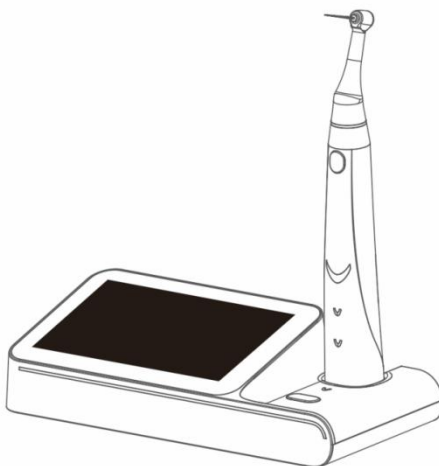


Endo Motor & Apex Locator

INSTRUCTION MANUAL

Please read the instruction manual carefully before using it for the first time



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Basic Product Information

Product Name: Endo Motor & Apex Locator

Model: EndoMaster

Service life: 5 Years

1. Intended Use

The Endo Motor & Apex Locator is mainly used in Endodontic treatment. It is a wireless endo motor with built-in apex locator. It is designed for use by dentists for driving dental root canal instruments for preparation and enlargement of root canals. Meanwhile, it supports the dentists in the determination of the working length during the endodontic treatment.

1.1 Scope of application

The device must only be used in hospital environments, clinics or dental offices, by qualified practitioners.

1.2 Intended clinical benefits

Effectively improve the apex positioning accuracy and control the working length accurately to reduce the risk of overcharge or undercharge.

Effectively improve the success rate of root canal treatment.

1.3 Patient population

Intended for use in individuals aged over 6 years.

1.4 Indication

Pulpitis, Apical parodontitis

2. Contraindications

- Doctors with pacemakers are disabled.
- Patients with pacemakers (or other electrical equipment) who are warned not to use small household appliances (such as electric shavers, hair dryers, etc.) are disabled.

3. Warning

- Before using this device for the first time, please read the instruction manual carefully.
- This device must be used in hospitals, dental clinics, and by a

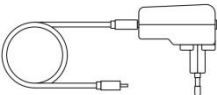
- qualified dentist.
- The patients are strictly forbidden to use this device on their own.
 - This device should only be used with its accompanying accessories, do not use any other power adapters, contra angles, lithium batteries, etc.
 - Incorrect replacement of lithium batteries can lead to unacceptable risks, please use the lithium battery provided by the original manufacturer and follow the correct steps in the instructions to replace the lithium battery.
 - Do not disassemble or repair the device by yourself, any self-disassembly and repair may violate safety regulations and cause injury to the patient. Any self-dismantling and repair will not be warranted by any promise.
 - Before the motor stops rotating, the contra angle cannot be removed, and the press cap of the contra angle cannot be pressed, otherwise the contra angle may be damaged.
 - The root canal file must not be removed until the motor stops rotating, as this may damage the operator.
 - Before starting the motor, make sure that the root canal file is assembled and locked.
 - Set the speed of the motor output and torque according to the parameters recommended by the file manufacturer.
 - Prolonged use of reciprocating mode may cause the motor handle to overheat, and it should be allowed to cool down before use. If the motor handle frequently overheats, please contact your local dealer.
 - Prolonged use of the device may cause the base to overheat, and it should be allowed to cool down before use. If the base frequently overheats, please contact your local dealer.
 - Do not place the device near flammable materials. Do not operate the device in the presence of a flammable anesthetic mixture of air, oxygen or nitrogen oxides.
 - Portable and mobile RF communication equipment may affect the performance of this device, avoid strong electromagnetic interference when using it, such as near mobile phones, microwave ovens, etc.
 - Do not place this device near a heat source. The unit must be operated and stored in a reliable environment.

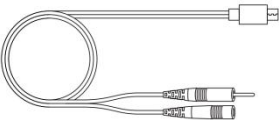
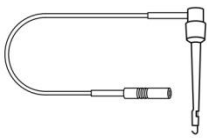
- The device should operate in +5° C - +40° C, relative air humidity 30%-75%, atmospheric pressure 70~106 kPa environment.
- The device should be sterilized and disinfected before the first use and after each use to the patient to avoid cross infection.
- The shank of the device cannot be autoclaved, and the surface can only be wiped with neutral disinfectant or alcohol.
- Do not use bent, deformed instruments or those that are non-compliant with ISO. (ISO17971-1: Ø2.334 - 2.350 mm)
- The accessories of this device that come into contact with patients (Contra Angle, file clip, lip hook, silicone sleeve) can be used repeatedly at least 250 times, before operation, high-temperature and high-pressure sterilization of the device are strictly needed accordingly. Please refer to the Section 9 of this manual for more details of sterilization method.
- Do not place the device where it is difficult to operate the disconnect device.
- **Warning:** Modification of the device is not permitted. Do not modify the device without the authorization of the manufacturer. It is necessary to carry out appropriate inspection and testing to ensure that the equipment can be used continuously and safely if modification of the device.

