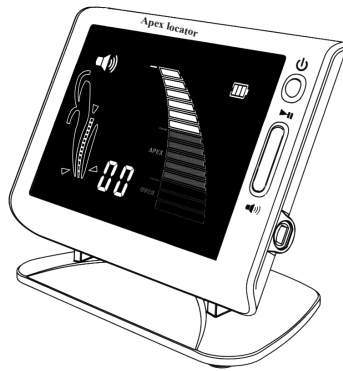


# RPEX 6

## Apex Locator User Manual

Please read the instructions before usage



Product Type:

Brand:

Model:

Producer Company:

Exporter Company:

Importer Company:

Apex Locator  
APPLE DENTAL

Rpex 6

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# Contents

1 Introduction	1
2 Notice	6
3 Installation	7
4 Operation	11
5 Trouble shooting	16
6 Disinfection, cleaning and sterilization procedure for the accessories	18
7 Storage, maintenance and transportation	22
8 Environmental protection	22
9 Warranty	23
10 Standard symbols	23
11 Statement	24

## **1 Introduction**

### 1.1 Description of the device

Apex locator is a supporting device of endodontic treatment, through measuring the apexworking length, helping dentists to finish the endodontic treatment.

Device Features:

- a) Advanced multi-frequency network technology of apex location and automatic calibrating ensures the measurements are accurate.
- b) Large colored display, touch button, different colors indicate the trajectory of the file clearly.
- c) High capacity rechargeable battery with 3.7V/2000mAh.
- d) The File clip, Lip hook and Touch probe can be sterilized by autoclaved sterilizer.
- e) Visual angle can be adjusted flexible.

### 1.2 Model, Dimensions and Weight of main unit

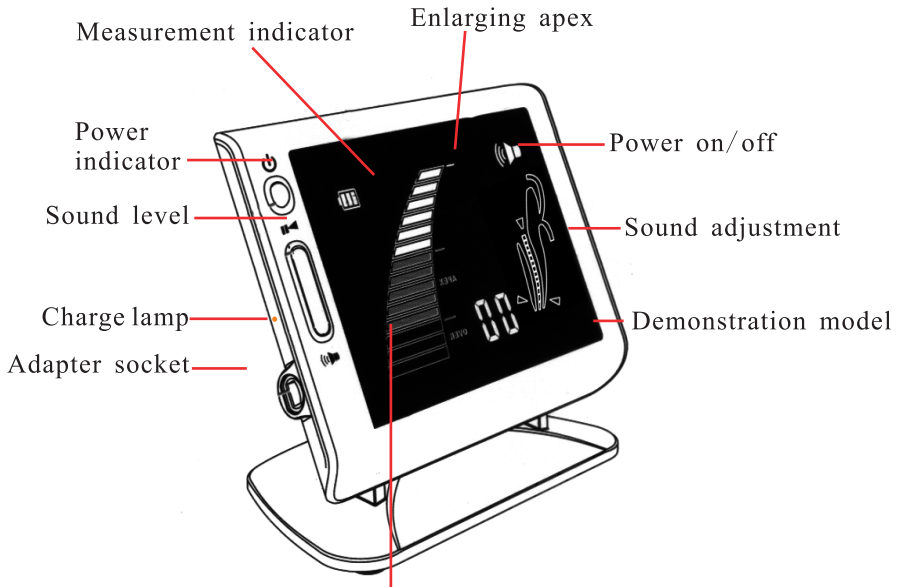
1.2.1 Model: RPEX 6

1.2.2 Dimensions: 131mm (Length) × 75mm (Width) × 105mm (Height)

1.2.3 Weight: 446g

### 1.3 Components

#### 1.3.1 The structural figure of the device. (Fig. 1.1)



The reduced figure indicates the file progression towards the apex

Fig. 1.1

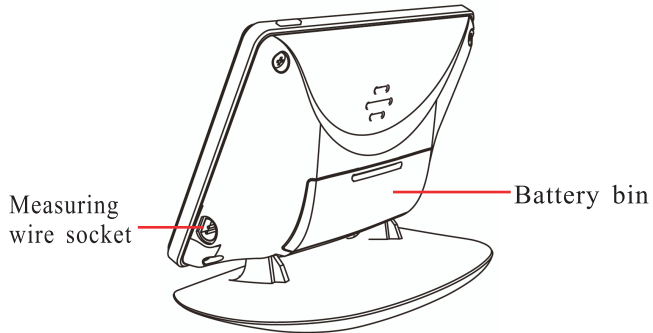
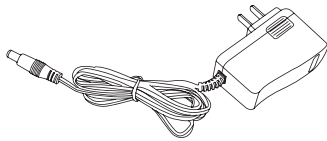
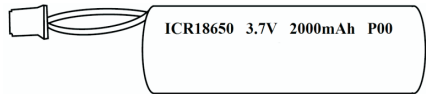


