

Wave Q

ENDO ACTIVATE DEVICE

INSTRUCTION MANUAL

Please read this manual before operation

CONTENTS

1	Product introduction	02
2	Contraindications	02
3	Precautions	03
4	Device description and accessories list	04
5	Installation	05
6	Equipment function and use	07
7	Maintenance	08
8	Troubleshooting	09
9	Cleaning, Disinfection, Sterilization	10
10	Disposal of waste products	11
11	Warranty	11
12	Symbol	12
13	EMC Information	13
14	Contact	18

1.Product introduction

Wave Q is specially designed Endo activate device for dentists. With the working tip, the flushing solution is activated through the vibration of the working tip to achieve the purpose of cleaning the root canal.

1.1 Scope of application

It should only be used by a qualified dentist in a hospital or dental clinic, applying for root canal washing in root canal treatment.

1.2 Product Introduction

- ① Small size, light weight, good hand feeling
- ② The contra angle is removable
- ③ The vibration amplitude is optional in 3 gears, which can be selected according to the use case.

1.3 Terms

- contra angle: Wave Q The detachable head of Wave Q is in the shape of an contra angle and transmits the oscillations of the working tip.
- Working tip:The working tip is an accessory that is used with the root canal washer and is installed at the contra angle. It is the working part of the root canal washer when working.

2.Contraindications

- a. The dentists with heart pacemaker are forbidden to use this device.
- b. Patients with pacemakers (or other electrical equipment) who are warned not to use small household appliances (such as electric shavers, hair dryers, etc.) are forbidden to use this device.
- c. The patient with hemophilia is forbidden to use this device.
- d. Heart disease patients, pregnant women and children should be cautious to use the equipment.
- e. People who are allergic to Silicone and POM plastic

3.Precautions

- Please Read this instruction manual carefully before using the device.
- It should only be used by a qualified dentist in a hospital or dental clinic
- This device can only be used with its accompanying working tips, do not use any other brand working tips.
- Patients cannot use this device on their own.
- This device can only be used with its accompanying accessories, do not use any other power adapter, contra angle, lithium battery, etc.
- Wrong replacement of the lithium battery will lead to unacceptable risks, please do not replace the lithium battery by yourself.
- Do not disassemble or repair the equipment by yourself, any self-disassembly and maintenance may violate safety regulations and cause injury to patients. Any self-dismantling and repair will not be warranted.
- Warning: Not allow the modification of this device, do not modify this device
 without the manufacturer's authorization, if you modify this equipment, be sure to
 carry out appropriate inspection and testing to ensure that the equipment can
 continue to be used safely.
- Do not remove or rotate the contra angle during use, in case damaging it.
- Do not remove the working tip during its working in case hurting user.
- Make sure the working tip is in the correct place and installed tightly before use.
- Keep the device away from 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, such as close to mobile phones, microwave ovens, etc.
- Do not place this device near a heat source. The device must be operated and stored in a reliable environment.
- Environmental parameters for the device: Temperature: +10°C ~ +40°C Humidity: 30% ~ 75%
- Air pressure: 70kPa ~ 106kPa
- This device should be sterilized and disinfected after the first use and after use by the patient to avoid cross-infection.
- The motor hand-piece part is not allow the high temperature autoclave sterilization, only neutral disinfectant or alcohol can be used to wipe the surface. Please refer to the content of cleaning, disinfection and sterilization for details.

4.Device description and accessories list

4.1 Product components

1.Main unit

2.contra angle





3.Adapter

4.working tip (specification refers to 5.2.3)





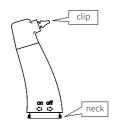
4.2 Technical Index

Manufacturers ¦	ShenzhenPerfect Medical Instruments Co.,Ltd.
Model Number ¦	Wave Q
Device Dimension	147*26*26mm
Weight :	60±2g
Battery capacity :	3.7V/800mAh lithium battery
Output power supply :	5V DC, 2A
Input power supply	AC100-240~50/60Hz
Classification :	Class II equipment with internal power supply
Applied part	BF type applied part: contra angle, working tip Applied part contact duration: 1~2mins
Applied part ;	contra angle: Plastic and silicone Working tip: POM plastic
Operating condition	Temperature:+10°C - +40°C Humidity:30% - 75% Air pressure:70kPa - 106kPa
Storage and transport condition	Temperature:-10°C- +50°C Humidity:10% - 85% Air pressure:70kPa - 106kPa

