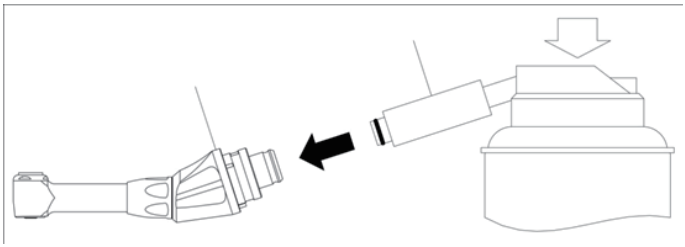
3. Check the product. If the accessories are found to be damaged, please replace it before use. And the new accessories for replacement must be cleaned, disinfected and dried.

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.

8.2.5 Calibration is recommended when using a new/other contra-angle or after an extend period of operation(At least once a month), as the running properties can change with usage, cleaning and sterilization.

8.2.6 Replace the battery if it seems to be running out of power sooner than it should. Please use the original lithium battery.

a) Turn the motor handpiece power off.

b) Use tweezers etc. to open the rubber cover and then remove the screw.

c) Remove the battery cover.

d) Remove the old battery and disconnect the connector.

e) Connect the new battery and put it in the motor handpiece.

f) Replace the cover and its screw.

It is recommended to contact local distributors or manufacturer to replace the battery.

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 Symbol instruction

CE 0197	CE marked product	SN	serial number
	Date of manufacture		Manufacturer
	Type B applied part		Class II equipment
IPX0	Ordinary equipment		Recovery
	Used indoor only		Keep dry
	Handle with care		Sound adjustment
	Power on / off	+55℃ -20℃	Temperature limitation
93% 10%	Humidity limitation	106kPa 70kPa	Atmospheric pressure for storage



Appliance compliance WEEE directive



Follow Instructions for Use

EC REP Authorised Representative in the EUROPEAN COMMUNITY

12 European authorized representative

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

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 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 Endo Radar is intended for use in the electromagnetic environment specified below. The customer or the user of the model Endo Radar 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 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 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 is intended for use in the electromagnetic environment specified below. The customer or the user of the model Endo Radar 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 requires continued operation during power mains interruptions, it is recommended that the models Endo Radar 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 is intended for use in.the electromagnetic environment specified below. The customer or the user of the models Endo Radar 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, 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 is used exceeds the applicable RF compliance level above, the model Endo Radar 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. 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

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

Guilin Woodpecker Medical Instrument Co., Ltd.
Information Industrial Park, Guilin National High-Tech
Zone, Guilin, Guangxi, 541004 P. R. China
Sales Dept.: +86-773-5873196
Http://www.glwoodpecker.com
E-mail: woodpecker@glwoodpecker.com

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

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