Fig. 1. 1 The device structure

1.3.2 The figure of the main accessories. (Fig. 1.2)

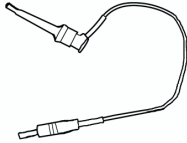


a Adapter

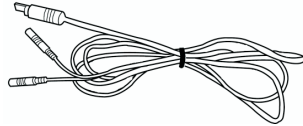


b Battery

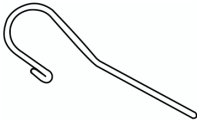
Fig. 1. 2 The main accessories



c File clip



d Measuring wire



e Lip hook



f Touch probe

#### 1.4 Structure

RPEX 6 is composed of main unit, measuring wire, lip hooks, file clip, touch probe, adapter, etc..

#### 1.5 Intended use

RPEX 6 is an electronic device used for apex location determination and working length determination. This product must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

#### 1.6 Contraindication

The RPEX 6 is not recommended for use:

a) In patients who have a pacemaker or other implanted electrical devices, or have been cautioned by their physicians

against the use of small electric appliances such as shavers, hair dryers etc.

b) In patients allergic to metals.

c) In children.

#### 1.7 The classification of the device

1.7.1 Type of protection against electric shock: Class II internally powered equipment.

1.7.2 Degree of protection against electric shock: Type BF applied part.

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

1.7.4 Device not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide.

1.7.5 Operation mode: Continuous operation.

#### 1.8 The main technical specifications

1.8.1 Battery: 3.7V/2000mAh

1.8.2 Adapter: ~100V-240V 50Hz/60Hz

1.8.3 Consumption power:  $\leq 0.5W$

1.8.4 Screen: 4.5" LCD

1.8.5 Buzzer alert: The buzzer will alert when the file is less than 2mm closed to the apex.

1.8.6 Operation condition

- a) Environment temperature: 0 ~ 40°C
- b) Relative humidity: 10 ~ 85%RH.
- c) Atmosphere pressure: 60kPa ~ 106kPa

## **2 Notice**

2.1 Please read the user manual carefully before the operation.

2.2 The scale indication on the RPEX 6 screen does not represent a distinct length or distance in mm or other linear units. It simply indicates the file progression towards the apex.

2.3 The following patient's related factors may prevent accurate readings: Blocked root canals, Cracked root canals, Perforated root canals, Root fracture or perforation, Metal crows or bridges contact with the file or the lip file, The inner liquid link to the outer liquid of root canals, Very dry root canals, The file or the file clip contact with other metal or instruments.

2.4 Inaccurate or incorrect readings due to the environment are likely to occur in the following cases:

- a) Presence of portable or movable radio frequency transmitters in the surroundings.
- b) Electromagnetic interference could cause improper operation of the device.

2.5 This device has electromagnetic interference which is similar



to other device, the patient or doctor who with a pacemaker are forbidden to use this device.

2.6 The apical position is located to the place apex locator screen indicates "00" , as a safety precaution in order to avoid over-instrumentation, it is recommended to subtract 0.5 mm to determine the working length for shaping.

2.7 If the screen makes a large movement suddenly or immediate display "OVER" when the file insert to the canal, continue push the file slightly towards the apex, the display will returns to normal.

2.8 In order to prevent leakage or interference between the root canal and resulting in inaccurate measurements, dry the cavity entrance with a cotton pellet.

