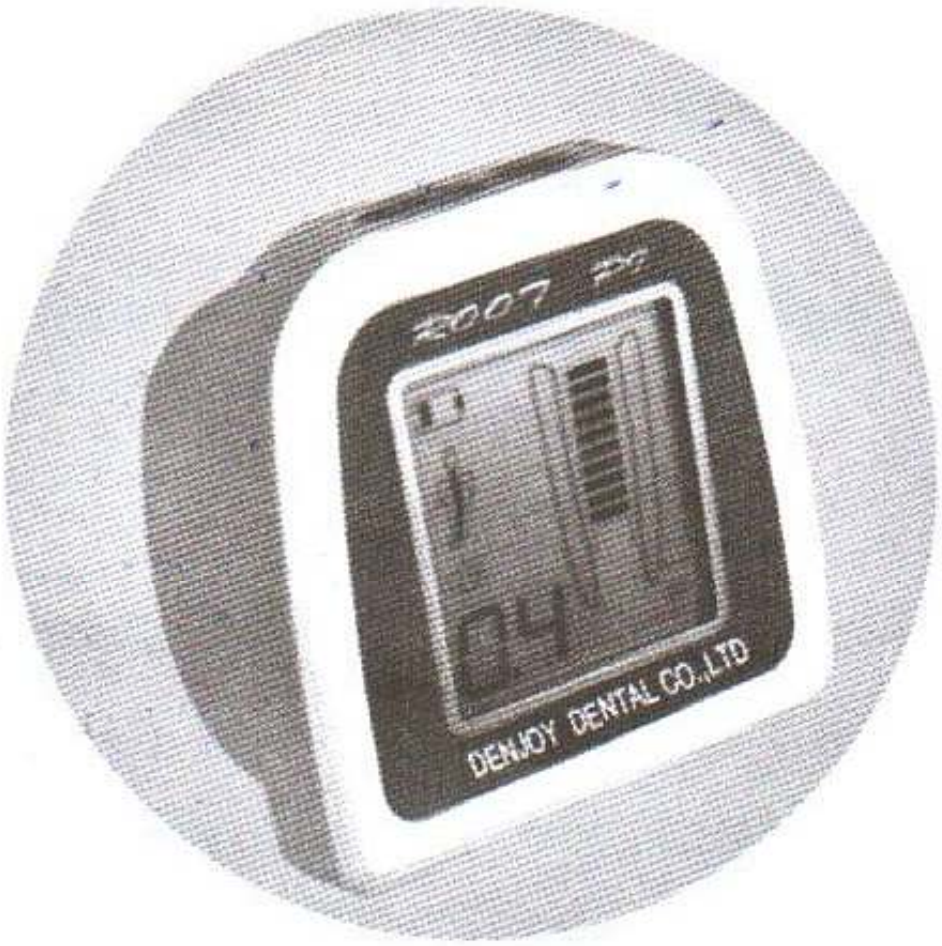
USER'S MANUAL



ROOT PI APEX LOCATOR

*The unit must be installed by a qualified dental engineer.

*Read this operation manual carefully before installation or operation.

CE 0197

SECTION 1: GENERAL INTRODUCTION

I. CONTACT INFORMATION

Apex Locator ROOT PI is manufactured by:

DENJOY DENTAL CO., LTD

Address: 7bldg. Xiangshuyuan, 8 Lutian Road, Lugu Base, Yuelu District, Changsha, China

Website: www.denjoy.cn

E-mail: denjoy@denjoy.cn

Manufacturing:

Company name: DENJOY DENTAL CO., LTD

Address: 7bldg. Xiangshuyuan, 8 Lutian Road, Lugu Base, Yuelu District, Changsha, China

Authorized European Representative:

Company name: Globe Dental

Address: Kalserjägerstraβe 13 W2

A-6170 Zirl Austria

II. PRODUCT DESCRIPTION

Apex locator ROOT PI is a kind of highly precise instrument used for determining the position of apex of root canal with the up-to-date technology and design! The unit is designed based on the principles of human engineering science, which is endowed with handsome apprearance and remarkable performance. It is very convenient to operate and maintain, and easy to clean and sterilize! The unit is operated by five AAA alkaline batteries to make sure that the unit keep run smoothly in a quite condition and conform to the requirement of medical environment!

