EDGEENDO®

EDGEAPEX™

Apex locator Instruction Manual

Contents

1 Introduction

1.1 Foreword

Guilin Woodpecker Medical Instrument Co., Ltd. is a professional manufacturer in researching, developing and producing dental equipment which has a wholesome quality assurance system.

Products include ultrasonic scaler, curing light, apex locator and ultrasurgery, etc.

1.2 Description of the device

Apex locator is a supporting equipment of endodontic treatment, through the measurement of the length of apical teeth, helping dentists to finish the endodontic treatment.

Features of the device:

a) Equipped with clear bright LCD, clear image and different colors indicate the trajectory of the file clearly.

b) Based on advanced multiple frequency network impedance measurement technology and automatic calibrating ensures the measurements are accurate.

c) The File clip, Lip hook , Touch probe and Pulp tester probe can be autoclaved under high temperature and high pressure. Avoiding cross infection effectively.

d) Battery is rechargeable, unnecessary to replace batteries repeatedly.

1.3 Model and dimensions

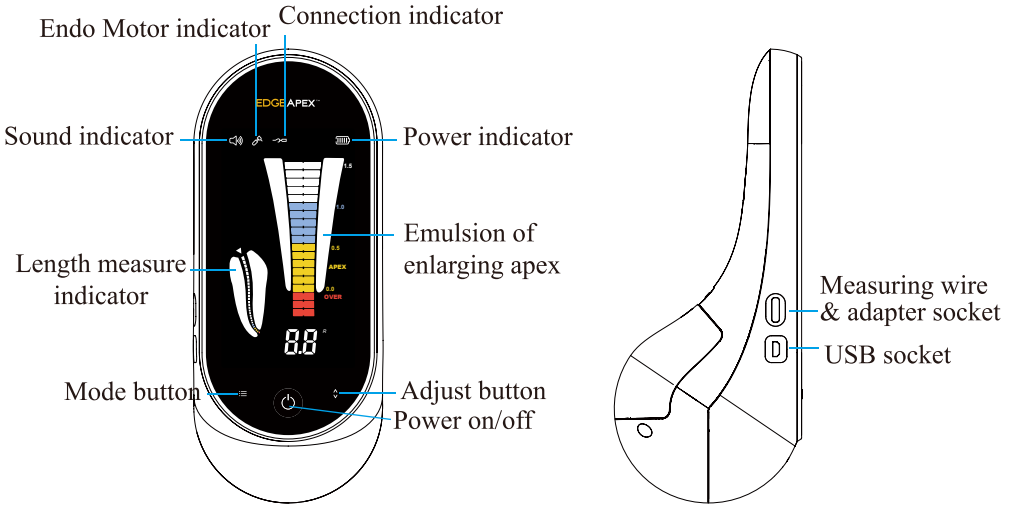
1.3.1 Dimensions: 101mm (length) × 101mm (width) × 175.5mm (height)

1.3.2 Weight: 685g

1.3.3 Model: EDGEAPEX

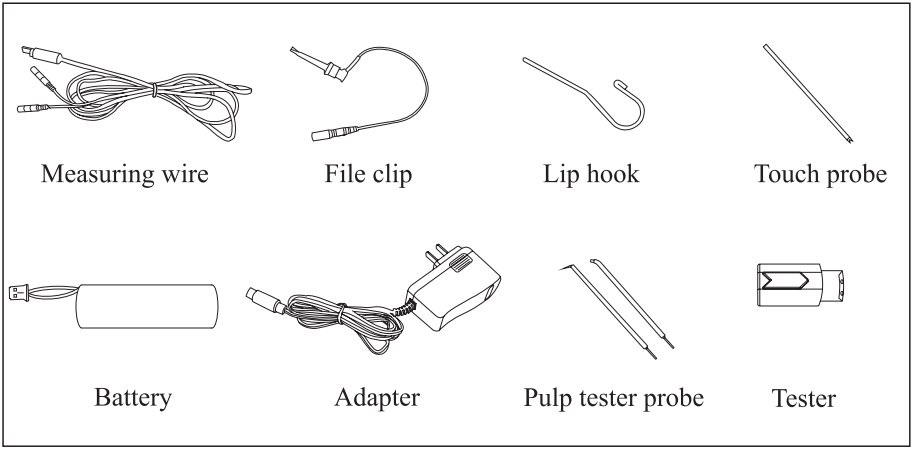
1.4 Components

1.4.1 Picture of the main unit. (Picture 1)



Picture 1

1.4.2 Pictures of the main accessories (Picture 2)



Picture 2

1.5 Structure

Is composed of main unit, measuring wire, lip hooks, file clip, touch probe, adapter, Pulp tester probe, etc..

1.6 Intended use

This equipment applies to the measurements below:

1.6.1 Used to help determine the working length of various types of dental root canals during root canal treatment.

1.6.2 Used to test pulp vitality.

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

1.7 Contraindication

We do not advise the use of the model on patients fitted with pacemakers (or other electrical equipment) or on those patients who are advised not to use the electric equipment (like electric shaver, electric blower) for safety reasons.

