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COXO®



Foshan COXO Medical Instrument Co., Ltd.

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Lotus NL B.V.

Koningin Julianaplein 10, 1e verd, 2595AA, Thi Hague, Netherlands. E-mail:peter@lotusnl.com Endo Motors
Model: C-Smart-I

Pilot

Manual

((



Introduction

Thank you for purchasing the instrument.

For optimum safety and performance, read this manual thoroughly before using the instrument and pay close attention to warning and notes.

Keep this manual in a handy place for quickly and easy reference.

Notice

The trademarks mentioned in this manual are the property of their legally registered companies.

The file manufacturers file system names and the file names quoted in this manual are for identification purposes only and are the property of their respective manufacturer or brands.



Recommended separation distances between portable and mobile RF communications instrument and the instrument.

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

Rated maximum output	Separation distance according to frequency of transmitter			
power of transmitter	150 kHz to 80 MHz 80 MHz to 800 80 MHz to 800 MHz			
(W)	d=1.2×P ^{1/2}	MHZ	d=2.3×	
		d=1.2×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 transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

Immunity	IEC 60601 test	Compliance level	Electromagnetic environment - guidance
test	level		
Conducted	3 Vrms	3 Vrms	Portable and mobile RF communications
RF	150 kHz to 80	150 kHz to 80 MHz	instrument should be used no closer to
IEC61000-4	MHz	6 Vrms in ISM	any part of the instrument, including
-6	6 Vrms in ISM	and amateur	cables, than the recommended separation
	and amateur	radio bands 3 V/m,	distance calculated from the equation
	radio bands 3	10 V/m	applicable to the frequency of the
	V/m, 10 V/m	80 MHz to 2.7	transmitter.
	80 MHz to 2.7	GHz	Recommended separation distance
	GHz		d=[3,5/V1]×P1/2 d=1.2×P ^{1/2} 80 MHz to
Radiated			800 MHz
RF			d=1.2×P ^{1/2} 800 MHz to 2,7 GHz
IEC			Where the maximum is output power
61000-4-3	385MHz-5785M	385MHz-	rating of the transmitter in watts (W)
	Hz Test	5785MHz Test	according to the transmitter manufacturer
	specifications for	specifications for	and d is the recommended separation
	ENCLOSUREP	ENCLOSUREPOR	distance in meters (m).
	ORT IMMUNITY	T IMMUNITY to RF	Field strengths from fixed RF transmitters,
	to RF wireless	wireless	as determined by an electromagnetic site
	communication	communication	survey, ^a should be less than the
	instrument(Refer	instrument(Refer to	compliance level in each frequency
	to table 9of IEC	table 9 of	range. ^b
	60601-1-2:2014)	IEC60601-1-2:201	Interference may occur in the vicinity of
		4)	instrument marked with the following
			symbol:

NOTE 1At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2These guidelines may not apply in all situations. Electromagnetic affected by absorption and reflection from structures, objects and people.

propagation is

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

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

Guidance and manufacture's declaration - electromagnetic immunity

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

Immunity	IEC 60601 test	Compliance level	Electromagnetic environment - guidance
test	level		
Electrostatic discharge (ESD)IEC 61000-4-2 Electrical fast transient/bu rst IEC 61000-4-4 Surge IEC	±8 kV contact ±2 kV, ±4 kV,±8kV,±15 kV air ±2kV for power supply lines ±1 kV for Input/output lines ±0.5 kV, ±1 kV	±8 kV contact ±2 kV, ±4 kV,±8kV, ±15 kV air ±2kV for power supply lines ±1 kV for Input/output lines ±0.5 kV, ±1 kV	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. Mains power quality should be that of atypical commercial or hospital environment. Mains power quality should be that of a
61000-4-5	line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	line to line	typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variationson power supply input lines IEC 61000-4-11	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95 % dip in UT) for 5/6 sec	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95 % dip in UT) for 5/6 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the instrument requires continued operation during power mains interruptions, it is recommended that the instrument be powered from a underuptible power supply or a battery.
Power frequency(5 0/60 Hz)magneti c field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospite environment.

NOTE:U_T is the a.C mains voltage prior to application of the test level.

Guidance and manufacture's declaration - electromagnetic immunity

1. User guide

1.1 Requirement

Read these instructions prior to first time use in order to avoid misuse and prevent damage.

Hazard levels

The warning caution and safety notes in this document must be observed to prevent personal injury and damage to the instrument. The warnings are as follow:



/I\ WARNING:

In cases which – if not prevented – could lead to death or severe injury.



CAUTION:

If not heeded could lead to minor or moderate injury.



NOTE:

In cases which – if not prevented – could cause damage to the instrument.

1.2 Target Reader

This document is intended for dentists, dental clinic workers, and service agents.

1.3 Repair service

For repairs, please contact the manufacturer or authorized dealers.

1.4 Terms and conditions of warranty

Within the scope of the applicable manufacturer delivery and payment conditions, the manufacturer guarantees proper function, absence of defects in the instrument for a period of 24 months from the date of purchase. The date of purchase should be confirmed by the salesperson.

1.4.1 Disclaimer

Manufacturer will not be responsible for accidents, instrument damage, or bodily injury resulting from:

- Repairs made by personnel not authorized by the manufacturer.
- · Any changes, modifications, or alterations of its products.
- The use of any products or instruments made by other manufacturers which are not included as approved by the manufacturer.
- Maintenance or repairs using parts or components other than those specified by the manufacturer and any alterations from original condition of the instrument.
- Operating the instrument in ways other than the operating procedures described in this manual or resulting from the safety precautions and warnings in this manual not being



observed.

- Workplace conditions and environment or installation conditions which do not conform to those stated in this manual such as improper electrical power supply.
- Fires, earthquakes, floods, lightning, natural disasters, or any other unforeseeable forces.

1.4.2 In case of accident

If an accident occurs, the instrument must not be used until repairs have been completed by a qualified and trained technician authorized by the manufacturer.

1.4.3 User qualifications

Intended Operator Profile

- Qualification: Legally qualified person such as dentists for endodontic instrument operation (it may differs among countries).
- Education and Knowledge: It is assumed the user is thoroughly familiar with root canal measuring and treatment including the prevention of cross contamination.
- · Language Understanding: English (Intended for professional use as described above).
- Experience: Experienced person in operating with an endodontic instrument.

