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Apex locator Minipex

Instruction Manual

CE 0197

Guilin Woodpecker Medical Instrument Co., Ltd.

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.

There are two brands of WOODPECKER Company: WOODPECKER and DTE. 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) 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 and Touch probe can be autoclaved under high temperature and high pressure, avoiding cross infection effectively.

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

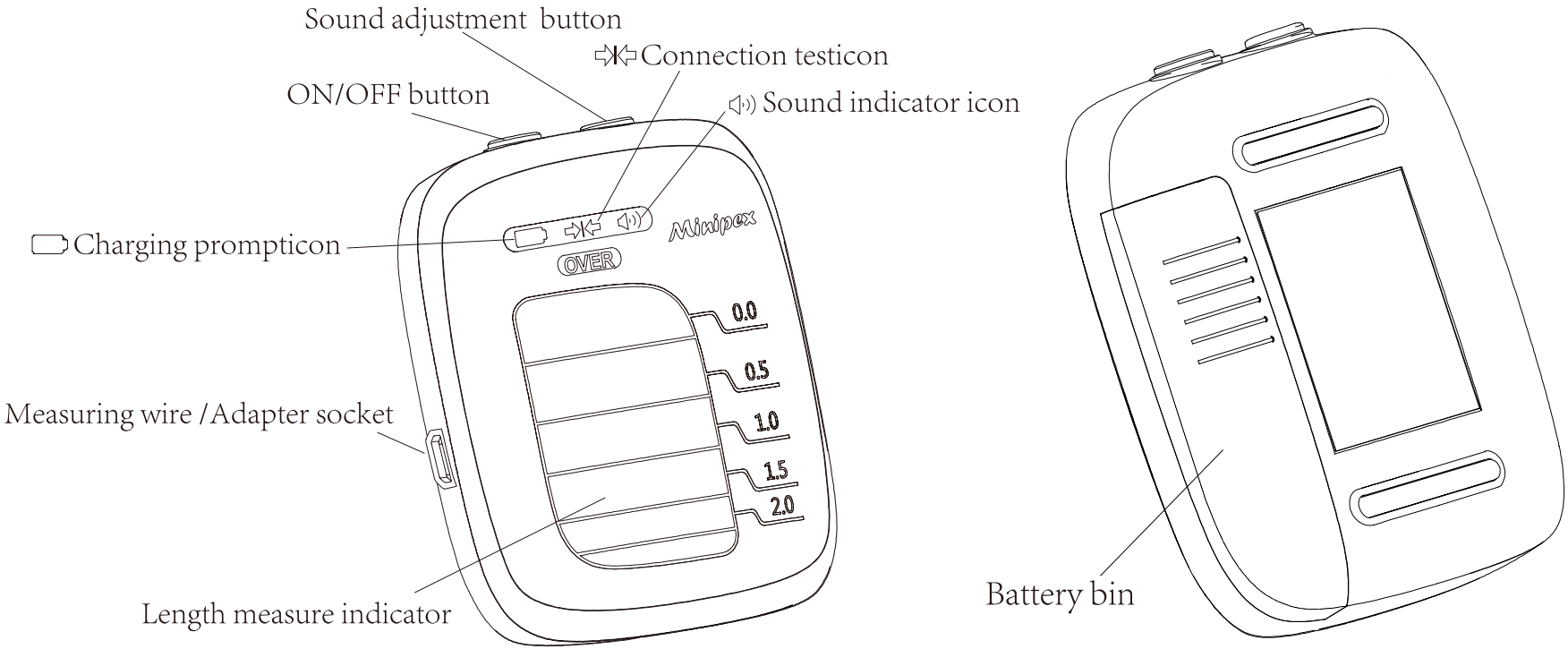
1.3 Model and dimensions

1.3.1 Model: Minipex

1.3.2 Dimensions: 70mm (length) × 62mm (width) × 20mm (height)

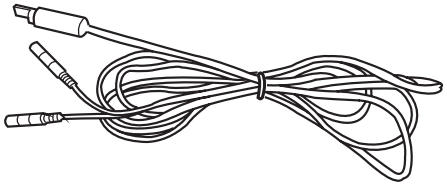
1.4 Components

1.4.1 Picture of the main unit. (Picture 1)

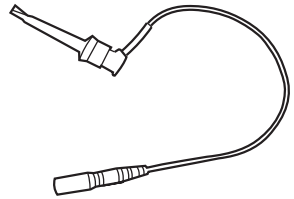


Picture 1

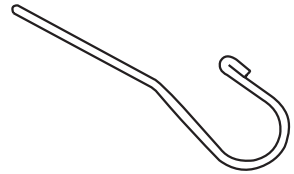
1.4.2 Pictures of the main accessories (Picture 2)



