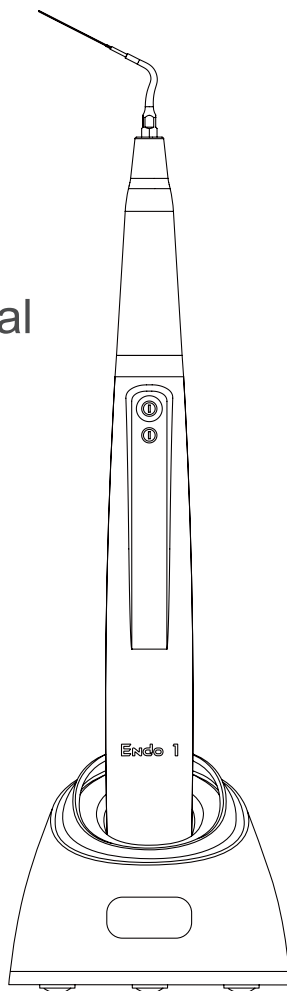


# Endo 1

## Instruction Manual

Please read this manual before operating



CE 0197

**Guilin Woodpecker Medical Instrument Co., Ltd.**

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## **Preface**

Guilin Woodpecker Medical Instrument Co., Ltd is a professional manufacturer researching, developing, and producing dental products. Woodpecker owns a sound quality control system. Its main products include Ultrasonic Scaler, Ultrasonic Endo Ultrasonic Endo Activate Device, Curing light, Apex locator, Ultrasurgery, Automatic water supply system, etc.

### **1 Product introduction**

#### **1.1 The features of Endo 1 Ultrasonic Endo Activate Device**

a) The work process of this machine adopts microcomputer automatic control, which is easy to operate and of high efficiency. Only one mode switching button, the machine can be started or turned off by pressing the mode switch button.

b) This machine has two modes Sleep Mode and Irrigation Mode (work mode).

c) This machine is of stable performance and adopts automatic frequency tracking system which can automatically searching for the best work state.

d) The tips, Endo wrench and handpiece are removable and can be autoclaved under high temperature of 134°C and high pressure of 0.22Mpa.

e) Root canal vibration amplitude is small, which will not hurt the root canal. Meanwhile, it is closer to the bottom of the root canal. Root canal vibration frequency is high, making Irrigation more efficient.

#### **1.2 Product model**

Endo 1

#### **1.3 Product principle and scope of application**

##### **1.3.1 Product principle**

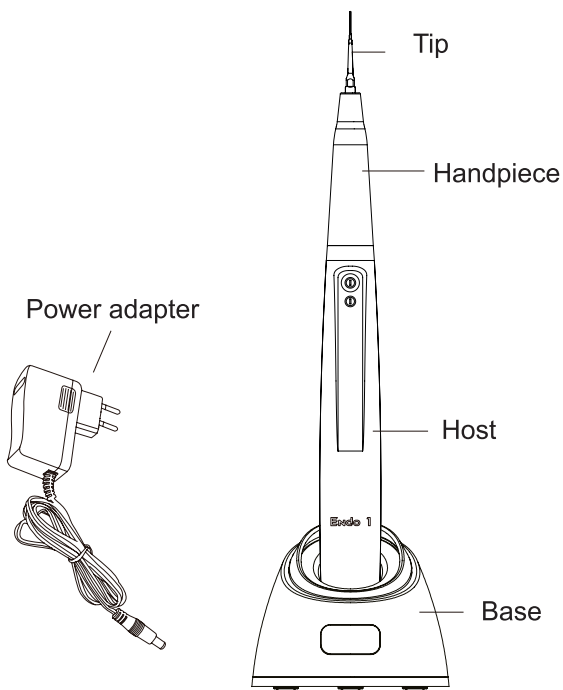
Endo 1 Ultrasonic Endo Activate Device mainly generates high-frequency oscillating signals from the high-frequency oscillating circuit and acts on the ultrasonic transducer. The ultrasonic vibration is generated by the inverse piezoelectric effect, and the tip is stimulated to generate resonance. It can deep into the root canal and utilizes various effects produced by ultrasonic waves to drive the drug or liquid in the root canal, generating ultrasonic flow and cavitation effects, and achieving the effect of irrigating stains and debris.

##### **1.3.2 Scope of application**

Endo 1 Ultrasonic Endo Activate Device applies to root canal irrigation.

### **2 Product components**

Product model: Endo 1. This product is composed of host, handpiece, tips, Endo wrench, charging base, 5V power adapter, etc.



