



# Endodontic Obturation Devices

## User Manual



Read this Operation carefully before use.

Keep this User Manual for future reference.

Thank you very much for choosing the Endodontic Obturation Devices of  
FANTA DENTAL

- To give full play to the function of this device, and operate and maintain it correctly and safely, please read this User Manual carefully before using it, and keep this User Manual properly for reference at any time

**Classification of device safety level:**

- Classification of electric shock protection type: Class II, Internal electrical power source device
- Classification of electric shock protection level: Type B applied part
- Classification of liquid entry prevention level: IPX0(Device), IPX6(Wireless Pedal)
- Sterilization or disinfection method: refer to sterilization part in the manual
- Classified by the safety level in the case of using the product with flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide: not to be used in the case of using the product with flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide
- Classification by mode of operation: Continuous operation
- Software release version: 1.0



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# **1. Product Introduction**

## **1.1 Brief Introduction**

Endodontic Obturation Devices (hereinafter referred to as “eHeater” or “device” ) is used to soften and cut off the gutta percha point by heating. It is used to assist dentists with root canal treatment.

The features of this device are as follows:

- a) This device adopts PWM control mode to achieve constant temperature heating;
- b) Monitoring of the state of Heating needle;
- c) The Heating needle can be carried out high temperature and high pressure moist heat sterilization;
- d) This device can be illuminated to make it clearer;
- e) Bluetooth foot control.

## **1.2 Model**

Model: eHeater

## **1.3 Intended use, user, patient**

1.3.1 Intended use: It is used to soften and/or cut off the gutta percha point outside the mouth for root canal filling.

1.3.2 Intended user: Dentist.

1.3.3 Intended patient: People who need root canal shaping and cleaning, and root canal shape is good.

1.3.4 Use place: Hospital or dental clinic.

## **1.4 Contraindications**

None

## **1.5 Precaution and warning**

Please read the following warnings before use:

- It is contraindicated by hemophiliacs, patients with cardiac pacemaker or cochlear implant and doctors;
- It should be used with caution on patients with heart disease, pregnant women and young children;
- Do not perform any dental operations other than root canal filling;
- Do not use this device in the presence of free oxygen, flammable anesthetic mixtures or flammable substances;
- This device shall not be placed in a humid environment or any place where

it may come into contact with any type of liquid;

- Patients are at risk of thermal hazards;
- Do not expose this device to direct or indirect heat source. This device must be operated and stored in a safe environment;
- With regard to electromagnetic compatibility (EMC), this device requires special precautions and must be installed and operated in strict accordance with EMC information. In particular, this device should not be used near fluorescent amplifiers, radio transmitter remote controls, portable or movable communication devices, nor should it be charged, operated or stored at high temperatures. This device shall comply with the specified operating and storage conditions;
- Please use disposable gloves and rubber dam during treatment;
- If the device is abnormal during the treatment, please turn it off and then contact the local distributor or manufacturer.;
- Please do not disassemble and repair this device without permission, otherwise it may automatically lose the warranty qualification;
- Please be sure to use the original accessories, such as Heating needle and Power adapter;
- When the operator is in use (including charging), do not place it in a location where it is difficult to disconnect the power, when it is dangerous.

## **1.6 Performance characteristics**

### 1.6.1 Appearance and structure:

The appearance of the Endodontic Obturation Devices should be easy to clean, the shell should have no edges, burrs and cracks, and the plastic parts should have no foaming, cracking and deformation; The panel of the Endodontic Obturation Devices shall be free of coating shedding or rust, and the text and marks on the panel shall be clearly visible.

### 1.6.2 Temperature setting:

When the equipment is in non-heating state, press the adjust button to adjust the preset temperature. The adjustable temperature includes 110°C, 140°C, 170°C, 200°C and 230°C recycling;

## **1.7 Clinical benefit**

The performance of Endodontic Obturation Devices has been fully identified and evaluated, the product can meet the clinical intended use, and

the related risks have been fully evaluated, and the residual risks are acceptable.

## **1.8 Contact information**

Website: [www.fanta-dental.com](http://www.fanta-dental.com)

After launch of European Database on Medical Devices/EUDAMED, the summary of safety and clinical performance will be made available to the public at <https://ec.europa.eu/tools/eudamed>.