2.9 Please recharge the battery when the battery power is low and indicator flashes.

2.10 Only the original accessories to this device.

### **3 Installation**

#### 3.1 Connect the Measuring Wire

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

3.1.2 Insert the file clip and lip hook respectively into the two sockets of the measuring wire. (Fig. 3.1)

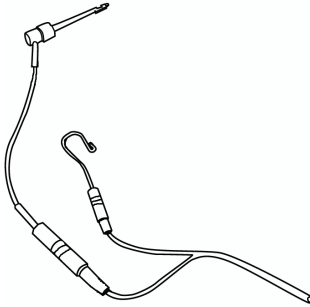


Fig. 3.1  
The connection of File clip,  
lip hook and measuring

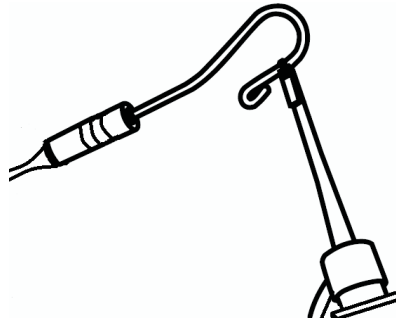


Fig. 3.2  
Test the file clip and  
measuring wire

3.1.3 Press the power switch, the screen will display the root canal measuring scene. The device will shutdown automatically after 5 minutes without operation.

3.1.4 Make the lip hook touch the bent wire of the file clip (as showed in Fig. 3.2), the screen will be displayed " — — " , (as showed in Fig. 3.3 c), otherwise, it means the file clip or the measuring wire is damaged, should be replaced.

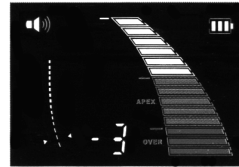
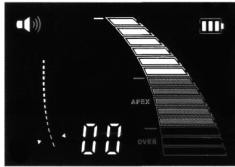
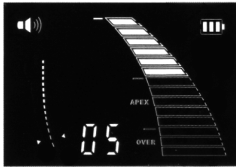
3.1.5 Explain the interfaces displayed

a) The white region of instruction bars on the screen is the front region of the apical foramen. (Fig. 3.3a)

b) The file position is near by the apical foramen when the green bars displayed. (Fig. 3.3b)

c) The file exceed the apical foramen, the screen will display “— —” and make a continuous beep sound. (Fig. 3.3c)

3.1.5 Enlarged display of apical foramen. (Fig. 3.3)



a The front region of apex

b The file is near apex

c The file exceed the apex

### 3.2 Demonstrated model

Demonstrated model can show the movement track of file.

Operation is as follows:

a) Pulling out the measuring wire and adapter.

b) Turn on the device.

c) Pressing the touch button “▶” last for 1 second can enter

the demonstrated model which shows the movement track of file.

d) Reprress the demonstrated model touch button or the

demonstration is finished, then the demonstration is exit.

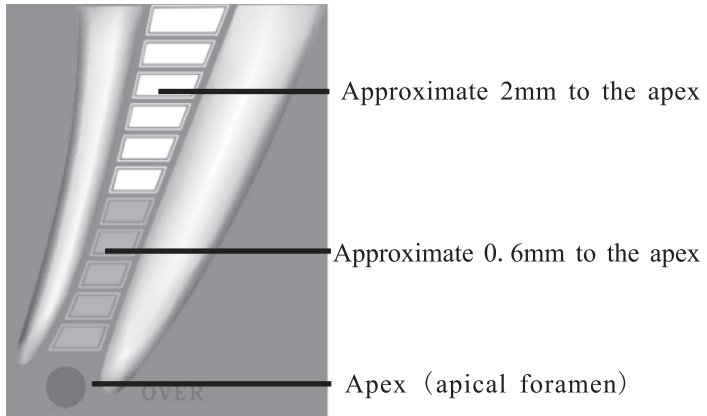


Fig3. 4

### 3.3 Charge the battery

When the power indicator flashes, please stop using the device and recharge the battery.

- a) Connect the AC adapter with the left side socket of the device properly, and insert the AC adapter plug to the power socket.
- b) The yellow indicator is lighted when the device is charging, it means charging has finished when the yellow indicator turns

down. It may spend 6 hours for charging because of the high capacity battery.

Attention: Please don't use the device when it is charging.

## **4 Operation**

### 4.1 Preparations

4.1.1 The use of apex locators alone without a preoperative and postoperative radiograph is not a recommended practice, since apex locators may not be able to work properly in all conditions. It is recommended to take an X-ray prior to the use of the unit, and compare the information given by both means.

4.1.2 The dentists should know the teeth position and average length well, and master the operation skills.

4.1.3 The root cavity exposes sufficiently and the root canal can not be blocked.

4.1.4 Size of the measuring differing significantly from the canal diameter. Ideally, the selected file should be the thickest one capable of reaching the apex.