4 Product description & component list

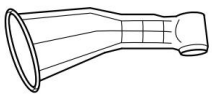
4.1 Product structure

4.1.1 Component list

1. Motor handpiece	2. Contra-angle
	
3. Adapter	4. Base
	

5.Measuring wire	6.Lip hook
	
7.File clip	
	

Accompanying accessories

Protective silicon cover	Lubricator
	

4. 2 Technical data description

Manufacturer	Shanwei Perfect Medical Instruments Co., Ltd
Model	EndoMaster
Size	237(L)X173(W)x108(H)mm (Package)
Weight	Handpiece: 140g Base: 430g
Contra-angle	Gear ratio 6: 1
Power supply (Handpiece)	3.7V/1200mAh Lithium Battery
Power supply (Base)	7.2V/3300mAh Lithium Battery
Power adapter output	5V DC, 2A

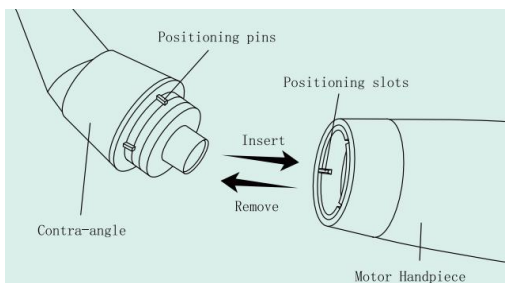
Power adapter input	AC100-240~50/60Hz
Electrical safety classification	Class II device with internal power supply
Application part	Type B application part: Contra angle, File clip; Lip hook;silicone cover;Touch probe Application part contact time: 1~10 minutes
Materials of Application part	Contra angle: stainless steel,copper Lip hook:stainless steel File clip:Silicone,nylon,stainless steel Silicone cover:silicone
Speed range	100rpm-3000rpm
Torque range	0.4N.cm-5N.cm
Operating conditions	Operating temperature: +5°C to +40°C Operating humidity: 30% - 75% Atmospheric pressure: 70kPa - 106kPa
Storage conditions	Storage temperature: -10°C to +50°C Storage humidity: 10% - 85% Atmospheric pressure: 70kPa - 106kPa

5. Device installation

5.1 Installation and removal of contra angle

5.1.1 Installation

Align any positioning pin of the contra-angle with the positioning groove on the motor shank, push it horizontally into the contra-angle, and cooperate with the three positioning grooves on the motor handle through the three positioning pins on the contra-angle, and the "click" sound indicates that the installation is in the right place.



5. 1. 2 Removal

When removing the contra angle, pull it straight out horizontally.



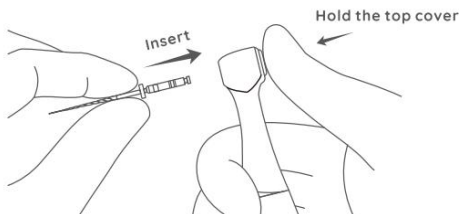
Warning

Please make sure the device is under power off status and with no rotary during installation and removal of the Contra angle.

5. 2 Insertion and removal of the File

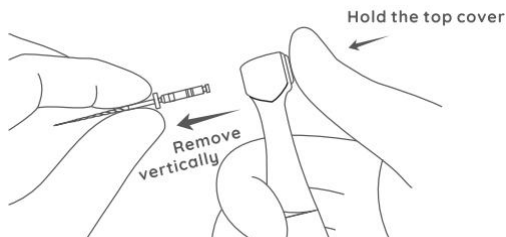
5. 2. 1 The File insertion

Press the top cover of the contra-angle and insert the file until the end of the file shank is loaded into the latch slot inside the contra-angle. Release the top contra-angle cover and gently pull the file needle outward to confirm that the file needle is locked firmly.



5. 2. 2 File removal

Press the top cover of the contra-angle while pulling the file out at the angle of the vertical drive shaft of the shank.

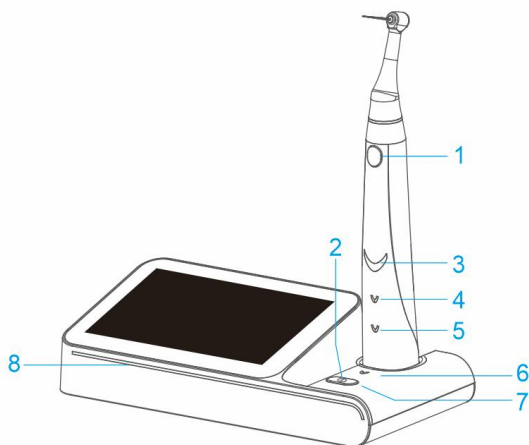


Warning

- Please make sure the device is under power off status and with no rotary during installation and removal of the Contra angle, to avoid any injury to the operator.
- When inserting and removing root canal files, it is necessary to press the top cover of the Contra angle until the insertion or removal action is completed. Otherwise, it will damage the locking pin components inside Contra angle.
- Please use a file with an ISO standard file handle.(ISO standards: $\Phi 2.334-2.350\text{mm}$)