1.5 Operating ,Transport and Storage conditions

Operating:

Temperature: 5°C to 40°C Humidity: 20%RH to 80%RH

Atmospheric pressure: 86kPa to 106kPa

Transport and Storage:

Temperature: -10°C to 55°C

Humidity: ≤ 93%RH(without condensation) Atmospheric pressure: 50 kPa to 106 kPa

1.6 Disposal of medical instruments



In accordance with the principles, standards, and requirements of the country (region) in which you are located. When disposing of the old electrical instrument ensure that pollution is not produced in the process of waste disposal.

14. Guarantee

Product and technical services are in charge of our company, the technical department will provide technical support for you when there are technical problems.

The control unit and motor handpiece guaranteed for 24 months from the date of purchase.

- The accessories (adaptor, contra-angle, file clip and so on) are guaranteed for 6 months.
- The guarantee is valid for normal usage conditions. Any modification or accidental damage will render the guarantee void.

15. Guidance and manufacturer's declaration--EMC:

This instrument needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this instrument can be affected by portable and mobile RF communications instrument.

Caution:

Do not use mobile phone or other instruments that emit electromagnetic fields, near the instrument. This may result in incorrect operation of the instrument.

This instrument has been thoroughly tested and inspected to assure proper performance and operation! This instrument should not be used adjacent to or stacked with other instrument and that if adjacent or stacked use is necessary, this instrument should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacture's declaration – electromagnetic emission				
The instrument is intended for use in the electromagnetic environment specified below. The customer				
or the user of the instru	or the user of the instrument should assure that it is used in such an environment.			
Emission test	Emission test Compliance Electromagnetic environment – guidance			
RF emissions	Group 1	The instrument use RF energy only for its internal function.		
CISPR 11		Therefore, its RF emissions are very low and are not likely to		
		cause any interference in nearby electronic instrument.		
RF emission	Class B	The instrument is suitable for use in all establishments,		
CISPR 11		including domestic establishments directly connected to the		
Harmonic emissions	Class A	public low-voltage power supply network with specific		
IEC 61000-3-2		requirement.		
Voltage	Complies			
fluctuations/flicker				
emissions				
IEC 61000-3-3				



	Auto reverse is not set	Turn on the auto reverse
Motor stops automatically	The load is too large to exceed the maximum output of the instrument	Manually release the load
Handpiece	LED light is not turned on	Turn on the LED light on the settings page
LED is not light	LED light is damaged	Contact the dealer
Calibration	The motor is under resistance	Reconnect the contra-angle
failed	Contra-angle is damaged	Contact the dealer

13. Symbols

$\overline{\mathbb{V}}$	Warning/ Caution	i	Note
134°C	Autoclave	•••	Manufacturer
EC REP	European union agent	SN	Serial number
†	Type B applied part	Ť	Keep dry
C € ₀₁₉₇	CE marked product	Ţ	Fragile
<u>††</u>	Vertical up		Direct current
X	Special disposal of waste electrical and electronic equipment (Directive2002/96/EE C)	③	Follow instruction for use
	Class II product	ĭ	Thermo-disinfector
▶:■	Start/Stop button	APEX	Apex indicator
(N)	Battery indicator	*	Bluetooth indicator
Ф	Handpiece power button	REF	Catalogue number
LOT	Batch code		Indoor use
~	Alternating Current	(((•)))	Bluetooth Wireless Device

2. Safety

The instructions for use are a component of the product and must be read carefully prior to use and be accessible at all times.

The instrument may only be used in accordance with the intended use; any other type of use is not permitted.

2.1 Infection hazard

Patients, users, or third parties could be infected by contaminated medical instruments.

- · Take suitable personal protective measures.
- · Follow the instructions for using the components.
- Before and after each use, reprocess and sterilize the medical instrument and accessories accordingly.
- · Carry out the cleaning and sterilization as described in the instructions for use.
- The procedure has been validated by the manufacturer.
- It is essential to ensure the effectiveness of the cleaning and sterilization in the case of deviation in procedure.
- Prior to disposal, the product and accessories must be appropriately reprocessed or sterilized.

2.2 Explosion hazard area

Electrical sparks in the product can lead to explosion or fire.

- · Do not use product in explosive hazardous areas.
- Do not operate the product in an oxygen-enriched environment.
- · Do not use the product near the vicinity of flammable gases.

2.3 Technical condition

A damaged instrument or components could injure patients, users, and third parties. A damaged power cable or missing protective conductor can lead to electrical shock.

- Only operate instruments or components if they are undamaged on the outside.
- · Check the power cable before use.
- Connect only to sockets with a protective contact that meet the respective national regulations.
- Check the proper working order and proper condition of product and accessories before each use.
- Have parts with sites of breakage or surface changes checked by authorized service personnel.
- Safety checks may only be performed by trained service personnel.

2.4 Ingress of liquids

Use of the product in moist or electrically conductive environments can lead to electrical shock and injury to patients, users, and third parties.

- Only use the product in dry environments.
- Use the product only in environments that are not electrically conductive.
- · Prevent liquid from entering the openings of the product.
- Do not place the product in long or narrow containers.
- If any liquid is detected on the instrument, disconnect the power cable immediately and do not touch the product.
- Make sure that the surface of the product is absolutely dry before plugging the power cable back into the socket.
- After interventions on and repairs of the instrument and before re-use, have the service personnel perform safety checks on the instrument.

2.5 Accessories and combinations with other instrument

Use of unauthorized accessories or unauthorized modifications of the instrument could lead to injury.

- Only use accessories that have been approved for combination with the product by the manufacturer.
- Only use accessories that are equipped with standardized interfaces.
- Do not make any modifications to the instrument unless these have been approved by the manufacturer of the product.

2.6 Electromagnetic fields

Electromagnetic fields might interfere with the functions of implanted systems (such as pacemakers).

