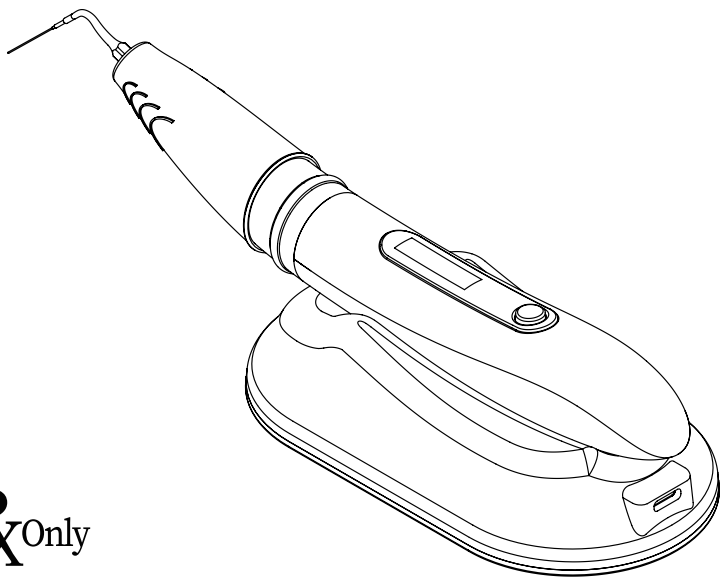
EDGEENDO®

EDGEACTIVATOR™

Ultrasonic Endo Activator Device

INSTRUCTIONS FOR USE

Please read this manual before operating



℞ Only

CE 0197

ZMN-SM-1143 V1.0-20260327

Contents

1 Product introduction---------- 1
2 Product components---------- 2
3 Basic technical parameters---------- 2
4 Installation and removal method ---------- 3
5 Operation---------- 4
6 Charging instructions---------- 5
7 Safety precautions---------- 6
8 Product contraindications---------- 7
9 Cleaning, disinfection and sterilization ---------- 7
10 Daily maintenance---------- 14
11 Troubleshooting ---------- 15
12 Storage and transportation---------- 15
13 After-sales service---------- 16
14 Environment protection---------- 16
15 Symbol instruction ---------- 16
16 Electromagnetic compatibility---------- 17

1 Product introduction

1.1 The features of EDGEACTIVATOR Ultrasonic Endo Activator Device

a) Adopt microcomputer automatic control for the working process, which makes the operation easier and efficient. There are one mode switching button and a ring switch button. Press the mode switching button to adjust the working state of the machine, and press the ring switch button to start or shut down the machine.

b) This machine has three modes: shutdown mode, hot standby mode (in this mode, power adjustment and time adjustment can be carried out) and irrigation mode (working mode).

c) The machine has stable performance and adopts an automatic frequency tracking system to automatically search for the best working state.

d) The tips, Torque wrench and protective silicone cover can be autoclaved under high temperature of 134°C and high pressure of 0.22Mpa.

e) The small vibration amplitude and high frequency of the tip enable the efficient and safe irrigation.

1.2 Product model

EDGEACTIVATOR

1.3 Product principle and scope of application

1.3.1 Product principle

EDGEACTIVATOR Ultrasonic Endo Activator 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 Product description: This product is an Ultrasonic Endo Activator Device,consisting of host, charging base, and tip. Its working principle involves converting electrical energy into high-frequency mechanical vibrations, which drive the tip to irrigate and clean the root canal.

1.3.3 Indications for Use:

For use in root canal therapy to:

- Assist irrigation and debridement of the root canal system;
- Remove pulp tissue, debris, and smear layer in the root canal;
- Enhance the penetration and exchange of root canal irrigants;
- Facilitate the cleaning and shaping of root canals before obturation.

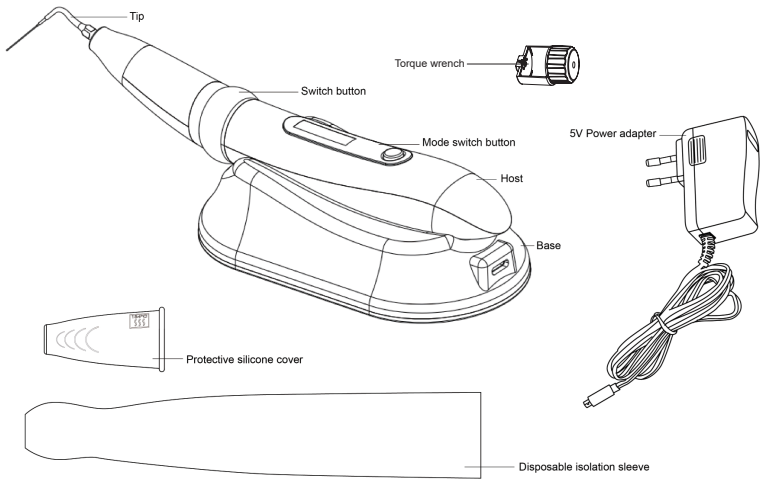
1.3.4 Intended Use: EDGEACTIVATOR Ultrasonic Endo Activator Device applies to root canal irrigation.

1.3.5 Intended Environment:
- Dental clinics, dental hospitals, and medical institutions equipped with standard dental treatment units;
- Indoor clinical environment with stable power supply;
- Environment free from strong electromagnetic interference, flammable or explosive gases.
1.3.6 Intended Population: People who need root canal irrigation.
1.3.7 Intended user: Professional dentists.

2 Product components

This product is composed of host, charging base, tips, Torque wrench, 5V power adapter, disposable isolation sleeve, protective silicone cover.

Note: The isolation sleeve is for single use only, please do not reuse.



3 Basic technical parameters

3.1 Dimensions: 173.8mm×25.8mm×35.8mm

3.2 Net weight: 78g

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 mode: 14500

Nominal voltage: 3.6V

Capacity: 750mAh

3.6 Power adapter:

Input: 100V-240V~ 50Hz/60Hz 0.4A MAX
Output: DC 5V/1A
Build-in fuse: T1AL 250V

3.7 Working tip parameters:

Output tip vibration frequency: 40kHz±10kHz

3.8 Software Version:V1.0.0

3.9 Environment parameters:

Environment temperature: +5°C ~+40°C
Relative humidity at 30% -75%
Atmospheric pressure:70kPa ~ 106kPa

3.10 Device safety classification:

3.10.1 Applied part: Tips
3.10.2 Type of Operation mode: Non continuous operating device.
Duty cycle:ON/OFF:Max 1min/Min 2min
3.10.3 Type of protection against electric shock: Class II equipment with internal power supply
3.10.4 The contact duration of applied part:No more than 1 minute.
3.10.5 The temperature of the surface of applied part may reach 48℃.
3.10.6 Degree of protection against electric shock: BF type applied part
3.10.7 Degree of protection against harmful ingress of water: Ordinary equipment (IPX0)
3.10.8 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

Before use: Install the disposable isolation sleeve first, then install the protective silicone cover, and finally install the tip.
After use: First remove the tip, then remove the protective silicone cover, and finally remove the disposable isolation sleeve.

4.1 Installation and removal of disposable isolation sleeve

4.1.1 Installation
Before each use of the host and after the host is cleaned and disinfected, put on a disposable isolation sleeve. Take the isolation sleeve out of the isolation sleeve box, then insert the isolation sleeve into the host from the thin end of the host, and install the isolation sleeve until there is no obvious wrinkle.
4.1.2 Removing

After each use, slowly pull the isolation sleeve from the thin end of the host.
Warning: Isolation sleeves are not reusable.

4.2 Installation and removal of protective silicone cover

4.2.1 Installation

Before each use of the host, put on a sterilized protective silicone cover. Align the protective silicone cover with the head of the host and put it on gently.

4.2.2 Removal

After each use, slowly remove the protective silicone cover from the host.

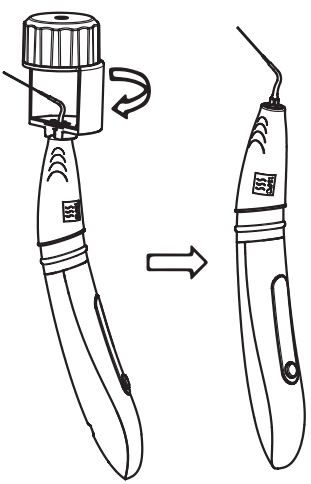
4.3 Installation and removal of the tip

Screw the tip with an Torque wrench in clockwise direction and press the button to use the machine. (Rotate the tip counterclockwise to remove it.) The installation and removal method of the tip is shown in the figure below:

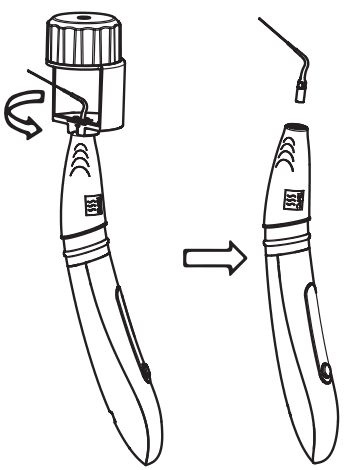
Note:

The installation or removal of the tip shall be carried out under the shutdown mode of the host.

Only the torque wrench configured with the machine can be used to install or remove the tip.



Tighten clockwise to install the tip

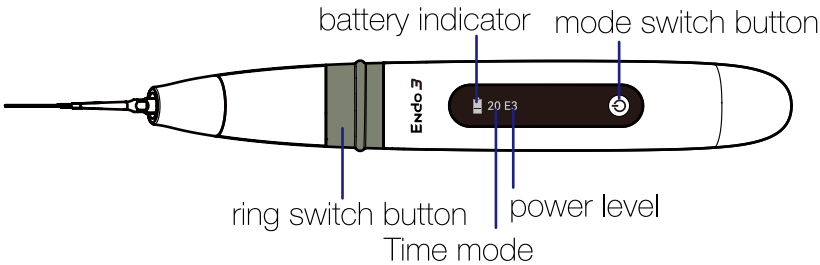


Unscrew counterclockwise to remove the tip

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

Buttons and screen display:



5.1 Under the shutdown mode of the host, press the mode switching button lightly and the host would enter the hot standby mode. Under the hot standby mode, lightly press the mode switching button to select the power level of the host. After selecting the power, press the mode switching button and the ring switch button at the same time, the host will enter the time adjustment state (at this time, the middle character will jump constantly). And then, lightly press the mode switching button to select the duration time of the irrigation mode. There are four kinds of working time of this machine: 10, 15, 20 and --, which means 10s, 15s, 20s and 10min respectively.After selection, press the mode switching button and ring switch button at the same time again, the host will exit the time adjustment state.

5.2 When using, first inject the liquid medicine into the root canal, next set the power level and the irrigation time of the host, then put the tip into the appropriate position of the root canal, lightly press the ring switch button of the host, and the host will automatically adjust to the best working condition for work. After the irrigation, press the ring switch button to stop irrigation (or the host will stop irrigation after the irrigation time is over). After replacing the liquid medicine, lightly press the ring switch button again to re-enter the irrigation mode. In general, a complete root canal irrigation requires replacing the liquid medicine 7-8 times.

5.3 After the treatment, long press the mode switching button and the host would enter the shutdown mode.

5.4 The tip and Torque wrench can be autoclaved under high temperature of 134°C and high pressure of 0.22MPa.

5.5 Low voltage indication: If the screen shows that there is only 1 grid voltage left, it means that the battery is about to be exhausted and needs to be charged as soon as possible.

6 Charging instructions

6.1 Use the charging base corresponding to this machine to charge: Connect the power adapter to the charging base and turn on the power, and then put the main unit of Ultrasonic Endo Activator on the charging base. When charging, the battery indicator on the screen will continue

to flip. When the indicator stops at 4 grids position and stops flipping, it means charging is finished. Under normal circumstances, it takes 4 hours to charge. When fully charged, the machine can continue to work for 1 hours.

6.2 The battery used in this product has no memory and can be charged at any time.

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

7 Safety precautions

7.1 A tip engraved with the "WOODPECKER" logo cannot be used on a host engraved with the "DTE" logo and vice versa.

7.2 Keep the machine clean before and after operation.

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

7.4 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.

7.5 The tip,protective silicone cover and Torque wrench must be sterilized before each treatment.

7.6 Please install or remove the tip under shutdown mode.

7.7 The tip must be tightly screwed.

7.8 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.

7.9 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.

7.10 Don’t twist or polish work tip.

7.11 Don’t strike or scratch the host.

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

7.13 Please long press the mode switching button to make the host enter the shutdown mode after each treatment.

7.14 Replacement of lithium batteries by inadequately trained personnel and incorrect replacement of lithium batteries could result in a HAZARD,so please contact local distributors to replace the battery if necessary.

7.15 The adapter plug can be used to disconnect from the network power supply.Don't position the device to make it difficult to operate the disconnection device.

7.16 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 or Woodpecker” and operated according to instruction manual.

7.17 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 host, resulting in damage beyond repair of the Ultrasonic Endo activating file. Please use “DTE or Woodpecker” brand work tips.

7.18 HAZARDS that can result from unauthorized modification of the device.

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 doctors 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

This product is provided non-sterile, please clean, disinfect and sterilize tip, Torque wrench and protective silicon cover before use.The cleaning, disinfection and sterilization of tip, Torque wrench and protective silicon cover 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.

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 tips is 300 times. For wrench, it is 1000 times. And for protective silicon cover, it is 300 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 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:

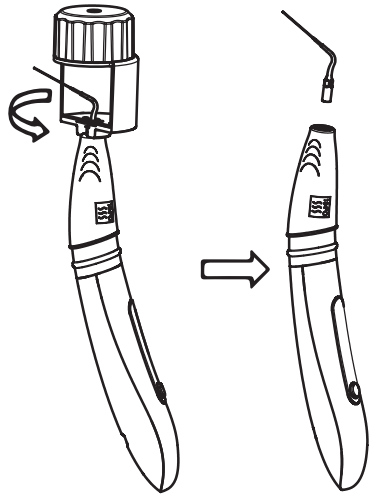
Tools: Torque wrench, tray, soft brush, clean and dry soft cloth

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

2. Remove the protective silicon cover from host and put it into the tray.

3. Remove the disposable isolation sleeve from host.

Disassembling steps



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.

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 used here must be compatible with the product and only freshly prepared solutions can be used.

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 in accordance with the cytotoxicity test.

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. Start the program.

3. 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").

The intrinsic suitability of the product for effective cleaning and disinfection using the above automated cleaning and disinfection procedures was verified by a certified facility. (Use the G 7836 CD washer disinfector, Miele & Cie. KG, Gutersloh,(thermal disinfection), and the cleaning agent neodisher MediZym (Dr. Weigert)).

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 is cold deionized water. (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) For the disinfection here, the temperature is 93 °C, the time is 5 min, and A0>3000.

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

Pharmacopoeia).

f) After cleaning and disinfection, the chemical residue should be in accordance with the cytotoxicity test.

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

h) Regularly repair and inspect the disinfector.

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.

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.

9.6.5 If necessary,please contact your local dealer for replacement or maintenance.We will make available on request circuit diagrams, component part lists,etc.that will assist local dealers to repair the device.

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 5 minutes at a temperature of 134 °C.
- 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. (Used the Systec DX-150 Middle-sized hospital moist heat sterilizer, MMM GmbH, Eurofins Munich).

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.

d) After cleaning and disinfecting the host, you must install a disposable isolation sleeve before use. (For detailed installation steps, see section 4.1)

2 Post-Op processing

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

Tools: Nap-free soft cloth, tray

1. Remove the protective silicon cover from the host, place it in a clean tray, and then remove the disposable isolation sleeve from the host.
2. Soak the nap-free soft cloth with distilled water or deionized water, and then wipe all the surfaces of the components such as the host, tip, etc. until the surface of the component is not stained.
3. Remove the tip from the host, place it in a clean tray.
4. Wet the dry soft cloth with 75% alcohol, and then wipe all surfaces of the host for 3 minutes.
5. 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 Torque wrench, protective silicon cover 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 diffluent 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 EDGEACTIVATOR Ultrasonic Endo Activator 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.
	EDGEACTIVATOR Ultrasonic Endo Activator 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 is10% ~ 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 Environment protection

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

15 Symbol instruction

	Date of manufacture		CE marked product
	BF type applied part		Class II equipment
IPX0	Ordinary equipment	IPX1	Anti-drip device
	Serial number		Used indoor only
	Manufacturer		Mode switching button
	Products comply with WEEE directive	DC 5.0V	5V Direct current
	Sterilizable up to the temperature specified		Follow instructions for use
	Keep dry		Handle with care
	Recovery		Do Not Reuse
	Medical Device		Reference number
 edgeendo.com	eIFU		Ring switch button



Caution



Made in China



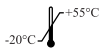
Caution: Federal law restricts this device to sale by or on the order of a licensed dental professional



Humidity limit for storage: 10% ~ 93%



Atmospheric pressure for storage: 70kPa—106kPa



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

EU REP Authorised Representative in the EUROPEAN COMMUNITY

CH REP Authorised Representative in Switzerland

16 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 EDGEACTIVATOR Ultrasonic Endo Activator 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.

16.1 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.

16.2 Guidance and manufacturer's declaration – electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions

EDGEACTIVATOR Ultrasonic Endo Activator Device is intended for being used in the electromagnetic environment specified below. The customers or users of EDGEACTIVATOR Ultrasonic Endo Activator Device should assure that it is used in such an environment.		
Emmission test	Compliance	Electromagnetic environment – guidance
RF emissions GB 4824	Group 1	EDGEACTIVATOR Ultrasonic Endo Activator Device use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic device.
Conducted emissions GB 4824	Class B	EDGEACTIVATOR Ultrasonic Endo Activator Device is suitable for being used in domestic establishment and in establishment that is directly connected to a low voltage power supply network which is for domestic power supply.
Harmonic emissions GB 17625.1	Not applicable	
Voltage fluctuations/ flicker emissions GB 17625.2	Compliance	

16.3 Guidance and manufacturer's declaration – electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
EDGEACTIVATOR Ultrasonic Endo Activator Device is intended for being used in the electromagnetic environment specified below. The customers or users of EDGEACTIVATOR Ultrasonic Endo Activator Device should assure that it is used in such environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV Contact discharge ±8kV Air discharge	±6kV contact discharge ±8kV Air discharge	Floors should be made of wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should at least reach 30%.
Electrical fast transient bursts GB/T 17626.4	±2kV For power supply lines ±1kV For Input/ Output lines	±2kV For power supply lines ±1kV For interconnecting cable	Mains power should be of the quality to be used in commercial or hospital environment.

Surge GB/T 17626.5	±1kV Line to line ±2kV Line to earth	±1kV Line to line	Mains power should be of the quality to be used in commercial or hospital environment.
Voltage dips, short interruption and voltage variations on power supply input lines. GB/T 17626.11	< 5%UT, (> 95% dip in UT) for 0.5 circle 40%UT, (60% dip in UT) for 5 circles 70%UT, (30% dip in UT) for 25 circles < 5%UT, (> 95% dip in UT) for 5s	< 5%UT, (> 95% dip in UT) for 0.5 circle 40%UT, (60% dip in UT) for 5 circles 70%UT, (30% dip in UT) for 25 circles < 5%UT, (> 95% dip in UT) for 5s	Mains power should be of the quality to be used in commercial or hospital environment. If the user of EDGEACTIVATOR Ultrasonic Endo Activator Device requires continued operation during power mains interruptions, it is recommended that the EDGEACTIVATOR Ultrasonic Endo Activator Device be powered from an uninterruptable power supply or a battery.
Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the alternative current mains voltage prior to application of the test level.			

16.4 Guidance and manufacturer's declaration – electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
EDGEACTIVATOR Ultrasonic Endo Activator Device is intended for being used in the electromagnetic environment specified below. The customers or users of EDGEACTIVATOR Ultrasonic Endo Activator Device should assure that it is used in such environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

Conducted RF GB/T 17626.6 Radiated RF GB/T 17626.3	3Vrms 150kHz~80MHz 3V/m 80MHz~2.5GHz	3Vrms 3V/m	Portable and mobile RF communications equipment should not be used closer than the recommended separation distance to any part of EDGEACTIVATOR Ultrasonic Endo Activator Device, including cables. The separation distance should be calculated from the corresponding formula of transmitter frequency. Recommended separation distance: $d=[3.5/V_1]P$ $d=[3.5/E_1]P^{1/2}$ 80 MHz to 800 MHz $d=[7/E_1]P^{1/2}$ 800 MHz to 2.7 GHz P is the maximum rated power output of the transmitter in Watts (W) provided by transmitter manufacturer. d is the recommended separation distance in meters (m). As field strength from fixed RF transmitters is determined by an electromagnetic site survey [a], therefore it should be less than the compliance level in each frequency range. Interference may occur near the device marked by the following symbols.
Note 1: At 80MHz and 800MHz frequency, adopt formula of higher frequency range. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and human body.			

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 taken into consideration. If the measured field strength in the location where Endo 3 Ultrasonic Endo Activator Device is used exceeds the applicable RF compliance level above, the EDGEACTIVATOR Ultrasonic Endo Activator Device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EDGEACTIVATOR Ultrasonic Endo Activator Device.
b) Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3V/m.

16.5 Recommended separation distance between portable and mobile RF communications equipment and the EDGEACTIVATOR Ultrasonic Endo Activator Device

Recommended separation distance between portable and mobile RF communications equipment and the EDGEACTIVATOR Ultrasonic Endo Activator Device			
EDGEACTIVATOR Ultrasonic Endo Activator Device is intended for being used in electromagnetic environment where radiated RF disturbances is controlled. As per the maximum power output of communication device, the customer or user of EDGEACTIVATOR Ultrasonic Endo Activator Device can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication device (transmitter) and EDGEACTIVATOR Ultrasonic Endo Activator Device recommended below.			
Maximum rated power output of transmitter/ W	Separation distance according to frequency of transmitter /m		
	150kHz to 80MHz $d=[3.5/V_1]P^{1/2}$	80MHz to 800MHz $d=[3.5/E_1]P^{1/2}$	800MHz to 2,5GHz $d=[7/E_1]P^{1/2}$
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) according to the transmitter manufacturer.

Note 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all solutions. Electromagnetic propagation is affected by absorption and reflection from buildings, objects, and human body.

EDGEACTIVATOR Ultrasonic Endo Activator 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.

EDGEENDO®

Made in China

MD

Guilin Woodpecker Medical Instrument Co.,Ltd.
Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi, 541004 P. R. China
Sales Dept.: +86-0773-5873196/2350599
After-sales Service Dept.: +86-0773-5827898
E-mail: woodpecker4@glwoodpecker.com
Website: http://www.glwoodpecker.com
EU REP MedNet EC-REP C IIb GmbH
Borkstrasse 10, 48163 Muenster, Germany
CH REP MedNet SWISS GmbH
D4 Platz 4,6039 Root D4, Switzerland