Features:

a. Both dry and wet conditions of root canal could get accurate reading! Therefore, the root canal is dry, or filled with electrolyte, blood or physiological brine will not affect the measuring result.

b. The measurement is not affected by thickness of the file.

c. The LCD screen visually displays the moving trace of file in the root canal.

d. There is beep alarm to indicate the apex when the display number on the LCD is below 2mm

e. The power of the unit is supplied with 5 pieces of AAA dry Li-on battery.

f. File holder & electrode can be autoclavable!

III. ELECTROMAGNETIC COMPATIBILITY DESCRIPTIONS

Table 201 – Guidance and manufacturer's declaration – electromagnetic emissions – for all EQUIPMENT and SYSTEMS

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

Table 202 – Guidance and manufacturer's declaration – electromagnetic immunity –for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The ROOT PI is intended for use in the electromagnetic environment specified below. The customer or the user of the ROOT PI 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 transient/burst IEC 61000-4-4	2 kV for power supply lines 1kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	Not applicable	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 % U_T (>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 in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [EQUIPMENT or SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [EQUIPMENT or SYSTEM] be powered from an uninterruptible power, supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE 1 U_T is the a.c. mains voltage prior to application of the test level.
NOTE 2 The ROOT PI is internally powered equipment without the option of a.c. or d.c. power inputs, and has only patient-coupled cables which is less than 3 m in length. The electrical fast transient/burst immunity test (IEC 61000-4-4), the surge immunity test (IEC 61000-4-5) and the voltage dips, short interruptions and voltage variations immunity test (IEC 61000-4-11) do not apply.

Table 204 – Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The ROOT PI is intended for use in the electromagnetic environment specified below. The customer or the user of the ROOT PI 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	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ROOT PI, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz 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 metres (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.

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 ROOT PI is used exceeds the applicable RF compliance level above, the ROOT PI should be observed to verify normal operation. If abnormal performance is observed, additional

b measures may be necessary, such as reorienting or relocating the ROOT PI.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

Table 206 – Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM –for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the ROOT PI			
The ROOT PI is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ROOT PI can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ROOT PI 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**		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3,5}{E_1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
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 metres (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) according 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.			

IV. SYMBOL DESCRIPTIONS

The following symbols may appear in this manual, on the label, or on it's accessories. Some of the symbols represent standards and compliances associated with the Apex Locator and its use.

Caution: Consult accompanying documents

Authorized Representative in the European Community

CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.

Date of manufacture.

Manufacturer

SN Specifies serial number

Type BF applied part

Direct current

Sterilizable up to the temperature specified at most

The device should not be used after the end of the shown or the day

DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.

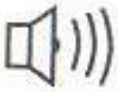
length adjustor of apical constriction to decrease the length displayed on the panel

length adjustor of apical constriction to increase the length displayed on the panel

alert adjustor displayed on the panel to select required volume level or call off function of alert

power on/off control button displayed on the panel

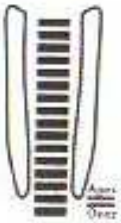
ROOT PI Font of ROOT PI displayed on the surface



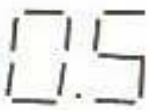
alert indicator displayed on the LCD screen

battery indicator displayed on the LCD screen

Position of the file in the root canal during operation displayed on the LCD screen



Display the magnified apex portion below 1.5 mm in the form of scale displayed on the LCD screen, each square stands for 1 mm.