Medical electrical instruments are subject to special precautions regarding electromagnetic compatibility and must be installed and operated in accordance with the tables of electromagnetic compatibility. About electromagnetic compatibility refer to "15.EMC" High-frequency communications instruments may interfere with medical electrical instruments.

- Ask patients if they have a cardiac pacemaker or other system implanted before you start the treatment.
- Comply with the tables of electromagnetic compatibility during installation and commissioning.
- If the instrument needs to be used in the immediate vicinity of other instrument, monitor the instrument or system for malfunctions.

2.7 Contra-angle

- · Only use the original contra-angle.
- Never press the contra-angle push button when handpiece is running. It will cause the file to fall off.
- Never remove the contra-angle during operation.
- Only use undamaged root canal instruments, refer to "6.4 Check apex locator function".

Functional Testing, Maintenance:	Visual inspection for cleanliness of the instruments and reassembling. Functional testing according to instructions of use. If necessary, perform reprocessing process again until instrument is visibly clean. Defective accessories should be immediately discarded. The defects include: plastic deformation and corrosion Maintenance is not required. Instruments oil must not be used
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. Minimal requirements: 3 min at 134 °C In EU, 5 min at 134 °C is required. Maximal sterilization temperature: 137°C
Storage:	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures refer to label and instructions for use.
Reprocessing validation study information	The above-mentioned reprocessing process (cleaning, disinfection sterilization) has been successfully validated.

Additional Instructions: None

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.

12. Troubleshooting

Malfunction	Cause	Remedy
Cannot turn on	The battery is low	Please charge in time
the power	Battery failure	Replace the battery
Cannot charge	The adapter does not fit	Check if it is the original adapter
the battery	Battery failure	Replacement battery
	Test wire connection unreliable	Reconnect the test wire or you can contact the file clip to lip hook directly to check the connection status
Apex locator imprecise/ not sensitive	The test wire has an open circuit or a short circuit	Replace test wire
	The root canal is in poor condition	Refer to "7.3EMR"
	Low voltage protection	Please charge in time
Cannot start the motor/	Contra-angle stuck	Clean or replace the contra-angle
motor does not work	Handpiece failure	Replace handpiece
	Control unit failure	Contact the dealer



Decontamination of other parts than Contra- angle , File clip ,Lip hook :	After operation, take out the Motor handpiece and AC adapter on the work bench Soak a soft cloth completely with distilled water or deionized water, Decontamination and wipe all the surfaces of these components, until the surface of the parts the components is visually clean For decontamination, soak a dry soft cloth with 75% alcohol or other contra-angle, File clip, disinfects which are approved for its efficacy by VAH/DGHM-LISTING-Lip hook and CE marking, FDA and Health Canada Approval lighting device: Wipe all surfaces of Motor handpiece, AC adapter and other components with the wet soft cloth for about 3 minutes. Please follow the instructions of manufacturer of disinfectant swipe the surface of the component with a dry soft lint-free cloth	
Pre-Cleaning:	Following instruction are only relevant for Contra-angle, File clip and Lip hook! Not use automated cleaning, disinfection and sterilization for other parts than Contra-angle, File clip and Lip hook 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 surface with a soft bristol brush	
Cleaning:	Clean the surface with a soft bristol brush. 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 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: 4 min pre-washing with cold water (<40°C) emptying 5 min washing with a mild alkaline cleaner at 55°C emptying 3 min neutralizing with warm water (>40°C) emptying 5 min intermediate rinsing with warm water (>40°C) Emptying The automated cleaning processes have been validated by using0. 5% neodisher MediClean forte (Dr Weigert) Note Acc to en ISO 17664 no manual reprocessing methods are required for these devices. If a manual reprocessing method has to be used, please validate it prior to use	
Disinfection:	Automated Disinfection: Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0-Value (see EN 15883). A disinfection cycle of 5 min disinfection at 93°C has been validated for the device to achieve an A0 value of 3000.	
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	

- Never place your fingers on the moving parts of the instrument while it is running.
- Before use, check the contra-angle for any damage or loose part.

2.8 Root canal instruments

- Never use continuous rotary instruments in reciprocating mode.
- Never use reciprocating instruments in rotary mode.
- Refer to the file manufacturer's instructions to adjust the speed and torque.

3. Description of the product

Endo Motor products are mainly used in dental root canal preparation is used for each model pulpit and pulp necrosis and various root tooth root canal treatment of important instrument.

3.1 Intended use

The Endo Motors device is an endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge the canals while monitoring the position of the file tip inside the canal.

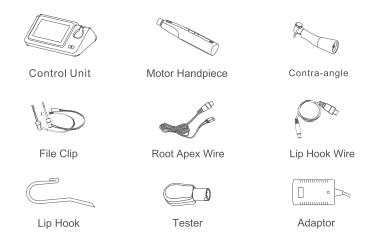
The instrument must only be used in hospital environments, clinics or dental offices, by qualified practitioners.

3.2 Contraindications

- In cases where a patient has been fitted with an implanted heart pacemaker (or other
 electrical equipment) and has been cautioned against the use of small electrical
 appliances (such as electric shavers, hair dryers, etc) it is recommended not to use the
 instrument.
- Safety and effectiveness have not been established in pregnant women and children.
- · Clinical judgment needs to be applied by the end user of the device.

3.3 Instrument overview

3.3.1 Components and accessories





If the accessories of this product are damaged, please purchase original accessories and replace and use them according to the instructions.

- Slide the built-in electrode onto the guide bar and line up the screw whole.
- Slowly turn the screw and make sure the built-in electrode goes into the head properly.
- Tighten the screw securely and then hold down the push button and pull out the guide bar.

MARNING:

Make sure screws are firm enough; otherwise it will cause claw and parts of the holder to loosen, causing rotation failure or inaccurate measurement



11. Cleaning, Disinfection and Sterilization

Device:	Contra angle, File clip, Lip hook and Motor handpiece. The procedure for cleaning, disinfection and sterilization applies only to the accessories Contra angle, File clip, and Lip hook.
ADVICE:	Reprocessing procedures have only limited implications to a surgical instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device. There is no limit of maximum allowable reprocessing cycles. 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 Instr	
Preparation at the Point of Use:	Disconnect the Contra angle from handpiece, the File clip from the test wire and the Lip hook. 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.
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 and Lip hook can be cleaned and disinfected with automated methods and sterilized with steam sterilization process. Do not sterilize the Motor handpiece and AC adapter. The Motor handpiece and AC adapter cannot be cleaned and disinfected in a washer/disinfector. For these parts, only a general wipe decontamination is possible!





