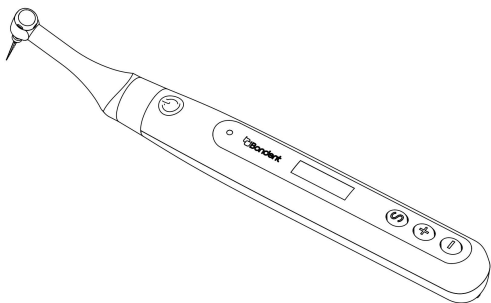


# Dental Electrical Motors User Manual



Read this Operation carefully before use. Keep this User Manual for future reference.

Thank you very much for choosing the Dental Electrical Motors 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**

- Classification by type of protection against electric shock: Class II, Internal electrical power source device
- Classification by degree of protection against electric shock: Type B applied part
- Classification of protection against ingress of water: IPX0(Device), IPX1(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: V1

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## 1. Product Introduction

### 1.1 Brief Introduction

Dental Electrical Motors are used for root canal treatment and can help dentists clean and prepare root canals more effectively, providing better conditions for subsequent filling work.

The features of the device are as follows:

- a) With brush, brushless different models to choose from, the motor is stable and reliable, speed, torque control precision;
- b) The motor speed, torque and rotation direction can be adjusted, and the Contra angle can be rotated  $360^{\circ}$  ;
- c) The site in contact with the patient can be reused by high heat sterilization;
- d) Wireless handle, The battery has strong battery life;.

### 1.2 Model

Model: iBon Mini, iBon Mini-SE

<b>Model</b>	iBon Mini	iBon Mini-SE
<b>Speed</b>	150-1500rpm	150-800rpm
<b>Motor</b>	Brushless motor	Brushed motor
<b>Reduction ratio of Contra angle</b>	6:1	1:1
<b>Software release version</b>	V1	V1

### 1.3 Intended use, user, patient

1.3.1 Intended use: The dental electrical motors are a compact, cordless endodontic treatment motorized handpiece for preparation and enlargement of root canals.

1.3.2 Intended user: The use of Dental Electrical Motor is intended exclusively for qualified dentist.

1.3.3 Intended patient: Adult people over 18 years old who need root canal preparation and enlargement, and root canal shape is good.

1.3.4 Use place: Hospital or dental clinic.

## 1.4 Contraindications

None

## 1.5 Precaution and warning

- Dental Electrical Motors are repeated use medical devices, please clean and disinfect/sterilization before use, please take the method in the instruction manual for reference.
- Please read the following precautions and warnings carefully before use. To ensure that the device is used in safe conditions, follow these instructions;



### 【Notice】

- The battery used in the device is a special lithium battery that can be recharged.
- Do not use a bent, damaged, deformed or non- ISO-conforming file. It may cause personal injury due to sudden breakage or flying off during rotation.
- Do not use or leave the device in a high-temperature environment such as under strong direct sunlight, in a car under a blazing sun, by a fire or near a stove.
- Check the device before use, if there ' s abnormal loose, vibration, noise and temperature (heat generation). Immediately stop using and contact with your dealer.
- Keep the handpiece away from dirt, it will affect the concentricity of contra-angle handpiece and the judgment of the torque.
- Before changing the contra-angle handpiece or file or Maintenance of motor, turn off the power of the motor.
- Do not lubricate any part of the motor except the contra-angle handpiece.
- If use corrosive solutions during the operation, please clean the motor handpiece immediately after operation.
- This device is for indoor use only.
- The power consumption of the device is very small after shutdown, but any battery has self-discharge phenomenon, so it is recommended to fully charge the

host after each use, or if you do not use for a long time (such as one month), you should charge the host once.

- When the host detects that the power is too low, it automatically turns off the power and can be turned on again after being placed for a period of time. However, such operation is not allowed, because it is a unique power return phenomenon of the battery, which will cause damage to the battery or reduce its life. Therefore, charge the battery as soon as possible.
- If the battery is completely drained, it may be damaged. Contact the manufacturer to replace the battery.
- No special training is required for the use of this device. Please follow the instructions in the manual to use and maintain the device.