03

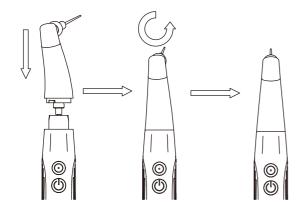
5.Installation

5.1 Installation and disassembly for contra angle



5.1.1 Installation

Align the card slot of the contra angle with the positioning slot on the Motor hand-piece, push the contra angle horizontally, rotate the contra angle counterclockwise, about 30 degrees until hearing the "click", indicating that the contra angle has been installed into the Motor hand-piece, at the same time, shake the buckle of the contra angle head, if it can be operated normally, it means that the contra angle has been installed in place, otherwise it needs to be reinstalled.

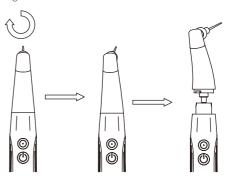


WARNING

Contra angle installation must be in place, otherwise abnormal work or overload alarm may occur

5.1.2 Disassembly

Turn the contra angle to the end



WARNING

When installing and removing the contra angle, the motor needs to be shut down so that it is not running

5.2 Installation and disassembly of working tips

WARNING

Use the manufacturer's working tips for matching the machine

5.2.1 Installation of working tips

Insert the working tip into the buckle of the contra angle and press it firmly



5.2.2 Disassembly of working tips

Pull out the working tip directly

5.2.3 Three specifications of the attached working tip are as follows

specification	I I	Taper
3504		0.04
2504		0.04
2002	1	0.02



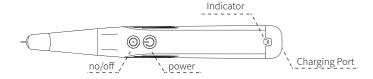
WARNING

When installing and disassembling the working tip, it is necessary to close the motor so that it is not in running state, to avoid damaging user.

Please use the working tip that matches this product. The company's matching work tip is for single - use which must be disinfected before use.

6.Equipment function and use

6.1 Buttons and setting



6.2 Power on and off

Long press the power "" to turn on the Motor hand-piece. The indicator is steady on in white.

Under ON state, long press power "" to shut down the Motor hand-piece. The indicator goes out.

Note: The device will automatically shut down after 3 minutes without any operation.

6.3 Motor on and off

Under ON state, short press "O" to start the motor. The working tip starts to work, and press "@" again, it will stop working.

6.4 Gear adjustment

Under ON state, Short press the power "" to shift ,gear adjustment to 1 -2 -3 gear cycle. At the same time, the corresponding gear light is on, 1 light in 1st gear, 2 lights in 2nd gear and 3 lights in 3rd gear.

6.5 Motor overload

When the contra angle is not assembled in place, or the motor is stuck or the current is too large, the motor will warning for overload, In the meanwhile, the gear light will blink, and the power light will blink red.

6.6 Low battery warning

When the battery is low, the indicator is steady red. Please charge the battery in time.

6.7 Charging

This product has a built-in rechargeable lithium battery. Insert the power adapter into the charging port at the bottom of the handle, and the device will enter the charging

While charging, the indicator is steady on in pink, and the device automatically enters the ON state.

When fully charged, the indicator is steady on in green. Remove the power adapter when fully charged.



WARNING

Away from the heat sources while charging.

7. Maintenance

7.1 Battery replacement

The battery should be replaced with the lithium battery provided by the manufacturer, please contact the local dealer or manufacturer for replacement.

Replacement steps:

- 1) Ensure that the device is powered off
- 2) Remove the battery cover clasp with tweezers
- 3) Remove the battery cover and remove the old battery
- 4) Put the new battery in and power on to make sure it works
- 5) Install the battery cover and fasten the buckle



- Do not remove parts unrelated to battery replacement.
- Do not replace the battery with wet hands; otherwise, the battery may be short-circuiting and the device may be damaged.
- Do not use lithium batteries other than those from the original factory.
- Otherwise, the device may be damaged.
- If the device is not in use for a long time, take out the lithium battery.

8.Troubleshooting

Fault	Cause	Solution
Motor shut down	Low battery power Aging contra angle, excessive resistance	Charge the device Change the contra angle
Motor hand-piece heats up	It has been used for too long under overload	Shut down the service and enable it till the motor hand-piece temperature recovers
The service time after each charging is shortened	The battery ages and the battery capacity become smaller	Contact local distributor or manufacturer to buy new batteries for replacement
After starting, the motor does not work, and the gear light blinks and the power light blinks red	1.Motor overload mode 2.Motor damaged 3.contra angle not fitted in place	1.Check if the motor is stuck. 2.Contact local distributor or manufacturer to buy new product or motor hand-piece. 3.Remove contra angle and reassemble

If the problem still cannot be solved, please contact with the manufacturer by Phone: +86(0755) 28540953 Email: sales@dental-perfect.com 9. Cleaning, Disinfection, Sterilization

9.1Cleaning, Disinfection and Sterilization for the contra angle

For hygiene and health safety purposes, the contra angle must be cleaned, disinfected and sterilized before first use and after each use to prevent cross infection.

