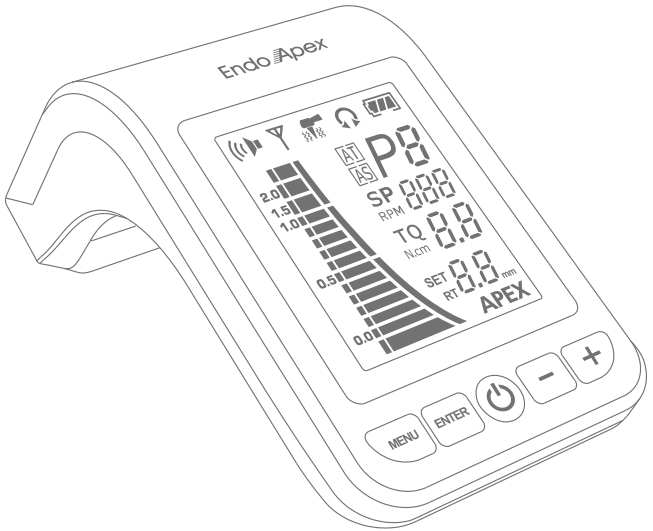
Endo Apex User Manual



Shenzhen Perfect Medical Instruments Co., Ltd.

REV:E-EAP-SPEC-02

Shenzhen Perfect
Medical Instruments

Endo Apex

Congratulations!

- Thank you for purchasing the ENDO APEX
- For optimum safety and performance, read this manual thoroughly before using the instrument and pay close attention to warnings and notes
- Keep this manual in a handy place for your quick and easy reference
- Hotline: 86(0755) 28540953
- E-mail: sales@dental-perfect.com

CONTENT

1 PRODUCT INTRODUCTION

1.1. Product description

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

1.2. Scope of application

For root canal treatment only.
The device must be operated in hospital or clinic by the qualified dentists.

1.3. Safety measures and warnings

- The PATIENT shall not be an intended OPERATOR.
- Never open or repair the device by yourself, otherwise void the warranty.
- Prevent liquid from entering the enclosure from the enclosure.
- Away from the heat source and make sure that there is no combustible surrounding.
- Sterilize and disinfect each patient to avoid cross-infection.
- Strictly follow the manufacturer's instructions for the use of endodontic instruments
- Do not use instruments that are bent, deformed, or inconsistent with ISO requirements.
- As a safety precaution in order to avoid over-instrumentation, it is recommended to proceed as follows: place the file onto an endodontic ruler, where the apex locator screen indicates '0.0'. Subtract 0.5-1 mm from the measured file length as the Working Length.
- In order to confirm the file clip and measuring wire makes good contact,test the wire connecting before each use(See 3.1.3).

2 STANDARD COMPONENT

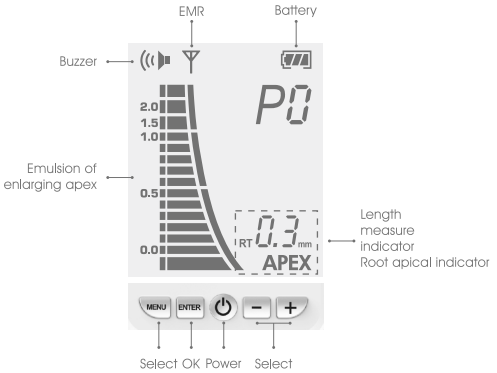
2.1. Component list

ENDO APEX component list, As shown fig 1:
1.Main unit 2. Adapter 3. Measuring wire, File clip, Contrary Electrode 4.Tester

Fig.1

2.2 LCD interface

Introduction to
the display interface



2.3 Main unit key function

2.3.1 Key function introduction

1.Select the menu key
2.Confirmation key
3.Device power on/off key
4.Parameter adjustment

2.3.2 Parameter preset range

Preset depth of root canal needle to apical foramen: 0.0mm~1.0mm

3 TECHNICAL PARAMETERS

Electrical and maintenance device specifications answer the requirements of: EN 60601-1:2006, EN 80601-2-60-2015, EN 60601-1-2:2015