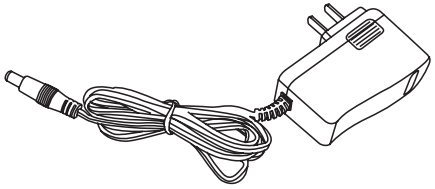
Measuring wire



File clip

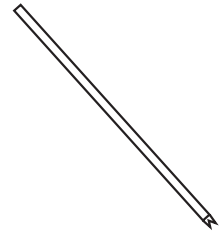


Lip hook



Adapter

Battery



Touch probe

Picture 2

1.5 Structure

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

1.6 Intended use

This equipment applies to the measurements below:

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

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

1.6.3 Measurement of the tooth length of transplantation and retransplantation.

1.7 Contraindication

We do not advise the use of Minipex 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 BF 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

1.9 The main technical specifications

1.9.1 Battery: 3.7V/320mAh

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

1.9.3 Consumption power: ≤0.5W

1.9.4 Screen: Segment digital tube

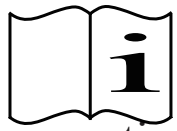
1.9.5 Buzzer alert: The buzzer will alert when the endo file is less than 2mm to the apex.

1.9.6 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



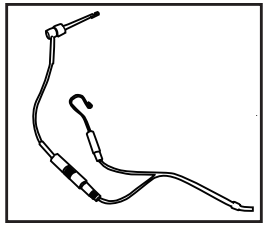
2.1 Please read the instruction manual carefully before the operation.
2.2 As a safety precaution in order to avoid over-instrumentation, it is recommended to proceed as follows: place the file onto an endodontic ruler, where the apex locator screen indicates '00'. Subtract 0.5-1 mm from the measured file length as the Working Length.
2.3 The scale indication on the apex locator screen does not represent a distinct length or distance in mm or other linear units. It simply indicates the touch probe progression towards the apex 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 3.1.3).
2.8 The file clip, lip hook and touch 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.
2.10 When the battery is low, a battery indicator "  " appears on the status bar of the screen. Please recharge the battery when the battery charging prompt icon is blinking.
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

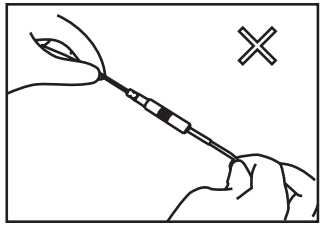
to other device which produces electromagnetic interference. Dentists should be cautious about operation under such environment.
2.16 The guarantee is valid for normal usage conditions. Any disassembly will render the guarantee void, the professionals of Woodpecker company will offer the repair service 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.

3 Installation of the device

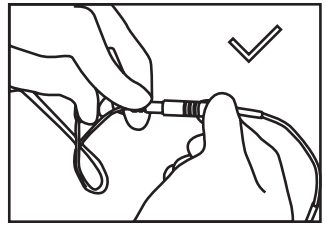
3.1 The Connection of the Measuring Wire
3.1.1 Insert the plug of the measuring wire into the left side socket of the unit.
Attention:
a) Please be careful to use the device, keep it stable and avoid hit. Incautious use will lead to the damage or the failure of the machine.
b) Measurement can not be proceeded without the complete insertion of the plug.
c) Be sure not to hit the plug. Keep the device away.
3.1.2 Insert the file clip and lip hook respectively into the two sockets of the measuring wire. [Picture 3(a)]



Picture 3(a)



Picture 3(b)



Picture 3(c)

Attention:

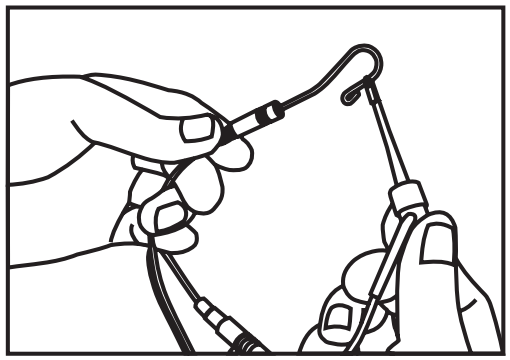
Be sure not to pull the wire when inserting or pulling out the the measuring wire and the file clip. [Picture 3(b)]

Correct operation showed as in Picture 3(c).