1.8 The classification of the device

1.8.1 Type of protection against electric shock: Class II equipment

1.8.2 Degree of protection against electric shock: Type B applied part

1.8.3 Degree of protection against water shock: Ordinary equipment (IPX0)

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

1.8.5 Operation mode: Continous operation

1.8.6 Applied part: Touch probe, Lip hook, File clip, Pulp tester probe

1.9 The main technical specifications

1.9.1 Battery: 3.7V/2000mAh (Model: 18500)

1.9.2 Adapter (Model: DJ-0500100-A5/ADS-6AM-06N 05050):

Input: ~100V-240V 50Hz/60Hz 0.4A MAX

Output: DC5V/1A

1.9.3 Consumption power: ≤0.5W

1.9.4 Screen: 3.8'' LCD

1.9.5 Buzzer alert: The buzzer will alert when the endo file is close to the apex.

1.9.6 Release software version: V1

1.9.7 Operation condition

a) Environment temperature: +5℃～+40℃

b) Relative humidity: 30% ~75%.

c) Atmosphere pressure: 70kPa～106kPa

2 Notice of installing and using the device

2.1 Please read the instruction manual carefully before the operation.

2.2 When the indicating bar reaches the position of the dial 0.0, and there is "APEX" on screen, the endo file has reached the anatomical apical foramen. To guarantee the safety, the work length is clinically obtained by subtracting 0.5-1mm from the length measured by the Apex locator.

2.3 The scales 0.5 and 1.0 on the screen dial do not indicate that the distance to the apex is 0.5 mm or 1.0 mm. It just reminds the operator that the file is getting close to or away from the apical foramen.

2.4 If the screen bar graph suddenly makes a large movement or immediate display ‘OVER’ in the upper part of the canal, continue slightly towards the apex so the signal returns to normal.

2.5 In order to prevent leakage or interference between the root canal and resulting in inaccurate measurements, dry the access cavity with a cotton pellet or air-blower before each use.

2.6 Use a file size adapted to the root canal diameter. The selected file is too small for a large root canal might cause the screen digital display is not steady during the procedure.

2.7 In order to confirm the file clip and measuring wire makes good contact, test the wire connecting before each use(See 3.1.2).

2.8 The file clip, lip hook and touch probe, Pulp tester probe are reusable. Please make sure they are autoclaved under high pressure and high temperature before each operation. The endo files should not be used more than 3 times.

2.9 The batteries must be taken out for storage when the device is not used for a

long time.

2.10 Please recharge the battery when low battery indicator flashes.

2.11 Please use original components, the components made by other companies may cause inaccurate measurement or un-measurable.

2.12 Avoid the connection between the outside and inside liquid of endodontic during measuring in order to avoid the measuring difference.

2.13 Keep endo file and file clip away from any other metal or instruments.

2.14 To ensure that short circuits do not impair the measurements, be particularly careful with patients fitted with metal crowns or bridges. Please confirm the wetness of the endo to ensure the reliability of the measuring. If it is confirmed that the endo file hasn't reached the apex yet the data showed on the apex locator is too low, please check whether the endo is too dry and confirm it with X-ray.

2.15 This device have electromagnetic interference, the patient or doctor who with a heart pace maker are forbidden to use this device and the device is susceptible to other device which produces electromagnetic interference. Dentists should be cautious about operation under such environment.

2.16 The guarantee is valid for normal usage conditions. Any disassembly will render the guarantee void, the professionals of Woodpecker company will offer the repair service during guarantee period.

2.17 Any modification will render the guarantee void and may cause harm to the patient.

2.18 Only the original adapter and lithium battery could be used to this machine.

2.19 Not to position equipment to make it diffcult to operate the disconnection device.

2.20 The adapter must be connected to an appropriate power source in the instructions.

2.21 Error in replacing lithium batteries can lead to unacceptable risks, so use the original lithium battery and replace the lithium battery according to the correct steps in the instructions.

2.22 Please to remove the battery if the me equipment is not likely to be used for some time.

2.23 Do not place foreign bodies such as metal in the groove of the base.

3 Installation of the device

3.1 Apex Locator Mode

3.1.1 Preparation

Insert the plug of the measuring wire into the right side socket of the unit.

Attention:

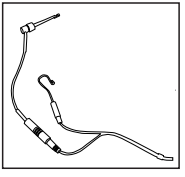
a) Please be careful to use the device, keep it stable and avoid hit. Incautious use will lead to the damage or the failure of the machine.

b) Measurement can not be proceeded without the complete insertion of the plug.

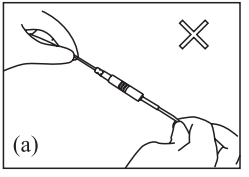
c) Be sure not to hit the plug. Keep the device away.