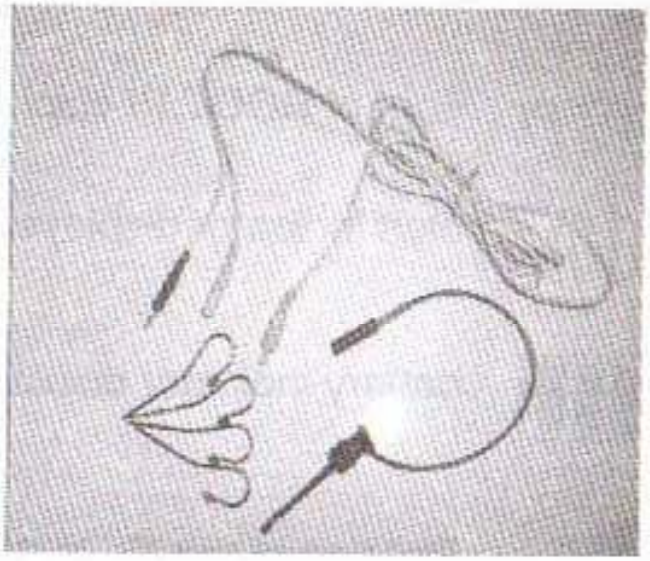
Length between top of file and the apex of root canal during operation displayed on the lower left corner of LCD

SECTION 2: MAIN TECHNICAL INDEX

1. Classification: Internally powered equipment
2. Power source: powered by battery (5×1.5V DC)
3. Power consumption: 0.36w
4. Current: 10μA 5. Voltage: 80mv.AC
6. Display mode: color LCD screen and piezoelectric buzzer
7. Feature: W120×H118×D80mm 8. Weight: about 600g

SECTION 3: COMPONENTS

Main body

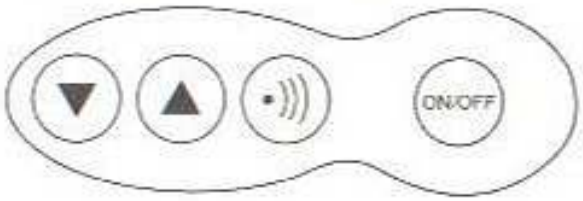


Accessories

1. Testing Wire
2. File holder
3. Electrode

SECTION 4: FUNCTIONS

Panel Description on the top of unit



Symbols 1---2-----3----------4

1-length adjustor of apical constriction to decrease the length displayed on the panel

2-length adjustor of apical constriction to increase the length displayed on the panel

3-alert adjustor displayed on the panel to select required volume level or call off function of alert

4-power on/off control button displayed on the panel

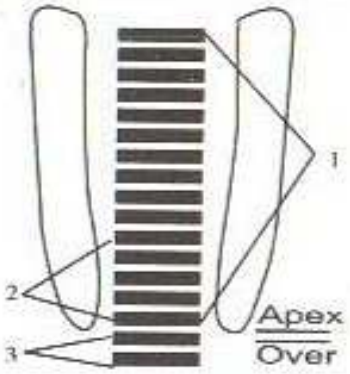
Notice:

Holding down the on/off key for more than two seconds turns on the power and the LCD panel lights.

Holding down the on/off key for more than two seconds while the power is on turns off the power and the LCD panel display turns off.

LCD Description

1. magnified apex portion & overstepping area



The magnified apex portion below 1.5 mm in the form of scale displayed on the LCD screen, each square stands for 1 mm.

Figure 1—15 yellow-squares defined as apex portion (1.5 mm in total)

Figure 2—5 yellow-squares defined as apical constriction (0.5 mm in total)

Figure 3 –2 red-squares defined as overstepping area (perforation)

Notice:

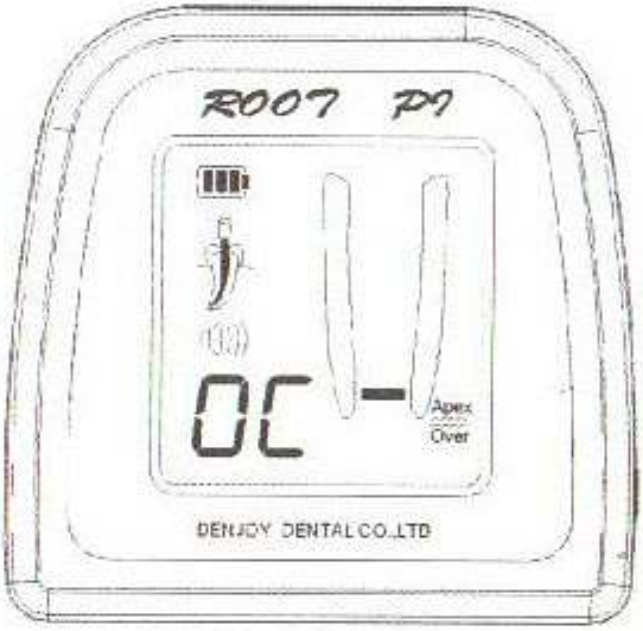
The original length of apical constriction is 0.5mm, which can be adjusted by function button if necessary. You are free to set more or less than 5 yellow squares as the apical constriction of apex. You just press function button of length adjustor of apical constriction to set the length you want.

While turning on, the toppest yellow square of apical constriction of is flashing (Inactive status).

Please refer to the following chart.

set the length of apical constriction as 0.5 mm and 0.2 mm

Inactive status 0.5 mm



Inactive status 0.2 mm

2. The digital figure shows the length between top of file and the apex of root canal during operation displayed on the lower left corner of LCD screen.

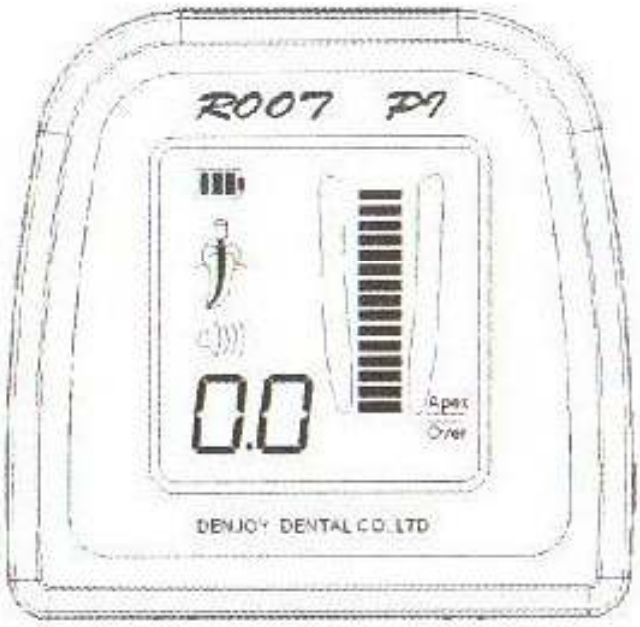
Notice: The following 4 charts show that the process of file is moving in the root canal!

1.0 mm to apex------0.5 mm to apex------0 mm to apex -----Perforation

1.0 mm to apex

0.5 mm to apex

0 mmto apex



Perforation

3. Alert indicator

Push button (the third button of the panel on the top of unit) to select required volume level or switch off the function of alert indicator if necessary. The volume level is shown in the follow

sequence along with each progressive press of the button:

High Medium Low Off

When the file reaches the position 2.0 mm away from the apex of the root-canal, there will be continuous alarm.

4. Battery indicator

The symbol lies on the top left corner of the screen, showing the leftover power. Change the battery immediately while the battery sign is flashed.

 Full charge

 Appro. 30-75% remains

 Less than 30%

 Low voltage. Change the batter immediately

SECTION 5: OPERATION

a. The plug of the testing wire should be completely inserted into the socket on the right side of the main body.

b. Press the button of the power on/off. Check that the figure can appear on the screen and the yellow squares of scale displaying the magnified apex area are twinkling.