Manufacture	SHENZHEN PERFECT MEDICAL INSTRUMENTS CO., LTD
Model	ENDO APEX
Dimensions	184mm*135mm*97mm (package)
Weight	690g
Power supply	Battery: 3.7V/1050 mAh Li-ion battery
Charging	5V DC, 1A
Adapter rating	AC100-240~50/60Hz
Electrical safety class	Class II or internally powered
Applied part	Type B : dental root canal file Accessible parts that come into contact with the patient : Contra-angle
Fuse	Current rating:1.5A Interrupting Rating:50A@65VDC Size: L:3.2mm±0.2mm W:1.60mm + 0.3mm/ -0.2mm H:0.85mm±0.3mm
Operation conditions	Temperature:10℃to 40℃ Humidity:30% to 75% Pressure:70kPa to 106kPa
Storage and transport conditions	Temperature:-10℃to 50℃ Humidity:10% to 85% Pressure:70kPa to 106kPa

4 DEVICE CHARGING

4.1 Charging

"ENDO APEX" is powered by a rechargeable lithium battery, The first time you use this device, fully charge the lithium battery is required.
Connect the device and adapter as shown:

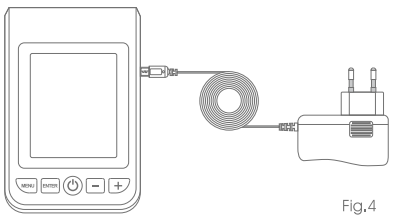


Fig.4

When the display battery icon is buffered, it indicates that the lithium battery is charging.When the lithium battery is fully charged, the battery icon shows full.

Warning!

- Only the original adapter could be used.
- Unplug the adapter from the outlet when the device is not charging.

4.2 Battery charge indication

When the lithium battery is below the minimum allowable power(< 20%), the battery icon shows" ". Charge the lithium battery according to P4.1.
Otherwise, the device will automatically shut down when the battery drops to 10%.

Note! When the battery is below 20%, it is recommended to charge the device!

4.3 Shut down the device

Short press the power icon to turn on the device, press and hold the button for about 2 seconds to turn off the device.
it will automatically shut down after 5 minutes without any operation.

5 DEVICE OPERATION GUIDELINES

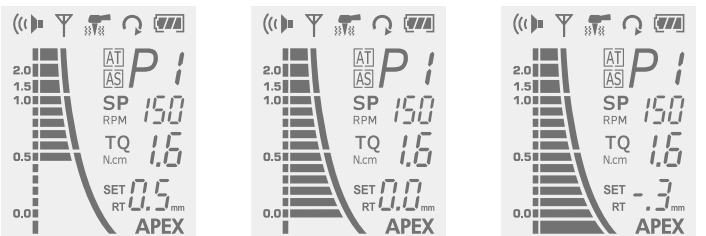
5.1 Root depth setting and operation precautions

(1) Explanation of the display interface

(a) When the file is closed to the apex of the root canal, Display the 0.5mm area as a root canal curve on the display interface. Fig.a

(b) When the curve reaches the red indication., it indicates that the root canal files has reached the vicinity of the apical hole. Fig.b

(c) When the curve reaches -0.3mm in the red indication area, the root canal files has passed through the apex of the root canal and the device will continue to beep.Fig.c



a b c

(2) Root depth measurement preset

The root depth measurement preset value described in this paper refers to the position of the root canal from the apex of the root canal. The preset range is 0.0mm～1.0mm. When the root canal reaches the preset position, the motor will reverse the root canal.

Press the menu select key, when the "5-Fig.5 area

"is beating, then press "+" "-"to choose parameter you need, finally press the enter key (2-Fig.3)to complete the preset.

Warning!