### 3 Basic technical parameters

3.1 Dimensions: 246mm×25mm×25mm

3.2 Net weight: 99g

3.3 Machine configuration list: See details in packing list

3.4 Classified by power supply: Powered by rechargeable batteries

3.5 Rechargeable lithium battery:

Battery model: DLG14500

Nominal voltage: 3.6V

Capacity: 750mAh

3.6 Power adapter:

Input: ~100V-240V 50Hz/60Hz 0.5-0.2A

Output: DC 5V/1A

Build-in fuse: T1A 250V

### 3.7 Working tip parameters:

Output tip vibration frequency:  $45\text{kHz} \pm 4\text{kHz}$

### 3.8 Environment parameters:

Environment temperature:  $+5^{\circ}\text{C} \sim +40^{\circ}\text{C}$

Relative humidity at 30% -75%

Atmospheric pressure:  $70\text{kPa} \sim 106\text{kPa}$

### 3.9 Device safety classification:

Classified by operation mode: Short time operating device

Type of protection against electric shock: Class II equipment with internal power supply

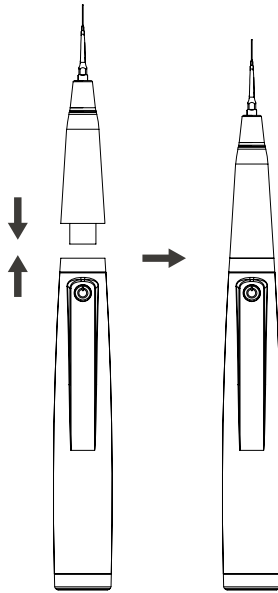
Degree of protection against electric shock: BF type applied part

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

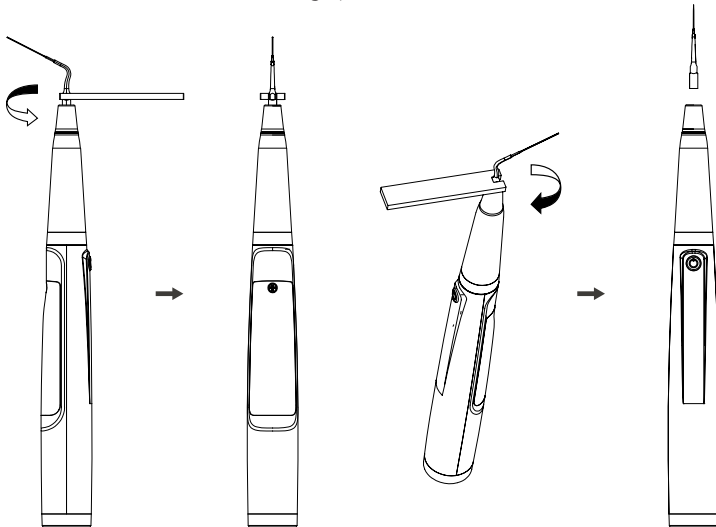
Degree of safety application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide: Equipment cannot be used in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

## **4 Installation and removal method**

4.1 Open the package, check whether the equipment is complete as per the packing list, place the host on a solid plane, holding it directly facing the operator, and then insert the handpiece. As shown below:



4.2 Screw the tip in clockwise direction and press the button to use the machine. The methods of removing tips are as follow:



4.3 When replacing the battery, please open the battery cover, first remove the lithium battery, and then gently pull out the plug-in, put the new battery connector plug correctly into the host, and then put new battery in. Put the battery cover on the host mounting port, push up, and cover the battery.

4.4 For battery charging, plug the host into the charging base and press tightly to make the host and base tightly match. While not charging, please keep the charging base power off.

## **5 Operation**

5.1 When using, first put the top of the tip into the proper position of the root canal, click Mode switch button, and the machine will automatically adjust to the best working state to work. The set irrigation time is 20s. After 20s, the machine automatically enters the sleep mode. After changing the irrigating solution, press the switch again to enter the irrigation mode again. Under normal circumstances, during a complete root canal irrigation, operators needs to replace the irrigation solution for 7-8 times.

5.2 The tips, Endo wrench and handpiece are removable and can be autoclaved under high temperature of 134°C and high pressure of 0.22MPa.

5.3 Low voltage indication: If the light of mode switching button turns dark or the power is not enough, it means that the battery capacity is low and it needs to charge immediately.

## **6 Charging instructions**

6.1 Use the corresponding charging base: Connect the power adapter with charging base, and plug the host into the charging base. While charging, the mode switching button light would flash. If the light turns to be normally on, it means that battery charging is over. Generally a charging process lasts for 1.5 hours. And under full charged condition, the machine can continuously work for 1 hour.

6.2 The battery of this product is of no memory. It can be used while charging.

6.3 Before first use of this machine, please charge for at least 4 hours.

## **7 Safety precautions**

7.1 Keep the machine clean before and after operation.

7.2 Operators should be equipped with adequate protections such as goggles, masks, etc. to prevent cross-infection while operating.

7.3 The use of the product must meet the requirements of the relevant operation normalization and relevant regulations of medical department, and the use is limited to the trained doctors or technicians.

7.4 The tip and endodontic wrench must be sterilized before each treatment.

7.5 Don't install or remove the handpiece or tip under working mode

(Irrigation Mode) as the tip is vibrating.

7.6 The tip must be tightly screwed.

7.7 During operation, it is necessary to drip water for cooling. At the same time, the water dripping instrument needs to be isolated from the earth.

7.8 The damage or wear of working tip will result in vibration intensity decrease. The operator should replace the work tip according to the clinical situation.

7.9 Don't twist or polish work tip.

7.10 Don't strike or scratch the handpiece.

7.11 When charging with the adapter, keep the contact with the adapter housing for less than 1 min.

7.12 Please turn off the power switch after each treatment.

7.13 Woodpecker is specialized in producing medical instrument. We are only responsible for the safety on the following conditions:

a) The maintenance, repair, and modification are made by the manufacturer or the authorized dealers.

b) The charged components are original of "DTE" and operated according to instruction manual.

7.14 The internal thread of Ultrasonic Endo activating file produced by some other manufacturers maybe coarse, rusty, collapse, or use other standard thread. It will be easy to be broken or cause slide teeth while matching the external thread of handpiece, resulting in damage beyond repair of the Ultrasonic Endo activating file. Please use "DTE" brand work tips.

## **8 Product contraindications**

8.1 The hemophilia patient is forbidden to use this equipment.

8.2 The patients with heart pacemaker are forbidden to use this equipment.

8.3 The patients with heart pacemaker are forbidden to use this equipment.

8.4 Heart disease patients, pregnant women and children should be cautious to use the equipment.

## **9 Cleaning, disinfection and sterilization**

The cleaning, disinfection and sterilization of handpiece, tip, and Endo wrench are as follow.

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

### **Warnings**

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

Do not clean the handpiece with ultrasound cleaning machine.

The products may not be exposed to temperature above 138°C.

### **Processing limit**

The products have been designed for a large number of sterilization cycles.



The materials used in manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. The maximum number of sterilizations for handpiece is 600 times. For tips, it is 300 times. And for wrench, it is 1000 times.

## 9.1 Initial processing

### 9.1.1 Processing principles

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

Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic, especially with regard to the additional requirements for the inactivation of prions.

### 9.1.2 Post-operative treatment

The post-operative treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows:

1. Wet the soft cloth completely with distilled water or deionized water, and then wipe all the surfaces of the handpiece, tip and host until the surface of the component is not stained;

2. Dry the product with a clean, soft cloth and place it in a clean tray.

#### **Notes:**

- a) The water used here must be pure water, distilled water or deionized water.

## 9.2 Preparation before cleaning

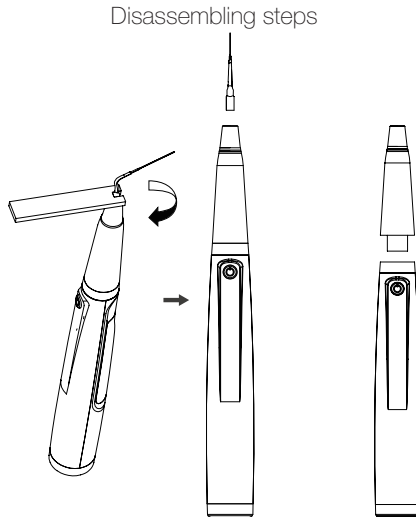
Steps:

Tools: endo wrench, tray, soft brush, clean and dry soft cloth

1. Remove the tip from handpiece with Endo wrench provided by Guilin Woodpecker Medical Instrument Co., Ltd, and then put the tip and wrench into a clean tray.

2. Remove the handpiece from host, and then unscrew the nipple of handpiece counterclockwise, and put them in the tray.

3. Use a clean soft brush to carefully brush the joints between handpiece and the connector of cable, front thread, horn, nipple until the dirt on surface is not visible. Then use soft cloth to dry the handpiece and accessories and put them into a clean tray. The cleaning agent can be pure water, distilled water or deionized water.