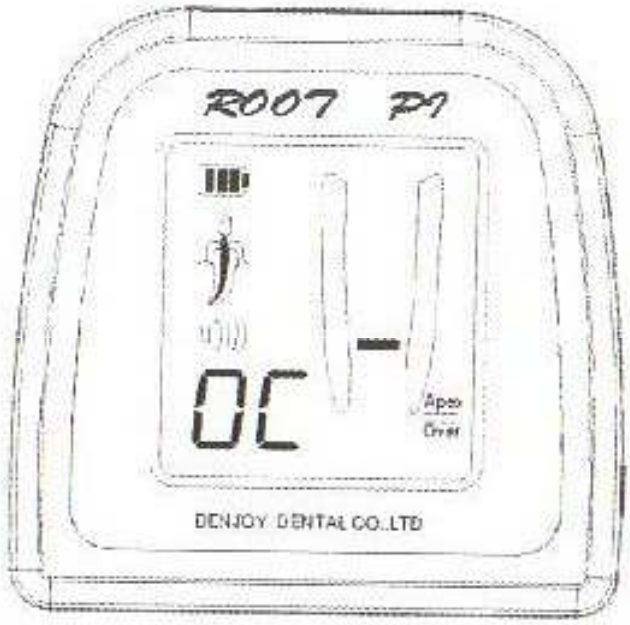
Then insert the file into the root-canal with the file holder.

c. Please connect the holder to testing wire and insert the stainless electrode into the interface, then hang it up at any side of the sufferer's mouth.

d. Clip the metal part of the file with the holder.

e. IMPORTANT STEP

Firstly set the length of apical constriction as 0.5mm. When the endodontic file reach the position refering to Chart B, the digital figure on the LCD panel is 0.5mm.



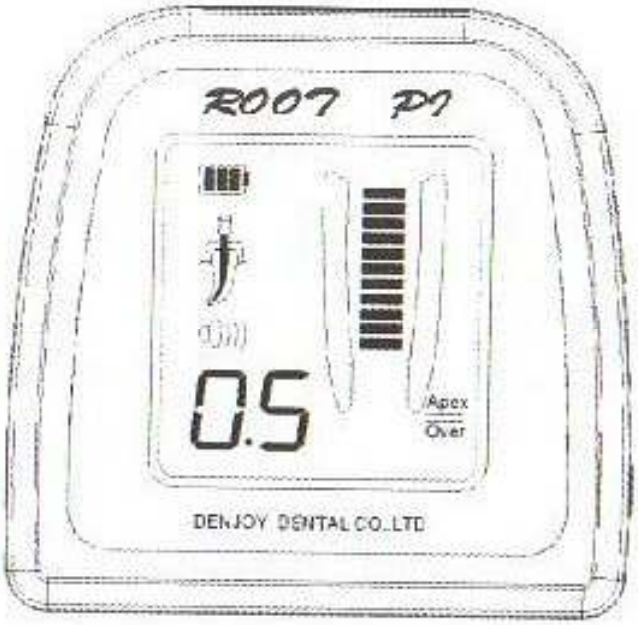


Chart A **Chart B**

Secondly, At this time, **STOP** probing into the apex with endodontic file.

Thirdly, please fasten the file with the rubber vernier caliper on the reference point of the tooth crest(cutting edge or the edge of pit and fissure).

Fourthly, pull the endodontic file out of root canal. And this means that the file has reach the position of the apical constriction. (Generally the length of apical constriction is ranging from 0.2 to 0.5mm.)

f. IMPORTANT STEP

Deciding the working length of root canal

Measure the distance from the bottom of rubber vernier caliper to the tip of the file. Note down this **figure.** So this **figure** need to minus 0.01-0.03 mm is the most suitable **working length of root-canal**.

REMARKS: The working length of root canal varies from each other for the reason of different shapes of teeth and root-canal.

g. After operation, please switch off the instrument. If the dentists forgot to switch off the instrument, the instrument will automatically be power off.