**【Warning】**

- Portable and mobile RF communications equipment can affect Medical Electrical device. Do not use RF equipment outskirts for the device.
- Do not impact or pressure the device, especially where the battery is placed. The battery may leak or explode.
- Do not put the device and the battery in the device into fire, which will cause battery leakage or explosion.
- Do not sterilize the host at high temperature or steam, otherwise the battery in the host will burn or explode.
- If the device has not been used for a long time, please check whether the device works properly before use.
- Pay attention to contact with water, do not charge and operate with water on hand.
- Do not sprinkle water or medicine drops on the main engine, which may cause short circuit, fire and other risks.
- Do not disassemble the device yourself.
- If there' s liquid leakage on the battery, or handpiece deform or fade, immediately stop using and contact with your dealer.
- Keep the charging interface away from something conductive such as copper

scrap.

- Please use original charger to charge the battery.
- Before use, it is necessary to carefully read the speed, torque range and use times allowed by the manufacturer of the root canal file to set the parameters of the root canal preparation machine;
- Do not touch the charging port and the patient at the same time;
- It is prohibited to use in them such as patients with hemophilia or heart disease. Patients and doctors with pacemakers. Pregnant women and young children need to use caution.
- 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.
- 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
- 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 Apex locator, including cables specified by the MANUFACTURER. Otherwise, degradation of the performance of this equipment could result.

## 1.6 Performance characteristics

The Dental Electrical Motor connects with the file which must meet the requirements of the type 1 in ISO 1797-1.

Speed:

	iBon Mini	iBon Mini-SE
Min rotation speed	150 rpm	150 rpm
Max rotation speed	1500rpm	800rpm

Torque:

	iBon Mini	iBon Mini-SE
Min torque	0.6 N·cm	0.6 N·cm
Max torque	4 N·cm	4 N·cm

## 1.7 Clinical benefit

The performance of Dental Electrical Motors 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

Tel.: 86 0519-88991980

Website: [www.bome-dent.com](http://www.bome-dent.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: 697107537iBonMiniQ9/ 697107537iBonMiniSEY2

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)

- name of manufacturer or distributor;
- type of instruments, product identification;
- product size;

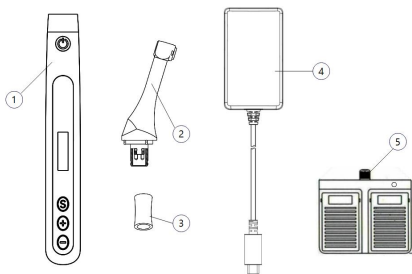
Complete Contraindications, Warnings and Precautions will be available and kept up to date on the IFU.

For additional information, contact your United Dental Changzhou Sales


Representative or ChangZhou BoMedent Medical Technology Co., LTD. Customer Service. No electronic version of the IFU provided.





## 2. Product Configuration

Dental Electrical Motors are composed of the Central Unit(Contains the motor), Contra angle(6:1/1:1), Adaptor, Spray nozzle, Wireless Pedal(optional) and the software (release version number V1).



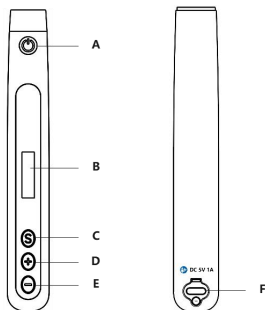
### 2.1 Main Accessories of Product

No.	Components	Photo	Type	Count
1	Central Unit(Contains the motor)		iBon Mini / iBon Mini-SE	1PC

2	Contra angle		6:1 (Applicable to iBon Mini)	1PC
	Contra angle		1:1 (Applicable to iBon Mini-SE)	1PC
3	Spray nozzle		/	1PC
4	Adaptor(Contains European standard plug)		UES06WNCP-050100SP A	1PC
5	Wireless Pedal (optional)		BMWP0001	1PC
6	IFU	/	/	1PC

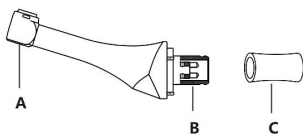
If the user wants to purchase an additional accessory, he or she needs to contact the local designated dealer or manufacturer, and can't change the accessory at will, otherwise the risk is not acceptable.