6. Device function and operation

6. 1 Device keys and lighting definition



1	Handpiece power/start button: Handpiece power button and Handpiece start button
2	Base power key
3	Handpiece atmosphere light/torque display: display atmosphere light when standby, torque indicator when the handpiece is working (varies with the torque)
4	Bluetooth indicator: The blue light is steady on when connected, and the blue light is blinking when not connected
5	Handpiece status light/Charging light: Green when starting up, orange when charging
6	Base wireless charging light: The orange light is steady on during wireless charging and goes off before charging. Blinking indicates that the base battery is low and the wireless charging stops
7	Base charging light: Orange when charging, green when full
8	Base atmosphere light: display atmosphere light when standby, torque indicator when handpiece is working, root test indicator (varies with torque/root test value)

6.2 Software operation interface and function introduction

① Device Power ON and OFF

Handpiece Power ON and OFF

Press the power/Start button to turn on the handpiece.

Long-press the power/Start button to turn off the handpiece.

Base Power ON and OFF

Press the power button to turn on the base.

Long-press the power button for 2 seconds to turn off the base.

The device will automatically shut down after 5 minutes (default) without any operation.

② Handpiece start and stop

When the handpiece is on, select the appropriate mode, press the power/Start button to start the handpiece, and press the power/Start button again to stop the handpiece.

6.3 Control Base interface definition and operation

Note: The base is controlled by screen touch operation

Main interface	Apex	Preset	Customize	Setting
	Root measurement interface	Preset mode	User defined	System settings
Function	Touch "+" and "-" to preset the root measurement value	This mode pre-stores the preset program of each manufacturer's root canal file, speed and	Users can customize the forward, reverse, reciprocating rotation, speed, torque and reciprocating	Can set Auto power off time, Sound, Calibration, Restore defaults, Bluetooth connection,

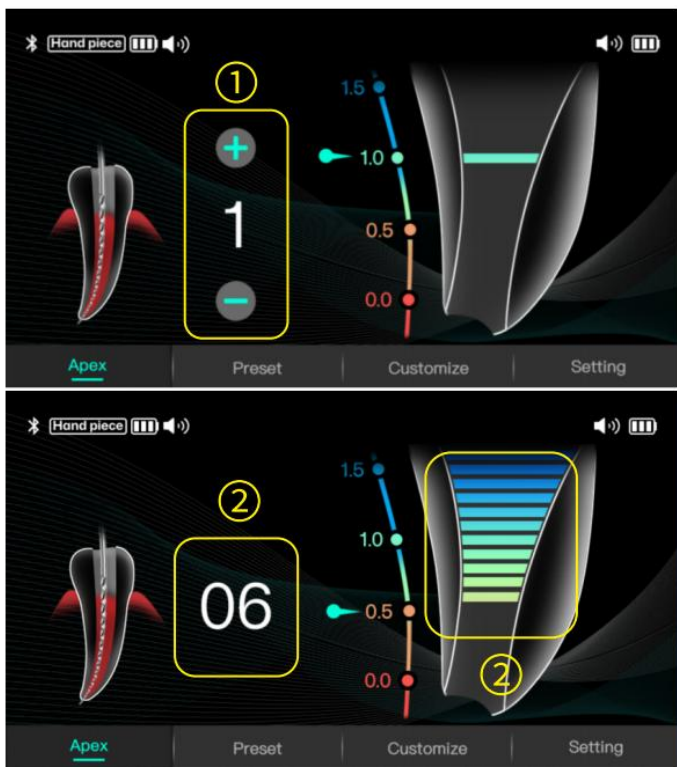
		torque for the manufacturer's recommended values.	rotation angle Settings.	Screen brightness, Combined mode.
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6. 4 Root canal length measurement interface

Interface description

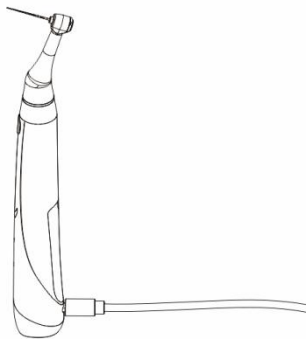
①Root canal measurement value setting

②Real-time measurement



6. 4. 1Root canal measurement function

Apex is a separate root canal length measurement mode, which can be measured by inserting the USB end of measuring wire into the USB port on the back of the handpiece.



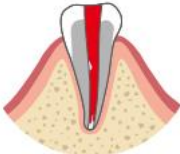
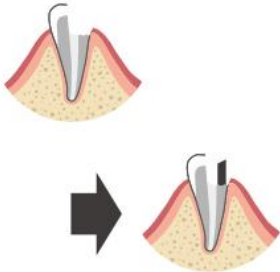
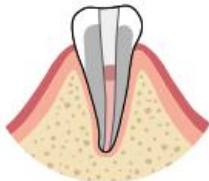
Pre-set a root canal length value, when tests the root canal length, the file close to the set value, there will be an alarm sound and atmosphere light warning, as the distance closer to the preset value, the warning tone frequency faster! The base atmosphere light will also change!

