

MINI APEX INSTRUCTION MANUAL

Light
Adaptive
Precise



Apex Locator
For dental use

Please read the instruction
manual carefully before using

Shanwei Perfect Medical Instruments Co.,Ltd.

Catalogue

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1 Basic Information

1. 1 Product Introduction

The apex locator is an auxiliary instrument for root canal treatment, which helps the dentist to complete the root canal treatment by measuring the length of the tooth apical.

| | |
|----------------|---------------------------------|
| Model | Mini Apex |
| Dimension | 52.5*34*14.5mm |
| Weight | 21g |
| Power supply | DC 3.7V/160 mAh lithium battery |
| Adapter output | DC 5V, 2A |
| Adapter input | AC100–240V 50/60Hz |
| Input power | 10VA |

EQUIPMENT SECURITY CLASSIFICATION

| | |
|--|--|
| By mode of operation | Intermittent running equipment |
| Classification by type of anti-motor | Class II equipment with internal power supply |
| By degree of protection against incoming liquids | General equipment (IPX0). |
| Application section | Lip hooks, file clips |
| Application section contact time | 1~10 minutes |
| Operating conditions | Operating temperature: 10°C to 40°C Operating humidity: 30% to 75% Atmospheric pressure: 70kPa to 106kPa |
| Storage conditions | Storage temperature: -10°C to 50°C Storage humidity: 10% to 85%. Atmospheric pressure: 70kPa to 106kPa |

1. 2 Security measures and warnings

- Please read the instruction manual carefully before using this device.
- This device must be used in hospitals and dental clinics by a qualified dentist.
- Patients shouldn't use this device on their own.
- This device should only be used in conjunction with its accompanying accessories, e. g. do not use any other power adapters and lithium batteries.
- Incorrect replacement of the lithium battery can lead to unacceptable risks, please use the original lithium battery provided.
- Do not dismantle or repair the equipment yourself. Any self-dismantling and repair may violate safety regulations and cause injury to the patient. Any self-dismantling or repair will not be guaranteed.
- Do not place the device near flammable substances. Do not operate the device in the presence of a flammable anesthetic mixture of air, oxygen or nitrogen oxides.
- Portable and mobile RF communication devices may affect the performance of this equipment, avoid strong electromagnetic interference when using it, e. g. near mobile phones, microwave ovens.
- Do not place this device near heat sources. The unit must be operated and stored in a reliable environment.
- The equipment is normally operated at +10 °C to +40 °C, 30% to 75% relative air humidity and 70 to 106 kPa atmospheric pressure.
- This device should be sterilized and disinfected at first use and after use on patients to avoid cross-contamination.
- Do not use instruments that are bent out of shape or do not meet ISO requirements. As a safety precaution, to avoid overuse of instruments, it is recommended to follow the procedure: When the root canal length reaches 0, subtract 0.5–1.0mm here as the working length of the root canal
- To confirm good contact between the filling needle and the electrode wire, test the wire connection before each use (see 3.13)

1. 3 Contraindications

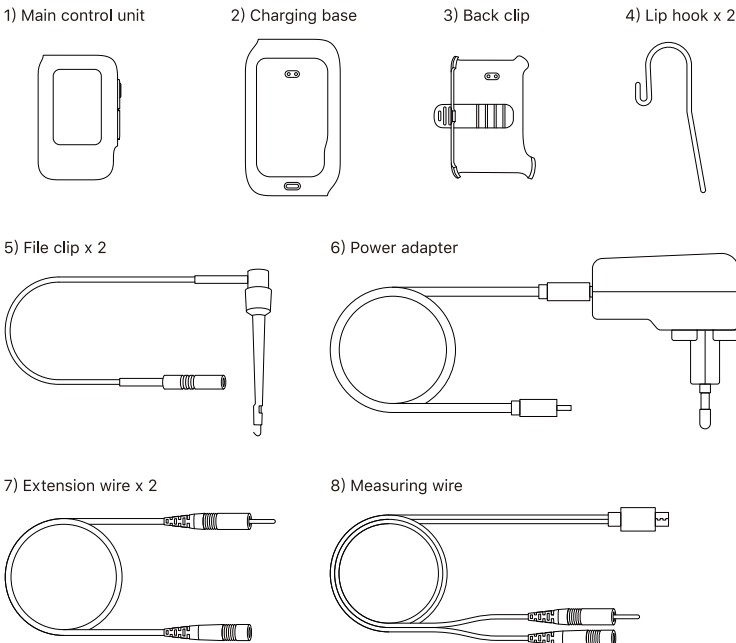
Prohibited for physicians with pacemakers.