3.1.3 Connection Test

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

The device will shutdown automatically after 5 minutes without operation.



Picture 4

Picture 5

b) Make sure if the plug of the measuring wire is inserted into the socket correctly.
c) Make sure if the file clip and lip hook are connected well to the measuring wire.
d) Make the file clip nip the lip hook[as showed in picture 4], the “Connection test⇨|⇦” icon must appear on the status bar[as showed in picture 5]. If no icon appears, it means that the file clip or the measuring wire was damaged, should be replaced.

3.1.4 Explanations on the interfaces displayed

a) The screen displays the front region of the apical foramen by bars. Please refer to the blue region as showed. [Picture 6(a)]
b) The file has gone to the position near by the apical foramen when the yellow bars displayed [Picture 6 (b)].
c) The file has exceeded the apical foramen when the "OVER" bars displayed. A continuous beep sound will be generated at the same time [Picture 6 (c)].

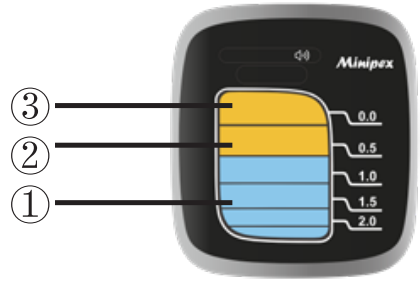
3.1.5 Enlarged display of apical foramen. [Picture 7]

Picture 6 (a)

Picture 6 (b)

Picture 6 (c)

①Approx 2mm to apical foramen
②Approx 0.6mm to apical foramen
③Apex(apical foramen)



Picture 7

3.2 Charge the battery

When the battery is low, a battery indicator appears on the status bar of the screen. Please recharge the battery when the battery charging prompt icon is blinking. However, it is still functional for several treatments before the device shuts down.

3.2.1 Connect the AC adapter and the socket on the left of the device properly, and insert the AC adapter plug to the adapter socket.

3.2.2 During battery charging the battery symbol will blinking, then will remain steady when charging is completed.

3.2.3 After charging, please pull the AC adapter and plug out.

3.3 Sound adjustment

The device is equipped with an audio indicator which enables monitoring of the progression of the file within the canal in addition to visual monitoring.

The volume can be adjusted to three different levels: mute, low, normal, by

successively pressing the “  Sound adjustment” button.

When sound level is muted the “  Sound indicator” icon is turned off. At other sound levels the “  Sound indicator” icon remains turned on.

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 A fully exposed access cavity to show the pulpal cabin.

4.1.4 An 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.

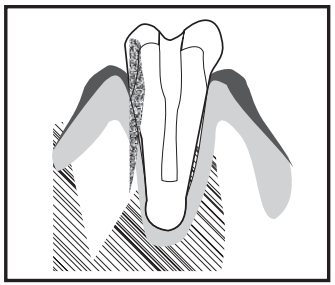
In this case, the measurement result of the length of the root canal will be shorter than its real because of the hypoplasia of the root [Picture 8].

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

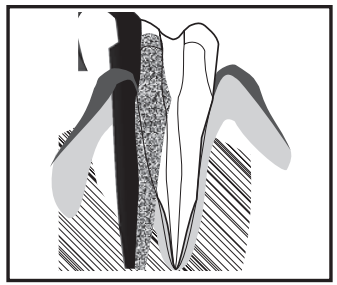
In this case, the blood will overflow from the root canal and reaches gingival that the blood and the gingival will be on a conducting state which will cause an inaccurate result while measuring. The measurement can be continued when the bleeding is stopped [Picture 9].

c) The tooth crown is broken.