CAUTION:

- · Only use original battery
- · Do not use a battery if it is leaking, deformed, discolored or if its label is peeled off. It might overheat



NOTE

- Turn off power before replacing the battery
- Avoid opening the rubber cover too hard
- Do not remove the battery cover if the handpiece is wet
- Do not tighten the cover screw too much. This could strip the threads
- · Dispose of old batteries in an environmentally safe way and in strict according to local regulations

10.3 Lubrication

- · Remove the contra-angle from handpiece.
- Mount the tip nozzle into the spray can port and align the nozzle to the contra-angle, Spray lubricating oil into contra-angle until clean liquid flows out.





- When the head overflows with clean liquid, the entire cleaning and maintenance steps should be repeated
- It is recommended to inject lubricating oil before sterilization

10.4 Replacing file electrode

In the multi-function mode, the root canal indicator bar flashes or the indicator bar does not light up when the file touches the opposite electrode, and the problem cannot be solved after cleaning the rotor axle and the built-in electrode. The built-in electrode is worn out and the following steps must be followed replace with new electrode.

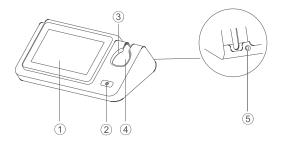
- Loosen the screw and remove the built-in electrode.
- Clean the rotor axle with Ethanol (Ethanol 70 to 80 %).
- Use blow air to remove remaining moisture.
- Hold down the push button, insert the guide bar and turn it back and forth until it fits into the latch groove then release the push button to secure the bar.



CAUTION:

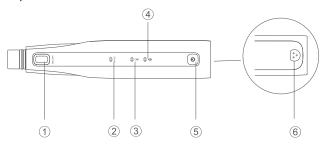
- Always use the guide bar and ensure that other parts will fix in place
- If the guide bar cannot be properly fixed in place, the internal contact could be bent, and then the instrument might not be able to make accurate measurements or it might malfunction
- Do not run the motor with the guide bar inserted

3.3.2 Control unit



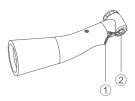
- 1 Touch screen
- (2) ON/OFF Button, short press to turn on, long press to turn off
- (3) Handpiece charging light, refer to "5.5 charging"
- (4) Handpiece charger
- (5) Power supply Jack, refer to "5.5 charging"

3.3.3 Handpiece



- (1) ON/OFF Button, refer to "8. Endo Motor Mode/Multi function Mode" and "9. Smart pilot"
- 2 Apex locator Indicator, refer to "7. Apex Locator Mode"
- 3 Battery indicator, refer to "5.4 Battery of control unit and handpiece"
- 4 Bluetooth indicator, refer to "4.3 Bluetooh connection"
- (5) Power button, short press to turn on, long press to turn off
- (6) Lip hook wire jacket/Root apex test wire jacket/Tester jacket

3.3.4 Contra-Angle



- 1 Handpiece light, it will provide lighting during operation, refer to "6. Setting and Adjustment"
- (2) Built-in electrode, connect file to perform root canal measurement and preparation, replace electrode refer to

"10.4 Replace file electrode"

3.4 Technical Specifications

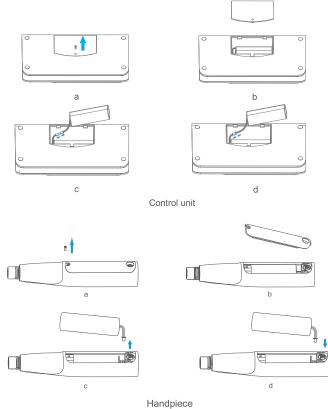
AC adapter	Input: AC100-240V Output: DC10V 1.5A
	Frequency: 50/60Hz
Operating frequency	WPT:112-205kHz, BLE:2402-2480MHz
Maximum RF Output Power	WPT:27.10dBuA/m@3m, BLE:1.15dBm
Control unit's battery	Lithium ion battery (DC7.4V 2600mAh)
Handpiece's battery	Lithium ion battery (DC3.7V 1200mAh)
LED	3.3V
Speed	150-1000rpm
Torque	0.6-3.9Ncm
Protection against electric shock	Type B applied part
Classification of protection against electric shock	Class II(adapter)
Input power	35VA
Operation mode	Non-continuous
Gear ratio	1.9:1
File of contra-angle	ISO1797-1Type1 diameter:2.35mm,minmum fitting length:11mm,overalllength:max23mm, working diameter: max 2mm
	File of root apex locators meet the ISO 3630-1 Type 1
File of file clip	Neck diameter (d16): min 0.52mm, max 1.72mm
	Head diameter (D): min 0.20mm, max 1.40mm
	Working length (I16): 16mm
Applied part	Contra-angle, File clip, Lip hook
Measurement accuracy	±0.5mm
Degree of protection(IEC 60529)	IPX0

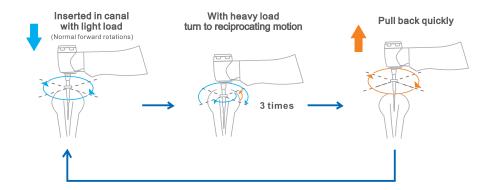
Disconnecting:

- Press (to enter setup state and then press to prepare disconnecting.
- Follow the prompt step by step.

10.2 Replacement battery

- a) Open the rubber cover or remove the screw.
- b) Remove the battery cover as shown in the illustration.
- c) Remove the old battery.
- d) Connect the new battery.
- e) Install the cover and its screw or rubber cover.





10. Maintenance

10.1 Bluetooth re-pair

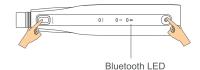
This operation is only required after replacing control unit or handpiece.

Pairing:

- Press

 and

 at the same time, until Bluetooth LED solid.



• During Bluetooth pairing, the symbol changes as shown in below:





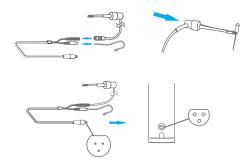
- Before the Bluetooth connection, the Bluetooth indicator (blue) on handpiece is flashing. When paired, the indicator is on
- · The Bluetooth connection will be saved automatically

4. Preparation

4.1 Connection

A: Used for apex locator mode or multi-function mode.

Connect lip hook, file clip, endo file, root apex test wire and handpiece. Insert lip hook into white jack of root apex test wire and file clip into gray jack of root apex test wire as below:

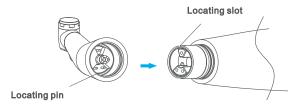


B: Used for endo motor mode or multi-function mode.

B.1 contra-angle

Align and connect the locating slot and the locating pin.

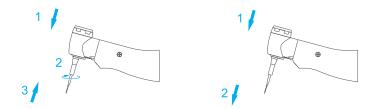
Disconnecting: Pull it straight out.



B.2 File

- Hold down the push button on the contra-angle and insert the file.
- Pull on the file gently to make sure it is locked.

Disconnecting: Press the push button and pull out the file.





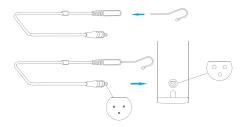
- · Make sure the connection is not damaged
- · Never use stretched, deformed or damaged files



- Be careful when inserting and removing files to avoid injury to fingers
- Inserting and removing files without holding the push button may damage the chuck
- · Gently drag the file to confirm that it is locked

B.3 Lip hook (Used for multi - function)

Connect lip hook, lip hook wire and handpiece.



CAUTION:

- Do not use damaged or worn file clip, file and contra-angle
- Do not bump the plugs and wind the probe cord around the instrument
- · Make sure the plug is all the way in

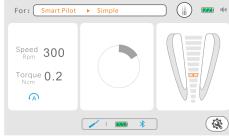
4.2 First charge

Prior to first use, you need to charge the control unit and handpiece, refer to "5.5 charging "to charge.

4.3 Bluetooth concoction

- Bluetooth will automatically connect after control unit and handpiece are turned on.
- Disconnection: Bluetooth indicator on handpiece is flashing and the status bar on control unit as below:





Endo Motor Mode

Multi-function Mode

Start working

Press the button on handpiece:

- The motor rotates according to the set speed. When the load reaches the set triggering value, motor starts reciprocating motion.
- Illumination will be provided when the LED is turned on.
- If apex locator mode is available, the movement of the file is displayed on the right side of the screen, accompanied by different prompt sounds. When the file reaches the set apex position, motor will:
 - > Apical auto reverse ON: The motor will automatically reverse, When far away from the set position, the motor will automatically return to forward rotation.
 - > Apical auto reverse OFF: It will continue to rotate forward.



Note:

- Torque auto reverse function and auto reverse function are not available.
- · Suitable files:
 - Nickel-Titanium:#20
- larger shaping files

Stop

During operation, press the button on handpiece again:

- Stop working.
- LED will continue to light up until the delay time expires.

Operating

- When the torque reaches the set triggering value, the motor will automatically turn to the reciprocating motion.
- > Advance the file slowly to start canal shaping, pull the file up quickly every three reverse rotation ,repeat the sequence as below:

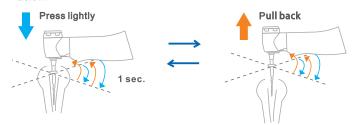
- Start working
 - Press the button on handpiece:
- Motor makes reciprocating motion at preset speed and default angle.
- Illumination will be provided when the LED is turned on.



- Torque auto reverse function, apical auto reverse function and auto reverse function are not available.
- Suitable files:
 - Nickel-Titanium: #10-20 (t02)
- Stainless Steel: # 10-15 (t02)
- Glide path files
- Stop

During operation, press the button on handpiece again:

- Stop working.
- LED will continue to light up until the delay time expires.
- Operating:
 - > The motor reproduces the subtle and delicate finger movements of an experienced
 - > Press down for approximately 1 second then pull it up. Repeat the sequence as below:



9.5 Canal Shaping

Stand-by



For: Smart Pilot ➤ Simple Speed 350 Torque 0.2 A / I 🗪 🔻

Endo Motor Mode

Multi-function Mode

Connection: Bluetooth indicator on handpiece is always on and the status bar on control unit as below:





The content in status bar depends on the type of handpiece connection, the set parameters and the actual battery

To re-pair Bluetooth or replace handpiece, please refer to "10.1 Bluetooth re-pair."

5. Introduction

5.1 Mode

Apex Locator Mode: Measure the length of the root canal, without motor function, refer to "7. Apex Locator mode".

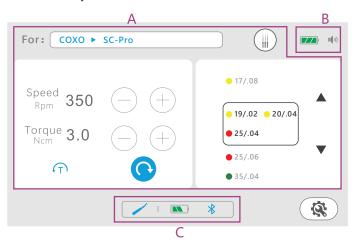
Endo Motor Mode: Prepare the root canal, without apex locator function; refer to "8. Endo Motor Mode/Multi-function mode".

Multi-function Mode:Measuring the length while root canal preparation; refer to

"8. Endo Motor Mode/Multi-function mode".

Smart Pilot: It is an intelligent mode of root canal preparation, which is only suitable for continuous rotating NITI system. Compared with torque reversal mode, it can be safer and more efficient, refer to "9. Smart pilot"

5.2 Main interface symbols



A: Work area, refer to "Chapter 7-9".



B: Control unit

	Control unit power, refer to "5.4 Battery"
1(1))	Control unit volume,refer to "6.1 Setting"

C: Handpiece

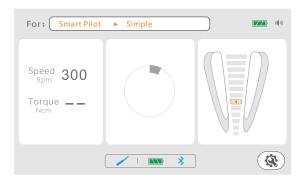


Multi-function Mode

Working



Endo Motor Mode



Multi-function Mode

Start working

Press the button on handpiece:

- The motor rotates according to the set speed.
- Illumination will be provided when the LED is turned on.
- Display current torque, When load reaches preset torque limit value, motor will:
 - > Torque auto reverse ON: Motor will automatically reverse. When the load is reduced, the motor will automatically return to forward rotation.
 - > Torque auto reverse OFF: Stop.
- If apex locator mode is available, the movement of the file is displayed on the right side of the screen, accompanied by different prompt sounds. When the file reaches the set apex position, motor will:
 - > Apical auto reverse ON: The motor will automatically reverse, When far away from the set position, the motor will automatically return to forward rotation.
 - Apical auto reverse OFF: It will continue rotate.
- If apex locator mode is available, the movement of the file is displayed on the right side of the screen, accompanied by different prompt sounds. When the file tip reaches the position where the apex locating value is "1.0", the motor will:
 - Auto apical slow down ON: The motor will automatically slow down. When apex locator mode is greater than 1.0, the motor will automatically restore the speed.
 - > Auto apical slow down OFF: It will continue to The maintain speed.

Stop

During operation, press the button on handpiece again:

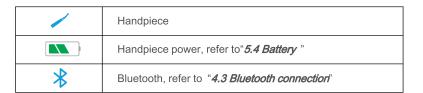
- Stop working.
- LED will continue to light up until the delay time expires.

9.4 Patency/Glide Path

Stand-by



Endo Motor Mode



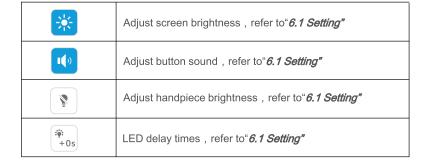
Other



5.3 Setup interface

Press $\textcircled{\textcircled{3}}$ to enter setup interface, press X to exit.



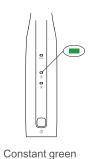




	Disconnect or renair Pluoteeth button refer to "10.1
*	Disconnect or repair Bluetooth button , refer to "10.1
	Bluetooth re-pair
3 4 1	Internal charging , refer to "5.5 Charging"
	Torque Auto Reverse function, refer to "6.6 Torque auto
(tl)	reverse"
	Apical Auto Reverse function, refer to "6.7 Apical auto
(A)	reverse"
	Auto Apical Slow Down function, refer to "6.8 Auto Apical"
	Slow Down"
	Torque Calibration function,refer to "6.3 Calibration"
	Factory Defaults function, refer to "6.8 Factory Reset"

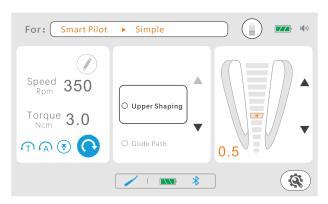
5.4 Battery

- The battery symbol on screen
 - High battery
 - Medium battery
 - Low battery, please charge in time
 - Very low battery, charge immediately
- Battery indicator of handpiece



0 0 0

Flashing orange



Multi-function Mode

Working



Endo Motor Mode



Multi-function Mode



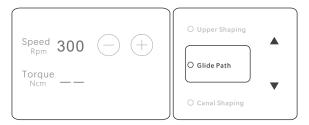


- **Upper Shaping**: Enlarge the upper part of the canal to make treatment easier.
- Glide Path: Use a thin file to make the glide path needed for shaping.
- Canal Shaping: Change file sizes as you shape the canal.



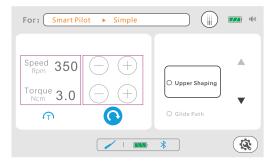
Canal length measurement refers to "7. Apex Locator Mode"

Press ▲ / ▼ to select step, screen will display corresponding parameters, charge parameters refer to "6.2.3 Parameter adjustment".



9.3 Upper Shaping

- Refer to "8. Endo Motor Mode / Multi-function Mode "to use.
- Stand-by



Endo Motor Mode

- Constant green: Sufficient power to support normal operation.
- Flashing orange: Charge immediately.

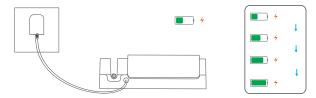


When control unit or handpiece is very low battery, red symbol will appear on screen

5.5 Charging

a) Control unit:

Connect control unit and adapter to charge the handpiece, the charging status is shown as follows:



When control unit charging, the screen displays the charging symbol and status. After 1 minute of inactivity, the symbol will disappear. You can press the ON / OFF button or touch the screen to check the charging status.



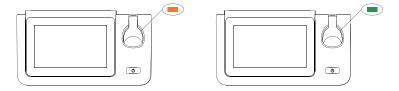
b) Handpiece:

- External charging: Connect handpiece and adapter, and place handpiece on handpiece charger to charge.
- Internal charging: Control unit can charges handpiece without external input.
- Press (to enter setup state and then press / to turn on/off internal charging.
- When the host battery is low, this function is unavailable and the button is displayed in gray



The function turns off when control unit 'battery level is less than 30%

The handpiece charging light will illuminate flashing orange, indicating battery is charging and will show constant green when fully charged.





When the charging is over current, handpiece charging will automatically stops and is accompanied by light flashing and E3 appear, which can be recharged after power is cut off and restarted



- Only use the adapter provided by manufacturer
- Do not charge in humid places

6. Setting and Adjustment

6.1 Setting

a) Control unit

Screen brightness: Press button to change status as below:



Button sound: Press button to switch it on/off.





The change will be automatically saved

9. Smart Pilot

Smart Pilot is an intelligent mode of root canal preparation, it contain Upper Shaping, Glide Path/Patency, Canal Shaping three steps.

9.1 Canal type selection

a) Smart pilot



b) Canal type



Simple: Very straight and smooth canal

Normal: Canals with normal shapes, slightly curved canals, etc.

Complex: Extremely carved canals, ledged canals, blocked canals, etc.

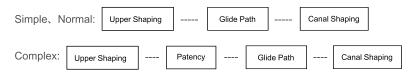
9.2 Steps for root canal preparation

Upper Shaping: Enlarge the upper part of the canal to make treatment easier.

Glide Path: Use a thin file to make the glide path needed for shaping.

Canal Shaping: Change file sizes as you shape the canal.

c) Steps





During operation, do not apply excessive force to the file

8.4 Stop

During operation, press the button on handpiece again:

- Stop working
- LED will continue to light up until the delay time expires.