4.1.5 Prior to the use of the device, the liquid and/or tissue debris in the access cavity must be wipe out with a cotton pellet and keep the access cavity dry.

4.1.6 The file and file clip can not contact with the gingival, the metallic dental structure and other metal or device. Be

particularly careful with patients fitted with metal crowns or bridges. If the tooth crown is broken, the tissue of the gingival contact with the cavity of the root cavity, the measurement can be continued when the crown is fixed by gypsum or other insulators.

4.1.7 The very dry canals must be moistened with an irrigation solution, such as the normal saline or hydrogen peroxide solutions, and then dry the access cavity with a cotton pellet/air-blower.

4.1.8 If the root canal is bleeding or the blood overflow from the apical foramen, the measurement can be continued when the bleeding is stopped.

4.1.9 The retreatment of the root canals must be completely removing the remnants prior to use.

4.1.10 Concentrations of NaClO solutions higher than 3% may result in reduced accuracy.

4.1.11 As a safety precaution in order to avoid over-instrumentation, it is recommended to subtract 0.5mm to determine the working length for shaping.

4.1.12 If the bar graph makes a sudden large movement or immediate display 'OVER' when the file insert to the canal, continue push the file slowly towards the apex the displays returns to normal.

4.1.13 Accessories including file lip, lip hooks or forks should be clean and without residue of chemical disinfectants or other medicinal solutions.

4.1.14 Mark an anatomized symbol on the diseased tooth and memorize it on the medical records. 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.

4.1.15 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.

4.1.16 The cases are not suited for a normal measurement as follows:

- a) The measurement length of the root canal will be shorter than its real length because of the root hypoplasia when the root size is similar to apical foramen size.
- b) The crack root may cause the electric leakage which will affect the accuracy of measurement.

4.1.17 The improper shooting angle of X-ray may cause the illusion that the file tip haven't reached the root canal tip.

Sometimes, the results of the Apex Locator and X-rays does not

match well, which is neither because the machine is not normal, nor the photo is incorrectly taken, this is due to the apical foramen slightly to the side of the root canal crown, this is very common. According to the photo shooting angle as follows, it will cause illusion that the file tip hasn't reached the root canal tip.(Fig. 4.1)

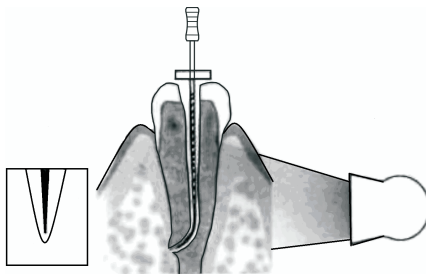


Fig. 4. 1 The improper shooting angle of X-ray may cause the illusion that the file tip haven't reached the root canal tip

## 4.2 Operation procedure

4.2.1 Insert the plug of measuring wire into the left side socket of main unit. Turn it on. The screen will display the measuring interface.

4.2.2 Touch the touch button slightly, and adjust the suitable volume.

4.2.3 Hang the lip hook on the lip, make sure it contact the oral mucosa as a reference electrode. (Fig. 4.2)



4.2.4 Clip the metal part near the file shank vertically with the file clip, and then push the file towards to the apex slowly, the continuous alarm will sound when the distance is less than 2mm. Attention: Please use the resin needle file, wear gloves and don't touch the metal part with finger.

4.2.5 The apical position is located to the place when the apex locator screen indicates '00', when the file reaches the apical position, adjust the rubber piece set of the file to the reference point (incisal edge or fossa edge), then pull out the file, measure the length between the file tip and the rubber piece, and the length is the working length of the tooth. It also can use the touch probe instead of file clip, when it is inconvenient to measure the back teeth. (Fig.4.2)