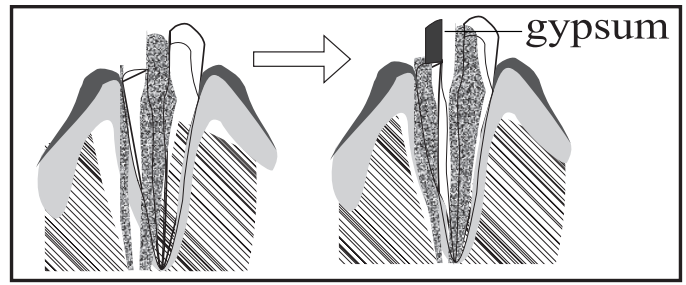
The tissue of the gingival may reach the cavity of the endo hole at the broken point which will cause inaccuracy because of the electronic conduction. The measurement can be continued when the crown is fixed by gypsum or other insulators [Picture 10].



Picture 8



Picture 9



Picture 10

d) There is a crack on the tooth root

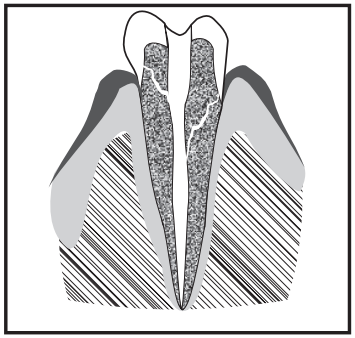
In this case, the crack may cause the electric leakage which will affect the accuracy of measurement [Picture 11].

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

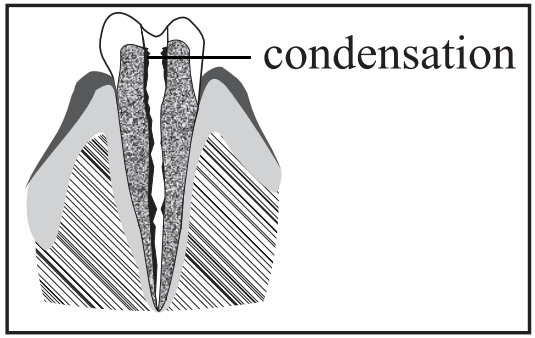
Clean the remaining material in the root canal and fill it with little normal saline before a measurement [Picture 12].

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

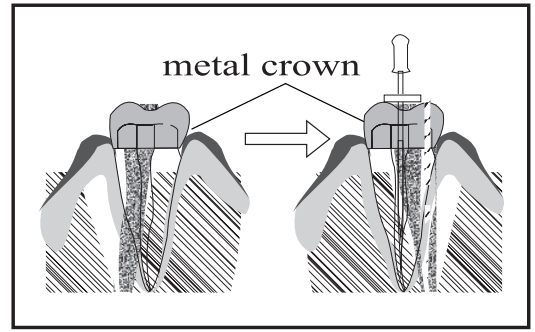
It will cause inaccuracy when the endo file touches metal crown [Picture 13].



Picture 11

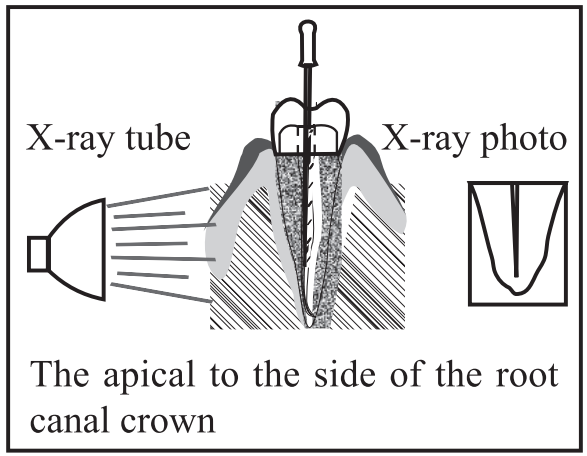


Picture 12



Picture 13

Sometimes, the results of the Apex Locator and X-rays do not meet each other,which is neither because 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 pictures show, it will cause illusion that the front tip of the root canal haven't reached the canal tip. [Picture 14] (Because of the angles 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.)



Picture 14

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.

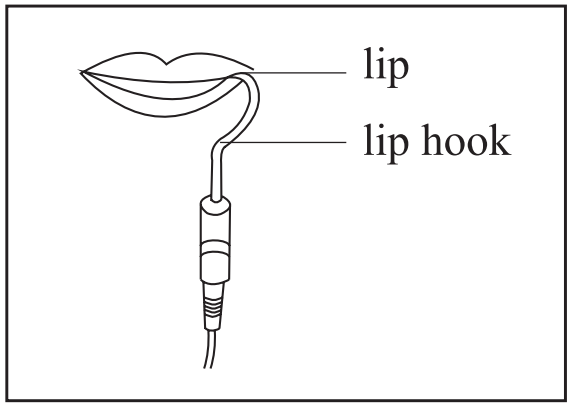
4.2.2 The equipment is in the normal condition. The equipment shuts down after 5

minutes without use.