8.5 Manual reversal

- Before working, press on the screen or long press on the handpiece to change rotary direction.
- During working, user can only change the direction by long press on the handpiece.



Note:

- When the motor reverses, there will be a buzzer prompt
- When the motor stops, the direction returns to clockwise

b) Handpiece

LED: Press button to change the status as below:







High

Medium

OFF



Only suitable for root canal preparation

- After the motor stops running, the LED will illuminate until the delay time expires.
- Press button as below to select delay time.











Only suitable for root canal preparation and LED switch must be turned on

6.2 File system

- The instrument presents a library of files of major brands, user can choose to use without setting, and also contains two user's systems: Rotary File and Recipro File.
- Press (||) to enter the NITI system, choose manufacturer and systems by pressing NITI system name according to your needs.



Note:

Not available in apex locator mode.

6.2.1 File selection

a) Manufacturer and NITI system

to switch pages and press
 o
 to exit.



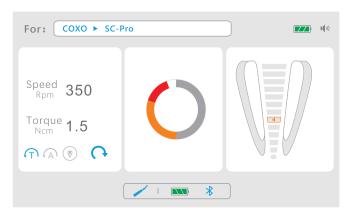
 After the selection is completed, the status bar of the main page displays the selected NITI system.



- B1File manufacturer
- B2NITI system name
- User can also press (B3) to select different NITI system under the same manufacturer.

b) File selection





Multi-function Mode



: The current torque, gray indicates that the limit torque is within 50%, orange is

50%-80%, and red is more than 80%.

8.3 Start working

Press the button on handpiece:

- The motor rotates according to the set speed.
- Illumination will be provided when the LED is turned on.
- Display current torque, When load reaches preset torque limit value, motor will:
 - > Torque auto reverse ON: motor will automatically reverse. When the load is reduced, the motor will automatically return to forward rotation.
 - > Torque auto reverse OFF: Stop.
- If apex locator mode is available, the movement of the file is displayed on the right side of the screen, accompanied by different prompt sounds. When the file reaches the set apex position, motor will:
 - > Apical auto reverse ON: The motor will automatically reverse, When far away from the set position, the motor will automatically return to forward rotation.
 - > Apical auto reverse OFF: It will continue to rotate forward.
- If apex locator mode is available, the movement of the file is displayed on the right side of the screen, accompanied by different prompt sounds. When the file tip reaches the position where the apex locating value is "1.0", the motor will:
 - Auto apical slow down ON: The motor will automatically slow down. When apex locator mode is greater than 1.0, the motor will automatically restore the speed.
 - Auto apical slow down OFF: It will continue to The maintain speed.





Motor reverse button



Clockwise







Depends on whether this function is turned on, refer to "6.6 Torque auto reverse"



Depends on whether this function is turned on, Single endo motor mode is available. refer to "6.7 Apical auto reverse"



Depends on whether this function is turned on, Single endo motor mode is available. refer to "6.8 Auto apical slow down"



Depends on the set apex position, Single endo motor mode is available. refer to "6.5 Set the apex position"

8.2 Working



Endo Motor Mode



- C1 File list in the current NITI system
- C2File(s) selected for use
- User can press ▲ / ▼ (C3) to select file(s)
- C4 Speed and torque value of the currently selected file(s), change speed and torque refer to "6.2.3 Parameter adjustment."

6.2.2 User system

- The instrument contains two user's systems: Rotary File and Recipro File.
- Rotary File: There is 5 continuous rotary files in the system and user can set speed and torque as required.
- Recipro File: There is a reciprocation rotary file in the system and user can set speed and rotation angle as required.

6.2.3 Parameter adjustment



Usually, the default settings do not need to be adjusted; however, user can refer to the file manufacturer's instructions to modify parameter

- Press () () on the screen to adjust parameter.
- The parameter can be adjusted:
- > Rotary File: Speed and Torque
- Recipro File: Speed and Angle
- When the setting is changed, Rpm (Ncm) will become RPM (Ncm).





• The change will be saved automatically. To restore the default settings, refer to "6.8"

Factory reset "

· While motor handpiece is in motion or in a reciprocating rotary file mode, speed and torque cannot be changed

6.3 Calibration

Calibration is required to ensure the motor parameters are accurate.

Press (to prepare the calibration;



- Follow the prompt step by step.
- During calibration, the pop-up windows mean:



Calibrating

Torque calibration completed

Calibration complete



Calibration failed



Calibration failed refers to" 12 Troubleshooting"



Calibration is required after disinfection, sterilization, replacement of a new contra-angle or before use

6.4 Check apex locator function

Before apex locator mode or when the measurement is inaccurate, you can check the function as follow.



Suitable for apex locator mode and muti-function.

6.4.1 Check with tester

- Connect tester to handpiece;
- Confirm whether indicators are lit between 0.1 -0.5.

8. Endo Motor Mode / Multi-function Mode

Refer to "4.1 B" to connect accessories to enter multi-function mode.



If the lip hook wire is not connected, there is only single endo motor mode.

8.1 Stand-by



Endo Motor Mode



Multi-function Mode



then put a little saline in the canal, but do not let it overflow the canal opening.

Crown or metal prosthesis touching gingival tissue

Accurate measurement cannot be obtained if the file touches a metal prosthesis that is touching gingival tissue. In this case, widen the opening at the top of the crown so that the file will not touch the metal prosthesis before taking a measurement.

Cutting debris on tooth

Pulp inside canal

Thoroughly remove all cutting debris on the tooth.

Thoroughly remove all the pulp inside the canal. Otherwise an accurate measurement cannot be obtained.

Caries touching the gums

In this case, electrical leakage through the caries infected area to the gums will make it impossible to obtain an accurate measurement.

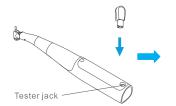
Blocked canal

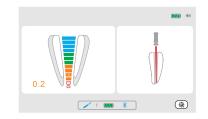
The meter will not move if the canal is blocked.

Open the canal all the way to the apical constriction to measure it.

Extremely dry canal

If the canal is extremely dry, the meter may not move until it is quite close to the apex. In this case, try moistening the canal with oxydolor saline.