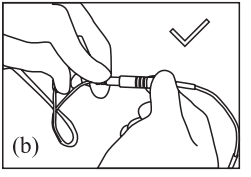
Insert the file clip and lip hook respectively into the two sockets of the measuring

wire. When the Apex Locator is used alone, there is no difference between the gray end and the white end of measuring wire [Picture 3]. But if the Apex Locator is connected to the Endo Motor, please connect the white end with the lip hook and the gray end is suspended.



Picture 3





Picture 4

Attention:

Be sure not to pull the wire when inserting or pulling out the the measuring wire and the file clip. [Picture 4 (a)]

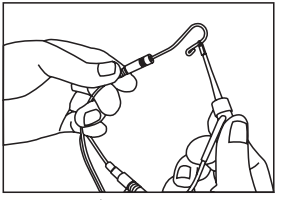
Correct operation showed as in picture 4 (b).

3.1.2 Test the wire connecting (Test before each use)

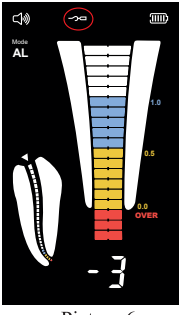
a) Press the power switch. Make sure the scene of measuring the length of the root canal displayed on the LCD screen.

The device will shutdown automatically after 5 minutes without operation.

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



Picture 5



Picture 6

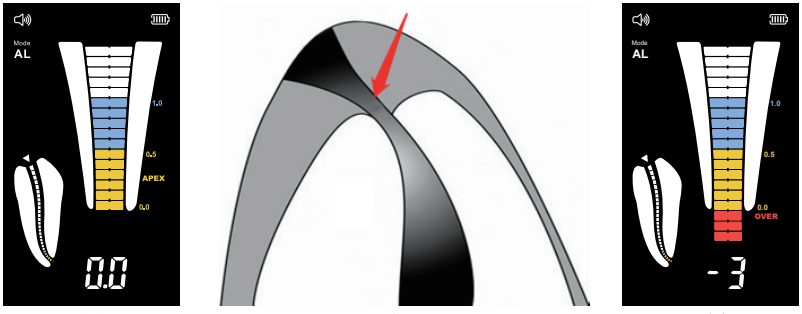
c) Make sure if the file clip and lip hook are connected well to the measuring wire.

d) Make the lip hook touch the bent wire of the file clip [as showed in Picture 5] make sure the connection icon on the LCD screen shows steadily [as showed in Picture 6], otherwise, it means that the file clip or the measuring wire is damaged, should be replaced.

3.1.3 Determine the working length

a) When the indicating bar reaches the position of the dial 0.0[Picture 7(a)], [Picture 7(b)] and there is "APEX" on screen, the endo file has reached the anatomical apical foramen. On the basis of measured length, subtract 0.5-1.0 mm to get the working length.

b) When the indicating bar reaches the red area "OVER"[Picture 7(c)], it indicates that the endo file has exceeded the apical foramen.



(a) (b) (c)

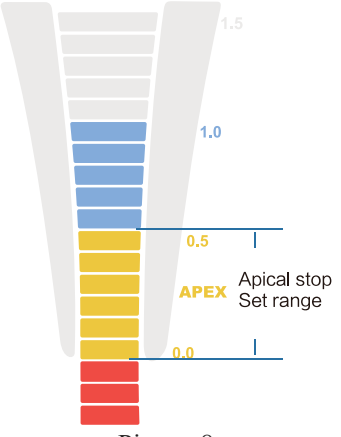
Picture 7

* The working length will differ somewhat depending on each individual tooth. This discrepancy must be judged by the dentist as he/she works on the tooth.

* Make sure to take an X-ray to check the results.

3.1.4 Apical Stop Setting

Set the Apical Stop between 0.0 and 0.5 by pressing the middle button, and the set parameter will be automatically saved. When the file reaches the Apical Stop, the device will beep continually.

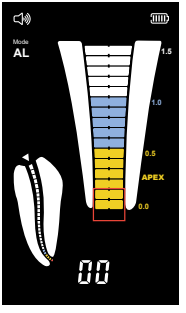


Picture 8

3.1.5 Testing the device by tester(Test every two weeks)

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

a) Pulling out the the measuring wire and turn off the device.