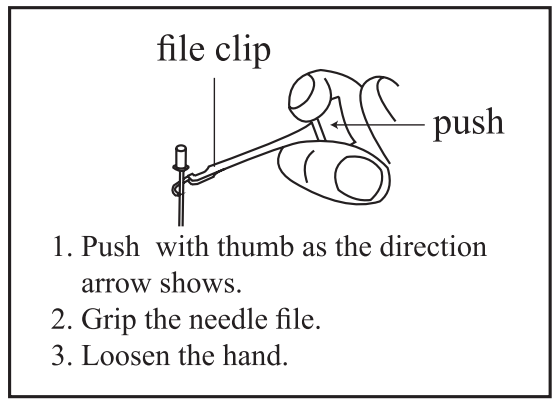
4.2.3 The volume is adjustable. Please press the volume bottom for a setting.

4.2.4 Hang the lip hook on the lip, make sure it contact the oral mucosa as a reference electrode [Picture 15].

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 16].



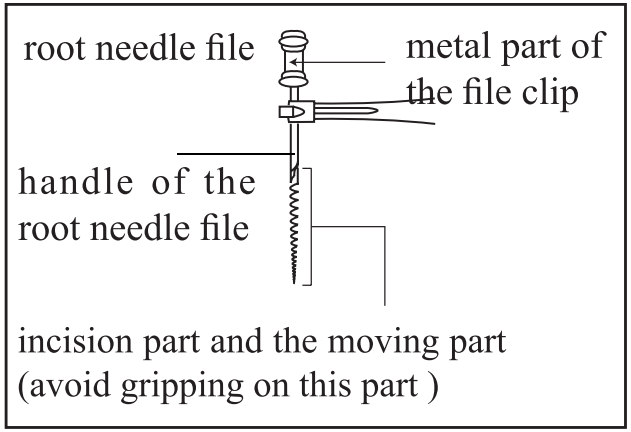
Picture 15



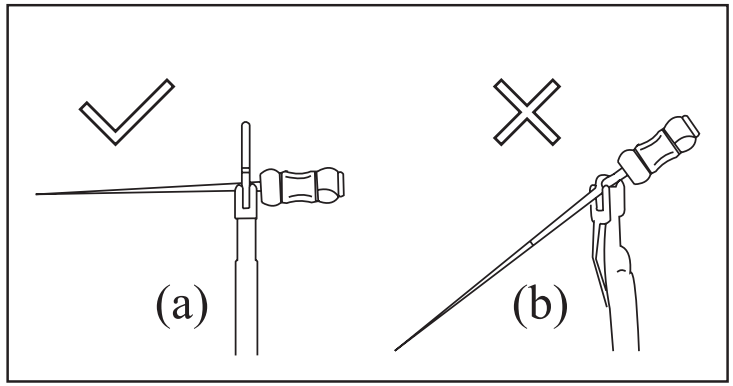
Picture 16

Attention:

a) When grip the root canal with a needle file, please grip the upper of the metal part (near the root canal at the needle handle). If you grip the lower part (blade or moving part), it will wear the metal part of the file folder and the resin part. [Picture 17]