- It is recommended to insert the tester before using the root test function. If the root length measure indicator shows 0.2 0.3 or 0.4, the device is normal.
- Before using the equipment, the line connection test must be carried out. See (Fig.8) to confirm that the clamp and the measurement are in good connection. When the root length measure indicator shows that -0.3, it indicates that the connection is good, otherwise the line is not connected, the cause should be checked.
- The data arc displayed in the device does not represent a certain length or distance or other linear units which expressed in millimeters and the date reduction merely indicates that the needle moves toward the apex.
- In the root length measure indicator, a beating horizontal line appears, indicating the preset distance from the apex.
- The instrument's test stop (red area, showing the number "0.0") is an anatomical apical hole, clinically used as a safety measure, the length of the root canal length measuring instrument measured minus 0.5-1mm, as the root canal working length.
- In order to prevent measurement errors caused by liquid contact with the gums or adjacent root canal, the cotton pulp must be dried with a cotton ball before testing.
- Use a file that matches the diameter of the root canal, a large root canal with a small file will result in unstable screen digital display.
- The instrument's contact with the patient's accessories (file clip, lip hook and file) can be reused and must be autoclaved before each use. It is recommended that the root canal be used no more than three times.
- Avoid the internal fluid of the root canal to connect with the external fluid of the root canal, or it will cause measurement error.
- Make sure the file and file clip are not connecting with other metals or instruments during measurement.
- To ensure that the measurement results are not affected by short circuits, special attention should be paid to patients with metal crowns or bridges. Make sure that the root canal is wet enough to ensure measurement reliability, If it is determined that the file has not reached the apex and the value indicated on the display is too low, On the one hand, check if the root canal is too dry, and on the other hand, take X-rays for approval.

Fig.7

Fig.8

Warning!

- Make sure the motor is stopped when insert the file.
- Pull on the file gently to make sure it is locked.

6 CLEANING, DISINFECTION AND STERILIZATION

6.1 Foreword

The lip hook and the file clip must be cleaned, disinfected and sterilized before each use to prevent any contamination. This concerns the first use as well as the subsequent uses.

6.2 Procedure for lip hook, the file clip

Operation	Operation mode	Warning
1.Pre-Disinfection or Decontamination	Soak immediately just after usage all instruments in a disinfectant solution combined with proteolytic enzyme if possible.	The disinfectant solution should be aldehyde free(to avoid blood Jimpurities fixation). Do not use disinfectant solution containing Phenol or any products which are not compatible with the instruments For visible impurities that are observed on instruments, a pre-cleaning is recommended by brushing them manually with soft material.
2.Rinsing	Rinse manually and abundantly the accessories with current water	
3.Manual Cleaning	Clean manually the accessories with an adequate brush, preliminary soaked in a clean pre-disinfectant solution	
4.Rinsing	Rinse manually and abundantly the accessories with current water	
5.Disinfection	Immerse the accessories in a disinfectant solution (bactericidal, virucidal, fungicidal,tuberculocidal and aldehyde free)according to the manufacturer recommendations	
6.Final rinsing	After rinsing, the accessories have to dried.	
7.Packing	Pack the devices in "Sterilization pouches"	
8.Sterilization	Steam sterilization at: 134e°Cduring 18 min.	The accessories (lip hook, file clip and touch probe)must be sterilized according to the packaging labeling.-Use fractionated vacum or gravity (less preferred) autoclaves (according to EN 13060,EN285).-Use validated sterilization procedure according to ISO 17665-1-Respect maintenance procedure of the autoclave device given by the manufacturer.-Use only the listed sterilization procedures.
9.Storage	Keep devices in sterilization packaging in a dry and clean environment -Sterility cannot be guaranteed if packaging is open, damaged or wet(check the packaging before using the instruments).	Check the packaging and the accessories before using it (packaging integrity, no humidity and validity period).

7 REFRESH THE BATTERY

ENDO APEX operates on a rechargeable battery. It can be recharged not less 300times, depending on the operating conditions of the device.

The battery needs to be replaced if the operating time or battery recharging time becomes shorter or the rotation power weaker, and the battery refresh function has not resolved the problem.

When replacing, be sure to observe the following "Precautions on changing battery". Note thatManufacturer shall not be held liable for any malfunction or failure resulting from the failure to follow the "Precautions on changing battery".

Ensure adequate maintenance of med equipment containing rechargeable batteries to be maintained by anyone other than service personnel.

Warning!

- Only after-sales personnel can replace the battery.
- Replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable risk.
- Do not open any part other than the battery cover.
- Be sure to purchase and use only the recommended battery.Otherwise, battery may cause damage, fluid leakage or explode.
- Do not change the battery with wet hands as this may cause short-circuiting of the battery and moisture infiltrating the device.
- The battery compartment is located at the rear of the unit.
- Disconnect the Adapter.
- Take out the battery and pull out the cord, holding it at the connector.
- Close the battery cover.
- Do not charge the device while using it.
- Away from the heat source and make sure that there is no combustible surrounding.
- Charge the device fully when battery is low. Frequently charging in low power state for short time will shorten the battery life.