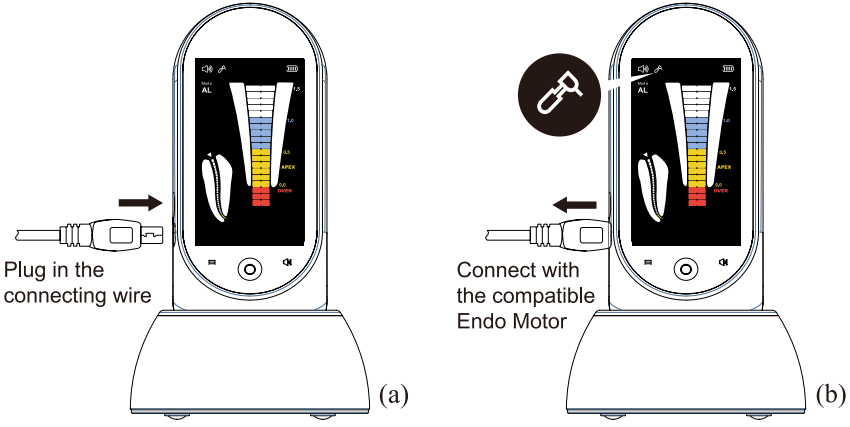
Picture 9

b) Insert the tester.

c) After powered on, If the indicating bar indicates within ±1 bars away from the dial 0.0 the device functions normally [Picture 9]. If the indicating bar is outside the range, the device cannot measure accurately. On this occasion, please contact authorized distributor or manufacturer for help.

3.1.6 Connect to compatible Endo Motor. (Optional)

Plug one end of the USB line into the USB socket on the right side of the device, and connect the other end with compatible Endo Motor as shown in Picture 10 (a). There is no difference between those two ends. As shown in Picture 10 (b), when the Contra-angle icon is lit, the Apex locator and Endo Motor can communicate normally, so that the 2-in-1 function can be realized in Endo Motor.



Picture 10

【Cautions】:

① Please use the Apex locator carefully and do not drop it or hit it. Careless use may bring risk of damage to the machine or malfunction.

② If the USB wire was not completely plugged into the USB socket, the Apex locator cannot communicate with the Endo Motor.

③ After plugging the USB wire into the USB socket, please do not drop anything on it, and do not hit the USB socket.

3.2 Pulp test mode

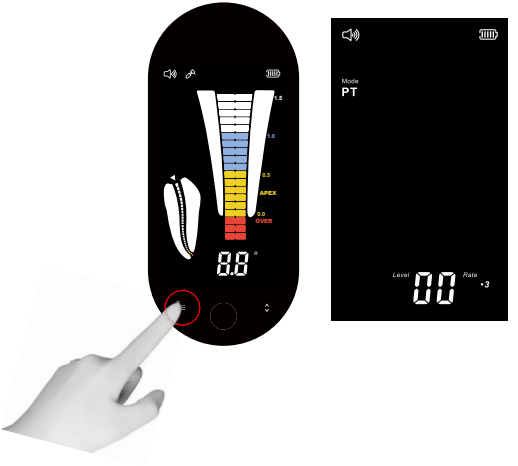
This mode is a method to determine pulp condition by observing the tolerance of the teeth to pulse signals of different intensities. The pulse signal intensity of pulp automatically increases from low to high, with values ranging from 0 to 80.

3.2.1 How to use the pulp test function:

1. The purpose of the test should be explained to the patient to eliminate unnecessary nervousness and to win the patient's cooperation. The patient should also be instructed to raise his or her hand immediately when there is a feeling of tingling.

2. Insert the measuring wire into the corresponding interface of the machine, and insert the pulp tester probe and the lip hook into any two sockets of the measuring wire respectively.

3. Power on and long press the mode button for more than 2s to switch to the pulp test mode (PT mode), as shown in Figure 11.



Picture 11

4. Select the volume and pulse level by pressing the mode button, and then adjust the volume and pulse speed by pressing the adjustment button.

5. Isolate the tooth under test from moisture and blow to dry the tooth surface. If there is calculus at the tooth neck, it must be cleaned.

6. Place the lip hook at the corner of the patient's mouth, and apply a layer of conductive agent (e.g. toothpaste) to the pulp tester probe. Place the probe on the middle 1/3 of the labial (buccal) surface or 1/3 of the tooth neck.

7. When the probe and the hook are in good contact, the reading will automatically increase slowly from "0". Remove the probe when the patient reacts and record the value causing the reaction. Generally, the test can be repeated twice and the average value should be taken. If there is a big difference between the two values, the third test should be performed, and then the average of two similar values should be taken.

8. If the contact with the tooth to be tested is interrupted and contact is made again within 1s, the pulse value will not be cleared, and the test can be continued without resetting.

9. Before testing the affected tooth, a normal control tooth needs to be tested to obtain a relative normal response value as a control. The control tooth is preferred to the contralateral normal tooth of the same name, followed by the corresponding jaw tooth of the same name and finally the healthy adjacent tooth in the same quadrant as the affected tooth.

Note: The value obtained by the pulp tester must be compared with the normal control tooth before it is of diagnostic value. Since the intensity of response to the pulse signal varies from patient to patient, there will be false positive or false negative performance in practice, so pulp test cannot be used as the only basis for diagnosis.

3.2.2 Possible causes of false positive results of pulp test

1.The probe touches a large area of the metal restoration or the gums, causing the current to flow to the periodontal tissue.