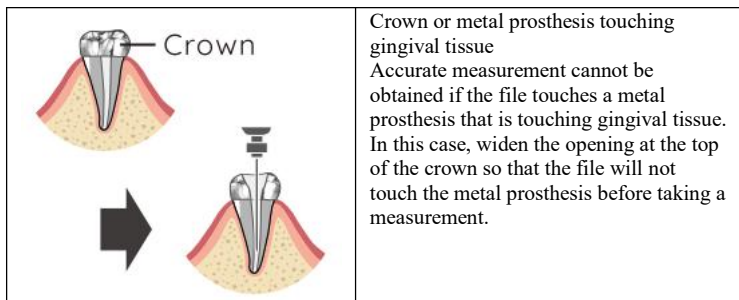


Root canal measurements are not suitable for the following situations:



Root canal with large apical foramen
Root canal with a large apical foramen
root canal that has an exceptionally large
apical foramen due to a lesion or
incomplete development cannot be
accurately measured. The results may
show shorter measurement than the
actual length

	Root canal with blood overflowing from the opening Blood overflows from the opening of the root canal and contacts the gums, this will result in electrical leakage and an accurate measurement cannot be obtained. Wait for bleeding to stop completely. Clean the inside and opening of the canal through to get rid of all blood, and then make a measurement
	Broken crown the crown is broken and a section of the gingival tissue intrudes into the cavity surrounding the canal opening, contact between the gingival tissue and the file will result in electrical leakage and an accurate measurement cannot be obtained. In this case, build up the tooth with a suitable material to insulate the gingival tissue.
	Fractured tooth Leakage through a branch canal fractured tooth will cause electrical leakage and an accurate measurement cannot be obtained.
	Re-treatment of a root filled with gutta-percha The gutta-percha must be completely removed to eliminate its insulating effect. After removing the gutta-percha, pass a small file all the way through the apical foramen and then put a little saline in the canal, but do not let it overflow the canal opening.



6.4.2 Root canal enlargement combined length determination function

When using this function, the measuring wire is connected to the handpiece, and the end of the measuring wire lip hook can be hung on the patient's lip, and the measurement function can be performed when the file enters the root canal.



Warning

Before using this function, it is necessary to test the connection, and the testing method is as follows:

Connect the lip hook with the file, when the root measurement is -2, it indicates a good connection.



6.5 Preset mode interface

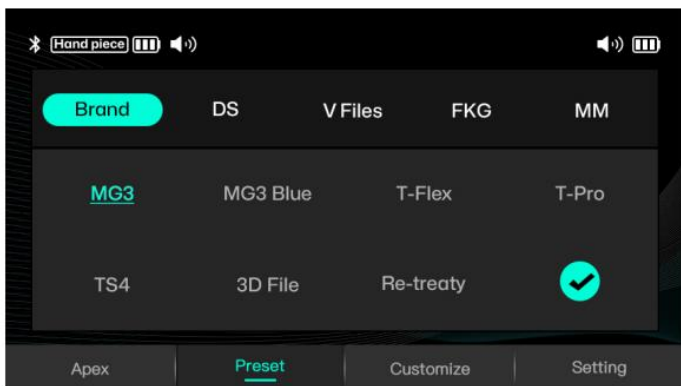
6.5.1 Interface description

①Brand selection ②File model switch



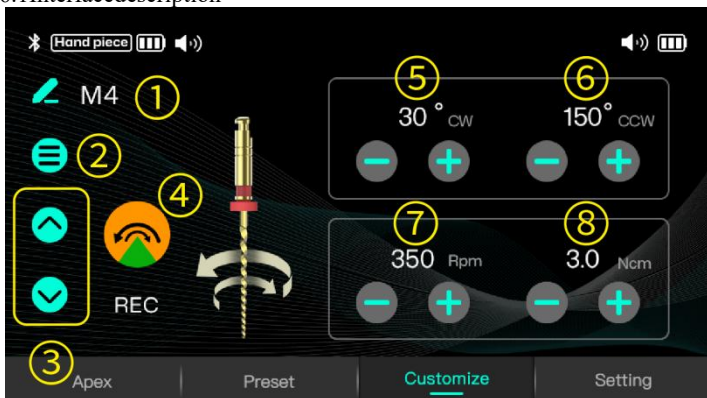
6.5.2 Choose from various brands and root canal file series

As shown above, click the ①perfect icon to enter the brand selection and ② root canal file series selection.



6.6 Customize interface

6.6.1 Interfacedescription



1. Custom mode/model editing; 2. Customize mode/model selection;
3. Customize mode switching; 4. Mode switching (forward → reverse → reciprocating → adaptive mode); 5. Positive rotation Angle; 6. Reverse

Angle; 7. Speed setting(100-3000rpm). 8. Torque setting (0.4~5Ncm).