Patients with pacemakers (or other electrical equipment) and warned not to use small appliances (e. g. electric razors, hairdryers, etc.) are prohibited.

2 Standard Components

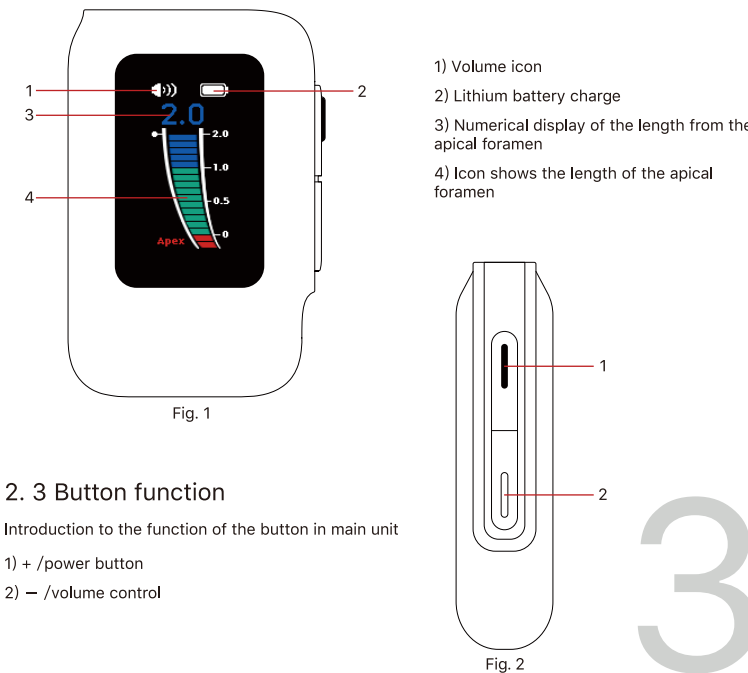
2. 1 List of component

The list of Mini Apex components is shown below:



2. 2 LCD interface

Display Interface Introduction



2. 3 Button function

Introduction to the function of the button in main unit

- 1) + /power button
- 2) – /volume control

3 Operation Instructions

3. 1 Device Charging

The device is powered by a rechargeable lithium battery, which needs to be fully charged the first time this device is used. The lithium battery should be charged as follows, as shown in Fig. 3:

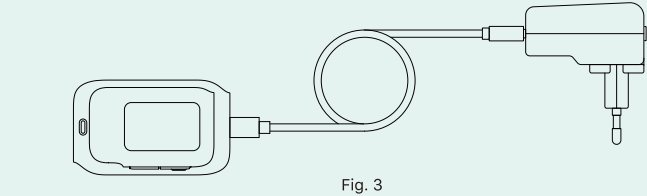


Fig. 3

Connect the power adapter to the charging base and plug the male USB connector of the charger into the female USB connector of the charging base; or connect the power adapter to the main control unit

Connect the power adapter to a 100–240V supply;

When the display battery icon refreshes, the device is charging. When the lithium battery is fully charged, the battery icon is shown as full and is not refreshing.

Warning! Do not use other types of power adapters, as this may damage the device.

3. 2 Battery level indication

When the lithium battery level falls below the minimum permissible charge (<20%), a warning " " indication will appear on the device display. Charge the lithium battery in according with 4. 1. When the battery level falls to a critical value (<10%), the device will automatically switch off.

Attention! Charge the device promptly when the power falls below 20%!

3. 3 Automatic switch-off function

It will automatically switch off after 5 minutes without doing anything to the device.

3. 4 Root test mode operation

3. 4. 1 Use measuring wire

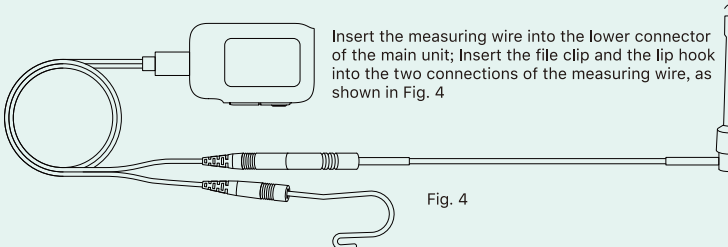


Fig. 4

3. 4. 2 Use lip hook with file clip

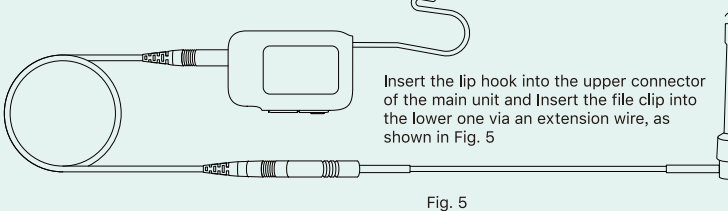


Fig. 5

Attention!

- Ensure that the plug is fully inserted into the connector when carrying out the root canal treatment
- Do not pull the wires by hand when unplugging measuring wire and file clip
- Do not hit the plug hard when it is inserted into the connector

3. 5 Root measurement length setting and operation considerations

3. 5. 1 Explanatory notes on the display screen

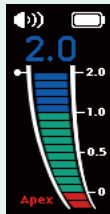


Fig. 6

- a. The position of the anterior end of the apical foramen is shown on the display as a root canal cue curve in the 0.5mm area.
- b. When the root canal indicator curve reaches the red zone, it indicates that the endodontic instrument has reached the vicinity of the apical foramen.
- c. When the root canal indication curve reaches the red indication zone –2, the endodontic instrument has punctured the apical foramen and a continuous beep will sound.

3. 5. 2 Root measurement length preset

The preset values for root measurement length described in this document refer to the position of the root measurement instrument from the apical foramen and set in the range 0.0 to 1.0. Press the "+" "–" buttons to adjust the required parameters.

Attention!

- A wire connection test must be carried out before each use of the instrument. After connecting the wire according to 5. 1. 1 or 5. 1. 2, short circuit the metal part of the file clip and the lip hook to confirm that the wire is in good contact. When the root canal measurement area shows –2 indicates a good connection, otherwise the wire is not working and the cause needs to be investigated.
- The numerical cues on the screen of the instrument do not mean the length or distance; the numerical changes merely indicates the movement of the shaping files towards the apex.
- Set the preset value for the root canal measurement length and a jumping dot horizontal line will appear in the area of Fig. 6 indicating the preset distance from the apical foramen position.
- The stop dot of the instrument (red area, showing the number "0.0") is the anatomical apical foramen. To use clinically as a safety measure, the length shown is subtracted by 0.5–1mm as the working length of the root canal.

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|--|--|-----------------------------|--|-------------------------|--|--|--|---|--|--|--|
| Email: sales@dental-perfect.com | | Website: www.sw-perfect.com | | Fax: +86(0660) 6128899 | | Phone: +86(0660) 6128899 | | Zip code: 516600 | | Address: No. 29, South side of Sanhe Road, West District, Hongcaoyuan District, High-tech Zone, Shanwei,516600 Guangdong,P.R.China | |
| Shanwei Perfect Medical Instruments Co.,Ltd. | | | | | | | | | | | |
| MANUFACTURER | | | | | | | | | | | |
| Model Number | | Importer | | Version: PF07-IFUE-01 | | Copyright: Shanwei Perfect Medical Instruments Co.,Ltd. | | # | | non-sterile | |
| Issued: 2022.11.05 | | Country of Manufacture | | Keep away from Sunlight | | Use-by date | | Batch Code | | Distributor | |
| UDI | | MD | | LOT | | Store in clean & dry place, protected from rain,snow, fog, salt and water. | | AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY | | EC REP | |

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•To prevent measurement errors caused by fluid contact with the gingiva or interference between adjacent root canals, the bottom of the pulp chamber must be dried with a cotton ball before testing.

•Use the files that match the size of the root canals. i.e. a large root canal measured with a small size root canal file will cause the screen numbers to display erratically.

•The instrument's patient–contacting accessories (file clips, lip hooks) are reusable and must be high temperature and pressure disinfection before each use, and it is recommended that no more than three times of use.

•Take care during the measurement to avoid connecting the internal fluid of the root canal with the external fluid of the root canal and creating electrical conductivity leading to measurement errors.

•Ensure that the file clip does not come into contact with other metals or instruments when measuring.

•To ensure that the results are not affected by a short circuit, special attention should be paid to patients with metal crowns or bridges; make sure that the root canal is sufficiently moist to ensure reliable measurements. If the apical foramen has not been reached and the value indicated on the display is too low, check if the root canal is too dry and take an X–ray to confirm this.

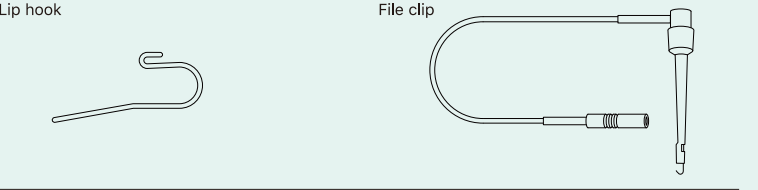
3. 6 Volume adjustment and sound interpretation

The sound volume can be changed via the buttons "+" or "–".
The device sound signals are detailed in the table below, with a total of three volume level sound indications.

| | |
|----------------------------------|---|
| Function | The type of sound signals |
| The device on | Signal for one short "drip" |
| Press the bottom | Signal for one short "drip" |
| Instruments approaching the apex | The "drop" sound becomes faster as it gets closer |
| Root canal perforation | Long "drip" doesn't stop |
| Power off | Ring a long signal |

4 Cleaning, Disinfection and Sterilization

For hygiene and sanitary safety purposes, this equipment must be cleaned, disinfected and sterilized before and after each use to prevent cross–infection.



The above components can be autoclaved

Cleaning: Clean the main unit and the measuring wires and extension wires with a soft cloth moistened with a mild aldehyde–free cleaning solution. Wash the assembly with water and wipe off excess water. Use a tee syringe etc. to blow off residual water inside the assembly.

Disinfection: Wipe the parts five times for 2 minutes each with a gauze soaked in alcohol (70–80 vol%).

Sterilization: Lip hooks and file clips must be sterilized at a temperature of 134°C, pressure of 0.22MPa and time of 5 minutes prior to each treatment.
Measuring wires and extension wires cannot be autoclaved. Dry for at least 8 minutes after sterilization.

Storage: Keep the sterilized parts in the special pouch for sterilization and store in a dry and clean environment. Check the integrity of the packaging before use and that it is within the expiry date specified for the sterilized pouch.

Warning!

- Please observe the relevant regulations for disinfection and sterilization.
- Please be careful when carrying out maintenance to avoid cross–infection.
- Autoclaving must be carried out before first use and after each use.

5 Battery Maintenance & Replacement

Timely replacement of lithium batteries in the context of durability yield; Replace lithium batteries once every two years for optimal operation; The built–in lithium battery of this device can be charged no less than 300 times

Warning!

- The battery must be replaced using the one provided by the manufacturer. if you need to replace the battery, please contact your local dealer or the manufacturer.
- If the operating time or battery charging time becomes shorter or the full battery life becomes shorter, the battery needs to be replaced.
- Do not open any parts other than the battery cover.
- Be sure to purchase and use the recommended batteries. Otherwise the device may be damaged.
- Do not replace the battery with wet hands as this may result in short circuit.
- If the device is not in use within one year, the user should check the battery, and if it is necessary the device should be replaced the battery.
- If the device is not used for a long time, the battery should be removed.
- The battery compartment is located at the rear of the unit and the cover needs to be opened with a Phillips screwdriver.

6 Troubleshooting

| Fault | Cause | Measure |
|--|---|--|
| The device cannot be turn on. " " displays | The lithium battery is running low | Charging |
| Shorter usage time after battery charging | Lithium battery life decay | Contact after–sales for lithium battery replacement |
| The device cannot charge | •No voltage in the network •Damaged power charger | • Check the connection • Check the power wire for voltage • Replace the main charger with the service department |
| The root canal measurement function is invalid | • The accessories are connected incorrectly • The measuring wire is broken | Make sure the measuring wire socket is firmly inserted and check the wire is not broken by contact the lip hook and the file clip |
| Unstable display during measurement: •The measured lengths is short or long; •The accuracy is poor; •The values are irregular | •The lip hook maintains bad contact with the oral mucosa •Blood and medical fluid spilled and stained on the crown •The root canal is filled with blood or medicinal fluid •There is medicinal fluid or debris on the tooth surface •The instruments contact with the gums •There is still pulp in the root canal •The instruments touch the metal restoration •The adjacencies is present on the adjoining surface •There are lateral branches or broken roots •The crown is low or there is stump remains due to removal of the medullary roof •There is a cyst at the apex •The file clip is broken or not clean; The measuring wire is damaged or poorly contacted | • Move the lip hook to a position that is in good contact with the oral mucosa • It can cause a short circuit • Dry the spilled blood and medicine fluid • Clean the tooth surface • The LCD display jumps to “–2” as soon as the instrument touches the gingiva • The length of cannot be correctly measured • The current is lost from the pulp or periodontal and the display jumps to “–2” • The current flows from the adjacent surface caries to the gingiva • The current flows out of the periodontium and the display immediately jumps to “–2” • Use a rubber barrier to prevent current flowing to the gums • In the presence of a cyst, the root canal length cannot accurately determined • Wipe the file with sterile alcohol or replace it; Short circuit the two ends of measuring wires, the display shows “–2” indicating good connection |
| The length measurement cue bar is only fully displayed near the APEX | •The root canal is occluded •The root canal is extremely dry •The instrument used is too small | • The display will be normal after penetrating the apical stenosis • Wet the root canal with hydrogen peroxide or saline solution • Select the right size of instruments |

7 Handling of Device



Do not dispose of equipment in the domestic waste system, dispose of it in accordance with local laws and regulations.

8 EMC Information

Attention!

Mini Apex meets the requirements of the YY0505 standard for EMC.

Users should install and use them in accordance with the EMC information provided in the accompanying documentation.

Portable and mobile RF communication equipment may affect the performance of the equipment and should be used in such a way as to avoid strong. electromagnetic interference, e.g. near mobile phones, microwave ovens, etc.

The guidelines and manufacturer's declaration are detailed in the annex.

Warning!

The device should not be used in proximity or stacked with other devices. If it must, it should be observed to verify that it will function properly in the configuration in which it is used.

Class B equipment intended for use in industrial environments where it may be potentially difficult to ensure EMC in other environments due to Mini Apex conducted and radiated nuisances;

| Name | Wire length (m) | Shielded or not | Remark |
|--------------------|-----------------|-----------------|--------|
| Power adapter wire | 1. 5 | No | / |
| Measuring wire | 1. 5 | No | / |
| Extension wire | 0.2 | No | / |

Guidelines and manufacturer's statement — Electromagnetic emission

The Mini Apex is expected to be used in the following specified electromagnetic environment and the purchaser or user should ensure that it is used in such an electromagnetic environment:

| Launch tests | Conformity | Electromagnetic environment — Guide |
|--|----------------|---|
| RF emission GB 4824 | 1 group | The Mini Apex uses RF energy only for its internal functions. As a result, it has low RF emissions and little potential for interference with nearby electronics |
| RF emission GB 4824 | Category B | The Mini Apex is suitable for use in all installations that are not domestic and not directly connected to the residential public low–voltage supply network for domestic use |
| Harmonic emission GB 17625.1 | Not applicable | |
| Voltage fluctuations/ flicker emissions GB 17625.2 | Not applicable | |

Guidelines and manufacturer's statement — Electromagnetic Immunity

The Mini Apex is intended to for use in the following specified electromagnetic environment and the purchaser or user shall warrant that it will be used in such electromagnetic environment:

| Immunity tests | IEC 60601 test | Conformity | Electromagnetic environment — Guide |
|---|--|--|---|
| Electrostatic discharge GB/T 17626.2 | ±6kV contact discharge ±8kV air discharge | ±6kV contact discharge ±8kV air discharge | The floor should be wood, concrete or tile, or at least 30% relative humidity if the floor is covered with a synthetic material |
| Electrical fast transient bursts GB/T 17626.4 | ± 2kV pair of power cables | ± 2kV pair of power cables | The network power supply should be of aquality typical of use in acommercial or hospital environment |
| Swell GB/T 17626.5 | ±1kV wire–to–wire ± 2kV wire–to–ground | ±1kV wire–to–wire ± 2kV wire–to–ground | The network power should be of a quality typical of use in a commercial or hospital environment |

| | | | |
|--|---|---|---|
| Voltage transients, short interruptions and voltage variations on the power input wire GB/T 17626.11 | <5% UT for 0.5 cycles (On UT, > 95% dip). 40 % UT for 5 cycles (On UT, 60% dip). 70% UT for 25 cycles (On UT, 30% dip). <5 % UT for 5s (On UT, > 95% dip). | <5% UT for 0.5 cycles (On UT, > 95% dip). 40 % UT for 5 cycles (On UT, 60% dip). 70% UT for 25 cycles (On UT, 30% dip). <5 % UT for 5s (On UT, > 95% dip). | The network power supply should be of aquality typical of use in acommercial or hospital environment. If the user of the Mini Apex requires continuous operation during a power interruption, it is recommended that the Mini Apex be powered by an uninterruptible power supply or battery |
| Industrial frequency magnetic field (50/60Hz) GB/T 17626.8 | 3A/m | 3A/m, 50/60Hz | The FT magnetic field should have the characteristics of the FT magnetic field levels typical of a site in a typical commercial or hospital environment |

Note: UT refers to the AC network voltage before the test voltage is applied

Guidelines and manufacturer's statement — Electromagnetic Immunity

The Mini Apex is intended to for use in the following specified electromagnetic environment and the purchaser or user shall warrant that it will be used in such electromagnetic environment:

| Immunity tests | IEC 60601 test | Conformity | Electromagnetic environment — Guide |
|--|--------------------------------------|----------------|---|
| RF conduction GB/T 17626.6 | 3 V (valid value). 150 kHz~80 MHz | Not applicable | Portable and mobile RF communication devices shouldn't be used closer to any part of the Mini Apex than the recommended isolation distance. This distance should be calculated by the formula corresponding to the transmitter frequency. Recommended isolation distances $d = 1.2\sqrt{P}$ $d = 80\text{ MHz } 1.2\sqrt{P} \sim 800\text{ MHz}$ $d = 800\text{ MHz } 2.3\sqrt{P} \sim 2.5\text{ GHz}$ |
| Radio frequency radiation GB/T 17626.3 | 3 V/m 80 MHz~2. 5 GHz | | In the formula: P — the maximum rated output power of the transmitter in watts (W) according to the transmitter manufacturer. d —Recommended isolation distance in meters (m) b —The field strength of a stationary RF transmitter is determined by surveying the electromagnetic field c —which should be lower than the compliance level at each frequency range d —Interference may occur in the vicinity of devices marked with the following symbols. () |

Note 1: At 80MHz and 800MHz frequencies, the formula for higher band is used.

Note 2: These guidelines may not be suitable for all situations in all cases, electromagnetic propagation is influenced by absorption and reflection from buildings, objects and the human body.

a. The field strength of fixed transmitters, such as: base stations for wireless (cellular/cordless) telephones and terrestrial mobile radios, amateur radio, AM and FM radio broadcasts and television broadcasts, cannot theoretically be accurately predicted. In order to assess the electromagnetic environment of a fixed RF transmitter. A survey of the electromagnetic field should be considered, If the field strength of the site where the Mini Apex is located is measured to be higher than the applicable RF compliance level described above, the Mini Apex should be observed to verify that it is functioning properly. If abnormal performance is observed,additional measures may be necessary, such as reorienting or repositioning the Mini Apex.

b. The field strength should be less than 3 V/m over the entire frequency range of 150KHz to 80 MHz.

Recommended isolation distance between portable and mobile RF devices and Mini Apex

The Mini Apex is intended for use in electromagnetic environments with controlled RF radiation disturbances. Depending on the maximum rated output power of the communication equipment, the purchaser or user may be protect from electromagnetic interference by maintaining the minimum distance between portable and mobile RF communication devices (transmitter) and (device or system) as recommended below.

| | Corresponding to the isolation distance of different frequencies of the transmitter/m | | |
|---|---|---------------------------------------|--|
| Rated maximum output power of the transmitter/W | 150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$ | 80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$ | 800 MHz~ 2. 5 GHz $d = 2.3\sqrt{P}$ |
| 0. 01 | 0. 12 | 0. 12 | 0. 23 |
| 0. 1 | 0. 38 | 0. 38 | 0. 73 |
| 1 | 1. 2 | 1. 2 | 2. 3 |
| 10 | 3. 8 | 3. 8 | 7. 3 |
| 100 | 12 | 12 | 23 |

For transmitter rated maximum output power not listed in the table above, the recommended isolation distance d, in meters (m), can be determined using the formula in the corresponding transmitter frequency column, where P is the transmitter's maximum output power rating in watts (W) as supplied by the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz frequencies, the formulae for the higher frequency range are used.

Note 2: These guidelines may not be appropriate in all cases.electromagnetic propagation is influenced by absorption and reflection from buildings, objects and the human body.

9 Commitment

- 1) This product is covered by the Mini Apex warranty for 12months from the date of purchase by the user.
- 2) The product and its components are repaired by Shanwei Perfect Medical Instruments Co., Ltd. or its authorized service partners. Maintenance materials such as circuit diagrams, component lists, illustrations, calibration rules aren't provided.
- 3) If the damage proves was caused by the negligence of the user in routine maintenance, it is not covered by the warranty.
- 4) Disassembly and repair by unauthorized personnel is not permitted.
- 5) Use of this device for purposes and applications contrary to those specified in these instructions for use will not be warranted.

10 Symbol Description

| | | | |
|--|---------------------------------------|--|--|
| Manufacturer | Power switch | Serial number | Dry storage |
| Transport and storage air pressure limits | Date of manufacture | Class II equipment | Type B application section |
| Warning, if done improperly, may endanger the user | Transport and storage humidity limits | Transport and storage temperature limits | Please refer to the instructions for use |
| Follow the instruction manual | Caution | Do not dispose the device in the domestic waste system | For indoor use only |
| High temperatures up to 135°C steam sterilization | DC (power connection) | AC(alternating current) | Conformity European |