2. Insufficient moisture isolation or drying of the tested tooth causes current leakage to periodontal tissue. Periodontal and pulpal responses are significantly different. Prior to pulp test, the sensation of the tooth to be tested can be compared with the direct stimulation of the periodontal tissue.

3. Liquefied necrotic pulp has the potential to conduct current to the periapical tissue and the patient may have a slight reaction when the current is adjusted to the maximum scale.

4. What the patient feels is the stimulation of the adjacent teeth.

5. The patient is so stressed and anxious that he/she signals a response when the probe first touches the tooth surface or when he/she is asked about feelings.

3.2.3 Possible causes of false negative results of pulp test

1. The patient has had prior use of analgesics, narcotics, or alcoholic, etc. that prevent the teeth from perceiving electrical stimulation properly.

2. The pulp test probe fails to effectively contact the tooth surface, preventing the transmission of the pulse signal to the pulp.

3. The pulp of newly erupted teeth with immature apices is usually unresponsive to electrical stimulation.

4. The pulp of over-calcified teeth in the root canal is usually unresponsive to electrical stimulation and is common in affected teeth of some elderly.

5. Recently traumatized affected teeth may not respond to electrical stimulation.

6. Other conditions that cause degeneration of the dental nerve.

Warning: The pulp test may interfere with the operation of the pacemaker and is therefore contraindicated in patients with pacemakers in the heart. Please refer to the

relevant contraindications in section 1.7 for details.

4 Product function and operation

4.1 Usage requirements

Apex locator should be precise, repeatable, and easy to operate. The following requirements are necessary besides the proper operation method.

4.1.1 The operation should be according to the manual.

4.1.2 The dentists should have the knowledge of teeth position and average length and the skill to operate the device.

4.1.3 An fully exposed access cavity to show the pulpal cabin.

4.1.4 A X-ray photo to show the whole length and root canal of the teeth.

4.1.5 The endo file should not be too big nor too small to avoid cutting through the apical foramen.

4.1.6 Mark an anatomized symbol on the diseased tooth and memorize it on the case history. This symbol should be marked on the health bridge or on the tooth filled integrated. The position of the mark should be on the incisal edge of the anterior tooth or on the spire of the molars. For those bridge that's broken obviously, this symbol should be on the tooth surface supported by the dentin instead of on the suspended enamel.

4.1.7 The acute inflammation surrounding the apex has been gone and the infected material has been cleaned. It is also necessary to get rid of the pulp and necrosis tissue.

4.1.8 The following cases are not suited for a normal measurement:

a) The size of the root similar to the size of apical foramen.

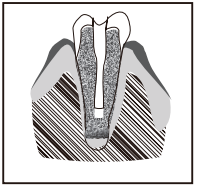
In this case, the measurement result of the length of the root canal will be shorter than its real because of the hypoplasia of the root [Picture 12].

b) Bleeding or the blood overflow from the apical foramen.

In this case, the blood will overflow from the root canal and reaches gingival that the blood and the gingival will be on a conducting state which will cause an inaccurate result while measuring. The measurement can be continued when the bleeding is stopped [Picture 13].

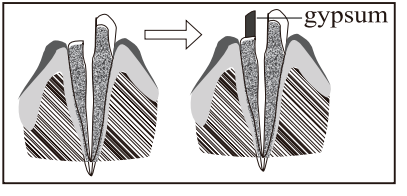
c) The tooth crown is broken.

The tissue of the gingival may reach the cavity of the endo hole at the broken point which will cause inaccuracy because of the electronic conduction. The measurement can be continued when the crown is fixed by gypsum or other insulators [Picture 14]



Picture12

Picture13



Picture14

d) There is a crack on the tooth root.

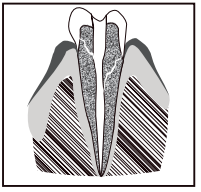
In this case, the crack may cause the electric leakage which will affect the accuracy of measurement [Picture 15].

e) A retreatment to an endo which was filled with gutta-percha.

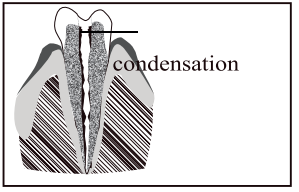
Clean the remaining material in the root canal and fill it with little normal saline before a measurement [Picture 16].

f) There is a metal crown which has connected to the gingival.

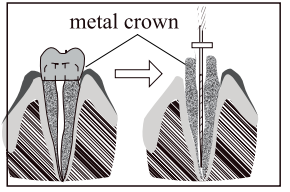
It will cause an inaccuracy when the endo file touches metal crown [Picture 17].