Basic UDI-DI: 697107537eHeaterWR

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website:

[https://ec.europa.eu/growth/sectors/medical-devices/contacts\\_en](https://ec.europa.eu/growth/sectors/medical-devices/contacts_en)

- a) name of manufacturer or distributor;
- b) type of instruments, product identification;
- c) product size;

Complete Contraindications, Warnings and Precautions will be available and kept up to date on the IFU.

For additional information, contact your Fanta Dental Sales Representative or Shanghai Fanta Dental Materials Co., LTD. Customer Service. No electronic version of the IFU provided.

## **2. Product Configuration**

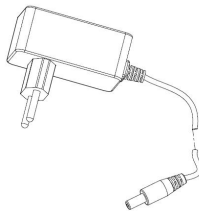
### **2.1 External Structure of Main Frame**



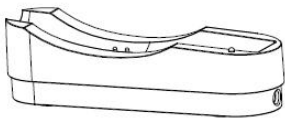
## 2.2 Main Accessories of Product



Heating needle



Power adapter



Charging base



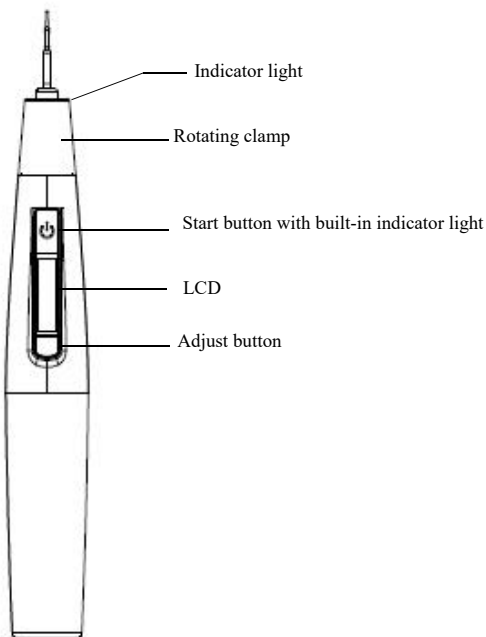
Wireless pedal (optional)

## 2.3 Accessories List

Components	Type	No.
Main Frame	eHeater	1
Heating needle	BMHN0001 (40/04)	1
	BMHN0002 (45/04)	1
	BMHN0003 (50/04)	1
	BMHN0004 (55/08)	1
Power adaptor	UES12LCP-050200SPA	1
Charging base	BMCB0003	1
Wireless pedal (optional)	iPedal	1

If the user wants to purchase an additional accessory, he or she needs to contact the local designated dealer or manufacturer, and can't change the accessory at will, otherwise the risk is not acceptable. Please see the packing list for the device configuration.

### 3. User Interface



#### 3.1 Buttons

##### Start button:

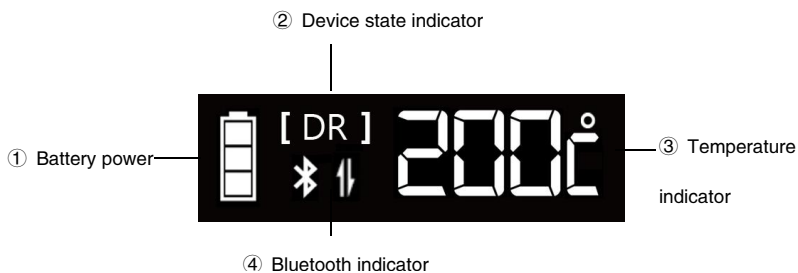
- Start up: press and hold the start button for more than 1s, accompanied by a prompt tone, the device starts up and enters the standby state;
- Operate: press the start button to heat, and release the start button to stop heating;
- Indicator light:
  - 【 DR 】 In standby state, the indicator light is always on in blue;
  - 【 HT 】 In heating state, the indicator light is always on in red;
  - 【 CD 】 In cooling state, the indicator light flashes in blue;

- 【 E0 】 / 【 E1 】 In error state, the indicator light flashes in red.


#### Adjust button:


- Adjust the temperature: press the adjust button to adjust the temperature, including 110°C, 140°C, 170°C, 200°C and 230°C;
- Turn on and off the bluetooth: press and hold the adjust button for more than 1s to turn on the bluetooth; press and hold the adjust button for more than 1s to turn off the bluetooth.


### 3.2 LCD




#### ① Battery power display:

: 60–100% battery power;

: 40–60% battery power ;

: 10–40% battery power;

: 0–10% battery power.

The battery runs down. Please charge the device right away.

#### ② Device state indicator:

[ DR ] —— standby state: the device is ready to enter the standby mode;

[ HT ] —— heating state: the device is heated;

[ CD ] —— cooling state: the device is cooled;

[ E0 ] / [ E1 ] —— Error state: see Section 6 Troubleshooting for details.

### ③ Temperature indicator:

Display the preset temperature, including 110 °C, 140 °C, 170 °C, 200 °C and 230 °C;

### ④ Bluetooth indicator:



: Bluetooth is open normally and can be connected;

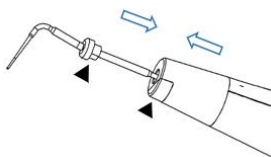


: Bluetooth has been connected.

## 4. Product Installation

### 4.1 Installation of Heating needle

Align the Heating needle holder to the slot of the Main Frame, where the Heating needle notch is aligned with the position of the illuminating light of the Main Frame (triangulated position as shown below), and push it to the appropriate position.



**The angle of the Heating needle is adjustable:** rotate the position of the silver clamp of the Main Frame to adjust its angle, and the rotation can be about 270° .



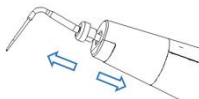
#### Warning:

- When installing the Heating needle, please ensure that the Main Frame is powered off;
- When the Heating needle is installed on the Main Frame, it will not become loose or fall off to ensure that the Heating needle is firmly installed;

- Before inserting the Heating needle, check the assembly interface between the Heating needle and the Main Frame. Please do not use the damaged Heating needle or device;
- If the Heating needle is not firmly installed, it may lead to unpredictable rotation or the Heating needle may fall off, and even hurt the patient;
- Please use the original Heating needle;
- The Heating needle has not been disinfected and sterilized when they leave the factory. Please clean, disinfect and sterilize the Heating needle before each treatment.

#### 4.2 Removal of Heating needle

When the Heating needle cools, pull it out in the opposite direction, as shown in the figure below.



#### Note:

- The number of Heating needles used does not exceed 20 operations.



#### Warning:

- When installing or removing the Heating needle, please be careful not to injure your finger;
- When installing or removing the Heating needle, please make sure the Main Frame stops working;
- To remove the Heating needle, please wait for it to cool for about 8s;

### 5. Product Use

#### 5.1 Operation

**Start the device:** press the switch button of the device for more than 1 second, the device starts up and enters the standby state, and the indicator light is always on in blue.

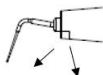
**Close the device:** in standby state, the device will automatically shut down after 1 minutes without any operation. When the Main Frame is placed on the Charging base, it will shut down automatically.

**Heating needle starts heating:** after the device enters the standby state, press and hold the start button to start heating the needle; the Heating needle is

continuously heated for 10s. After 10s, the device automatically stops heating and enters the cooling mode.

In heating state:

- The indicator light is always on in red, and the device state is [HT], display real-time temperature, accompanied by a beep tone;
- The illuminating light is on during the heating process, as shown in the figure below;



Caution:

- If the error code E1 appears in the process of use, it indicates that the Heating needle is not installed or the Heating needle has been damaged;
- Only the end of the Heating needle (about 4–5mm) will be heated. The area as shown in the figure below is used to cut off the gutta percha;



**Heating needle starts cooling:** release the start button to cool the Heating needle;

In cooling state:

- The indicator light flashes in blue, display real-time temperature, and the cooling time is 8s;
- The device is in the state of [CD], and waits for the Heating needle to cool;
- After cooling, the device is in the state of [DR] and enters standby mode. The indicator light is always on in blue;

**Adjust the preset temperature:** When the equipment is in non heating state, press the adjust button to adjust the preset temperature. The adjustable temperature includes 110°C, 140°C, 170°C, 200°C and 230°C recycling;.



Caution:

- When the equipment is in [HT] standby mode, the temperature cannot be adjusted;

## 5.2 Charging

- Insert the USB cable into the Charging base (Figure a);
- When the Power adapter is inserted into the mains socket, the power indicator light of the Charging base is always in green;
- When the Main Frame is placed on the Charging base, it enters the charging state and automatically shuts down, and the power indicator light on the Charging base turns to be always on in blue; When the charging is full the power indicator light on the Charging base turns to be always on in green

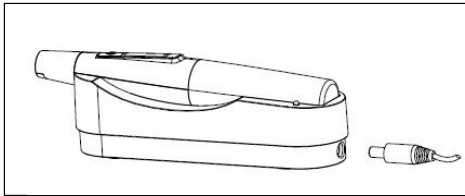


Figure a



Caution:

- When the error code E0 appears during the use, accompanied by a prompt tone, it indicates that the battery power is low and the device should be charged;
- When the Main Frame is inserted into the Charging base, but it does not enter the charging state, please stop charging it immediately and then contact the local distributor;
- When charging with the Charging base, please place the Charging base or the Main Frame in a dry and safe place where they are not easily knocked over;
- The Power adapter should meet the requirements of the IEC 60601-1 standard. Please use the Power adapter and cable provided by the manufacturer for charging;




- It normally takes about 180 minutes for the device to be fully charged, but that also depends on the battery loss and remaining battery power;
- After the battery is discharged completely, the battery may not be recharged, thus causing it to be damaged. When the device is not used for a long time, it should be fully charged every one to two months;
- Do not place the Charging base or Main Frame in dust, or especially in the environment with metal debris. Please pay special attention to the protection of charging port.

### 5.3 Wireless Connection Control

We always design the product from the perspective of the doctor's use to make its operation easier. eHeater is a safe, accurate, compact and convenient product. In order to provide doctors with more convenient operation experience, we also provide an optional wireless control solution. You can choose our Wireless pedal to achieve this function.

eHeater can be connected wirelessly with our Wireless pedal through bluetooth. After successful connection, the operation of eHeater can be controlled within 5 meters.

Bluetooth connection setting of eHeater:

- Step on any button of the foot switch to open the power supply of the Wireless Pedal;
- Turn on the power of eHeater, press and hold the adjust  button to turn on the bluetooth, and the bluetooth indicator  appears; eHeater will automatically search, pair and connect to the Wireless Pedal.
- After the connection is successful, the bluetooth indicator  appears. After pressing and holding any button of the foot switch, eHeater starts to run for heating; release the button to stop its operation;



#### Caution:

- Only when the Wireless pedal is in standby state, the bluetooth can be turned on by pressing the bluetooth button of eHeater;
- When multiple devices are searching and pairing at the same time, the target device may not be connected, so please pair it with one to one separately;

- In order to avoid the unrecognized risks to patients, operators or third parties, the equipment can not be connected to other IT networks (including other equipment);
- When turning on the bluetooth function, please stay away from other bluetooth, WiFi and other 2.4G wireless products;
- After successful bluetooth connection, the device information of the Wireless pedal will be automatically saved in the internal storage space of eHeater. This function is turned off by default.

## 6. Troubleshooting

When a trouble is found, check the following points before contacting your dealer, if none of these apply, Or if the trouble is not resolved even after taking action, the product may fail, contact your distributor business.

<b>Fault phenomenon</b>	<b>Check items</b>	<b>Fault analysis and handling method</b>	<b>Reference chapter or section</b>
The error code E0 appears	The battery power is low.	Charge it in time.	5.2
The error code E1 appears	The Heating needle is damaged	Replace the Heating needle with a new one	4.1
	The Heating needle is not installed The Heating needle is not installed firmly	Refer to Section 4.1 Installation of Heating needle	4.1
Fail to start up	The time to press the switch button is too short	Press and hold the switch button	5.1
The battery power indicator light on the Charging base is not on	The wrong Power adapter is used.	Please use the original Power adapter	5.2
	The Power adapter or USB cable is not connected	Check the connection	5.2
	The plug of the Power adapter is not plugged into the socket or the socket is not powered	Check the connection	5.2

## 7. Cleaning, Disinfection and Sterilization



### Caution:

- No part of eHeater is sterilized before leaving the factory



### Warning:

- Do not immerse the Main Frame in the ultrasonic cleaner.
- Do not use liquid or spray cleaner directly, especially on the screen.
- Except the Heating needle, all other parts for the device can't be sterilized by high temperature and pressure. See the following table for the cleaning methods of other parts
- Do not use any heat, radiation, formaldehyde, ethylene oxide or plasma for sterilization.



### Advice:

- Reprocessing procedures have only limited implications to this dental instruments. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. From the processing side there is no maximum number of allowable reprocessing. The device should no longer be reused in case of signs of material degradation.
- In case of damage the device should be reprocessed before sending back to the manufacturer for repair.

### Reprocessing Instructions

Step	Parameter
Preparation at the Point of Use:	Remove gross soiling of the instrument with cold water (<40 °C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residuals which may influence the result of the reprocessing process. Store the instruments in a humid surrounding, if required.
Transportation:	Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.
Preparation for	The devices must be reprocessed in a disassembled state, as far as possible.

Decontamination:	<p>Only Heating needle can be cleaned and disinfected with automated methods and sterilized with steam sterilization process.</p> <p>Do not sterilize the Main Frame, Power adapter, Charging base and Wireless Pedal!</p> <p>The Main Frame, Power adapter, Charging base and Wireless pedal cannot be cleaned and disinfected in a washer/disinfector! For these parts, only a general wipe decontamination is possible!</p>
Decontamination of other parts than Heating needle:	<p>After operation, take the Main Frame, Power adapter, Charging base and Wireless pedal on the workbench.</p> <p>Soak a soft cloth completely with distilled water or deionized water, and wipe all the surfaces of these components, until the surface of the components is visually clean.</p> <p>For decontamination, soak a dry soft cloth with 75% alcohol or other disinfects which are approved for its efficacy by VAH/DGHM-listing, CE marking, FDA and Health Canada Approval.</p> <p>Wipe all surfaces of the Main Frame, Power adapter, Charging base and other components with the wet soft cloth for about 3 minutes.</p> <p>Please follow the instructions of manufacturer of disinfectants.</p> <p>Wipe the surface of the component with a dry soft lint-free cloth.</p>
Following instructions are only relevant for Heating needle!	
Pre-Cleaning of Heating needle:	<p>Not use automated cleaning, disinfection and sterilization for other parts than Heating needle in this system!</p> <p>Do a manual pre-cleaning, until the instruments are visually clean.</p> <p>Submerge the instruments in a cleaning solution and flush the lumen with a water jet pistol with cold tap water for at least 10 seconds.</p> <p>Clean the surfaces with a soft bristle brush.</p>
Cleaning:	<p>Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety.</p> <p>Automated Cleaning:</p> <p>Use a washer-disinfector meeting the requirements of the ISO 15883 series.</p> <p>Put the instrument into the machine on a tray. Connect the instrument with the WD by using suitable adapter and start the program:</p> <ul style="list-style-type: none"> <li>● 4 min pre-washing with cold water (&lt;40°C);</li> <li>● emptying</li> <li>● 5 min washing with a mild alkaline cleaner at 55°C</li> <li>● emptying</li> <li>● 3 min neutralising with warm water (&gt;40°C);</li> <li>● emptying</li> <li>● 5 min intermediate rinsing with warm water (&gt;40°C)</li> <li>● Emptying</li> </ul> <p>The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).</p>

	Note Acc. to EN ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use.
Disinfection:	Automated thermal disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN 15883). A disinfection cycle of 5 min disinfection at 90°C has been validated for the device to achieve an A0 value of > 3000. Here we suggest a disinfection cycle of 5 min disinfection time at 93 °C.
Drying:	Automated Drying: Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.
Functional Testing, Maintenance:	Visual inspection for cleanliness of the instruments and reassembling, if required. Functional testing according to instructions of use. If necessary, perform reprocessing process again until instrument is visibly clean. Before packaging and autoclaving, make sure that these devices have been maintained acc. to manufacturer' s instruction.
Packaging:	Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.
Sterilization:	Sterilization of instruments by applying a fractionated pre–vacuum steam sterilization process (according to EN 285/EN 13060/EN ISO 17665) under consideration of the respective country requirements. Minimum requirements: 3 min at 134°C (in EU: 5 min at 134°C) Maximum sterilization temperature: 137°C Drying time: For steam sterilization, we recommend a drying time of 15 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave' s instructions for use. After sterilization: a. Remove the product from the autoclave. b. Let the product cool down at room temperature for at least 30 minutes. Do not use additional cooling. Check that the sterilization wraps or pouches are not damaged. Flash sterilization is not allowed on lumen instruments!
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures, refer to label and instructions for use.
It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.	

## **8. Storage, Maintenance and Transportation**

### **8.1 Storage**

- a. This product should be handled with care, kept away from earthquake source, and stored in a dry and ventilated place.
- b. This product should not be placed together with toxic, corrosive, flammable and explosive items.
- c. The relative humidity of the storage environment should be 10%~80%, the atmospheric pressure should be 500~1060hPa, and the temperature should be -10℃~ +50℃.

### **8.2 Maintenance**

- a. This product does not contain self-repair spare and accessory parts. Repair of this product should only be carried out by specialized maintenance personnel or special repair shops.
- b. Please keep this product dry. Rainwater, moisture and liquids may contain minerals that can corrode the electronic circuit of this product.
- c. Do not throw, knock or vibrate this product. Rough handling of this product may damage its internal circuit board and wires.
- d. Do not apply paint to this product, as it will leave debris in the removable parts, thus affecting its normal operation.

#### **➤ Change battery**

The device uses a rechargeable lithium battery. The battery life or number of recharges depends on the usage.

Lithium batteries have no memory effect, so you don't need to care too much about the timing of charging;

The factors that have great influence on battery life include:

a) Long-term storage may cause damage to the battery. It is recommended that the battery should be fully charged once within one month of storage when it is fully charged;

b) Don't charge at the ambient temperature exceeding the requirement. It is recommended that the ambient temperature is less than 40 degrees.

### Battery replacement procedure

1 Remove the battery compartment

As shown on the right, unscrew the battery compartment counterclockwise;

2 Remove the old battery

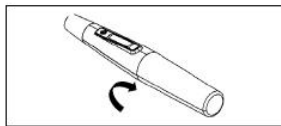
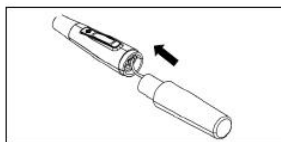
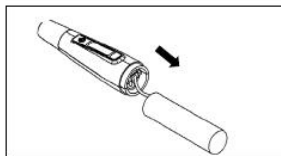
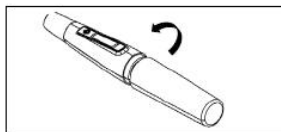
Hold the battery cable (connecting the battery connector part) with your hand, and pull out the battery connector from the motherboard socket;

3 Replace with new battery

Insert the new battery into the battery compartment, and insert the battery connector into the mother board socket, as shown in the right figure.

4 Install the battery compartment

According to the picture on the right, arrange the battery cable and tighten the battery compartment clockwise.



**WARNING:**

- Do not open any parts except the battery compartment on the host;
- Please use the battery provided by the manufacturer, do not use batteries of other specifications to avoid damage;
- Battery specification: 18650 cylindrical lithium battery, rated voltage 3.6V;
- If the battery is leaking or swollen, stop using it immediately;
- Do not use any damp cloth, alcohol, or other chemical reagents to wipe the surface of the battery;
- When replacing the battery, please keep your hands dry and free of water droplets; liquids can cause a short circuit of the battery, damage the device, and even cause the battery to catch fire, etc.;
- If battery liquid enters the eye area, immediately rinse with water and go to the hospital for treatment.
















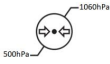





### 8.3 Transportation

- a. During the transportation, excessive impact and vibration should be prevented. Handle it with care. Placing it upside down should be avoided.
- b. This product should not be transported together with dangerous goods.
- c. This product should not be exposed to the sun, rain or snow during transportation.

### 9. Technical Parameters

Manufacturer	Changzhou Bomedent Medical Technology Co., Ltd.
Product name	Endodontic Obturation Devices
Model	eHeater
Dimensions	Main Frame: 170*26*26mm Charging base: 153*45*43mm
Packing weight	720g
Power supply mode	Lithium battery, DC 3.6V, 2600mAh
Charging base	Input: DC5V/2A Output: DC 3.6V, 2600mAh
Power adapter	Input: AC100–240V, 50/60Hz 0.5A Output: DC5V/2A
Liquid permeation protection	IPX0(Device) IPX6(Wireless Pedal)
Classification of electric shock protection type	Class II, Internal electrical power source device
Classification of electric shock protection level	Type B applied part
Heating temperature	110℃, 140℃, 170℃, 200, 230℃
Effective connection range of bluetooth	≤5m
Use environment	Temperature: 10–40℃ Humidity: 10–70% Atmospheric pressure: 700–1060hPa
Storage/transportation environment:	Temperature: –10–50℃ Humidity: 10–80% Atmospheric pressure: 500–1060hPa
Expected service life	4 years

## 10. Symbol instruction

	General warning sign		Refer to the Operation Manual
	Type B applied part		Class II equipment
	Direct current		Serial number
	Manufacturer		Date of manufacture
	For indoor use only		This way up
	Keep dry		Fragile, handle with care
	Washer-disinfector for thermal disinfection		Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Temperature limitation		Humidity limitation
	Atmospheric pressure limitation		Follow the waste of electric and electronic equipment (WEEE) Directive
	This conforms to CE European Directive of "Medical equipment directive 93/42/EEC" .		Authorized representative in the European Community
	Unique Device Identifier		Medical device

## 11. Environmental Protection

This product does not contain harmful ingredients and can be disposed and destroyed according to the relevant local regulations.

## 12. After-sales Service

The manufacturer provides quality assurance to the purchaser of the product due to quality problems caused by the product's own materials and workmanship during normal installation and use. The host and reducer are guaranteed for 1 year free of charge, and consumables such as batteries and accessories are not covered by the warranty. If the battery and accessories are damaged, please use the battery and accessories provided by the manufacturer. The maintenance of the components needs to be repaired by professional personnel. Please refer to "Warranty Card" for the warranty period and manufacturer details.

If the maintenance personnel need to use the circuit diagram, our company will provide it.

## 13. EMC Statement

Guidance and Manufacturer' s Declaration

Below cables information are provided for EMC reference.

Cable	Max. cable length, Shielded/unshielded		Number	Cable classification
DC Power Line (USB Cable)	1.5m	Unshielded	1 Set	DC Power

### Important information regarding Electro Magnetic Compatibility (EMC)

This electrical medical equipment needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; the equipment conforms to this IEC 60601-1-2:2014 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

The equipment with no ESSENTIAL PERFORMANCE is intended used in Professional healthcare facility environment except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally” .

The use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

**WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.”

**WARNING:** If the use location is near (e.g. less than 1.5 km from) AM, FM or TV broadcast antennas, before using this equipment, it should be observed to verify that it is operating normally to assure that the equipment remains safe with regard to electromagnetic disturbances throughout the expected service life.

## **EMI Compliance Table (Table 1)**

**Table 1 – Emission**

<b>Phenomenon</b>	<b>Compliance</b>	<b>Electromagnetic environment</b>
RF emissions	CISPR 11 Group 1, Class B	Professional healthcare facility environment
Harmonic distortion	IEC 61000–3–2 Class A	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 61000–3–3 Compliance	Professional healthcare facility environment

## EMS Compliance Table (Table 2–5)

### Table 2 – Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000–4–2	± 8 kV contact ± 2kV, ± 4kV, ± 8kV, ± 15kV air
Radiated RF EM field	IEC 61000–4–3	3V/m 80MHz–2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000–4–3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000–4–8	30A/m 50Hz or 60Hz

### Table 3 – Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380–390	Pulse modulation 18Hz, 27V/m
450	430–470	FM, ± 5kHz deviation, 1kHz sine, 28V/m
710	704–787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800–960	Pulse modulation 18Hz, 28V/m
870		
930		
1720		
1845	1700–1990	Pulse modulation 217Hz, 28V/m
1970		
2450	2400–2570	Pulse modulation 217Hz, 28V/m
5240	5100–5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

**Table 4 – Input a.c. power Port**

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	$\pm 2$ kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	$\pm 0.5$ kV, $\pm 1$ kV
Surges Line-to-ground	IEC 61000-4-5	$\pm 0.5$ kV, $\pm 1$ kV, $\pm 2$ kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz
Voltage dips	IEC 61000-4-11	0% $U_i$ ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% $U_i$ ; 1 cycle and 70% $U_i$ ; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0% $U_i$ ; 250/300 cycles

**Table 5 – Signal input/output parts Port**

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz





# Warranty Card

**Dear user:**

**For the warranty:**

1. We offer 1 year warranty for the product eHeater (excluding the accessories).
2. The following circumstance does not belong to the scope of free warranty:
  - a) Using the product did not follow the matters needing attentions in user's manual;
  - b) Disassembling the product by yourself;
  - c) Altering the invoice or without the invoice.
3. Fill up the following information, then send it back to us with our products.

User' s Name: \_\_\_\_\_

Telephone Number: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Trouble Description:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

(The information such as: When, Where and How it happened. How many times)

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