### 9.3 Cleaning

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

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

#### 9.3.1 Automated cleaning

- The cleaner is proved to be valid by CE certification in accordance with EN ISO 15883.
- There should be a flushing connector connected to the inner cavity of the product.
- The cleaning procedure is suitable for the product, and the irrigating period is sufficient.
- Do not clean the handpiece with ultrasound.

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

#### **Notes:**

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

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

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

## 9.4 Disinfection

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

### 9.4.1 Automated disinfection-Washer-disinfector

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

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

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

Cleaning and disinfecting steps by using Washer-disinfector

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

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

3. Start the program.

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

#### **Notes:**

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

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

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

d) Disinfection: (d1) Direct use after disinfection: temperature  $\geq 90$  ° C, time  $\geq 5$  min or AO  $\geq 3000$ ;

Sterilize it after disinfection and use: temperature  $\geq 90$  ° C, time  $\geq 1$  min or AO  $\geq 600$

(d2) For the disinfection here, the temperature is 93 ° C, the time is 2.5 min, and  $A0 > 3000$

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

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

g) The air used for drying must be filtered by HEPA.

h) Regularly repair and inspect the disinfectant.

## 9.5 Drying

If your cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.

Methods

1. Spread a clean white paper (white cloth) on the flat table, point the product against the white paper (white cloth), and then dry the product with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the product drying is completed.

2. It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80°C~120°C and the time should be 15~40 minutes.

### Notes:

a) The drying of product must be performed in a clean place.

b) The drying temperature should not exceed 138 °C;

c) The equipment used should be inspected and maintained regularly.

## 9.6 Inspection and maintenance

In this chapter, we only check the appearance of the product. After inspection, if there is no problem, the handpiece should be immediately reassembled, installing cone head in sequence to the handpiece, and then tighten the cone head clockwise.

9.6.1 Check the product. If there is still visible stain on the product after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.

9.6.2 Check the product. If it is obviously damaged, smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used.

9.6.3 Check the product. If the accessories are found to be damaged, please replace it before use. And the new accessories for replacement must be cleaned, disinfected and dried.

9.6.4 If the service time (number of times) of the product reaches the specified service life (number of times), please replace it in time.

## 9.7 Packaging

Install the disinfected and dried product and quickly package it in a medical

sterilization bag (or special holder, sterile box).

**Notes:**

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

### 9.8 Sterilization

Use only the following steam sterilization procedures (fractional pre-vacuum procedure\*) for sterilization, and other sterilization procedures are prohibited:

- The steam sterilizer complies with EN13060 or is certified according to EN 285 to comply with EN ISO 17665;
- The highest sterilization temperature is 138 °C;
- The sterilization time is at least 4 minutes at a temperature of 132 °C / 134 °C and a pressure of 2.0 bar ~ 2.3 bars.
- Allow a maximum sterilization time of 20 minutes at 134 °C.

Verification of the fundamental suitability of the products for effective steam sterilization was provided by a verified testing laboratory.

**Notes:**

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

\* Fractional pre-vacuum procedure = steam sterilization with repetitive pre-vacuum. The procedure used here is to perform steam sterilization through three pre-vacuums.

### 9.9 Storage

1. Store in a clean, dry, ventilated, non-corrosive atmosphere with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20 °C to +55 °C;
2. After sterilization, the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage

cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

**Notes:**

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

**9.10 Transportation**

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

The cleaning and disinfection of host and base are as follows.

**1 Pre-Op processing**

Before each use, the host must be cleaned and disinfected. The specific steps are as follows:

**Warning:** The host cannot be cleaned and disinfected with automatic equipment. Manual cleaning and disinfection is required.

**1.1 Manual cleaning steps:**

- 1. Wet the soft cloth completely with distilled water or deionized water, and then wipe all the surfaces of the host until the surface of the component is not stained.
- 2. Wipe the surface of the host with a dry soft nap-free cloth.
- 3. Repeat the above steps at least 3 times.

Note:

- a) Use distilled water or deionized water for cleaning at room temperature.

**1.2 Manual disinfection steps:**

- 1. Soak the dry soft cloth with 75% alcohol
- 2. Wipe all surfaces of host with a wet soft cloth for at least 3 minutes.
- 3. Wipe the surface of the host with a dry soft nap-free cloth.

Note:

- a) The cleaning and disinfection must be performed within 10min before use.
- b) The disinfectant used must be used immediately, no foaming is allowed.
- c) In addition to 75% alcohol, you can use non-residue disinfectants such as Oxytech from Germany, but you must respect the concentration, temperature and time specified by the disinfectant manufacturer.

**2 Post-Op processing**

After each use, clean and disinfect the host within 30 minutes. The specific steps are as follows:

Tools: Nap-free soft cloth, tray

1. Soak the nap-free soft cloth with distilled water or deionized water, and then wipe all the surfaces of the components such as the handpiece, host, tip, etc. until the surface of the component is not stained.

2. Remove the tip from the handpiece, place it in a clean tray, and then remove the handpiece from the host.

3. Wet the dry soft cloth with 75% alcohol, and then wipe all surfaces of the host for 3 minutes.

4. Put the host back into the clean storage area.

**Note:**

a) The cleaning and disinfection must be performed within 10min before use.

b) The disinfectant used must be used immediately, no foaming is allowed.

c) In addition to 75% alcohol, you can use non-residue disinfectants such as Oxytech from Germany, but you must respect the concentration, temperature and time specified by the disinfectant manufacturer.

## **10 Daily maintenance**

10.1 This product does not contain self-repair spare parts. The machine maintenance should be done by designated professionals or in the authorized maintenance shop.

10.2 For this product, only handpiece, torch wrench, and tips can be sterilized under high temperature of 134°C and high pressure of 0.22MPa. For the other spare parts, they can be cleaned or sterilized by using water or disinfectant to scrub their surface. Do not soak them in the solution. Do not use volatile and diffuent solvent to clean as it will result in the color fading of the marks on machine.

10.3 Please turn off the power switch, unplug the power plug when the device is not in use. If not use for a long time, please make the device get through to the power for five minutes once per month.

## 11 Troubleshooting

Fault	Possible cause	Solution
No indication; no action	The battery capacity of Endo 1 Ultrasonic Endo Activate Device is low.	Connect the power supply to charge / replace the battery
	The battery is damaged.	Replace the battery
	Continuously using for a long time, thermal protection circuit action.	Stop using for few minutes, and then it will function normally.
	Charging interface short circuit results in lithium battery getting into protection state.	Plug the device into the charging base to charge, and it will function normally.
	Endo 1 Ultrasonic Endo Activate Device is broken.	Contact with local dealers or manufacturer.
Tips abnormally working	Malfunction of host	Send to maintenance department
Do not charge after connecting to power adapter	The power supply was not well connected.	Pull out and connect again
	The power supply is broken, or the specification does not match.	Replace the battery
	There are impurities on the thimble of charging base.	Use ethyl alcohol to clean the thimble on charging base.
The battery can be used for a shorter time after charging	Battery capacity becomes smaller	Send to maintenance department

## 12 Storage and transportation

12.1 The equipment should be handled carefully and lightly. Be sure that it is far from the vibration, and installed or kept in a cool, dry, and ventilated place.

12.2 Do not store the machine together with articles that is poisonous, combustible, caustic, or explosive.

12.3 This machine should be stored in a room where the relative humidity



is 10%~93%, atmospheric pressure is 70kPa~106kPa, and the temperature is -20°C~+55°C.

12.4 Excessive impact and shake should be prevented during transportation. Lay it carefully and lightly.

12.5 Do not put it together with dangerous goods during transportation.

12.6 Avoid being exposed to sun, rain, and snow during transportation.

### 13 After-sales service

Since the date of sale, for the ill function of this machine caused by quality problem, our company is responsible for the maintenance during warranty. The warranty period and scope of warranty refers to the product warranty card.

### 14 European authorized representative

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

### 15 Environment protection

The device does not contain any harmful ingredients. It can be handled or destroyed in accordance with the relevant local regulations.

### 16 Symbol instruction



Product registered trademark



Product registered trademark



Connection of handpiece and hos



Mode switching button



Ordinary equipment

DC 5.0V

5V Direct current



Used indoor only



Date of manufacture



Manufacturer



Class II equipment



BF type applied part



Sterilizable up to the temperature specified



Products comply with WEEE directive



Follow instructions for use



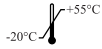
CE marked product



Humidity limit for storage: 10% ~ 93%



Atmospheric pressure for storage: 70kPa—106kPa



Temperature limit for storage: -20°C ~ +55°C



Authorised Representative in the EUROPEAN COMMUNITY

## 17 Electromagnetic compatibility

 Attention:

1) Without Woodpecker agreement and authorization, private modification of device may result in the electromagnetic compatibility problem of that device or other devices.

2) The design and test of Endo 1 Ultrasonic Endo Activate Device complies with the related operation regulations of electromagnetic compatibility.

Note: In the case of an electrical fast transient burst test, there may be a situation in which the power cannot be adjusted due to the interference of the touch key. This does not affect the output of the whole power and is self-recoverable after the test is completed. According to the experienced clinician and those professionals who are capable of using specific device or system, this risk is acceptable.

### 17.1 Electromagnetic compatibility key components

The electromagnetic compatibility key components of this product consist of power cord, circuit board, IC chip. The use or replacement of non-supporting accessories, cables, transducers, etc. will result in a significant reduction in electromagnetic compatibility emission and immunity performance. Please do not privately replace the machine parts.

### 17.2 Guidance and manufacturer's declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions

The model Endo 1 is intended for use in the electromagnetic environment specified below. The customer or the user of the model Endo 1 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
---------------	------------	--

RF emissions CISPR 11	Group 1	The model Endo 1 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 Endo 1 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliance	


### 17.3 Guidance & Declaration — electromagnetic immunity

Guidance & Declaration — electromagnetic immunity			
The model Endo 1 is intended for use in the electromagnetic environment specified below. The customer or the user of the model Endo 1 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±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 <5 % $U_T$ (>95% dip in $U_T$ ) for 1 cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles 70% $U_T$ (30% dip in $U_T$ ) for 25/30 cycles <5% $U_T$ (>95 % dip in $U_T$ ) for 5/6 sec	<5 % $U_T$ (>95% dip in $U_T$ ) for 0.5 cycle <5 % $U_T$ (>95% dip in $U_T$ ) for 1 cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycles 70% $U_T$ (30% dip in $U_T$ ) for 25/30 cycles <5% $U_T$ (>95 % dip in $U_T$ ) for 5/6 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model Endo 1 requires continued operation during power mains interruptions, it is recommended that the model Endo 1 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE $U_T$ is the a.c. mains voltage prior to application of the test level.			

#### 17.4 Guidance & Declaration - electromagnetic immunity concerning Conducted RF & Radiated RF

Guidance & Declaration - Electromagnetic immunity			
The model Endo 1 is intended for use in the electromagnetic environment specified below. The customer or the user of the model Endo 1 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>6 Vrms in ISM and amateur radio bands</p> <p>3 V/m, 10 V/m 80 MHz to 2.7 GHz</p> <p>385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>6 Vrms in ISM and amateur radio bands</p> <p>3 V/m, 10 V/m 80 MHz to 2.7 GHz</p> <p>385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the models Endo 1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance</p> <p><math>d = [3,5/V_1] \times P^{1/2}</math>  <math>d = 1.2 \times P^{1/2}</math></p> <p>80 MHz to 800 MHz  <math>d = 2.3 \times P^{1/2}</math></p> <p>800 MHz to 2.7 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,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup>  Interference may occur In the vicinity of equipment marked with the following symbol:</p> 
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NOTE 1 At 80 MHz and 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 Endo 1 is used exceeds the applicable RF compliance level above, the model Endo 1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model Endo 1.

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

### 17.5 Recommended separation distances between portable and mobile RF communications equipment and the model Endo 1

Recommended separation distances between portable and mobile RF communications equipment and the model Endo 1

The model Endo 1 is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model Endo 1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model Endo 1 is 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.

Endo 1 Ultrasonic Endo Activate Device has been tested in accordance with YY 0505-2012/IEC 60601-1-2-2014. This does not guarantee in any way that this device will not be affected by electromagnetic interference. Avoid using the device in high electromagnetic environment.

## **18 Statement**

Woodpecker reserves the right to change the design of the equipment, the technique, fittings, instruction manual and the content of the original packing list at any time without further notice. The pictures are only for reference. The final interpretation rights belong to Guilin Woodpecker Medical Instrument Co., Ltd.

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for more information



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

Tel:

Europe Sales Dept.: +86-773-5873196

North/South America & Oceania Sales Dep.: +86-773-5873198

Asia & Africa Sales Dep.: +86-773-5855350 Fax: +86-773-5822450

E-mail: [woodpecker@glwoodpecker.com](mailto:woodpecker@glwoodpecker.com), [sales@glwoodpecker.com](mailto:sales@glwoodpecker.com)

Website: <http://www.glwoodpecker.com>



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

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