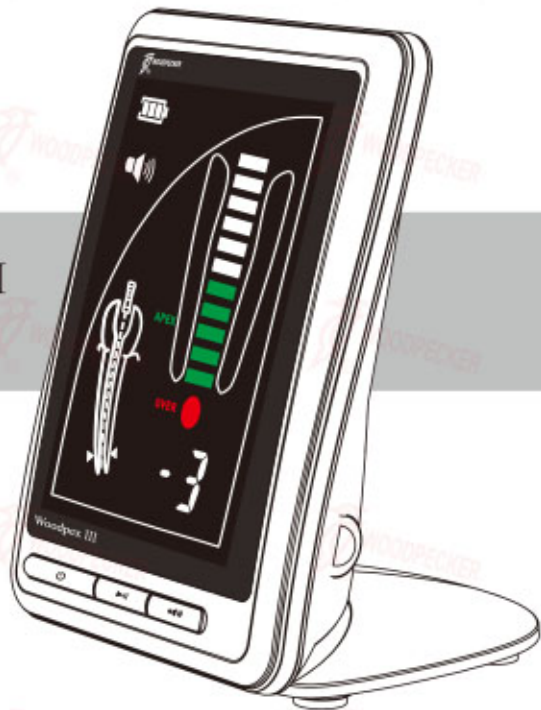




Apex locator Woodpex III Instruction Manual



CE 0197



- Certified Management System
- EN ISO 9001
- EN ISO 13485

Please read this manual before operating.
Industrial design patent No.: CN 201130379058.9

Guilin Woodpecker Medical Instrument Co., Ltd.

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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 the endodontic treatment, through the measurement of the length of apical teeth, help the dentist to finish the endodontic treatment.

Features of the device:

- a) Equipped with clear bright LCD, clear image and different color 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 accessories of the “Woodpex III” can be autoclaved under the high temperature and high pressure. Avoiding cross infection effectively.
- d) Battery is rechargeable, unnecessary to replace batteries repeatedly.