8 TROUBLE SHOOTING

Malfunction	Cause	Action
After charging the battery, the use time becomes shorter.	Battery life is over,along with lithium battery capacity becomes smaller and smaller.	Contact after-sale replacement lithium battery.
Root test function is invalid.	• Check connection • Check measurement wire	Confirm that the connection is secure and confirm that the measurement wire is intact.
Motor handpiece is getting hot.	Continuously use for a long time	Stop using after cooling.
The data is unstable when measured.	• Whether the lip hooks are in good contact with the oral mucosa. • Whether the blood and liquid spilled and stained in the crown. • Whether the root canal is full of blood, liquid medicine. • Whether there is liquid, crumb on the tooth surface. • Whether the file is in contact with the gums. • Whether the pulp remains in the root canal.	• Make sure the lip hooks are in good contact with the oral mucosa. • The blood and the liquid overflow in the root canal and stick to the crown or the neck, causing a short circuit, which causes an abnormal phenomenon. • Measure after drying the spilled blood solution. • Clean the tooth surface. • In the case where there are more pulps in the root canal, the root canal length cannot be correctly determined.

The MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair those parts of MED EQUIPMENT that are designated by the MANUFACTURER as repairable by SERVICE PERSONNEL.

If the problem still cannot be solved,please contact with the manufacturer by Phone: +86(0755) 28540953 , Email: sales@dental-perfect.com or address tothe service department.

9 DISPOSAL OF WASTE PRODUCTS

Do not throw the device into the system of household rubbish.
Disposal of waste in accordance with local laws and regulations.

10 EMC Tables

Guidance and manufacturer's declaration - electromagnetic emissions

The model ENDO APEX is intended for use in the electromagnetic environment specified below. The customer or the user of the model ENDO APEX 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 APEX 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 APEXR 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 IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance & Declaration — Electromagnetic immunity

The model ENDO APEX is intended for use in the electromagnetic environment specified below. The customer or the user of the model ENDO APEX should assure that It is used in such anenvironment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV,±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8kV, ±15 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 transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/ output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line	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 25/30 cycles <5% UT (>95 % dip in UT) for 5/6 sec	<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 25/30 cycles <5% UT (>95 % dip in UT) for 5/6 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model ENDO APEX requires continued operation during power mains interruptions, it is recommended that the model ENDO APEX be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m, 30 A/m	3 A/m, 30 A/m	Power 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 ENDO APEX is intended for use in the electromagnetic environment specified below. The customer or the user of the model ENDO APEX should assure that it is used in such an environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands 3 V/m, 10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communicati on equipment (Refer to table 9 of IEC 60601-1-2:2014)	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands 3 V/m, 10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communicati on equipment (Refer to table 9 of IEC 60601-1-2:2014)	Portable and mobile RF communications equipment should be used no closer to any part of the models ENDO APEX, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=[3,5/V 1]×P 1/2 d=1.2×P 1/2 80 MHz to 800 MHz d=2.3×P 1/2 800 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 1 At 80 MHz and 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.

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 APEX is used exceeds the applicable RF compliance level above, the model ENDO APEX 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 APEX.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 ENDO APEX

The model ENDO APEX is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model ENDO APEX can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model ENDO APEX 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 transmitterm		
	150kHz to 80MHz d=1.2×P 1/2	80MHz to 800MHz d=1.2×P 1/2	800MHz to 2,5GHz d=2.3×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

11 WARRANTY

- Manufacturer warrants products to the original purchaser against defect in material and workmanship under normal practices of installation, use and servicing.
- ENDO APEX is warranted for 24 months (exception: micro motor head & battery are covered by a 12 month warranty) from the date of purchase.
- In case the product fails within 30 days from the date of installation, contact with your distributor immediately (with relevant proof of purchase ready).

12 SYMBOL DESCRIPTIONS

SN	Serial number
	Manufacturer
	Date of manufacture
	Class II equipment
	Type B applied part
	Caution
	Do not dispose of with normal household waste.
	Power on/off.
	Direct current
	Alternating current
CE	Conformity European
	If the instruction are not followed properly, operation may lead to hazards for the product or the user/patient
	Refer to Instructions for use
EC REP	Authorized representative in the European Community

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