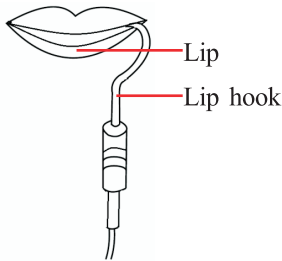


Fig. 4.2 Hang the lip hook on the lip

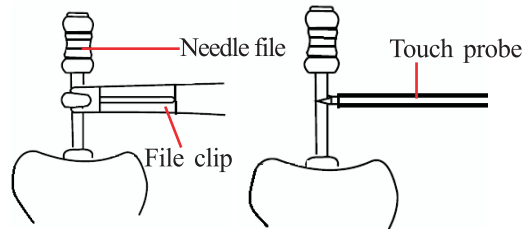


Fig. 4.3 Adjust the rubber and determine the working length

## 5 Trouble shooting

Problems	Possible causes	Solutions
No displays on the screen after turning on.	<ol style="list-style-type: none"> <li>1 The incorrect battery installation.</li> <li>2 The lower power.</li> </ol>	<ol style="list-style-type: none"> <li>1 Install the battery correctly.</li> <li>2 Recharge the battery.</li> </ol>
No sound during the procedure.	The sound control is set at "Mute" level.	Adjust to the suitable sound level.
Could not measure the root canal length.	<ol style="list-style-type: none"> <li>1 The connection of accessories is incorrect.</li> <li>2 The measuring wire is broken.</li> </ol>	<ol style="list-style-type: none"> <li>1 Connect the accessories correct.</li> <li>2 Change the measuring wire, contact the lip hook with the file clip check if the measuring wire is broken.</li> </ol>
Indication of the file position is not steady during the procedure.	<ol style="list-style-type: none"> <li>1 There is not a good contact between the lip clip and the oral mucosa.</li> <li>2 The connection lip hook is soiled.</li> <li>3 Deep caries provides a conductive path outside the canal.</li> <li>4 Perforation or the adjacent surface has caries.</li> <li>5 Large lateral canal.</li> </ol>	<ol style="list-style-type: none"> <li>1 Ensure a good contact between the mucosa and lip hook (Place the lip hook in the labial angle opposite the tooth to be treated).</li> <li>2 Clean the connection hook (with Ethanol)</li> <li>3 Block the external conductive path.</li> <li>4 Remove the file, close the perforation and repair the caries, then repeat the apex detection procedure, carefully inserting the file in canal.</li> <li>5 Try continuing the procedure by gently advancing the file.</li> </ol>

Problems	Possible causes	Solutions
<p>The device does not show file progressive inside the canal.</p>	<ol style="list-style-type: none"> <li>1 Bad electrical contact.</li> <li>2 The connection hook is not properly connected to the file.</li> <li>3 The root canal is obliterated.</li> <li>4 In the case of retreatment: old filling material residues may block the root canal.</li> <li>5 The root canal may be blocked by the remnants of a medication (e.g. calcium hydroxide).</li> <li>6 Root canal is extremely dry.</li> <li>7 The selected file is too small for a large root canal.</li> <li>8 Electronic malfunction.</li> </ol>	<ol style="list-style-type: none"> <li>1 Perform the cable connection test as described in the User Manual.</li> <li>2 Place the connection hook on the metal part of the file below the plastic handle.</li> <li>3 Check the comparative X-ray image for hints.</li> <li>4 Remove old root filling material residues prior to use.</li> <li>5 Completely remove the remnants prior to use.</li> <li>6 Rinse the root canal with NaCl solution. Dry the access cavity with a cotton pellet/ air-blower.</li> <li>7 If there is no parietal contact use large ISO size file. Important: exactly fitting files lead to precise results.</li> <li>8 Contact your distributor or us.</li> </ol>

Problems	Possible causes	Solutions
Display reaction is over-sensitive: apex/over is activated before it is reached.	<p>1 Short circuit due to excess liquid (irrigation solution, saliva, blood) in the pulp chamber.</p> <p>2 A direct contact of the file with the gingival or gingival proliferations, e.g. a fractured metal crown.</p> <p>3 A direct contact of the file with metal restorations (crown, parapulpal post, amalgam filling).</p>	<p>1 Dry the access cavity with a cotton pellet/air blower. In case of excess bleeding wait until it has stopped.</p> <p>2 For isolation:</p> <p>a) Adequate preparation filling.</p> <p>b) Use a rubber dam.</p> <p>3 Isolate the file by placing 2-3 silicon stoppers on it or insert the file in a small polyvinyl tube before use.</p>

**Notice: If the problem can not be solved yet, please contact the local distributors or us.**

## 6 Disinfection, cleaning and sterilization procedure for the accessories

### 6.1 Foreword

The lip hook, the file clip and the touch probe 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 General recommendations

- a) The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments.
- b) For your own safety, please wear personal protective equipment (gloves, glasses, mask).

c) Use only disinfecting solution which is approved for their efficacy (VAH/DGHM-listing, CE marking, FDA approval)