1.3 Model and dimensions

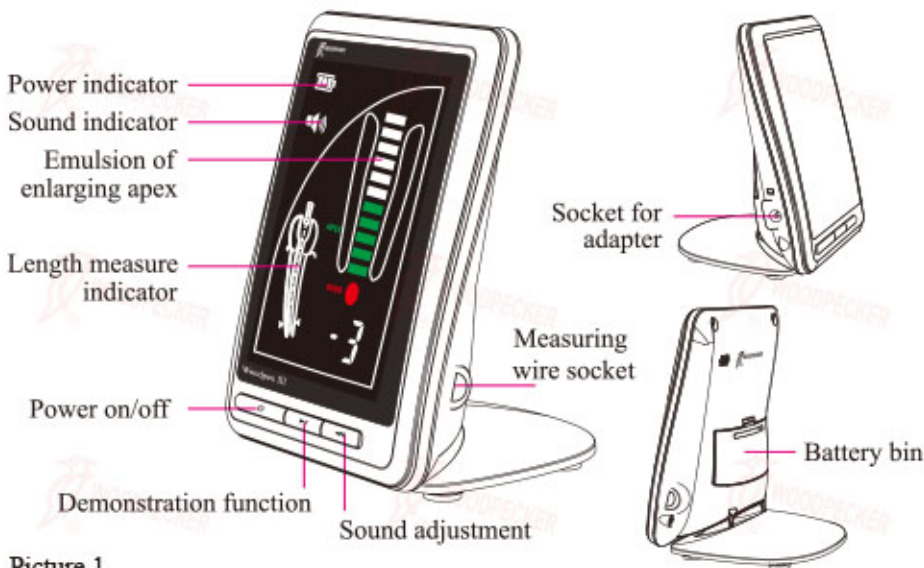
1.3.1 Model: Woodpex III

1.3.2 Dimensions: 84mm (length) × 88mm (width) × 112mm (height)

1.3.3 Weight: 336g

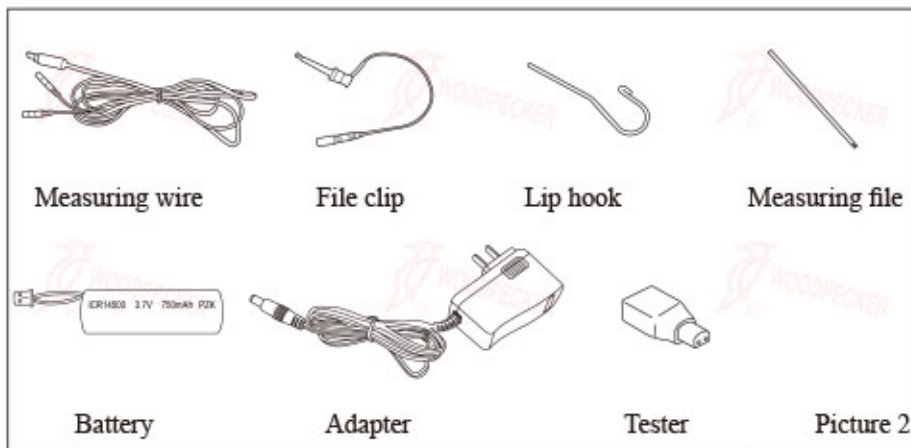
1.4 Components

1.4.1 Picture of the main unit. (Picture 1)



Picture 1

1.4.2 Pictures of the main accessories (Picture 2)



1.5 Structure

Woodpex III is composed of main unit, measuring wire, lip hooks, file clip, measuring file, 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 Woodpex III on patients fitted with pacemakers (or other electrical equipment) or on those patients who was 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: Continuous operation

1.9 The main technical specifications

- 1.9.1 Battery: 3.7V/750mAh
- 1.9.2 Adapter: ~100V-240V 50Hz/60Hz
- 1.9.3 Consumption power: $\leq 0.5W$
- 1.9.4 Screen: 4.5" LCD
- 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°C~+40°C
- b) Relative humidity: ≤80%.
- c) Atmosphere pressure: 50kPa~106kPa

2 Notice of installing and using the device



2.1 Please read the instruction manual carefully before the operation.

2.2 The file clip, lip hook and measuring file 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.

2.3 The batteries must be taken out for storage when the device is not used for a long time.

2.4 Please recharge the battery when low battery indicator flashes.

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

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

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

2.8 If the equipment indicates the endo file cut through the apex hole though the file does not reach apex yet, it shows or indicates that there is left pulp or other

electrolyte.

2.9 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.

2.10 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. The operation under such environment should be cautious.

2.11 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 in guarantee period.

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

2.13 Only the original adapter and Lithium battery could be used.

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 right side socket of the unit.

Attention:

- a) Please be careful to use the device, keep it stable and avoid hit. Incautious use will lead to the damage or the failure of the machine.
- b) Measurement can not be proceeded without the complete insertion of the plug.
- c) Be sure not to hit the plug. Keep the device away.
- 3.1.2 Insert the file clip and lip hook respectively into the two sockets of the measuring wire. [Picture 3]

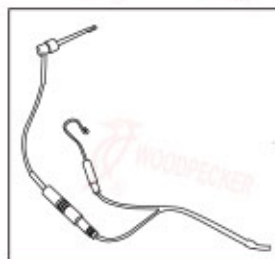
Attention:

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

Correct operation showed as in picture 4 (b).

3.1.3 The Operation Confirmation of the Device Before Use

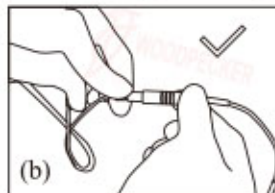
- a) Press the power switch. Make sure the scene of measuring the length of the root canal displayed on the LCD screen.



Picture 3



(a)



(b)

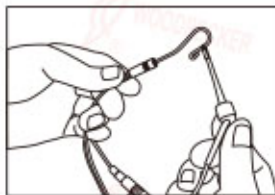
Picture 4

The device will shutdown automatically after 5 minutes without operation.
[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 lip hook touch the bent wire of the file clip [as showed in picture 6] to confirm all the instruction bars are displayed on the LCD screen.



Picture 5



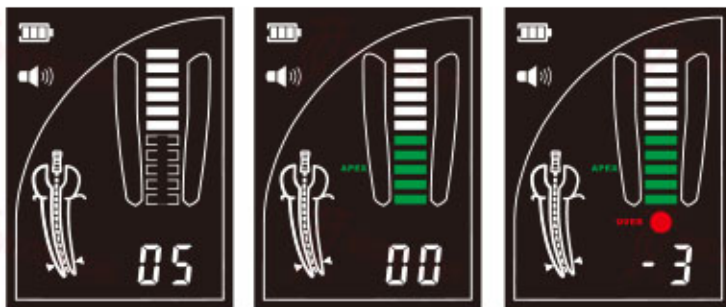
Picture 6

[as showed in picture 7 (c)] A continuous beep sound will be generated during the operation.

3.1.4 Explanations on the interfaces displayed

- a) The screen displays the front region of the apical foramen by instruction bars. Please refer to the white region as showed. [Picture 7(a)]
- b) The file has gone to the position near by the apical foramen when the green bars displayed [Picture 7 (b)].

c) The file has exceeded the apical foramen when the red bars displayed. A continuous beep sound will be generated at the same time [Picture 7 (c)].



Picture 7

(a)

(b)

(c)

3.2 Testing the device by tester

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

- Pulling out the the measuring wire and turn off the device.
- Insert the tester.
- Turn on the device, it is works fine when green area of the display light.

3.3 Demonstrate function

Demonstrate function can show the movement process of endo file when measuring. Specific operation are as follows:

- a) Pulling out the the measuring wire.
- b) Turn on the device.
- c) Long pressing the play button for 1 second can enter the demonstrate function which shows the movement process of endo file.
- d) Repress the demonstrate function button then exit demonstrate function.

3.4 Charge the battery

When the power indicator flash, please stop use the device, as it shows the remaining power is not enough.

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

3.4.2 When the yellow indicator on, it shows the device is charging; when the yellow indictor turns to green indicator, it shows charging has finished. It may take 120minutes for charging.

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

Attention: please don't use the device when it is charging, and the operator should be over 2meters away from the device.

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

4.1.5 The endo file should not be too big or 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

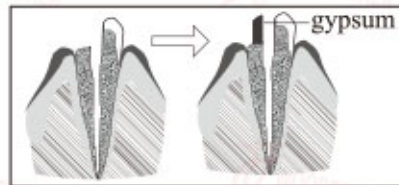
The tissue of the gingival may reach the cavity of the endo hole at the broken point which will cause inaccurate because of the electronic conduction. The measurement can be continued when the crown is fixed by gypsum or other insulators [Picture 10].



Picture 8



Picture 9



Picture 10

d) There is a crack on the tooth root

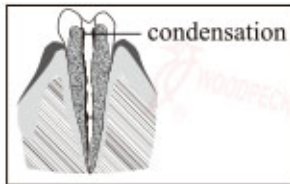
In this case, the crack may cause the electric leakage which will affect the accuracy of measurement [Picture 11].

e) A retreatment to an endo which was filled with condensation

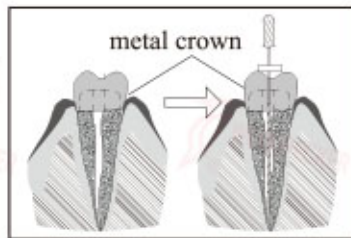
Clean the remaining material in the root canal and fill it with little normal saline before a measurement [Picture 12].



Picture 11



Picture 12



Picture 13

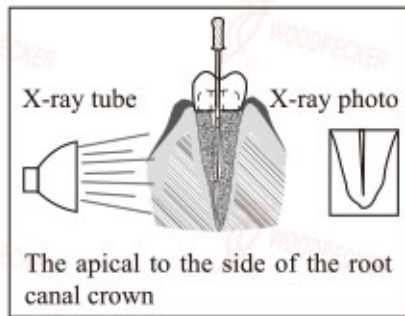
f) There is a metal crown which has connected to the gingival.

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

Sometimes, the results of the EMR and X-rays are not meet each other, which is neither 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 slightly to the side of the root canal crowns. In this case, according to the shooting angle as the following picture showed, it will cause the illusion that the front tip of the root canal haven't reached the canal tip. [Picture 14]

(Since of the angle of X-rays, sometimes it can't take photo of the apical properly, so



Picture 14

it can't show the accurate position of the apical foramen.)

4.2 Instruction

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

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

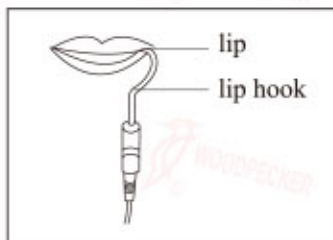
4.2.3 The volume is adjustable. Please press the volume bottom for a setting.

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

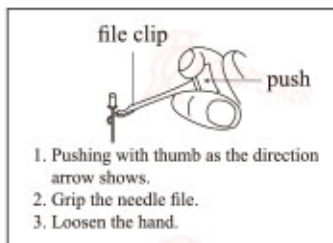
4.2.5 Clip the file with file clip, approach to the apex, then there will be continuous alarm when the distance is less than 2mm [Picture 16].

Attention:

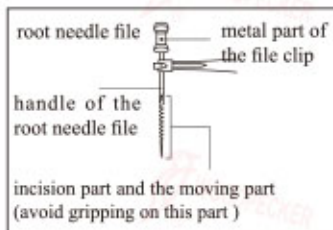
a) When grip the root canal with a needle file, please grip the upper of the metal part (near the root canal at the needle handle). If you grip the



Picture 15



Picture 16



Picture 17

lower part (blade or moving part), it will wear the metal part of the file folder and the resin part. [Picture 17]

b) When measure 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

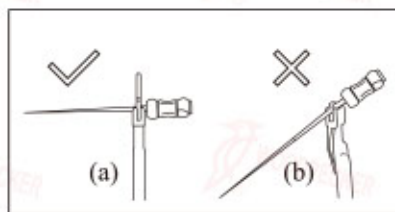
phenomenon and result of measurement is inaccurate. Therefore, please use the resin needle file and remember don't touch the metal part with finger.

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.

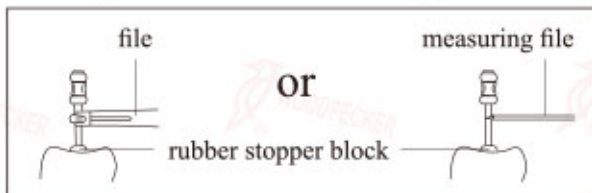
4.2.6 When the file reaches the apex, adjust the rubber piece set on the endo file to the reference point (incisal edge or fossa edge), then pull out the endo file, measure the length between the top of the file and the rubber piece, and this is the working length of the tooth. It also can use the measuring instead of file clip, when it is inconvenient to measure the back teeth [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 every month by 75% alcohol.



Picture 18

Attention: Avoiding the silk-screen when cleaning.



Picture 19

5 Trouble shooting

Phenomena of troubles	Possible cause	Solutions
No power and no signal on the screen after the power on.	1. If the battery is placed correctly? 2. If the battery is empty?	1. Re-install the batteries. 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.

Phenomena of troubles	Possible cause	Solutions
<p>Display not steady while measuring: the measurement result is rather longer or shorter; numerical display irregular.</p>	<p>If the connection between the lip hook and the oral mucosa is ok?</p>	<p>Make sure the lip hook has contacted the oral mucosa at a good position.</p>
	<p>Is there a blood/saliva overflowing, glued to the crown?</p>	<p>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. Cleaning the blood and the liquid.</p>
	<p>If the root canal is filled with blood, liquid?</p>	<p>Once the endo needle contact the surface of the root canal which fill 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.</p>
	<p>If there is liquid, scrap on the tooth surface?</p>	<p>Cleaning the tooth surface.</p>
<p>If the endo needle contact the gums?</p>	<p>The LCD will display "OVER" if the endo needle contact the gums.</p>	

Phenomena of troubles	Possible cause	Solutions
Display not steady while measuring: the measurement result is rather longer or shorter; numerical display irregular.	If there is still have pulp in the root canal?	If there is much pulp left in the root canal, the root canal length can't be measured correctly.
	If the needle touched the metal repaired material?	Once the needle touched the metal repaired material, current measurement from the gums to the periodontal tissue loss, the screen will display "OVER".
	If the adjacent surface has caries?	Current measurement flow from caries of the adjacent surface to gums, then the root canal length can't be measured correctly.
	Whether there is collateral or the tooth root is broken?	Once the needle reached the collateral or the broken part of the tooth root, current measurement will overflow from periodontal ligament, it display "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.

Phenomena of troubles	Possible cause	Solutions
Display not steady while measuring: the measurement result is rather longer or shorter; numerical display irregular.	Are there cysts apical?	If there has cysts, the length of root canal can't be measured accurately.
	Whether the file clip is not clean or broken?	Cleaning 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 display "-3".
The length measurement indicator only full display near narrow part of the apical.	Whether the root canal is occlusion?	The display will be normal after penetrating the narrow part of apical.
	If the root canal is too dry?	Wet the endo with Hydrogen peroxide or NaCl.
	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 and sterilization

6.1 The main unit and the measuring wire can be disinfected with alcohol cotton or disinfected cloth.

6.2 Do not use potent chemical, cleaning agent, etc. to clean the equipment. It will cause damage to the main unit and the measuring wire.

6.3 The file clip, lip hook and measuring file should be autoclaved under high pressure (0.22MPa) and high temperature (135°C) before each operation.

7 Storage, maintenance and transportation

7.1 Storage

7.1.1 This equipment should be stored in a room where the relative humidity is $\leq 80\%$, atmospheric pressure is 50kPa~106kPa, and the temperature is $-10^{\circ}\text{C}\sim+50^{\circ}\text{C}$.

7.1.2 Avoid the storage in a too hot condition. High temperature will shorten the life of electronic components, damage battery, reshape or melt some plastic.

7.1.3 Avoid the storage in a too cold condition. Otherwise, when the temperature of the equipment increases to a normal level, there will be dew that will possibly damage pc 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

There is no harmful factor in this product. You can deal with it based on the local law.

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 it has quality problems, please refer to the warranty card for the warranty period.

10 Symbol instruction



Trademark



CE marked product



Date of manufacture



Manufacturer



Type BF applied part



Manufacturer

IPX0

Ordinary equipment



Recovery



Used indoor only



Keep dry



Power on / off



Handle with care



Sound adjustment



Serial number



Demonstrate the measurement process





Consult the accompanying documents




Appliance compliance WEEE directive

 Humidity limitation

 Temperature limitation

 Atmospheric pressure for storage

 Authorised Representative in the EUROPEAN COMMUNITY



- Certified Management System
- EN ISO 9001
- EN ISO 13485

Got the quality management system certification and CE certification issued by TÜV Rheinland

11. For technical data, please contact

 Wellkang Ltd (www.CE-Marking.eu)
29 Harley St., LONDON, W1G 9QR, UK

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 take legal responsibilities.

13 Declaration of conformity

13.1 Product conforms to the following standards

EN 60601-1:2006

EN 60601-1-2:2007

EN 60601-1-4:1996

EN 60601-1-6:2007

EN 980:2008

EN ISO 9687:1995

EN 1041:2008

EN ISO 14971:2009

EN ISO 7405:2008

EN ISO 10993-1:2009

EN ISO 10993-5:2009

EN ISO 10993-10:2010

13.2 EMC - Declaration of conformity

Guidance and manufacturer's declaration - electromagnetic emissions		
The model Woodpex III is intended for use in the electromagnetic environment specified below. The customer or the user of the model Woodpex III should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model Woodpex III 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. The mode Woodpex III is suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
RF emissions CISPR11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance & Declaration — electromagnetic immunity


The model Woodpex III is intended for use in the electromagnetic environment specified below. The customer or the user of the model Woodpex III 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	±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 % U_T (>95% dip in U_T) for 0.5 cycle 40 % U_T (80% 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	<5 % U_T (>95% dip in U_T) for 0.5 cycle 40 % U_T (80% 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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model Woodpex III require continued operation during power mains interruptions, it is recommended that the model Woodpex III 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 U_T is the a.c. mains voltage prior to application of the test level.

Guidance & Declaration - Electromagnetic immunity

The model Woodpex III is intended for use in the electromagnetic environment specified below. The customer or the user of the model Woodpex III should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 81000-4-8 Radiated RF IEC 81000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the model Woodpex III, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance 3V $d=1.2\sqrt{P^{1/2}}$ 80 MHz to 800 MHz $d=2.3\sqrt{P^{1/2}}$ 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 1 At 80 MHz end 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model Woodpex III is used exceeds the applicable RF compliance level above, the model Woodpex III should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model Woodpex III.

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

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

The model Woodpex III is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model Woodpex III can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model Woodpex III 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		
	150kHz to 80MHz $d=1.2 \times P^{1/2}$	80MHz to 800MHz $d=1.2 \times P^{1/2}$	800MHz to 2.5GHz $d=2.3 \times P^{1/2}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation 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 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.

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.

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