## 2.2 Central Unit interface diagram



No.	The part name	Use
A	Run button	<ul style="list-style-type: none"> <li>● Long press the Run button to power on or off</li> <li>● Press the button in standby mode to start/stop the motor operation</li> <li>● Press the button in selection mode to confirm the current option</li> </ul>
B	Display screen	Used to display current preset mode, parameters, battery level, and other information
C	S Key	Used to enter parameter Settings and switch Settings menu
D	+ Key	Used to adjust the parameters or to select the settings
E	- Key	Used to adjust the parameters or to select the settings
F	Type-C charging interface	Use to connect the power adapter to charge the Central Unit

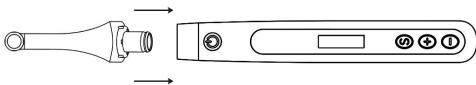
## 2.3 Schematic diagram of Contra angle components



No.	The part name	Use
A	Root Canal Files interface	Used to install Root Canal Files (medical instruments) to perform root canal surgery
B	Main engine (motor) interface	Used to connect the host motor to transmit power
C	Spray nozzle	Used for regular oiling maintenance of Contra angle

## 3. Product Installation

### 3.1 Install the Contra angle

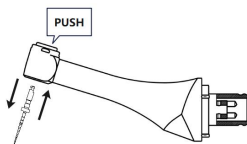


Align the positioning pin at the bottom of the Contra angle with the positioning slot of the Central Unit and insert it. After hearing a "click" sound, it indicates that it has been installed in place.

#### **【Warning】**

- If the installation is not firm, it may result in unpredictable rotation or Contra angle shedding, resulting in patient injury.

### 3.2 Install Root Canal Files



Hold down the rear cover button on the Contra angle to install / remove the Root Canal Files.

#### 【Notice】

- After loading, it can be gently pulled or rotated in reverse to ensure that the root canal file is installed in place and stuck tightly;

#### ⚠ 【Warning】

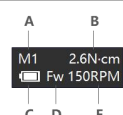
- The device must be compatible with Root Canal Files according to ISO 3630-1:2018. Do not install dental files or drill needles of other sizes to avoid irreversible damage to the Contra angle.

## 4. Product function and use

### 4.1 Motor switching and user interface (UI)

#### 4.1.1 Turn on

When the Central Unit is shut down, press [Run] to start the motor and enter the standby state. In the standby state, the display screen will display the following interface:

Interface	Display content	Description
	A—Current preset mode	The product contains a total of 10 preset modes, including M0, M1~M5, and P6~P9. Among them,

		M0: commonly used reversible preset function; M1 to M5: forward fast setting mode. P6 to P9: Forward, reverse, and forward full-function custom modes.
	B—Currently set torque value (unit: N·cm)	Setting range: 0.6–4N·cm
	C—Battery level display	—
	D—Currently set rotation mode	Fw: Forward rotation Rv: Reverse rotation Rec: Reciprocating motion
	E—Currently set speed (unit: rpm)	The iBon Mini ranges from 150 to 800rpm. The iBon mini-SE ranges from 150 to 1200rpm.

#### 4.1.2 Motor operation

In the standby state, press the [Run] key to enter the working state of the motor central unit, and the display interface is as follows:

Interface	Display content	Description
	A—Currently set torque value	—
	B—Torque scale (unit: N·cm)	—
	C—The real-time torque value of the current motor	Represents the actual torque output by the current motor (i.e. the resistance torque). When the set

		value is reached, the motor will start the reverse protection to prevent irreversible damage to the patient caused by excessive torque.
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Press [Run] again, the motor central unit stops running, and the standby state is restored.


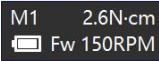

#### 4.1.3 Shutdown

In the standby state, long press the [Run] for 1s to shut down the motor and turn off the display.

## 4.2 Preset

### 4.2.1 Enter preset

In motor standby mode, press [+/-] to adjust and select preset.

Preset	Standby Display	Operation mode specification
<b>M0</b> Commonly used reciprocating mode		M0-Commonly used reciprocating mode: In this mode, non-adjustable rotation mode (default is forward rotation mode), and only [S key] can be pressed to switch the common forward rotation Angle.
<b>M1~M5</b> Forward (easy) mode		In this mode, non-adjustable rotation mode (default is forward rotation mode), press [S] key to enter the parameter setting menu, set [Speed speed] and [Torque torque].
<b>P6~P9</b> Full-featured custom mode		In this mode, press [S key] to enter the parameter setting menu, and you can set it: [Operation Mode Rotation mode] : Fw forward rotation, Rv reverse rotation, Rec

		<p>forward rotation.</p> <p>[Speed] : The value ranges from 150 to 800rpm for the iBon Mini and from 150 to 1200rpm for the iBon Mini-SE.</p> <p>[Torque] : The torque range is 0.6 to 4.0N • cm</p> <p>If the [Rec reciprocating rotation] mode is selected in the [Operation Mode rotation mode], the [Fw Angle forward rotation angle] and [Rv Angle reversal angle] can also be adjusted.</p>
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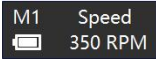


#### **【Warning】**

All parameters must be set according to the recommended values of the root canal file manufacturer. Improper setting may lead to the risk of the root canal file instrument separation.

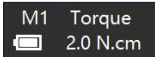
#### 4.2.2 Speed setting

In the standby state of M1-M5 and P6-P9 preset modes, press [S] to enter the speed setting:

Interface	Operation mode specification
	<ul style="list-style-type: none"> <li>● Press [+/- key] on the speed setting interface to adjust the speed;</li> <li>● Press [S] again to switch the parameter adjustment menu, or press [Run] to confirm the setting and return to the standby interface.</li> </ul>


#### 4.2.3 Torque setting

In the standby state of M1-M5 and P6-P9 preset modes, press the [S] key continuously until the speed setting is entered:

Interface	Operation mode specification
	<ul style="list-style-type: none"> <li>● Press the [+ / -key] in the torque setting interface to adjust the torque;</li> <li>● Press [S] again to switch the parameter adjustment menu, or press [Run] to confirm the setting and return to the standby interface.</li> </ul>

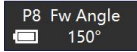
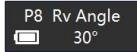
#### 4.2.4 Rotation mode setting

In the standby state of P6~P9 preset mode, continuously press [S] key until entering the rotation mode setting:

Interface	Operation mode specification
	<ul style="list-style-type: none"> <li>● Press [+ / -key] in the rotation mode setting interface to change the rotation mode: Fw turning forward, Rv reverse, Rec turning forward;</li> <li>● Press [S] again to switch the parameter adjustment menu, or press [Run] to confirm the setting and return to the standby interface.</li> </ul>

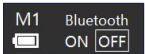
#### 4.2.5 Reciprocating angle setting

In the standby state of P6~P9 preset mode, if the mode has been set to [Rec to reverse] in the rotation mode setting interface, press [S key] again to enter the reciprocating Angle setting:

Interface	Operation mode specification
 	<ul style="list-style-type: none"> <li>● Press [+ / -key] in the reciprocating turn Angle setting interface to change [Fw Angle forward turn Angle] and [Rv Angle reverse Angle] respectively;</li> <li>● Press [S key] again to switch the parameter adjustment menu, or press [Run key] to confirm the setting and return to the standby interface.</li> </ul>

#### 4.2.6 Bluetooth pedal connection

Turn on the Bluetooth pedal and long press [S] 2s in all preset modes to enter the connection setting of the Bluetooth pedal.


Interface	Operation mode specification
	<ul style="list-style-type: none"><li>● Press [+ / -key] in the Bluetooth setting interface to change the Bluetooth connection [ON] / [OFF] (if the Bluetooth pedal is not turned on in advance, it cannot be adjusted to [ON]. Successful adjustment to [ON] indicates that the Bluetooth connection is successful, and the start and stop of the motor can be controlled by the pedal);</li><li>● Press [S] again to switch the parameter adjustment menu, or press [Run] to confirm the setting and return to the standby interface.</li></ul>

#### 【Notice】

The Dental Electrical Motors are only compatible with the supporting Bluetooth wireless pedal, and cannot be used with other pedals in the market.

### 4.3 System Settings

When the Central Unit is shut down, hold down [S] and then press [Run] to enter the system setting. The interface displays the current software version of 1s.

Interface	Operation mode specification
System volume Settings 	<ul style="list-style-type: none"><li>● Press [+/-] to adjust the volume of the system buzzer: [Vol.0 (Mute)], [Vol.1], [Vol.2], [Vol.3]</li><li>● Press [S] again to switch the system menu, or press [Run] to confirm the setting and return to the standby interface.</li></ul>

<p>Motor non-operation automatic shutdown time setting</p> <p style="text-align: center;"><b>Auto Power Off 5 min</b></p>	<ul style="list-style-type: none"> <li>● Press [+ / -key] to set the automatic shutdown time of the motor without operation.</li> <li>● Press [S key] again to switch the system menu, or press [Run] to confirm the setting and return to the standby interface.</li> </ul>
<p>The system has no operation, and the jump time is set automatically.</p> <p style="text-align: center;"><b>Auto Standby Scr 10 Sec</b></p>	<ul style="list-style-type: none"> <li>● Press [+ / -key] to set the time for the system to automatically jump to the standby interface without operation.</li> <li>● Press [S] again to switch the system menu, or press [Run] to confirm the setting and return to the standby interface.</li> </ul>
<p>Left and right hand display Settings</p> <p style="text-align: center;"><b>Dominant Hand Right</b></p>	<ul style="list-style-type: none"> <li>● Press [+/- key] to set the display of the left and right hands of the system (mirror display).</li> <li>● Press [S key] again to switch the system menu, or press [Run key] to confirm the setting and return to the standby interface.</li> </ul>
<p>Automatic calibration</p> <p style="text-align: center;"><b>Calibration OFF</b></p>	<ul style="list-style-type: none"> <li>● Press [+ / -key] to set whether to start the automatic calibration ON / OFF.</li> <li>● Press [S] again to switch to the system menu, or press [Run] to confirm that automatic calibration is started. The system will automatically shut down after automatic calibration.</li> </ul> <p><b>【Notice】</b> Do not touch the rotating parts of the motor during automatic calibration.</p>
<p>Factory data reset</p> <p style="text-align: center;"><b>Restore Defaults OFF</b></p>	<ul style="list-style-type: none"> <li>● Press [+ / -] to set whether to resume the factory setting ON / OFF.</li> <li>● Press [S key] to switch the system menu again, or press [Run] to confirm the return to the factory</li> </ul>

	Settings. After restoring the factory Settings, the system will automatically shut down.
--	--

## 4.4 Battery charging

The product can be recharged and used repeatedly. Insert the supporting power adapter into the Type-C charging port of the motor, the display will display the battery charging animation, and the battery is full (the animation is still).

### **【Warming】**

Please charge the product with the matching power adapter, using the non-matching power adapter may cause product damage or other unforeseen risks.

## 5. Trouble shooting

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>
The power is unable to turn on.	Battery has run out.	Recharge the battery.
	No battery inserted.	Insert battery.
	The internal fuse has burnt.	Contact your dealer.
Charge failure	Battery has been over used	Replace with new battery.
	Nothing is displayed on the panel of the handpiece even when it is loaded to the charger	Contact your dealer.
The motor hand piece	The contra angle has been blocked	Clean or reset the contra angle
The alarm sounds when the motor is working	The contra angle head has jammed up.	Clean the contra angle

Contra rotation failure	set to Auto Reverse mode, take off contra angle, there is NO click sound when working	Contact your dealer.
	set to Auto Reverse mode, take off contra angle, there is click sound	Clean the contra angle
The alarm sounds when the motor is working.	There is some residual contamination on the rotating shaft of the contra angle	Clean the contra angle

## 6. Cleaning, Disinfection and Sterilization



### 【Caution】:

- No part of the device is sterilized before leaving the factory.



### 【Warning】:

- Do not immerse the central unit in the ultrasonic cleaner.
- Do not use liquid or spray cleaner directly, especially on the screen.
- Except the contra angle, 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 Decontamination :	The devices must be reprocessed in a disassembled state, as far as possible. Only contra angle can be cleaned and disinfected with automated methods and sterilized with steam sterilization process. Do not sterilize the Central Unit , power adapter, USB cord! The Central Unit , power adapter and USB cord cannot be cleaned and disinfected in a washer/disinfector! For these parts, only a general wipe decontamination is possible!
Decontamination of other parts than Contra angle:	After operation, take the Central Unit , power adapter and USB cord on the workbench. 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. 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. Wipe all surfaces of the Central Unit , adapter and other components with the wet soft cloth for about 3 minutes. Please follow the instructions of manufacturer of disinfectants. Wipe the surface of the component with a dry soft lint-free cloth.
Following instructions are only relevant for contra angle!	
Pre-Cleaning of Contra angle:	Not use automated cleaning, disinfection and sterilization for other parts than contra angle in this system! Do a manual pre-cleaning, until the instruments are visually clean. Submerge the instruments in a cleaning solution and flush the lumens with a water jet pistol with cold tap water for at least 10 seconds. Clean the surfaces with a soft bristle brush.

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: Use a washer-disinfector meeting the requirements of the ISO 15883 series. 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><i>The automated cleaning processes have been validated by using 0.5% neodisher MediClean forte (Dr. Weigert).</i></p> <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.</p>
Disinfection:	<p>Automated thermal disinfection in washer/disinfector under consideration of national requirements in regards to A0 value (see EN 15883).</p> <p>A disinfection cycle of 5 min disinfection at 90°C has been validated for the device to achieve an A0 value of &gt; 3000. Here we suggest a disinfection cycle of 5 min disinfection time at 93 °C.</p>
Drying:	<p>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.</p>

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.	

## 7. Storage, Maintenance and Transportation

### 7.1 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.

## 7.2 Maintenance

### 7.2.1 Battery maintenance

Dental Electrical Motors use rechargeable lithium batteries. Battery life or number of charges depending on usage.

- Lithium battery has no memory effect, do not have to care too much about the timing of charging choice;
- Factors that have a large impact on battery life are:

Long-term placement of unused equipment, it is recommended to be fully charged at least once a month;

Charging beyond the required ambient temperature, the recommended ambient temperature is less than 40 degrees.

### 7.2.2 Lubricate the Contra angle

Please maintain the Contra angle with a lubricant after each use, before and after sterilization, or before calibration.

1) Using the provided Spray nozzle, insert one end of the Spray nozzle with a rubber ring into the head of the Contra angle (insert the end connected to the Central Unit);



2) Insert the provided Spray nozzle with the lubricant spray nozzle and spray it continuously for 2-3 seconds until the overflow liquid from the Contra angle head is clean;

3) After the Contra angle is thoroughly cleaned and lubricated, wipe the surface clean with a dry cotton cloth and place it vertically in an appropriate position until the

lubricant in the Contra angle is completely drained before installing it on the Central Unit for use.



**【Notice】**

- The Contra angle surface allows the use of relevant standard chemical reagents for spraying, wiping, and sterilization and disinfection;
- When pressing the lubricant spray, please hold Contra angle to avoid falling Contra angle;
- When using the lubricant, please hold the lubricant vertically;
- When the lubrication of Contra angle is completed, can not use any solvent to soak Contra angle, such as benzene;
- After each use, the file handle should be cleaned in time to avoid the blockage caused by dirt from the file handle into Contra angle, which affects the coaxial degree of Contra angle and the correct judgment of Central Unit on the strength of plugging;
- When not in use for a long time, the Contra angle is lubricated and maintained regularly.

### 7.3 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.
- d. The relative humidity of the transportation environment should be 10%~80%, the atmospheric pressure should be 500-1060hPa, and the temperature should be -10°C~ +50°C.
























## 8. Technical Parameters

Manufacturer	Changzhou Bomedent Medical Technology Co., Ltd.
Product name	Dental Electrical Motors
Model	iBon Mini、iBon Mini-SE

Software release version	V1
Dimensions	190*23*20mm
Product Net Weight	100g
Packing weight	300g
Power type	Rechargeable Lithium Battery, DC 3.7V, 950mAh
Power adapter	Input: 100-240V~50/60Hz Output: 5.0V===1.0A
Performance efficiency	Speed range: 150-1500rpm,±10%(iBon Mini); 150-800rpm,±10%(iBon Mini-SE); Torque range: 0.6-4.0N·cm,±20%
Classification by mode of operation:	Continuous operation
Liquid permeation protection	IPX0(Device) IPX1(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
Use environment	Temperature: 10-40°C Humidity: 10-70% Atmospheric pressure: 700-1060hPa
Storage/transportation environment:	Temperature: -10-50°C Humidity: 10-80% Atmospheric pressure: 500-1060hPa
Expected service life	10 years
Input/output data type	Not applicable. (The product does not include input and output of patient health data, user data, log and maintenance data, etc.)
Hardware environment (required hardware)	Processor: ARM 32-bit processor. The storage space (Flash) must be at least 128KB. Memory (RAM) is not less than 16 KB.
Software environment	Not applicable. (The software is not universal computing platform software, does not require external software environment support, and does not involve the operating system.)
Maximum concurrency	1

	(The software is not a general computing platform software, with no high concurrency.)
Bluetooth	Operating frequency: 2402.0Mhz~2480.0Mhz Type of Modulation: GFSK Number of Channel: 40 channels
Interface	User interface: display screen and keys, see Section 2 Physical interface: typeC charging interface Data interface: Bluetooth BLE 5.0
Access control	The software does not contain the user identification method and does not involve the user access authorization.

## 9. 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 thermal disinfection	for 	Sterilizable in a steam sterilizer (autoclave) at the temperature specified
	Temperature limit		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
	Catalogue number		

## **10. Environmental Protection**

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

## **11. After-sales Service**

1) Due to quality issues caused by the equipment's own materials and processes during normal installation and use, the manufacturer provides quality assurance to the equipment buyer;

2) Since the date of sale, if the equipment cannot work normally due to quality problems, our company shall be responsible for maintenance with the warranty card. For specific matters such as warranty period and warranty scope, please refer to the "Warranty Card";

3) If the battery and accessories are damaged, please use the batteries and accessories provided by the manufacturer. The maintenance of components requires professional personnel to carry out repairs. For detailed information on the warranty period and manufacturer, please refer to the "Warranty Card";

4) All parts cannot be maintained during use, please maintain them after use;

5) If maintenance personnel need to use circuit diagrams and other information can contact the manufacturer to obtain.

## **12. EMC Statement**


NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

<b>Manufacturer's Declaration – Electromagnetic Emissions</b>		
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions(CISPR 11)	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic environment.
RF emissions (IEC/CISPR 11)	Class A	The equipment is suitable for use in all establishments, other than non-domestic or domestic establishments directly connected to the public low-voltage power supply network that supplies buildings used.
Harmonic emissions (IEC 61000-3-2)	Not Applicable	
Voltage fluctuations/flicker emissions (IEC 61000-3-3)	Not Applicable	

<b>Manufacturer's Declaration – Electromagnetic Immunity</b>		
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Immunity test	Compliance Level	Electromagnetic environment-Guidance

Electromagnetic discharge(ESD) (IEC61000-4-2)	± 8 kV Contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air	Floors should be made of wood, concrete or ceramic tile that hardly produces static. If floors are covered with synthetic material that tends to produce static, the relative humidity should be at least 30%.
Electromagnetic fast transient/ burst (IEC61000-4-4)	± 2 kV for power supply lines ± 1 kV for signal lines	Mains power quality should be of a typical commercial (original condition feeding the facilities) or hospital environment.
Surge (IEC61000-4-5)	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines (IEC61000-4-11)	0% $U_T$ , 0.5cycle (At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°) 0% $U_T$ , 1 cycle 70% $U_T$ , 25/30 cycles Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment with highly reliable service. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply.

	0% $U_T$ , 250/300 cycles	
Power frequency (50/60 Hz) magnetic field (IEC 61000-4-8)	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity fields From RF wireless communications equipment (IEC 61000-4-3)	Refer to next table	Portable and mobile RF communications equipment should be used no closer to any part of the product
Proximity magnetic fields (IEC 61000-4-39)	134.2 kHz, PM, 2.1 kHz, 65 A/m 13.56 MHz, PM, 50 kHz, 7.5 A/m	The sources of proximity magnetic fields should be used no closer than 0.15 m to any part of the product
Conducted RF (IEC 61000-4-6)	3 Vrms, 150 kHz~80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance

<p>Radiated RF (IEC 61000-4-3)</p>	<p>3 V/m 80 MHz ~2.7 GHz</p>	<p><math>d = 1.2\sqrt{P}</math>  <math>d = 1.2\sqrt{P}</math> 80 MHz to 800 MHz  <math>d = 2.3\sqrt{P}</math> 800 MHz to 2.7 GHz</p> <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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey(a), should be less than the compliance level in each frequency range(b). Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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Note :

1.  $U_T$  is the AC mains voltage before application of the test level.
- 2: At 80 MHz and 800 MHz, the higher frequency range applies.
- 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- 4: To established the proximity threshold 0.15 m for Proximity magnetic fields, the IEC Subcommittee (SC) 62A considered the types of proximity magnetic field disturbance sources expected:
  - induction cooking appliances and ovens operating at frequencies up to 30 kHz;
  - RFID readers operating at both 134.2 kHz and 13.56 MHz;
  - electronic article surveillance (EAS) systems;
  - sponge detection systems;
  - equipment used for position detection (e.g. in catheter labs);

– wireless power transfer charging systems for electrical vehicles that operate in the frequency range of 80 kHz to 90 kHz.

These frequencies and applications are representative examples based on sources of magnetic field disturbance in use at the time of publication of the collateral standard IEC 60601-1-2:2014+A1:2020 .

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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the equipment.

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

#### Recommended minimum separation distances:

Nowadays, many RF wireless equipment have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. This Systems has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and this Systems as recommended below.

Test	Band	Service	Modulation	Maximum	Distance	Immunity
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frequency (MHz)	(MHz)			power (W)	(m)	test level (V/m)
385	380-390	TETRA 400	Pulse modulation  18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM  $\pm 5$ kHz deviation  1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation  217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900,  TETRA 800,  iDEN 820,  CDMA 850,  LTE Band 5	Pulse modulation  18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM	Pulse	2	0.3	28

1845		1800;	modulation			
1970		CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	217Hz			
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN	Pulse	0.2	0.3	9
5500		802.11	modulation			
5785		a/n	217Hz			

## Warranty Card

**Dear user:**

**For the warranty:**

1. We offer 1 year warranty for the product (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:

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

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