Parts need to be steam sterilized at 135°C

Contra angle





The above parts can be sterilized by high temperature steam

Cleaning: Use a soft brush to thoroughly rinse the components under running water to remove visible contaminants. Clean all components using a soft cloth dampened with a mild aldehyde-free cleaning solution. Wash the components under running water, then wipe dry. Use a three-way syringe to blow off residual water in the components.

Disinfection: Use a gauze soaked in alcohol (70-80vol% alcohol) to wipe the parts five times for 2 minutes each time.

Package: The contra angle shall be packed in special high-temperature steam sterilization bag according to EN 868-5.

sterilization: be autoclaved under high temperature of 134°C and high pressure of 0.22MPa.

Dry for at least 8 minutes after sterilization

Storage: After sterilization, the contra angle should be packaged in a medical sterilization bag, and stored in a dry and clean place. Before use, check the integrity of the package, and within the specified validity period of the sterilized bag.



WARNING

- 1. Please comply with relevant regulations for disinfection and sterilization. The company's matching work tip is for single use . Must be disinfected before use.
- 2. Be cautious during maintenance for cross infection
- 3. High temperature vapor sterilization must be carried out before the first use and after each use.
- 4. The contra angle can be repeated sterilization times at least 250 cycles.
- 5. The service life of the contra angle is 1 year. It also varies with the frequency and time of clinical use and affected with the complexity of the patient's oral root canal treatment.

09

9.2Cleaning and Disinfection for motor hand-piece handle

Use a gauze soaked in alcohol (70-80vol% alcohol) to wipe the surface



WARNING!

- 1, Do not use disinfectants other than alcohol to disinfect.
- 2. Do not use excessive alcohol to avoid alcohol infiltration and damage to components.
- 3. Disinfect before first use and after each use

10.Disposal of waste products



Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.

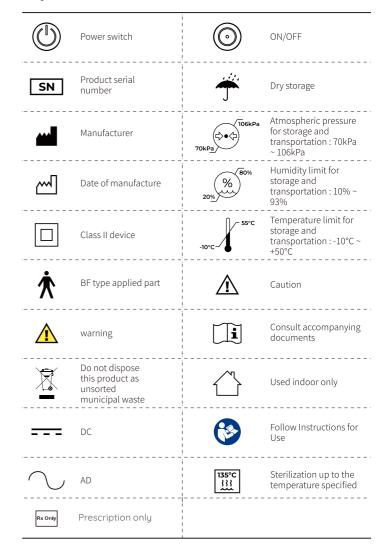
11.Warranty

1. The device is warranted for 12 months from the date of purchase.

The motor hand-piece and other components of this product shall be repaired by Shen Zhen Perfect Medical Instruments Co., Ltd. or the maintenance service partners authorized by Shen Zhen Perfect Medical Instruments Co., Ltd. The company does not provide maintenance materials such as circuit diagram, component list, drawing notes and correction rules for other organizations.

- 2. If the damage is proved to be caused by the user's negligence in daily maintenance, it is not covered by the warranty.
- 3. Disassembly and repair by unauthorized personnel.
- 4. Use of the product for a purpose or use contrary to the specific provisions in these Instructions of Use will not be covered by the warranty.
- 5. See below table for the schematic diagram of the device

12.Symbol



13.EMC information

Electromagnetic compatibility



!\ Caution

1)Wave Q complies with electromagnetic compatibility requirements of IEC60601-1 standard.;

2)The user shall install and use according to the EMC information provided in the accompanying file;

3) Portable and mobile RF communication devices may affect the performance of Wave Q. Avoid strong electromagnetic interference when using, such as close to the motor hand-piece, microwave oven, etc.

4) The guidelines and manufacturer's statement as attached.



Warnings

1) Wave Q should not be used in close proximity to or stacked with other devices. If it must be used in close proximity or stacked, it should be observed to verify that it can operate normally under the configuration used;

2) Except for the cables sold as spare parts for internal components by the manufacturer of Wave O, the use of other accessories and cables may result in increased emission or reduced immunity of Wave Q.