Picture 17



Picture 18

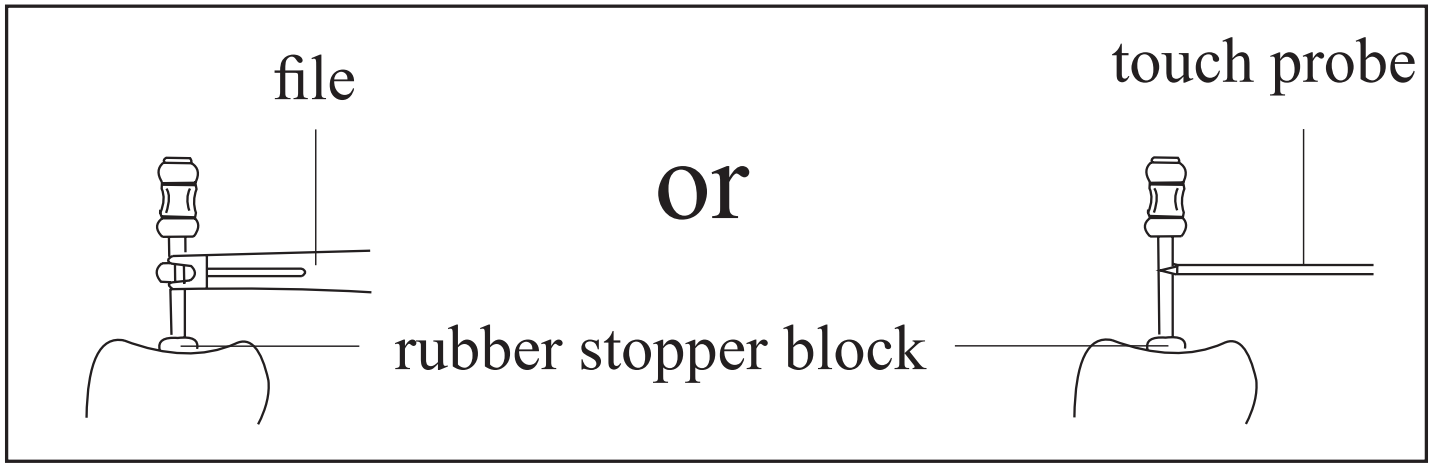
b) When measuring the length of root canal, please don't use the metal needle file. If you operate the device without the dentistry glove,it will cause leakage and the result of measurement will be inaccurate.Therefore, please use the resin needle file and remember don't touch the metal part with finger.

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

d) Please reference the [Picture 18 (a)] to grip the needle file. If as [Picture 18 (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.

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 used with the touch probe instead of file clip, when it is inconvenient to measure the back teeth [Picture 19].



Picture 19

4.2.7 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.
A**ttention:** Avoid the silk-screen when cleaning.

5 Trouble shooting

Problems	Possible causes	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 prompt” icon didn’t blinking when charging battery.	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.
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.

Problems	Possible causes	Solutions
	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?	It will display “OVER” if the endo needle contact the gums.
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.

Problems	Possible causes	Solutions
	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.
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 “ ⇨|⇦ ” icon.
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 cleaning, disinfection and sterilization of lip hook, file clip and touch probe are as follow.

Unless otherwise stated, they will be hereinafter referred to as “products”.

Warnings:

The use of strong detergent and disinfectant (alkaline pH>9 or acid pH <5) will reduce the life span of products. And in such cases, the manufacturer takes no responsibility.

This device shall not be exposed to high temperature above 138℃.

Processing limit

The products have been designed for a large number of sterilization cycles. The materials used in manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. The maximum number of sterilizations for file clip is 200 times. For lip hook and touch probe, it is 1000 times.

6.1 Initial processing

6.1.1 Processing principles

It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for cleaning/disinfection and sterilization, and that the

validated parameters are adhered to during every cycle.
Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic,especially with regard to the additional requirements for the inactivation of prions.
6.1.2 Post-operative treatment
The post-operative treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows:
1.Remove the measuring wire from the Apex Locator Device, and rinse away the dirt on the surface of product with pure water (or distilled water/deionized water);
2.Dry the product with a clean, soft cloth and place it in a clean tray.
Note:
The water used here must be pure water, distilled water or deionized water.
6.2 Preparation before cleaning
Steps:
Tools: tray, soft brush, clean and dry soft cloth
1.Remove lip hook, file clip and touch probe from the measuring wire, and then put them into a clean tray.
2.Use a clean soft brush to carefully brush the copper needle at the end of the file clip, the probe surface and the lip hook surface until no dirt can be seen on the surface, and put them into a clean tray.The cleaning agent can be pure water, distilled water or deionized water.

6.3 Cleaning

The cleaning should be performed no later than 24 hours after the operation.

The cleaning can be divided into automated cleaning and manual cleaning. Automated cleaning is preferred if conditions permit.

6.3.1 Automated cleaning

•The cleaner is proved to be valid by CE certificationin accordance with EN ISO 15883.

▪There should be a flushing connector connected to the inner cavity of the product.

▪The cleaning procedure is suitable for the product, and the irrigating period is sufficient.

•Do not clean the product with ultrasound.