Note: Only reciprocating selection and adaptive mode have Angle Settings.

6.6.2Customize mode function storage and switching

Click①in the figure above to enter the custom mode name editing. The editing mode is as follows: Users can customize the mode name, speed, torque, rotation Angle, etc. in this mode. A maximum of 10 custom modes can be stored.



6.6.3Customize mode selection

Click Figure② in section 6.6.1 to select the saved customize mode



6.6.4 Automatic reverse protection function

When the handpiece operates in one direction and the load torque reaches the preset value, it will automatically reverse; When the handpiece load again returns to half of the preset torque value, the handpiece returns to its original rotation direction.

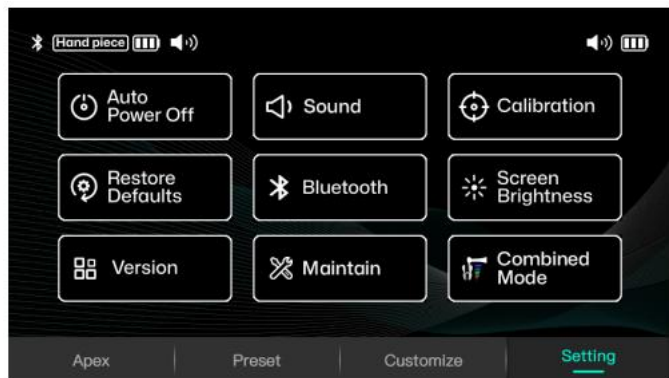


Warning

1. The auto reverse protection function takes effect only in single-direction rotation mode.
2. This function does not take effect in ATR mode.
3. When the device is low power, it is not enough to support the handpiece to reach the maximum torque value of 5Ncm, that is, the reverse function cannot work normally at this time, please charge it in time.

6.7 System settings

6.7.1 System setting interface



Auto power-off	The automatic shutdown time can be set to 5, 10, or 15 minutes
Sound	Settings of Root measurement sound, Base sound, handpiece sound, switch sound
Handpiece calibration	Calibrate the torque and speed of the handpiece
Restore defaults	Restore factory setting
Bluetooth	See 6.7.2 for details on Bluetooth connection Settings
Screen Brightness	Screen Brightness settings
Version	Software Version
Maintain	Maintenance instructions
Auxiliary Functions	Root canal expansion/canal measurement two-in-one function setting

6. 7. 2 Bluetooth Connection Details:

When the Bluetooth is not connected, the Bluetooth icon in the upper left corner of the page is a red warning, as shown below



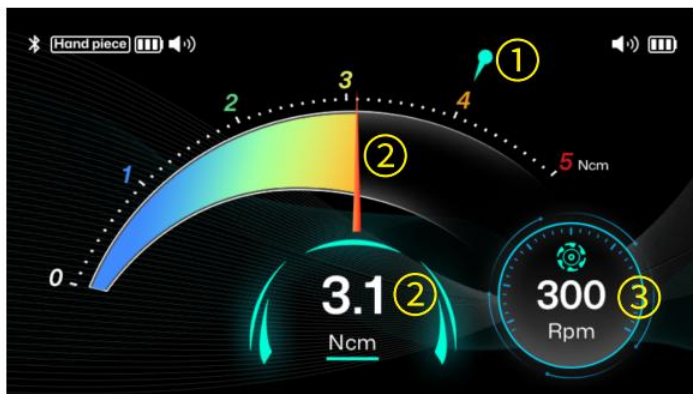
When the Bluetooth is connected, the Bluetooth icon is displayed normally, and the battery level and volume of the controller are displayed, as shown in the following figure:



6. 7. 3Accessibility details:

Apical Action	When the root canal file reaches the set working length of the root canal, the feedback status of the root canal file is STOP, REVERSE, OFF to disable this function
Auto Start	The root canal file enters the root canal and the handpiece starts automatically. ON-Enables this function,OFF- disables this function
Auto Stop	The root canal file exits the root canal and the handpiece stops automatically ON-Enables this function,OFF- disables this function
Auto slow down	handpiece deceleration function: When the device detects that the file is close to the bottom of the root canal, the handpiece automatically decelerates without pressing the main button

6.8 The Interface description of handpiece start up

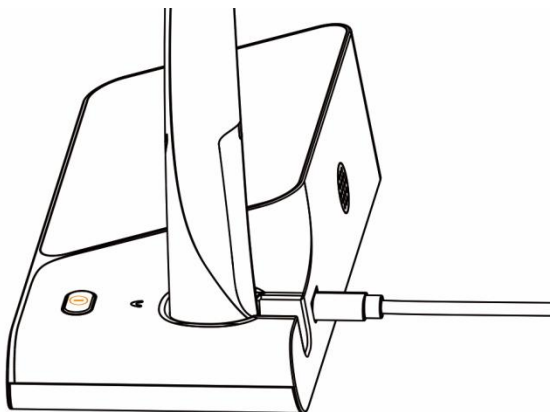


① Preset torque float, ② Real-time torque display, ③ Current speed value

6.9 Base and Handpiece charging

Base charging:

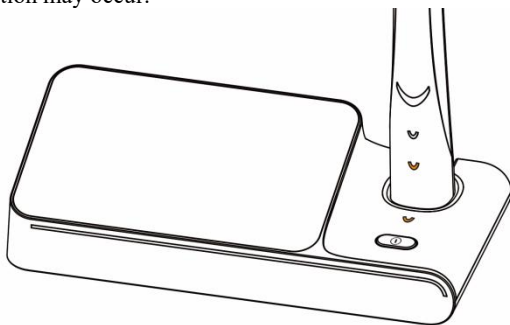
Use the power adapter to plug into the type C port of the base to charge. When charging, the base button power light is orange, and when it is full, it is green.



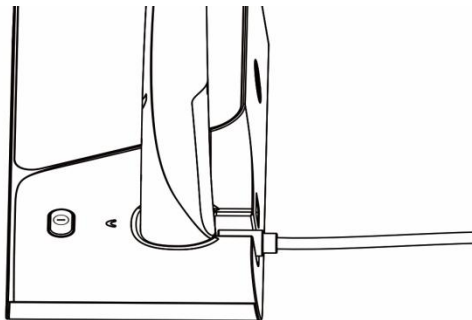
Handpiece charging:

Method 1: Wireless charging: Put the handpiece into the base slot of the base to charge. During wireless charging, the base wireless charging light is steady orange, the handpiece power light is orange, and the device is turned off when it is full.

Note: When placing the handpiece into the slot, slightly force the handpiece to ensure that it is in place; otherwise, wireless charging exception may occur.



Method 2: Wired charging: Use the power adapter to plug in the type C port to charge. When charging, the handle power light is orange, and it is turned off when full.



Note: When charging the base, you can put the handpiece into the slot and charge at the same time. It is normal for the base and handpiece to heat up slightly during charging. When the handpiece is placed in the base slot during wired charging, wireless charging will fail.



Warning

Charging should be keep away from heat sources.

7 Maintenance

7.1 Replace the battery

Replacement of the battery should use the original lithium battery provided by the manufacturer, please contact the local dealer or manufacturer for replacement.

Replacement steps:

- 1) Make sure the device is off.

- 2) Remove the silicone plug of the battery cover with forceps and remove the fixing screw with a screwdriver.
- 3) Remove the battery cover and remove the old battery.
- 4) Put the new battery into the battery compartment, turn it on, and ensure it is working properly.
- 5) Attach the battery cover, lock it with screws, and plug the silicone plug into the screw hole.



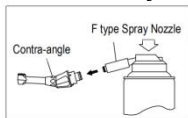
Warning!

- Do not disassemble parts that are not related to battery replacement.
- Do not replace the battery with wet hands, as this may cause the battery to short circuit and damage the device.
- Do not use lithium batteries other than the original, otherwise the device may be damaged.
- If the device is not used for a long time, the lithium battery should be removed.

7.2 Contra angle lubrication

To extend the life of the contra angle, it should be lubricated each time when the contra angle is used or sterilized.

- 1) Rotate the oil injector into the nozzle of the oil injector bottle



- 2) Insert the oil injector into the tail of the contra angle, and then inject the oil for 2~3 seconds until the lubricating oil flows out of the contra angle.
- 3) Leave the contra angle and tail upright for more than 30 minutes to drain excess lubricating oil by gravity.



Warning!

The motor handpiece cannot be filled with oil.



Note!

When filling oil, hold the Contra-angle tightly to prevent the Contra-angle from leaving the oil injector due to the oil injection pressure.

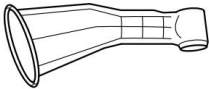
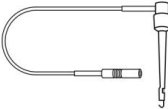
8 Troubleshooting

Failure status	Possible causes	Processing method
Motor calibration failed	1. The device is not fully charged 2. Excessive resistance of the contra angle	Charge the device to full capacity, or calibrate it while it is charging. Lubricate the contra angle
The motor handpiece heating	1. Excessive using under overload status 2. The reciprocating rotation is used for too long 3. While charging	Stop using it until the temperature of the handpiece returns to normal
Base heating	Use it for a long time While charging	Stop using it until the temperature returns to normal
The handle and base are not connected	Pairing failure The handle or base is faulty	Re-pair the Bluetooth Contact your local distributor or manufacturer
Battery life becomes shorter when fully charged	The battery capacity becomes smaller	Contact your local dealer or manufacturer to replace the battery
OVER LOAD	Current overload	Stop the motor, exit the root canal and activate it

If you do not find the information you need, you can contact the manufacturer through the following Hotline: +86-0660-6128899,
E-mail: sales@dental-perfect.com.

9 Cleaning, disinfection and sterilization

For hygiene and hygiene safety purposes, this appliance must be cleaned, disinfected, and sterilized before the first use and after each use to prevent cross-infection.

 Below Components can be sterilized with steam sterilization .	
Contra Angle 	Protective silicon cover 
Lip hook 	File clip 

Device	Contra-angle, File clip, lip hook and Protective silicon cover
Advice	The contra-angle, file clip, protective silicon cover and lip hook are reusable devices, and can be cleaning and disinfected with automated method. These parts can be sterilized with steam sterilization. Reprocessing procedures have only limited implications to these dental devices. 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.
Reprocessing Instructions	

Preparation at prior to processing:	Disconnect the Contra-angle, File clip, lip hook, Protective silicon cover from the motor handpiece. 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. Only Contra-angle, File clip, Lip hook and Protective silicon cover can be cleaned and disinfected with automated methods and sterilized with steam sterilization process. Do not sterilize the Motor Handpiece, adapter and base. The Motor Handpiece, adapter and base 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, file clip, protective silicon cover and lip hook:	After operation, take out the Motor Handpiece, adapter and base 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/DGHEM-listing, CE marking, FDA and Health Canada Approval. Wipe all surfaces of the handpiece, power adapter, base 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.
Pre-Cleaning of Contra-angle:	Following instructions are only relevant for Contra-angle, File clip, lip hook and Protective silicon cover! Do not use automated cleaning, disinfection and sterilisation for other parts than Contra-angle , File clip, lip hook and Protective silicon cover 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:	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. Automated Cleaning: Use a washer-disinfector meeting the requirements of the EN ISO 15883 series. Put the instrument into the machine on a tray. Connect the instrument with the WD and start the program: ● 4 min pre-washing with cold water(<40°C); ● emptying ● 5 min washing with a mild alkaline cleaner at 55°C ● emptying ● 3 min neutralising with warm water(>40°C); ● emptying ● 5 min intermediate rinsing with warm water(>40°C) ● Emptying The automated cleaning processes have been

	validated by using 0.5% neodisher MediClean forte(Dr. Weigert). Note Acc. to EN ISO17664 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 ISO 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 products. After cleaning and disinfection, a thorough inspection and maintenance ensures that the products are fit for use. - Check that the product has no dents, cracks, deformations, scratches or corrosion; - Check all markings on the product for clear visibility. Defective device should be immediately discarded. The defects include: material deformation and corrosion. 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. An CE-approved/legally marketed sterilization pouch should be used.
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) Drying time: For steam sterilization, we recommend a drying time of 20 to 40 minutes. Choose a suitable drying time, depending on the autoclave and load. Refer to the autoclave's instructions for use. After sterilization: - Remove the product from the autoclave. - 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.



Warning!

- Before each use, recommend use of a single-use isolation sleeve to wrap the handpiece, and then completely wrap the handpiece with a dental barrier film to ensure that the handpiece does not directly contact the patient's mouth during use.

A CE-cleared and legally marketed isolation sleeve and dental barrier film (similar products like: Snowdent) should be used to ensure compliance with infection control standards.

- Motor handpiece, Base, Measuring wire, Oil Injectors (Spray nozzle) and Adapter can not be sterilized with steam sterilization!

10 Disposal of products



! Do not dispose of the device in the household waste system. Dispose of waste in accordance with local laws and regulations.

11 Warranty

The device warranty for 12 months from the date of purchase by the user.

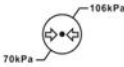
Shanwei Perfect Medical Instruments Co.,Ltd. and the cooperation partners for warranty service that authorized by Shanwei Perfect Medical Instruments Co.,Ltd. would provide the warranty service of the device and the other components, but Shanwei Perfect Medical Instruments Co.,Ltd does not provide technical data (such as circuit principles, component lists, drawing notes, calibration rules etc.) to other organizations.

The damage, failure or malfunction of the device which will be proved caused by the user daily maintenance with negligence according to the technical research and investigations from manufacturer, are not included within the warranty service content.

The unauthorized is not allowed to disassembly and repair the device.

Any warranty service requests of the device caused upon purposes and applications that are violated to the rules and instructions are not included within the warranty service content.

12 Symbol description

	Power switch		Dry storage
	Serial number		Air pressure restrictions for transport and storage
	Manufacturer		Humidity limits for transport and storage
	Date of manufacture		Temperature limits for transport and storage
	Class II equipment		Note, refer to the operating instructions
	Type B application section		Please refer to the instructions for using

	Warning, if not done properly, may endanger the user or the patient		Indoor use only
	Do not dispose of the device in the household waste system		Follow the instruction manual
	DC (power connection)		High temperature up to 134°C Steam sterilization
	AC power		Conformity European, Notified body number

13 EMC Information

Electromagnetic compatibility



Note!

- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

 - Reorient or relocate the receiving antenna.
 - Increase the separation between the equipment and receiver.
 - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
 - Consult the dealer or an experienced radio/TV technician for help.
- The device meets the electromagnetic compatibility requirements of

EN60601-1-2 standard.

- Users should install and use according to the electromagnetic compatibility information provided in the accompanying documents
- Portable and mobile RF communication equipment may affect the performance of this device, avoid strong electromagnetic interference when using it, such as near mobile phones, microwave ovens, etc.
- Please refer the attached for guidance and declaration of the manufacturer.



Warning!

- Any changes or modifications 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.
- This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
- The device should not be used in close proximity or stacked with other equipment. If they must be used in close proximity or stacked, they should be observed and verified to operate normally in the configuration they are used in;
- Except for cables sold as spare parts for internal components by manufacturers of the product, the use of accessories and cables outside of regulations may result in increased emissions or reduced immunity of the product;
- The use of unspecified accessories or cables with the device may result in increased emissions or reduced immunity of the device;
- The device may still be susceptible to interference from other equipment, even if such equipment complies with the applicable national standard emission requirements.
- The device does not have essential performance.
- * RF warning for Portable device:
- The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Name	Cable Length (m)	Shield/(Or Not)
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Power Adaptor Cable	1.5	No
Measuring Wire	1.3	Shield

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 product should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The device is suitable for used in domestic establishment and in establishment directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	

Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	
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Guidance & Declaration — electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that It is used in such environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast Transient IEC 61000-4-4	± 2 kV for power supply Lines ± 1 kV for input/output Lines 100 kHz repetition frequency	± 2 kV for power supply Lines Not applicable 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	$\pm 1\text{ kV}$ line(s) to line(s) $\pm 2\text{ kV}$ line(s) to earth	$\pm 1\text{ kV}$ line(s) to line(s) Not applicable	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	0%UT; 0,5 cycle At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° 0%UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0° 0%UT; 250/300 cycle	0%UT; 0,5 cycle At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° 0%UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0° 0%UT; 250/300 cycle	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 magnetic field (50/60Hz) IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U T is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity

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

Immunity test	IEC 60601 test	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V 150 kHz to 80 MHz 6V in ISM and amateur radio bands between 0.15 kHz and 80 MHz 80 % AM at 1 kHz 10 V 80 MHz – 2,7 GHz 80%	3 V 150 kHz to 80 MHz 6V in ISM and amateur radio bands between 0.15 kHz and 80 MHz 80 % AM at 1 kHz 10 V 80 MHz – 2,7 GHz 80% AM at 1 kHz	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. Recommended separation distance $d = [3,5 / \sqrt{P}] \times P^{1/2}$ $d = 1.2 \times P^{1/2}$ 80 MHz to 800 MHz $d = 2.3 \times P^{1/2}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the

	AM at 1 kHz		vicinity of equipment 
NOTE 1 At 80 MHz and 800 MHz. the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

- a Fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and ground mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts, cannot accurately predict their field strengths in theory. To assess the electromagnetic environment of fixed RF transmitters, consideration should be given to the investigation of electromagnetic sites. If the field strength of the location where the device is measured is higher than the applicable RF compliance level mentioned above, the device should be observed to verify its normal operation. If abnormal performance is observed, additional measures may be necessary, such as adjusting the direction or position of the device.
- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the model BR Touch.			
The device is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device is recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150kHz to 80MHz $d=1.2 \times P^{1/2}$	80MHz to 800MHz $d=1.2 \times P^{1/2}$	800MHz to 2,5GHz $d=2.3 \times P^{1/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For the rated maximum output power of transmitters not listed in the above table, it is recommended to isolate the distance d in meters (m), which can be determined by the formula in the corresponding transmitter frequency column. Here, P is the maximum output rated power of the transmitter provided by the transmitter manufacturer, in watts (W). Note 1: At the 80MHz and 800MHz frequency points, the formula for the higher frequency band is used. Note 2: The engineering and medical frequency bands between 150kHz and 80MHz refer to 6.765MHz to 6.795MHz, 13.553MHz to 13.567MHz, 26.957MHz to 27.283MHz, and 40.66MHz to 40.70MHz. Note 3: The additional factor of $10/3$ is used to calculate the recommended isolation distance for transmitters in the engineering and medical frequency			

bands of 150kHz to 80MHz and the frequency range of 80MHz to 2.5GHz, in order to reduce the possibility of interference caused by portable/mobile radio frequency communication equipment accidentally brought into the patient's area.

Note 4: These guidelines may not be suitable for all situations.

Electromagnetic propagation is influenced by the absorption and reflection of buildings, objects, and the human body.

14 EU Declaration of Conformity

Hereby, Shanwei Perfect Medical Instruments Co.,Ltd. declares that the radio equipment type: EndoMaster is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address: www.dental-perfect.com

This information will be made available in an official language of the European Union requested by the Member State where the product is marketed.

- Product name: Endo motor & Apex Locator
- Model NO.: EndoMaster

- Bluetooth Module Specifications:
- Bluetooth Version: BLE 4.2
- Type: 2.4 GHz wireless communication
- Transmission/Reception Frequency band: 2402~2480 MHz
- Modulation Type: GFSK
- Frequency Characteristics: Frequency-Hopping Spread Spectrum
- Maximum output Power: 0 dBm



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