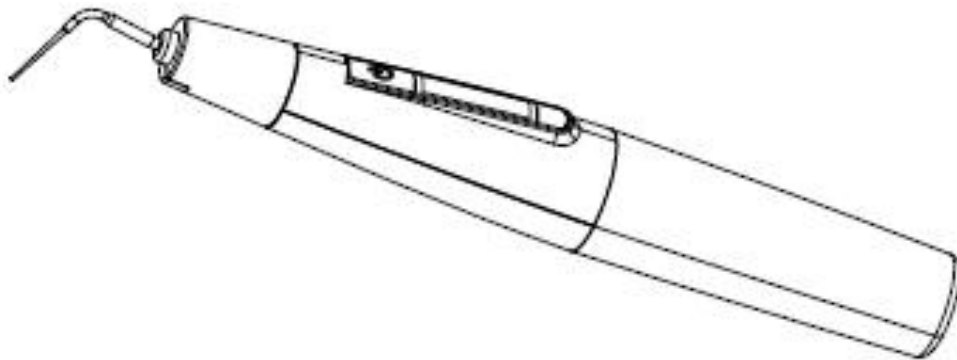


# Obturation System Down Pack

## User Manual



Changzhou Bomedent Medical Technology Co., Ltd.

Thank you very much for choosing the Obturation System Down Pack of Bomedent

- 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
- Classification of electric shock protection level: Class B
- Classification of liquid entry prevention level: IPX0
- Sterilization or disinfection method: please refer to the cleaning and disinfection section
- 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
- Operation mode: intermittent load continuous operation

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# **1. Product Introduction**

## **1.1 Brief Introduction**

Obturation System Down Pack (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 Scope of Application**

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

User: dentist.

Use place: hospital or dental clinic.

## **1.4 Contraindications**

- a) It is contraindicated by hemophiliacs, patients with cardiac pacemaker or cochlear implant and doctors;
- b) It should be used with caution on patients with heart disease, pregnant women and young children.

## **1.5 Precautions for Use**

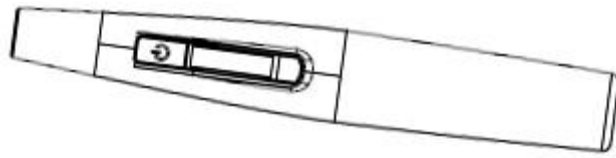
Please read the following warnings before use:

- 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;

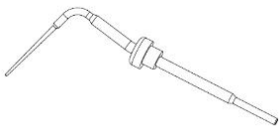
- This device shall not be placed in a humid environment or any place where it may come into contact with any type of liquid;
- Patients are at risk of thermal hazards;
- Do not expose this device to direct or indirect heat source. This device must be operated and stored in a safe environment;
- With 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 institution;
- 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.
- Please take attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
  - (1) This device may not cause harmful interference, and
  - (2) This device must accept any interference received, including interference that may cause undesired operation.

## 2. Product Configuration

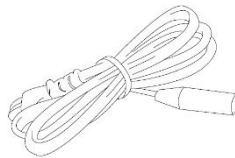
### 2.1 External Structure of Main Frame



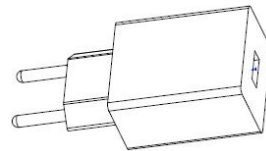
### 2.2 Main Accessories



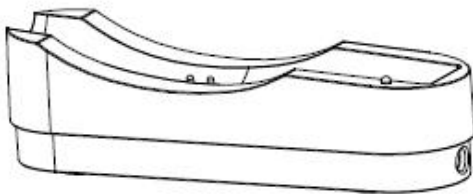
Heating needle



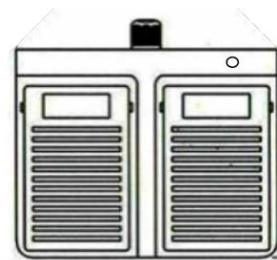
Power adapter



Power cord



Charging base

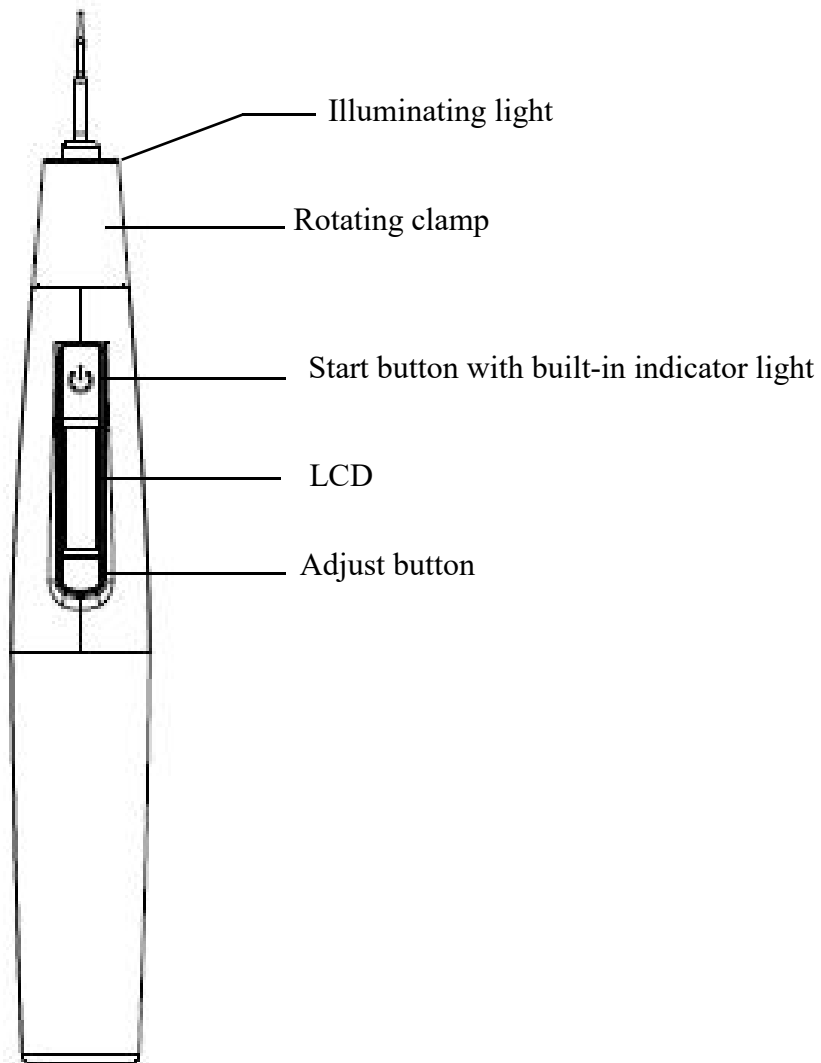


Wireless foot switch (optional)

### 2.3 Accessories List

Please see the packing list for the device configuration.

### 3. User Interface



#### 3.1 Buttons

##### Start button:

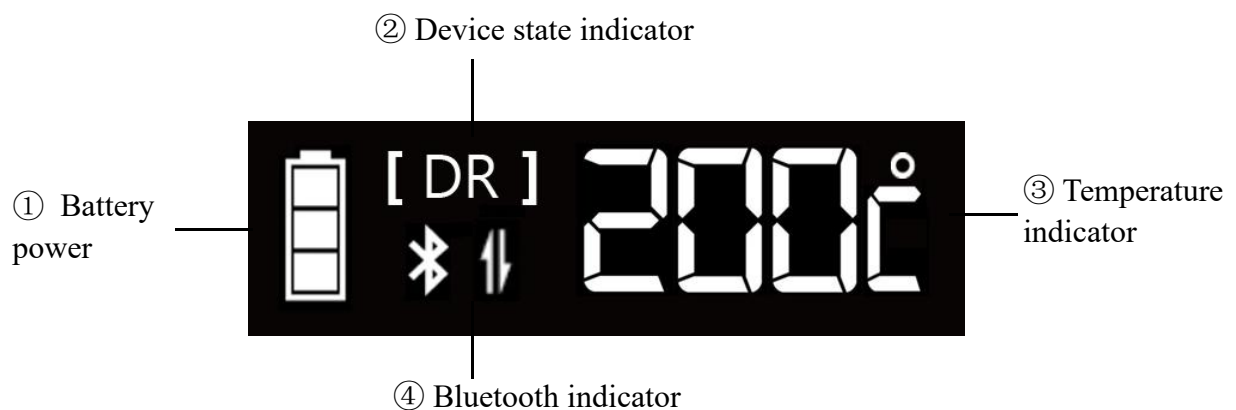
- Start up: press and hold the start button for more than 1s, accompanied by a prompt tone, the device starts up and enters the standby state;
- Operate: press the start button to heat, and release the start button to stop heating;
- Indicator light:
  - **【DR】** In standby state, the indicator light 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;

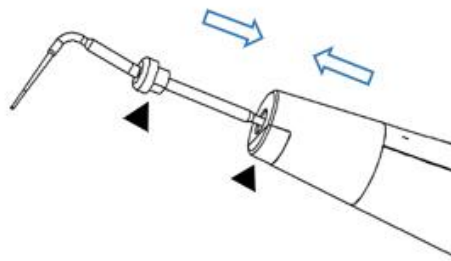


: Bluetooth has been connected.

## 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°.



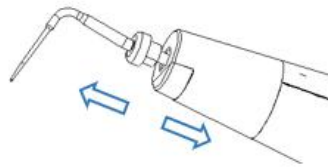
#### **Warning:**

- 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.



#### **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

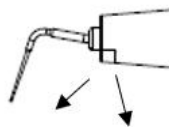
**Start the device:** press the switch button of the device for more than 1 second, the device starts up and enters the standby state, and the indicator light is always on in blue.

**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 5s. After 5s, the device automatically stops heating and enters the cooling mode.

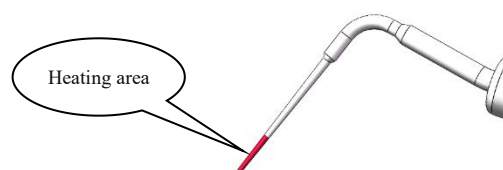
In heating state:

- 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 power adapter (Figure a);
- Insert the USB cable into the charging base (Figure b);
- When the power adapter is inserted into the mains socket, the power indicator light of the charging base is always on 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;

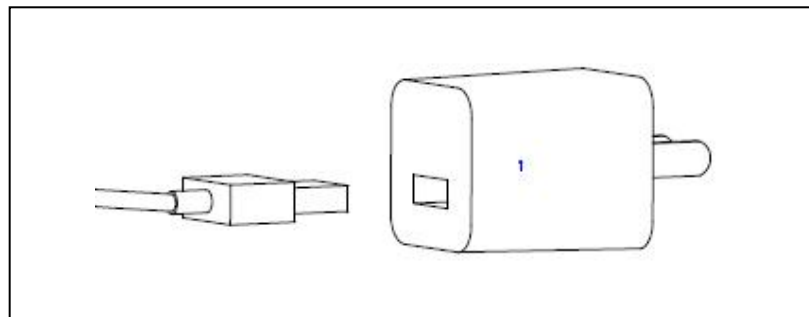


Figure a

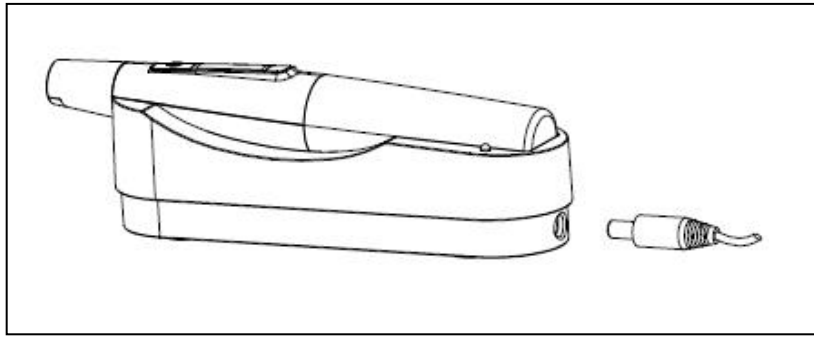


Figure b



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;
- 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 Foot 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 foot switch to achieve this function.

eHeater can be connected wirelessly with our wireless foot switch 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 foot switch;
- 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 foot switch.
- 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 foot switch is in standby state, the bluetooth can be turned on by pressing the bluetooth button of eHeater;
- This device is only for one-to-one connection through bluetooth, that is, one module can only be connected with one product;
- 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;
- 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 foot switch will be automatically saved in the internal storage space of eHeater. This function is turned off by default.

## 6. Troubleshooting

When a fault is found, please check the following points before contacting your distributor, and if none of these apply or if the fault is not resolved even after taking action, there may be something wrong with this product. Please contact your distributor.

<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:

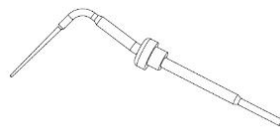
- No part of eHeater is sterilized before leaving the factory



### Warning:

- Please do not soak the main frame in the ultrasonic cleaning machine;
- It is recommended to use a soft cloth soaked in alcohol to wipe and disinfect the surface of the main frame of eHeater;
- Please do not use liquid or spray cleaner directly on the main frame, especially on the display screen;
- Please do not disinfect the main frame by heating;

➤ Part of eHeater that can be sterilized:



Heating needle

The heating needle has biocompatibility (in line with standard EN ISO 10993-1). The heating needle must be sterilized before they are used for each patient. High temperature and high pressure steam sterilization method is recommended. The recommended high temperature and high pressure steam sterilization parameters are as follows:

a) Perform steam sterilization at 134°C for 5 minutes (placed in a sterilization bag). The sterilization temperature should not exceed 135°C. The steam sterilizer shall be used in accordance with Standard EN 13060.

b) The heating needle can be repeatedly sterilized.



### Warning:

- Except for the above mentioned heating needle, no other parts of the eHeater can be sterilized;
- Do not sterilize by heating, radiation, formaldehyde, ethylene oxide and



plasma.

## 7.1 Cleaning and Sterilization of Heating Needle

### 1) Cleaning

Steps	Parameters
1. Wash	Wash the heating needle with running water for 2 minutes to remove its surface contaminants.
2. Wipe	Wet the soft clean cloth in the cleaner, and then use it to wipe the surface of the heating needle thoroughly 5 times. Replace it with a new one after each wipe. If there are still visible contaminants, wipe repeatedly until no contaminants are visible to naked eyes.
3. Scrub	Scrub the heating needle thoroughly for 3 minutes with an instrument brush with cleaner.
4. Soak	Soak the heating needle in the cleaner for 5 minutes.
5. Rinse	Rinse the heating needle with purified water for 2 minutes to remove residual cleaner on its surface.
6. Dry	Use a dry, absorbent and soft cloth to wipe the residual water on the surface of the heating needle.

### 2) Sterilization

Steps	Parameters
Sterilize	Put the cleaned heating needle into the disposable sterilization bag. The sterilization temperature should be 134°C. The sterilization time should be 5 minutes. The pressure should be 205.8kPa.

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

### **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°C~ +50°C.

### **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.













### **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	Obturation System Down Pack
Model	eHeater
Dimensions	Main frame: 170*26*26mm Charging base: 153*45*43mm
Weight	650g
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 0.3A max Output: DC5V/2A
Liquid permeation protection	IPX0
Classification of electric shock protection type	Class II
Classification of electric shock protection level	Class B
Heating temperature	110℃,140℃,170℃, 200℃ ,230℃;
Effective connection range of bluetooth	≤5m
Use environment	Temperature: 10-40℃ Humidity: 10-70% (no condensation) Atmospheric pressure: 700-1060hPa
Storage/transportation environment:	Temperature: -10-50℃ Humidity: 10-80% (no condensation) Atmospheric pressure: 500-1060hPa
Expected service life	4 years

## 10. Symbol Description

	Refer to the user manual		Warning: please read this manual before use
	Type B application device		Class II device
	The product complies with the directive on WEEE. This device must be disposed of as municipal solid waste when abandoned		Serial number
	Manufacturer		Date of manufacture
	For indoor use		Upward
	Damp-proof		Fragile. Please handle it with care

## 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

Since the date of sale, if this device cannot work normally due to quality problems, it can be repaired by our company or the designated agent by showing your warranty card. Please refer to the warranty card for warranty period and scope.

### 13. EMC Statement

Special precautions regarding electromagnetic compatibility (EMC) should be taken for this Obturation System Down Pack, and it must be installed and used in accordance with the EMC information specified in this manual.


Portable and movable RF communication equipment may affect this device.

With the exception of cables (transducers) sold as spare parts for internal components, the use of accessories and cables (transducers) other than those specified may result in an increase in emission or a decrease in immunity of this device or system.

This device or system shall not be used in proximity to or on top of other devices, and if it must be used in proximity to or on top of other devices, it shall be observed to verify that it can work properly in the configuration in which it is used.

Guidance and manufacturer' s declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that is used in such an environment.		
Emission test	Conformity	Emission test Conformity Electromagnetic Environment – guidance
RF Emissions CISPR11	Group 1	The appliance 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 equipment.  The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF Emissions CISPR11	Class B	
Harmonic emissions IEC61000–3–2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000–3–3	Conforms	

Guidance and manufacturer's declaration – electromagnetic emissions			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that is used in such an environment.			
Immunity test	IEC60601 test level	Compliance Level	Electromagnetic environment – guide
Electrostatic discharge(ESD) EN 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV 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	± 2 kV for power supply lines ± 1 kV for input/ Output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	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 % UT ( > 95 % dip in UT) for 0.5 cycles 40 % UT ( 60 % dip in UT) for 5 cycles < 5 % UT 70 % UT ( 30 % dip in UT) for 25 cycles < 5 % UT < 5 % UT ( > 95 % dip in UT) for 5 s	< 5 % UT ( > 95 % dip in UT) for 0.5 cycles 40 % UT ( 60 % dip in UT) for 5 cycles < 5 % UT 70 % UT ( 30 % dip in UT) for 25 cycles < 5 % UT < 5 % UT ( > 95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
<b>NOTE:</b> UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer' s declaration – electromagnetic emissions			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that is used in such an environment.			
Immunity test	level EN 60601-1-2	Compliance Level	Electromagnetic environment – guide
<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>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \quad 80 \text{ MHz} \sim 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz} \sim 2.5 \text{ GHz}$ <p>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).</p> <p>Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people.</p>			
<p>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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.</p> <p>b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the device			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter Watts [W]	Separation distance according to frequency of transmitter (in meters)		
	Meters [m]		
	150 kHz ~ 80 MHz	80 MHz ~ 800 MHz	800 MHz ~ 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For 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 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.			



After-sales service company: Changzhou Bomedent Medical Technology Co., Ltd.

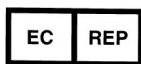
Tel: 0519-88991980



ChangZhou BoMedent Medical Technology Co.,Ltd.

NO.9 Changyang road, West Taihu Science &

Technology Industrial Park, Changzhou City, jiangsu, China



Caretechion GmbH

Niederrheinstr 71, 40474 Duesseldorf, Germany

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