It is recommended to use a washer-disinfector in accordance with EN ISO 15883. For the specific procedure, please refer to the automated disinfection section in the next section "Disinfection".

Note:

a)The cleaning agent does not have to be pure water. It can be distilled water, deionized water or multi-enzyme. But please ensure that the selected cleaning agent is compatible with the product.

b)In washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it would be difficult to remove.

c)After cleaning, the chemical residue should be less than 10mg / L.

6.4 Disinfection

Disinfection must be performed no later than 2 hours after the cleaning phase. Automated disinfection is preferred if conditions permit.

Automated disinfection-Washer-disinfector

·The washer-disinfector is proved to be valid by CE certification in accordance with EN ISO 15883.

·Use high temperature disinfection function. The temperature does not exceed 134 ° C, and the disinfection under the temperature cannot exceed 20 minutes.

·The disinfection cycle is in accordance with the disinfection cycle in EN ISO 15883.

Cleaning and disinfecting steps by using Washer-disinfector:

1.Carefully place the product into the disinfection basket. Fixation of product is needed only when the product is removable in the device. The products are not allowed to contact each other.

2.Use a suitable rinsing adaptor, and connect the internal water lines to the rinsing connection of the washer-disinfector.

3.Start the program.

4.After the program is finished, remove the product from the washer-disinfector, inspect (refer to section "Inspection and Maintenance") and packaging (refer to chapter "Packaging"). Dry the product repeatedly if necessary (refer to section "Drying").

Note:

Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.

b) With this equipment, cleaning, disinfection and drying will be carried out together.

c) Cleaning: (c1) The cleaning procedure should be suitable for the product to be treated. The flushing period should be sufficient (5-10 minutes). Pre-wash for 3 minutes, wash for another 5 minutes, and rinse it for twice with each rinse lasting for 1 minute. (c2) In the washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it is difficult to remove. (c3) The solution used can be pure water, distilled water, deionized water or multi-enzyme solution, etc., and only freshly prepared solutions can be used. (c4)During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed. The used cleaner is neodisher MediZym (Dr. Weigert).

d) Disinfection: (d1) Direct use after disinfection: temperature ≥ 90 ° C, time ≥ 5 min or A0 ≥ 3000;

Sterilize it after disinfection and use: temperature ≥ 90 ° C, time ≥ 1 min or A0 ≥ 600 (d2) For the disinfection here, the temperature is 93 ° C, the time is 2.5 min, and A0>3000

e) Only distilled or deionized water with a small amount of microorganisms (<10 cfu/ml) can be used for all rinsing steps. (For example, pure water that is in accordance

with the European Pharmacopoeia or the United States Pharmacopoeia).
f) After cleaning, the chemical residue should be less than 10mg / L.
g) The air used for drying must be filtered by HEPA.
h) Regularly repair and inspect the disinfector.
6.5 Drying
If your cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.
Methods:
1.Spread a clean white paper (white cloth) on the flat table, point the product against the white paper (white cloth), and then dry the product with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the product drying is completed.
2.It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80℃~120℃ and the time should be 15~40 minutes.
Note:
a)The drying of product must be performed in a clean place.
b)The drying temperature should not exceed 138 °C;
c)The equipment used should be inspected and maintained regularly.
6.6 Inspection and maintenance
1.Check the product. If there is still visible stain on the product after cleaning/

disinfection, the entire cleaning/disinfection process must be repeated.
2.Check the product. If it is obviously damaged, smashed, detached, corroded or ruptured, it must be scrapped and not allowed to continue to be used.
3.Check the product. If the accessories are found to be damaged, please replace it before use. And the new accessories for replacement must be cleaned, disinfected and dried.
4.If the service time (number of times) of the product reaches the specified service life (number of times), please replace it in time.

6.7 Packaging

Install the disinfected and dried product and quickly package it in a medical sterilization bag (or special holder, sterile box).

Note:

a)The package used conforms to ISO 11607;
b)It can withstand high temperature of 138 °C and has sufficient steam permeability;
c)The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants;
d)Avoid contact with parts of different metals when packaging.