Picture 15

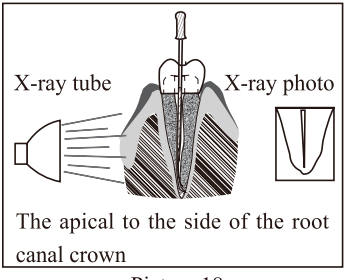


Picture 16



Picture 17

Sometimes, the results of the Apex Locator and X-rays do not meet each other,which is neither bdcause the machine is not normal, nor the photo is incorrect taken.The actual position of the apical foramen is different from the anatomical one, it is very common that the apical foramen slightly to the side of the root canal crowns.In this case, according to the shooting angle as the belowing picture show, it will cause illusion that the front tip of the root canal haven't reached the canal tip. [Picture 18]



Picture 18

(Because of the angle of X-rays,sometimes it can't take photo of the apical foramen properly, so it can't show the accurate position of the apical foramen.)

4.2 Instruction

4.2.1 Insert the plug of measuring wire into the socket in the side of main unit. Turn it on. The battery is on the left of screen.

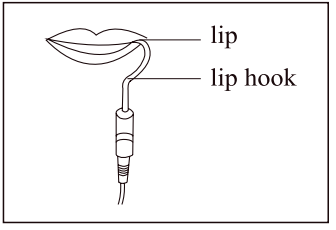
4.2.2 The equipment is in the normal condition. The equipment shuts down after 5 minutes without use.

4.2.3 The volume is adjustable. Please press the volume bottom for a setting.

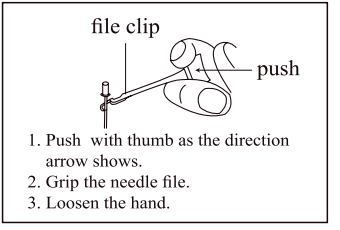
4.2.4 Hang the lip hook on the lip, make sure it contact the oral mucosa as a

reference electrode [Picture 19].

4.2.5 Clip the file with file clip, approach to the apex, then there will be continuous alarm when the distance is less than 2mm [Picture 20].



Picture 19



Picture 20

Attention:

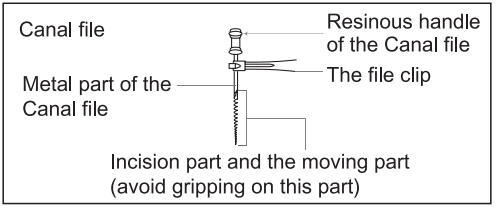
a) When gripping the root canal with a canal file, please grip the upper of the metal part (near the root canal at the needle handle). If you grip the lower part (blade or moving part), it will wear the file clip. [Picture 21]

b) When measuring the length of root canal, please use the canal file with the resinous handle.

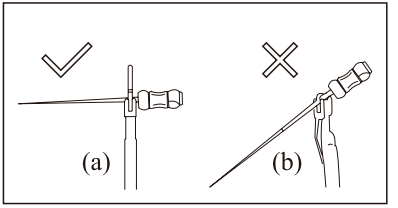
If you operate the device without the dentistry glove,it will cause leakage and the result of measurement will be inaccurate.Therefore, please use the resin needle file and remember don't touch the metal part with finger.

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

d) Please reference the [Picture 22 (a)] to grip the needle file. If as [Picture 22 (b)], it can't properly measure the length of the root canal due to the improper force, and the front of the root canal pin is easy to wear.

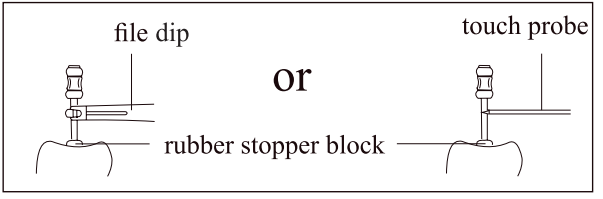


Picture 21



Picture 22

4.2.6 When the file reaches the apex, adjust the rubber piece set on the endo file to the reference point (incisal 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 use with the touch probe instead of file clip, when it is inconvenient to measure the back teeth [Picture 23].



Picture 23

4.2.7 Please remove the lip hook,file clip or touch probe after shutting down.

4.2.8 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.

Attention: Avoid the silk-screen when cleaning.

5 Trouble shooting

Problems	Possible cause	Solutions
No power and no signal on the screen after the power on.	1. If the battery is placed correctly? 2. If the battery with no power?	1. Re-install the battery. 2. Recharge the battery.
The length of the root canal cannot be measured.	1. If the measuring wire is connected correctly? 2. If the measuring wire is broken?	Confirm the measuring wire is plugged firmly, link the lip hook with the file clip to check if the measuring wire is broken.
No sound of alarm.	If the volume is set at “mute”?	Adjust the sound level.
The charging LED indicator goes out.	1.The adapter is not connected well. 2.Have used faulty adapter with excessive output. 3.The battery is not installed well. 4.The battery has been damaged.	1.Reconnect the adapter. 2.Change the adapter, must use the original adapter. 3.Reinsert the battery and then reconnect the adapter. 4.Change the battery and then reconnect the adapter.

Problems	Possible cause	Solutions
Display not steady while measuring: the measurement result is rather longer or shorter; numerical display irregular.	If the connection between the lip hook and the oral mucosa is ok?	Make sure the lip hook has contacted the oral mucosa at a good position.
	Is there a blood/saliva overflowing, glued to the crown?	Blood, liquid overflow from the root canal, glued to the crown or the tooth neck, will cause short-circuit then cause the in-normal phenomena. Clean the blood and the liquid.
	If the root canal is filled with blood, liquid?	Once the endo needle contact the surface of the root canal which is filled with blood, liquid, it will display “OVER” immediately. In this case, push the needle to the apical root canal, then the display will be normal, you can measure the length of the root canal correctly.
	If there is liquid, scrap on the tooth surface?	Clean the tooth surface.
	If the endo needle contact the gums?	The LCD will display “OVER” if the endo needle contact the gums.

Problems	Possible cause	Solutions
Display not steady while measuring: the measurement result is rather longer or shorter; numerical display irregular.	If there is still pulp in the root canal?	If there is much pulp left in the root canal, the root canal length can't be measured correctly.
	If the needle touched the metal repaired material?	Once the needle touched the metal repaired material, current measurement from the gums to the periodontal tissue loss, the screen will display "OVER".
	If the adjacent surface has caries?	Current measurement flow from caries of the adjacent surface to gums, then the root canal length can't be measured correctly.
	Whether there is collateral or the tooth root is broken?	Once the needle reached the collateral or the broken part of the tooth root, current measurement will overflow from periodontal ligament, it displays "OVER".
	Is it because in addition to the top pulp chamber, low tooth crown? Or there are residues left?	Use rubber dam to prevent the current flow to gums.

Problems	Possible cause	Solutions
Display not steady while measuring: the measurement result is rather longer or shorter; numerical display irregular.	Are there cysts apical?	If there has cysts, the length of root canal can't be measured accurately.
	Whether the file clip is not clean or broken?	Clean the file clip by alcohol, or replace it.
	Whether the measuring wire is broken or poor contact?	Contact the both end of the measuring wire directly, it displays "-3".
The length measurement indicator only full display near narrow part of the apical.	Whether the root canal is occlusive?	The display will be normal after penetrating the narrow part of apical.
	If the root canal is too dry?	Wet the root canal with normal saline solution or sodium hypochlorite solution.
	If the endo file is too small for a large root canal?	Replace the current endo file with a larger one.

* If all above measures do not work, please contact us.

6 Cleaning, Disinfection and Sterilization

The procedure for cleaning, disinfection and sterilization applies only to the accessories file clip, touch probe and lip hook.

Reprocessing procedures have only limited implications to this file clip, touch probe and lip hook. The limitation of the numbers of reprocessing procedures is therefore determined by the function/ wear of the device. However with every

renewed preparation for use, thermal and chemical stresses will result in ageing of the products. The specified maximum times of sterilization for File clip is 200 times. The specified maximum times of sterilization for Touch probe and Lip hook is 1000 times.

In case of damage the device should be reprocessed before sending back to the manufacturer for repair.

6.1 Preparation at the Point of Use:

Disconnect the file clip, touch probe and lip hook from the measuring wire. Remove gross soiling of he instrument with cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process. Store the instruments in a humid surrounding.

6.2 Transportation:

Safe storage and transportation to reprocessing area to avoid any damage and contamination to environment.

6.3 Preparation for Decontamination:

The devices must be reprocessed in a disassembled state.

6.4 Pre-Cleaning:

Do a manual pre-cleaning, until the instruments are visually clean. Submerge the instruments in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean the surfaces with a soft bristol brush.

6.5 Cleaning:

Regarding cleaning/ disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety.

Automated Cleaning:

Use a washer-disinfector meeting the requirements of the ISO 15883 series. Put the instrument into the machine on a tray. Connect the instrument with the WD by using suitable adapter and start the program:

- 4 min pre-washing with cold water (<40°C);
- emptying
- 5 min washing with a mild alkaline cleaner at 55°C
- emptying
- 3 min neutralising with warm water (>40°C);
- emptying
- 3 min neutralising with warm water (>40°C);
- emptying
- 5 min intermediate rinsing with warm water (>40°C)
- Emptying

The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert). Note Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.

6.6 Disinfection:

Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN 15883). A disinfection cycle of 5 min disinfection a 93°C has been validated for the device to achieve an A0 value of 3000.

6.7 Automated Drying:

Drying of outside of instrument through drying cycle of washer/ disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate

cavities of instruments by using sterile compressed air.

6.8 Functional Testing, Maintenance:

Visual inspection for cleanliness of the instruments and reassembling. Functional testing according to instructions of use. If necessary, perform reprocessing process again until instruments is visibly clean. Before packaging and autoclaving, make sure that the file clip, touch probe and lip hook has been maintained acc. to manufacturer's instruction.

6.9 Packaging:

Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 1167.

6.10 Sterilization:

Sterilization of instruments by applying a fractionated pre-vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO17665) under consideration of the respective country requirements. Minimum requirements: 3 min at 134°C (in EU: 5 min at 134°C) Maximum sterilization temperature: 137°C.

Note: Flash sterilization is not allowed on lumen instruments!

6.11 Storage:

Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.

7 Storage, maintenance and transportation

7.1 Storage

7.1.1 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.

7.1.2 Avoid the storage in a too hot condition. High temperature will shorten the

life of electronic components, damage battery, reshape or melt some plastic.

7.1.3 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.

7.2 Maintenance

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

7.2.2 Keep the equipment in a dry storage condition.

7.2.3 Do not throw, beat or shock the equipment.

7.2.4 Do not smear the equipment with pigments.

7.2.5 Replace the battery if it seems to be running out of power sooner than it should. Please use the original lithium battery. The procedure for battery replacement is as follows.

a) Turn the power off.

b) Remove the battery cover.

c) Remove the old battery and disconnect the connector.

d) Connect the new battery and put it in the Battery compartment.

e) Replace the battery cover .

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

7.3 Transportation

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

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

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

8 Environmental protection

Please dispose according to the local laws.

9 European authorized representative

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

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


Class Ⅱ equipment


Date of manufacture


Manufacturer


Type B applied part


Recovery

IPX0 Ordinary equipment


Keep dry


Used indoor only


Handle with care

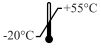

Power on / off


Mode key

Humidity limitation


Adjustment key


Appliance compliance WEEE directive



Atmospheric pressure for storage

EC REP Authorised Representative in the EUROPEAN COMMUNITY

SN Serial number

Temperature limitation

CE marked product


Follow Instructions for Use

12 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.

13 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.

Guidance and manufacturer's declaration - electromagnetic emissions		
The model is intended for use in the electromagnetic environment specified below. The customer or the user of the model should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The model use 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 is suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions lEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions lEC 61000-3-3	Complies	

Guidance & Declaration - electromagnetic immunity			
The model is intended for use in the electromagnetic environment specified below. The customer or the user of the model should assure that It is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV 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 tansient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for lnput/ output lines	±2kV for power supply lines ±1kV for interconnecting cable	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±2kV for power supply lines ±1kV for interconnecting cable	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 U_T) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip ,n U_T) for 25 cycles <5% Ur (>95 % dip in U_T) for 5 sec	<5 % Ur (> 9 5% dip in U_T) for O5 cycle 40 % Ur (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip 1n U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment If the user of the model require continued operation during power ma,ns 1n terrupt1ons, ,t 1s recommended that the model be powered from anuninter-ruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	PONer frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Guidance & Declaration - Electromagnetic immunity
The model is intended for use in the electromagnetic environment specified below. The customer or the user of the model 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 Radiated RF lEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the model, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance 3V $d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=2.3\times P^{1/2}$ 800 MHz to 2.5 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 is used exceeds the applicable RF compliance level above, the model should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

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

The model is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model is 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 $d=1.2\times P^{1/2}$	80MHz to 800MHz $d=1.2\times P^{1/2}$	800MHz to 2,5GHz $d=2.3\times P^{1/2}$
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 distanced in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where Pis the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.
NOTE 1 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.

Apex locator in the above specified electromagnetic environment, it will be safe, and it can provide the basic properties such as article 1.6.1-1.6.3;

1. Measurement of pulpitis, pulp necrosis, periapical periodontitis and tooth length.

2. Measurement of the tooth length before restoration of post crown.

3. Measurement of the tooth length of transplantation and retransplantation.

Cautions:

1. Cautions: User must regard EMC, please install and put in service the model according to the EMC information provided in the accompanying documents

2. Cautions:Portable and mobile RF communications equipment can affect medical electrical equipment.

3. Use is not specified for the Apex locator the model of the adapter, measuring wire, file clip may increase the radiation quantity or reduce the interference ability of the Apex locator system. A list of all cables and maximum lengths of cables is as follows, transducers and other accessories with Guilin Woodpecker Medical Instrument Co., Ltd. claims compliance with the requirements of Emission and Immunity. Please use original accessories.

Serial Number	Accessories name	Cable length	Whether shielding
1	adapter	1	No
2	measuring wire	1.7	No
3	file clip	0.2	No

4. Cautions:The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Guilin Woodpecker Medical Instrument Co., Ltd. as replacement parts for internal components, may result in increased Emissions or decreased Immunity of the model.

5. The model should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the model should be observed to verify normal operation in the configuration in which it will be used.

6.The accessories adapter,battery,measuring wire, file clip of Apex locator the model may affect the radiation quantity.The original accessories are in compliance with the requiments of the IEC 60601-1-2. Please use original accessories.

EDGEENDO®

EdgeEndo, LLC
5600 Wyoming Blvd. NE, Suite 100
Albuquerque, NM 87109
1-855-985-3636 • EdgeEndo.com

Packaged and Labeled by: HPR, Inc.
620 S. Placentia Ave.
Placentia, CA 92870

Made in China

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