SECTION 6: SAFETY PRECAUTIONS

CAUTIONS:

a. Before operation, you have to read user manual carefully.

b. Like all of the other electric facilities, this machine has an electromagnetism disturbance. When there is a patient who is now using the cardiac pacemaker, or there is an electronic operation,

please don't put the machine around. The cardiac pacemaker sufferer, viz. the serious cardiac pulse abnormality sufferer, is forbidden to use this machine.

c. Please put in the battery before use. Make sure that the power of the battery is in sufficient supply to guarantee the correct measurement result.

When change the battery, do not mix the old battery with the new one and mix the alkali battery with the manganic one.

Please take off the battery in the event of longtime nonuse or long –distance transit.

d. Please use the file with the resin handle rather than mental one. Even when using the file with the resin handle, please notice that the fingers should be avoided touching the mental part of the file.

e. Please clip the upper portion of the file rather than the down portion with the holder, other wise, the metal part of the holder and the resin part of the file would be damaged. The damaged holder will affect the measure result.

f. When the file accidentally touches the inner part of the root-canal, the reading of scale will get a bit abnormality, then will get right automatically a few seconds later.

g. The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.

h. The enclosure of the main body of device is not designed to

give any protection against ingress of water. Please keep the device away from any harmful ingress of water.

SECTION 7: MANTENANCE & SERVICE

I. MANTENANCE

The device is maintaained free of charge and doesn't require any routine maintenance within warranty period. The device cannot be repaired. Dispose it if there is any problem.

Do not modify and disassemble the device.

This instrument described below has been fully inspected and confronts to the current products specification.

This instrument is guaranteed for its designated use, against original defects in materials and workmanship for a period of 12 months from date of purchase.

Products warranty or service will not be extended if (1) the product is repaired, modified, misused, disassembled, or using the parts are not provided by the manufacturer, (2) The serial number of the product is defaced or missing.

II. CLEANING AND DISINFECTION

MAIN BODY CLEANING INSTRUCTION

When the surface of main body is polluted, please rub the surface with dry soft cloth ONLY.

REMARKS: Any liquid lotion like ethanol, banana oil and light oil are not allowed.

TESTING WIRE CLEANING INSTRUCTION

Please wipe the testing wire with the soft cloth stained with ethanol and reuse it after it is completely dry.

ELECTRODE AND FILE HOLDER DISINFECTION INSTRUCTION

The front part of the file holder, which is easily get polluted with rubbish and liquid medicine, should be disinfected by the ethanol.

Stainless electrode and file holder should be disinfected at temperature 121℃ for 20 minutes and disinfection by autoclave is preferred.

III. BATTERY REPLACEMENT

When the battery no longer holds a charge, it should be replaced by 5 pieces of 1.5V DC AAA dry Li-on battery. The batteries are recyclable. Remove the old battery from battery compartment and follow your local recycling guidelines.

SECTION 8: TOUBLESHOOTING GUIDE

Question: After switch on the machine, the LCD screen has no reaction.

Answer:

a. Check that the 5pcs dry batteries are fixed properly.

b. Check that the power of the battery is in sufficient supply.

Question: No alert

Answer:

a. Check the alert adjustor button of panel on top of unit.

b. The file has not reached the point less than 2mm at which the machine will give an alert.

Question: NO changes or incorrect reading on the LCD screen

Answer:

a. Do not clip the file with the holder firstly and switch on the machine secondly.

b. Remember to hang the stainless electrode up at any side of the sufferer's mouth.

c. Check testing wire connections both at unit and at AC outlet to be sure they are properly seated.

d. The metal part of the file holder may be polluted or corroded.

SECTION 9: ENVIRONMENTAL REQUIREMENTS

OPERATING CONDITIONS

Ambient temperature: 10℃ ~ 40℃

Relative humidity range: 10% ~ 93%

Atmospheric pressure: 86KPa~ 1006Kpa

STORAGE AND SHIPPING CONDITIONS

Ambient temperature: 10℃ ~ 40℃

Relative humidity range: 10% ~ 93%

Atmospheric pressure: 86KPa~ 1006KPa

Equipment is not suitable for storage in the presence of sunlight, rain, dust, corrosive gasoline and volatile without poor ventilation. Transportation is applicable to all common methods.