6.8 Sterilization

Use only the following steam sterilization procedures (fractional pre-vacuum procedure*) for sterilization, and other sterilization procedures are prohibited:
1.The steam sterilizer complies with EN13060 or is certified according to EN 285 to

comply with EN ISO 17665;
2.The highest sterilization temperature is 138 ° C;
3.The sterilization time is at least 4 minutes at a temperature of 132 ° C / 134 ° C and a pressure of 2.0 bar ~ 2.3 bars.
4.Allow a maximum sterilization time of 20 minutes at 134 °C.
Verification of the fundamental suitability of the products for effective steam sterilization was provided by a verified testing laboratory.

Note:

a)Only products that have been effectively cleaned and disinfected are allowed to be sterilized;
b)Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.
c)Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;
d)Please use the recommended sterilization procedures for sterilization. It is not recommended to sterilize with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended. If you use the sterilization procedures that have not been recommended, please adhere to related effective standards and verify the suitability and effectiveness.
*Fractional pre-vacuum procedure = steam sterilization with repetitive pre-vacuum.

The procedure used here is to perform steam sterilization through three pre-vacuums.

6.9 Storage

1. Store in a clean, dry, ventilated, non-corrosive atmosphere with a relative humidity of 10% to 93%, an atmospheric pressure of 70 kPa to 106KPa, and a temperature of -20 °C to +55 °C;
2. After sterilization, the product should be packaged in a medical sterilization bag and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

Notes:

a)The storage environment should be clean and must be disinfected regularly;
b)Product storage must be batched and marked and recorded.

6.10 Transportation

1. Prevent excessive shock and vibration during transportation, and handle with care;
2. It should not be mixed with dangerous goods during transportation.
3. Avoid exposure to sun or rain or snow during transportation.

The cleaning and disinfection of main unit and the measuring wire are as follows.

• Before each use, wipe the surface of the machine and the measuring wire with a soft cloth or paper towel soaked in 75% medical alcohol. Repeat the wipe for at least 3 times.

• After each use, wipe the surface of the device and the measuring wire with a soft cloth soaked in clean water (distilled or deionized water) or a clean disposable wipe. Repeat the wipe for at least 3 times.

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% to 93%(non-condensing), atmospheric pressure is 70kPa to106kPa, and the temperature is −20℃～+55℃.

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.

7.3 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 After service

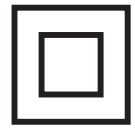
From the date this equipment has been sold, based on the warranty card, we will repair this equipment free of charge if there are quality problems. Please refer to the warranty card for the warranty period.

10 Symbol instruction


Date of manufacture


Manufacturer


Type BF applied part


Class II equipment

IPX0
Ordinary equipment


Recovery


Used indoor only


Keep dry

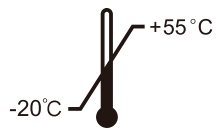

Power on / off


Handle with care


Sound adjustment

SN
serial number

Humidity limitation for storage



Temperature limitation for storage

Sound indicator icon

Charging prompt icon

Over-instrumentation icon

Connection test icon

Appliance compliance WEEE directive

Atmospheric pressure for storage

Follow Instructions for Use

CE marked product

Authorised Representative in the EUROPEAN COMMUNITY

11 For technical data, please contact

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

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 models Minipex are intended for use in the electromagnetic environment specified below. The customer or the user of the models Minipex should assure that it is used in such an environment.

Emissions test	Complianc	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The models Minipex 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 models Minipex are 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 models Minipex are intended for use in the electromagnetic environment specified below. The customer or the user of the models Minipex 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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±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 ±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	±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 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	<5 % UT (>95% dip in UT.) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models Minipex require continued operation during power mains interruptions, it is recommended that the models Minipex be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity
The models Minipex are intended for use in the electromagnetic environment specified below. The customer or the user of the models Minipex 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 bands 3 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 3 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication 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 Minipex, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=[3,5/V1]\times P^{1/2}$ $d=1.2\times P^{1/2}$ 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 models Minipex are used exceeds the applicable RF compliance level above, the model Minipex should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models Minipex.

[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 models Minipex

The models Minipex are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the models Minipex can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the models Minipex are recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150kHz to 80MHz d=1.2×P1/2	**80MHz to 800MHz d=1.2×P1/2**	**800MHz to 2,5GHz d=2.3×P1/2**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.
NOTE I At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 Minipex 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 Minipex 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 Minipex.
5. Minipex should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, Minipex 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 Minipex may affect the radiation quantity.The original accessories are in compliance with the requiments of the IEC 60601-1-2. Please use original accessories.

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