### 6.3 Procedure for lip hook, the file clip and the touch probe

Operation	Operation mode	Warning
Pre-Disinfection or Decontamination	Soak immediately just after usage all instruments in a disinfectant solution combined with proteolytic enzyme if possible.	<p>1 Follow instructions and observe concentrations and immersion time given by the manufacturer (an excessive concentration may cause corrosion or others defects on instruments).</p> <p>2 The disinfectant solution should be aldehyde free (to avoid blood impurities fixation).</p> <p>3 Do not use disinfectant solution containing Phenol or any products which are not compatible with the instruments (See general recommendation).</p> <p>4 For visible impurities that are observed on instruments, a pre-cleaning is recommended by brushing them manually with soft material.</p>
Rinsing	Rinse manually and abundantly the accessories with current water.	

Operation	Operation mode	Warning
Manual Cleaning	Clean manually the accessories with an adequate brush, preliminary soaked in a clean pre-disinfectant solution.	1 The hook mechanism has to be activated during the cleaning process (press several times the push button). 2 No visible impurities should be observed on the accessories.
Rinsing	See point # 2.	
Disinfection	Immerse the accessories in a disinfectant solution (bactericidal, virucidal, fungicidal, tuberculocidal and aldehyde free) according to the manufacturer recommendations.	Follow instructions and observe concentrations and time given by the manufacturer.
Final rinsing	1 See point # 2. 2 After rinsing, the accessories have to be dried.	
Inspection	Inspect devices and sort out those with defects.	Dirty instruments must be cleaned and disinfected again.

Operation	Operation mode	Warning
Packaging	Pack the devices in “Sterilization pouches”.	<p>1 Check the validity period of the pouch given by the manufacturer to determine the shelf life.</p> <p>2 Use packaging which are resistant up to a temperature of 141°C (286 °F) and in accordance with EN ISO 11607.</p>
Sterilization	Steam sterilization at: 134°C (237°F) during 18 min.	<p>1 The accessories (lip hook, file clip and touch probe) must be sterilized according to the packaging labeling.</p> <p>2 Use fractionated vacuum or gravity (less preferred) autoclaves (according to EN 13060, EN 285).</p> <p>3 Use validated sterilization procedure according to ISO 17665-1.</p> <p>4 Respect maintenance procedure of the autoclave device given by the manufacturer.</p> <p>5 Use only the listed sterilization procedures.</p>
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).environment.

## **7 Storage, maintenance and transportation**

### 7.1 Storage

7.1.1 This device should be stored in a room where the relative humidity is  $\leq 85\%$  RH, atmospheric pressure is 50kPa~106kPa, and the temperature is  $-10^{\circ}\text{C}\sim+50^{\circ}\text{C}$ .

7.1.2 Not suitable for use in the presence of flammable anesthetic mixtures with air. Oxygen or nitrous oxide.

### 7.2 Maintenance

7.2.1 The device does not contain user serviceable parts. The service and repair should be provided by trained service personnel only.

7.2.2 After each use, all the objects that were in contact with infectious agents should be cleaned using towels impregnated with a disinfecting and detergent solution (a bactericidal, fungicidal and aldehyde free solution). Use of chemical agents may cause damage to the equipment.

7.2.3 The file clip, the lip hook and the fork must be sterilized between treatments by autoclaving at  $134^{\circ}\text{C}$ .

7.2.4 The measuring cable can not be autoclaved.

## **8 Environmental protection**

There is no harmful substance in this product. You can dispose it according to the local law.



## 9 Warranty

9.1 RPEX 6 is warranted for 24 months from the date of purchase.

The accessories (cables, battery etc.) are warranted for 12 months from the date of purchase.

9.2 The warranty is valid for normal usage conditions. Any modification or accidental damage will render the warranty void.

## 10 Standard symbols



Power on/off



Sound adjustment



Demonstration model



Used indoor only



Date of manufacture



Manufacturer



Serial number



Attention, consult accompanying document



Class II equipment



Type BF Applied part



Direct current

**IPX0**

Ordinary equipment



Recovery



Keep dry



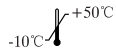
Handle with care



Storage relative humidity less than 85%RH



Storage atmospheric pressure at 50kPa~106kPa



Storage temperature at -10°C ~ +50°C



Deal with the product according to the WEEE (2002/96/EC)

## 11 Statement

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference.