Please read this manual before operating.
Industrial design patent No.: CN 201130378728.5

DTE®

Guilin Woodpecker Medical Instrument Co., Ltd.

DPEX I Apex Locator Instruction Manual

CE 0197

Contents

1 Introduction

1.1 Description of the device

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.

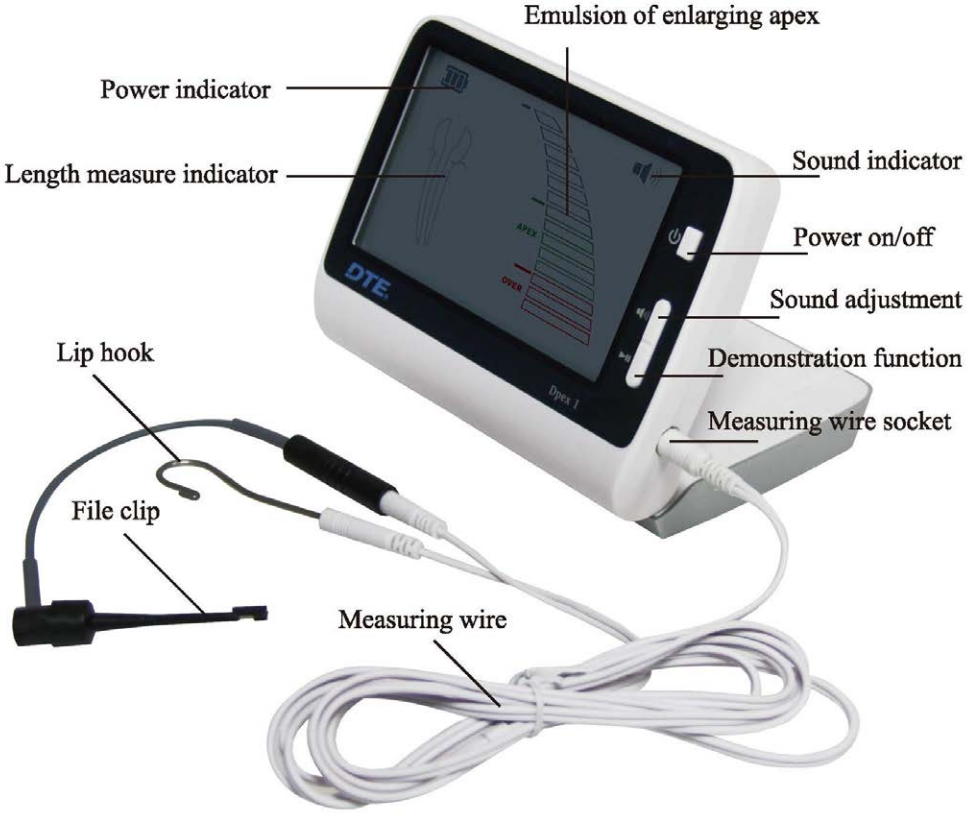
Features of the device:

a) Equipped with clear bright LCD, clear image and different colors indicate the trajectory of the file clearly.

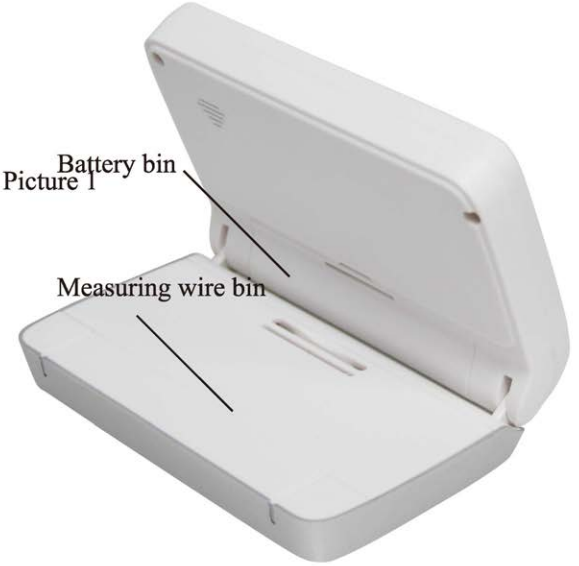
b) Based on advanced multiple frequency network impedance measurement technology and automatic calibrating ensures the measurements are accurate.

c) The File clip, Lip hook and Touch probe can be autoclaved under the high temperature and high pressure, avoiding cross infection effectively.

1.2 Model and dimensions

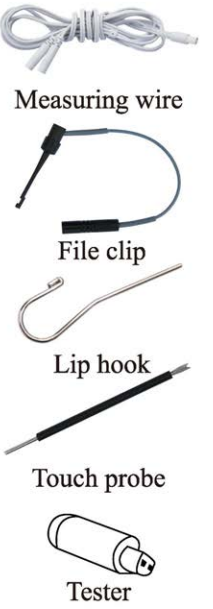

Emulsion of enlarging apex
Power indicator
Length measure indicator
Sound indicator
Power on/off
Sound adjustment
Demonstration function
Measuring wire socket
Lip hook
File clip
Measuring wire
APEX
OVER
DTE
Dpex 1

Picture 1



Picture 1

Picture 2



Picture 3

1.4 Structure

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

1.5 Intended use

This equipment applies to the measurements below:

1.5.1 Measurement of the endo length of all kinds of the tooth with pulpitis, pulp necrosis, periapical periodontitis.

1.5.2 Measurement of the endo length before restoration of post crown.

1.5.3 Measurement of the endo length of transplantation and re-transplantation.

1.6 Contraindication

We do not advise the use of DPEX I 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.

1.7 The classification of the device

1.7.1 Internal power device

1.7.2 Type BF device

1.7.3 Device not suitable for being used in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

1.7.4 Degree of protection against harmful ingress of water: Ordinary equipment (IPX0)

1.7.5 Operation mode: Continuous operation

1.8 The main technical specifications

1.8.1 Power: 3 pieces AAA alkaline batteries

1.8.2 Power consumption: ≤0.3W

1.8.3 Screen: 4.9" LCD

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

1.8.5 Operation condition

a) Environment temperature: +5℃+40℃

b) Relative humidity: ≤80%.

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 In order to confirm the file clip and measuring wire makes good contact, test the wire connecting before each use(See 3.2.3).

2.7 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.

2.8 Power Supply: 3 pcs of 1.5V LR03 alkaline battery. Please change them when their voltage is not enough to support the equipment.

Notice: Please handle the batteries according to the local laws.

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

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

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

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

2.13 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.
2.14 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.
2.15 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.
2.16 Any modification will render the guarantee void and may cause harm to the patient.

3 Installation of the device

3.1 Battery installation
Attention: As batteries are not installed on delivery, you need to remove the battery cover and install 3 AAA alkaline batteries.
3.1.1 Hold the shell, and push the button at the bottom of the device toward the LCD screen.
3.1.2 Push the battery cover and take it away from the unit.
3.1.3 Install 3 AAA alkaline batteries correctly according to the battery polarity labeled on the shell.

3.1.4 Attention: Do not invert the anode(+) and cathode (-).

3.1.5 Install the battery cover by pressing its convex part to the concave part of the device.

3.2 The Connection of the Measuring Wire

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

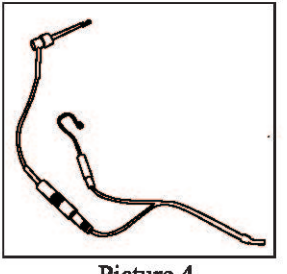
Attention:

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 cannot be operated without the complete insertion of the plug.

c) After the plug is inserted, please be sure not to hit or falling any object on the plug,

3.2.2 Insert the file clip and lip hook respectively into the two sockets of the measuring wire. [Picture 4]



Picture 4

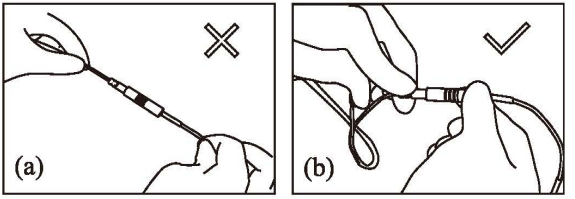
Attention:

Be sure not to pull the wire when inserting or pulling out the measuring wire and the file clip. [Picture 5(a)]. Correct operation showed as in picture 5(b).

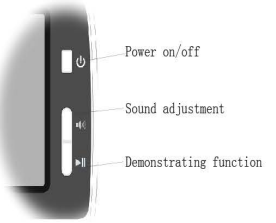
3.2.3 Test the wire connecting (Test before each use)

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

The device will shutdown automatically after 5 minutes without operation. [Picture 6]



Picture 5

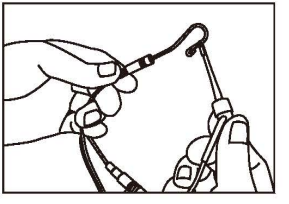


Picture 6

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 7]. To confirm all the instruction bars are displayed on the LCD screen and static display the digital '-3', otherwise , it means that the file clip or the measuring wire is damaged, should be replaced.[as showed in picture 8(c)]



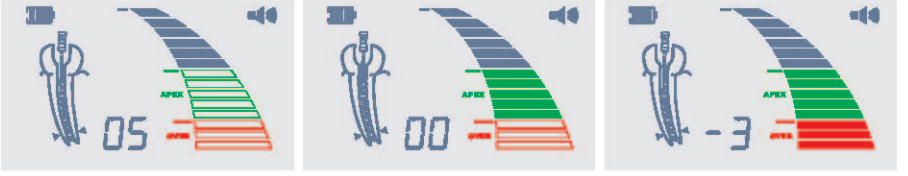
Picture 7

3.2.4 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 8(a)]

b) The file has gone to the position near by the apical foramen when the green bars displayed [Picture 8(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 8(c)].



picture 8 a b c

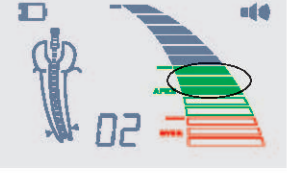
3.3 Check the machine by tester (Test every two weeks)

3.3.1 The tester is used for checking machine, the operation show as below.

3.3.2 Pulling out the measuring wire from machine and then shut down the machine by using Power on/off button.

3.3.3 Connect the tester to the machine.

3.3.4 Turn on the machine, while the green bars displayed the machine work well. (Digital display as 02, 03 or 04) [as showed in picture 9]



Picture 9

3.4 Demonstration function

3.4.1 The demonstration function can show the simulation of file's movement. The operation is as bellow.

3.4.2 Move away the measuring wire from machine.

3.4.3 Press the Power on/off button, turn on the machine.

3.4.4 Press the demonstration function button with one second and then we can enter the demonstration mode.
4.4.5 Press the demonstration function button again while demonstrating, the function will be turned off.

4 Product function and operation

4.1 Usage requirements
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 canal is big.

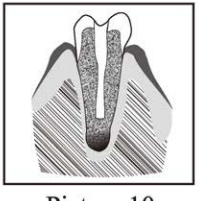
Teeth with periapical pathosis root resorption, or root hypoplasia. In this case, the measurement result of the length of the root canal will be shorter than real because of the hypoplasia of the root [Picture 10].

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 11].

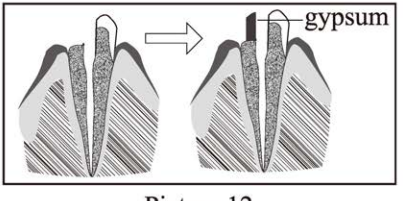
c) The tooth crown is broken.

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 12].



Picture 10

Picture 11



Picture 12

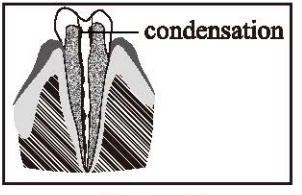
d) There is a crack on the tooth root.

In this case, the crack may cause the electric leakage which will affect the accuracy of measurement [Picture 13].

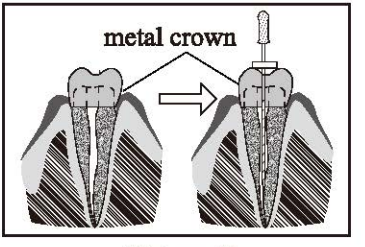
e) A retreatment to an endo which was filled with gutta-percha.

Clean the remaining material in the root canal and fill it with little normal saline before a measurement [Picture 14].

Picture 13



Picture 14

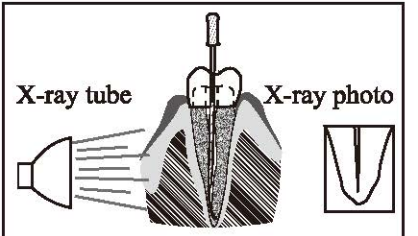


Picture 15

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

It will cause inaccuracy when the endo file touches metal crown [Picture 15]. 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 16]

(Because of the angle of X-rays, sometimes it can't take photo of the apical foramen appropriate, so it can't show the accurate position of the apical foramen.)



Picture 16

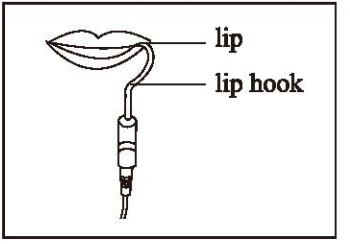
4.2 Instruction

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 17].



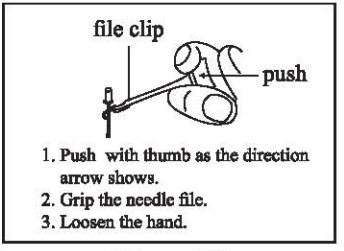
Picture 17

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 18].

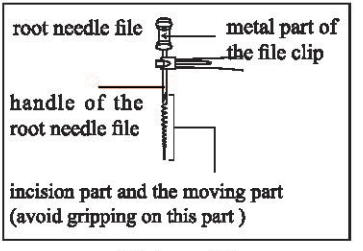
Attention:

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 19]



Picture 18



Picture 19

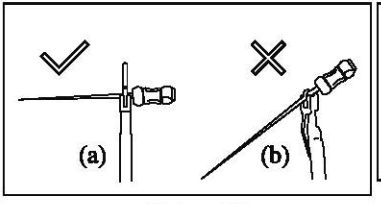
b) When measuring the length of root canal, please don't use the metal needle file. If you operate the device without the dentistry glove,it will cause leakage and the result of measurement will be inaccurate.Therefore, please use the resin needle file and remember don't touch the metal part with finger.

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

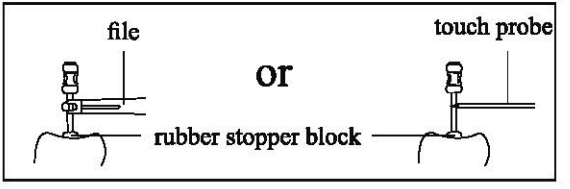
d) Please reference the [Picture 20(a)] to grip the needle file. If as [Picture 20(b)], it can't make the measurement inaccurate and the root needle file's apical will break easily.

4.2.6 When the file reaches the apex, adjust the rubber piece set on the endo file to the reference point (incision 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 21]



Picture 20



Picture 21

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.

Attention: Please avoid the seal 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.

Problems	Possible causes	Solutions
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.

Problems	Possible causes	Solutions
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.
	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.

Problems	Possible causes	Solutions
Display not steady while measuring: the measurement result is rather longer or shorter; numerical display irregular.	If there is liquid, scrap on the tooth surface?	Clean the tooth surface.
	If the endo needle contact the gums?	The LCD will display "OVER" if the endo needle contact the gums.
	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.

Problems	Possible causes	Solutions
Display not steady while measuring: the measurement result is rather longer or shorter; numerical display irregular.	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.
	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 "-3".

Problems	Possible causes	Solutions
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 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 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

• 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.

• For your own safety, please wear personal protective equipment (gloves, glasses, mask).
• 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	Operating mode	Warning
1. Pre-Disinfection or Decontamination	- Soak immediately just after usage all instruments in a disinfectant solution combined with proteolytic enzyme if possible.	- Follow instructions and observe concentrations and immersion time given by the manufacturer (an excessive concentration may cause corrosion or others defects on instruments). - The disinfectant solution should be aldehyde free (to avoid blood impurities fixation). - Do not use disinfectant solution containing Phenol or any products which are not compatible with the instruments (See general recommendation). - For visible impurities that are observed on instruments, a pre-cleaning is recommended by brushing them manually with soft material.

Operation	Operating mode	Warning
2. Rinsing	- Rinse manually and abundantly the accessories with current water	
3. Manual Cleaning	- clean manually the accessories with an adequate brush, preliminary soaked in a clean pre-disinfectant solution	- the file clip mechanism has to be activated during the cleaning process (press several times the push button) - no visible impurities should be observed on the accessories
4. Rinsing	See point # 2	
5. 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
6. Final rinsing	- See point # 2 - After rinsing, the accessories have to be dried.	
7. Inspection	- Inspect devices and sort out those with defects.	- Dirty instruments must be cleaned and disinfected again.

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

Operation	Operating mode	Warning
10. 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).	

6.4 The Measuring wire cannot be autoclaved.

7 Storage, maintenance and transportation

7.1 Storage

7.1.1 This equipment should be stored in a room where the relative humidity is ≤80%, atmospheric pressure is 70kPa-106kPa, and the temperature is -10℃+50℃.

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

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 there are quality problems. Please refer to the warranty card for the warranty period.

10 Symbol instruction

DTE® Trademark

CE 0197 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

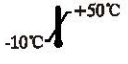
SN Serial number

 Demonstrate the measurement process

Humidity limitation

 Appliance compliance WEEE directive

Temperature limitation



Atmospheric pressure for storage

Open

 Consult the accompanying documents

EC REP Authorised Representative in the EUROPEAN COMMUNITY

11 For technical data, please contact

EC REP 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 undertake legal responsibilities.

13 Declaration of conformity

13.1 Product conforms to the following standards

EN 60601-1:2006	EN 60601-1-2:2007
EN 60601-1-6:2010	EN 62366:2008
EN 980:2008	EN ISO 9687:1995

EN 1041:2008
EN ISO 14971:2012
EN ISO 17665-1:2006
EN ISO 10993-1:2009
EN ISO 10993-10:2010
ISO 15223-1-2012
EN ISO 17664:2004
EN ISO 7405:2008 +A1:2003
EN ISO 10993-5:2009

13.2 EMC - Declaration of conformity

Guidance and manufacturer's declaration - electromagnetic emissions		
The model Dpex I is intended for use in the electromagnetic environment specified below. The customer or the user of the model Dpex I should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The model Dpex I uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The model Dpex I is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance & Declaration — electromagnetic immunity			
The model Dpex I is intended for use in the electromagnetic environment specified below. The customer or the user of the model Dpex I 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	Not applicable	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	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.	<5 % U_T (>95% dip in U_T) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model Dpex I requires continued operation during power mains interruptions, it is recommended that the model Dpex I 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 Dpex I is intended for use in.the electromagnetic environment specified below. The customer or the user of the model Dpex I 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 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 Dpex I, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** 3V $d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=2.3\times P$ 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 model Dpex I is used exceeds the applicable RF compliance level above, the model Dpex I should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model Dpex I.

[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 Dpex I

The model Dpex I is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model Dpex I can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model Dpex I 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 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.

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.

Scan and Login website
for more information

Guilin Woodpecker Medical Instrument Co., Ltd.
Information Industrial Park, National High-Tech
Zone, Guilin, Guangxi, 541004 P. R. China

Tel:
Europe Sales Dept.: +86-773-5873196, +86-773-2125222
North America, South America &
Oceania Sales Dept.:+86-773-5873198, +86-773-2125123
Asia & Africa Sales Dept.:+86-773-5855350, +86-773-2125896

Fax: +86-773-5822450
E-mail: woodpecker@glwoodpecker.com sales@glwoodpecker.com
Website: http://www.glwoodpecker.com

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

ZMN/WI-09-085 INS-AL-D1-ED-V1.6