Name	i	cable length (m)	i	Whether to block
Adapter cable		1.5	i	yes

Guidance and manufacturer's declaration - electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions GB 4824	Group 1	Wave Q 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 GB 4824	Class B	
Harmonic emissions GB 17625.1	Class A	Wave Q is suitable for used in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions GB 17625.2	Complies	

Guidance & Declaration — electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance	
Electrostatic discharge GB/T 17626.2	±6 kV contact ±8 kV air	±6 kV contact ±8 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/burst GB/T 17626.4	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment Mains power quality should be that of a typical commercial or hospital environment. If the user of the models Wave Q requires continued operation during power mains interruptions, it is recommended that the models Wave Q be powered from an uninterruptible power supply or a battery	
Surge GB/T 17626.5	±1 kV line to line ±2 kV line to earth	±1 kV line to line		
Voltage dips, short interruptions and voltage variations on power supply input lines GB/T 17626.11	<5 % UT, for 0.5 cycle (>95% dip in UT,) 40 % UT, for 5 cycles (60% dip in UT) 70 % UT, for 25 cycles (30% dip in UT) <5 % UT, for 5s (>95% dip in UT)	<5 % UT, for 0.5 cycle (>95% dip in UT,) 40 % UT, for 5 cycles (60% dip in UT) 70 % UT, for 25 cycles (30% dip in UT) <5 % UT, for 5s (>95% dip in UT)		
Power frequency Magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m,50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.	

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Guidance & Declaration - Electromagnetic immunity

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

Immunity test	IEC 60601 test	Compliance level	Electromagnetic environment - guidance
Conducted RF GB/T 17626.6	3 V 150 kHz∼80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the models Wave Q, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2.\(\int_{0}\) F80 MHz \(\times 800\) MHz d=2.3.\(\int_{0}\) F80 MHz \(\times 20.5\) GHz
Radiated RF GB/T 17626.3	3 V/m 80 MHz∼2.5 GHz	3V/m	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. Interference may occur In the vicinity of equipment marked with the following symbol:

NOTE I At 80 MHz end 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 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 model Wave Q is used exceeds the applicable RF compliance level above, the model Wave Q should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model Wave Q. 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 Wave Q

The model Wave Q is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model Wave Q can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model Wave Q as recommended below, according to the maximum output power of the communications equipment.

maximum output power	Separation distance according to frequency of transmitter/m				
of transmitter W	$ \begin{array}{ c c c c c c }\hline 150 \text{ kHz} \sim 80 \text{ MHz} & 80 \text{ MHz} \sim 800 \text{ MHz} \\ \text{d} = 1.2 \sqrt{p} & \text{d} = 1.2 \sqrt{p} \\ \hline \end{array} $		8800 MHz \sim 2.5 GHz d = 2.3 \sqrt{p}		
0.01	0.12	0.12	0.23		
0.1	0.38	0.38	0.73		
1	1.2	1.2	2.3		
10	3.8	3.8	7.3		
100	12	12	23		

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accord-able to the transmitter manufacturer.

NOTE I: At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

NOTE 2: The engineering medical band between 150kHz and 80MHz is referred to 6.765MHz \sim 6.795MHz, 13.553MHz \sim 13.567MHz, 26.957MHz \sim 27.283MHz and 40.66MHz \sim 40.70MHz $_{\circ}$

NOTE 3: The additional factor 10/3 is used to calculate the recommended isolation distance for transmitters in the engineering medical band of 150kHz to 80MHz and in the frequency range of 80MHz to 2.5GHz to reduce the possibility of interference if portable/mobile RF communication equipment is accidentally brought into the patient area.

NOTE 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Wave Q



Shenzhen Perfect Medical Instruments Co., Ltd.

Add: Room 103, Building 3, No. 2, Weiqun Road, 4th Community, Henggang Street, Longgang District, Shenzhen, 518115 Guangdong P.R.China

Tel:+86(0755) 28540953

Fax:+86(0755) 28540953

Website: www.dental-perfect.com Email: sales@dental-perfect.com

US Agent

Regrek LLC 19 Holly Cove Ln. Dover, Delaware, 19901, UNITED STATES

> Version: 01 PF08-IFUE-01 Issued: 2023.5.31

Copyright: Shenzhen Perfect Medical Instruments Co., Ltd.