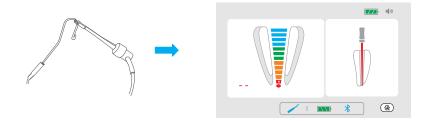


/ WARNING:

If indicators are not lit between 0.1-0.5, stop using the equipment immediately and repair it

6.4.2 Check test root apex test wire

Check the test root apex test wire and confirm whether indicators are lit.



6.4.3 Check lip hook wire

Check the lip hook wire and confirm whether indicators are lit.



/ WARNING:

If indicators are not lit within preset range, stop using the equipment immediately and repair it

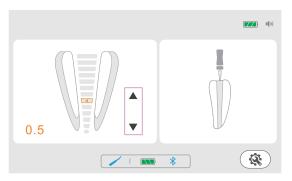
6.5 Set the apex position

Set the apex position according to your need.

When the file approaches or reaches the set position, it will be accompanied by different prompt sounds and motor actions (such as stop or reverse).







Apex Locator Mode



Multi-function Mode

Press \blacktriangle / \blacktriangledown on the screen to set the apex position.

6.6 Torque auto reverse

 When load reaches preset torque limit value, motor will automatically reverse to prevent the file from breaking due to excessive load.



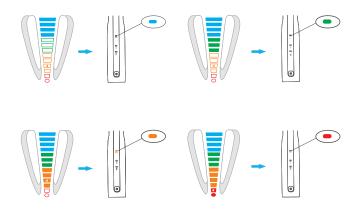
Function On

- The function is unviable in some steps of Smart pilot, refer to "9. smart pilot"
- Press \bigcap / \bigcap to turn on/off the function.

 $\widehat{\mathsf{T}}$

When the function is available it will disappear.







Exceed the apex location, Apex locator indicator flashes

7.3 EMR (Electric measurement of root canal length)

Accurate measurement cannot be obtained with the root canal conditions shown below.

A huge apical hole

Root canal that has an exceptionally large apical foramen due to a lesion or incomplete development cannot be accurately measured.

Root canal with blood overflowing from the opening

If the blood overflows and contact with the gums, it will cause electrical leakage, and accurate measurement results cannot be obtained. After the bleeding has completely stopped, thoroughly clean the inside of the root canal and the opening, and then perform the measurement.

Root canal with a chemical solution overflowing from the opening

An accurate measurement cannot be obtained if chemical solution is overflowing from the canal opening. In this case, clean the canal and its opening. It is important to get rid of the solution overflowing the opening.

Broken crown

If 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.

A branch canal will also cause electrical leakage.

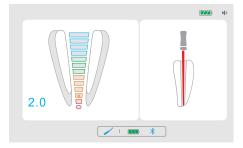
Re-treatment of a root filled with gutta-percha

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



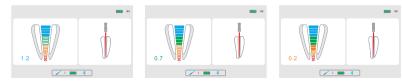


- Hook the lip hook in the corner of the patient's mouth and slowly insert the file into the
- · The file movement in the canal is shown on the full canal image as below.



Apex enlargement area:

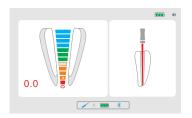
 Indicators indicates the exact position and changes accordingly from blue to green and then to yellow as shown below.

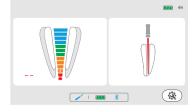


Blue (Close to apex area)

Green to yellow (Reach apex area)

- File movement is accompanied by audio signals as additional indication of file position.
 The shorter the sound interval, the closer the distance between file and apex.
- When file reaches apical foramen indicators is marked red and a constant sound is emitted.





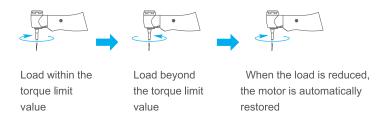
Red (Located in apex foramen)

Red (Beyond apex foramen)



- · Indicator does not represent a specific size
- · Measurement can be terminated at any time
- During measurement, the color of Apex locator indicator is displayed in synchronization with indicator bar's, as shown in below:

- **ON**: During operation, when load reaches preset torque limit value, motor will automatically reverse. When the load is reduced, the motor will automatically return to forward rotation.
- OFF: When load reaches preset torque limit value, motor will stop.





During operation, do not apply excessive force to the file

6.7 Apical auto reverse

 When file reaches the set apex position, motor will automatically reverse to prevent the file exceed the position.



- Suitable for multi-function mode only.
- The function is unviable in some steps of Smart pilot, refer to "9. Smart pilot"
- Press A / A to turn on/off the function.



- When the function is available it will disappear.
- When file reaches the set apex position.
 - > **ON:** The motor will automatically reverse
 - > OFF: It will continue to rotate forward



During operation, do not apply excessive force to the file

6.8 Auto apical slow down

• When the file tip reaches the root measurement "1.0" position (the first green root measurement grid), the motor speed is automatically reduced to 150rpm.







- · Suitable for multi-function mode only.
- The function is unviable in some steps of Smart pilot, refer to "9. Smart pilot"
- Press 🔻 / to turn on/off the function.





Function On

Function Off

- When the function is available it will disappear.
- When file reaches the set apex position.
- ➤ ON: The motor speed will automatically reduced to 150rpm.
- > OFF: It will continue to run at a set speed.



CAUTION:

During operation, do not apply excessive force to the file

6.9 Factory reset



Warning:

After factory setting, all parameters set by the user will be removed

- Press (to enter setup state and then press | to prepare to factory reset;
- Follow the pop-up window by step.



• After the factory settings are restored, it will return to the main page.

7. Apex Locator Mode

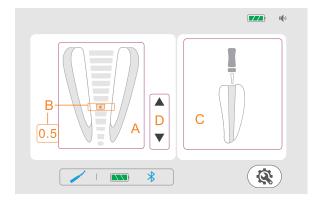
Refer to "4.1 A "to connect accessories to enter apex locator mode.



Note:

In the apex locator mode, without replacing the root apex test wire, press the start key on the handle () and the host automatically switches to the composite mode.

7.1 Stand-by



А	Root apex area, shows the root apex area and indicate where file was reached
В	Apical reference position(The number represents the relative position of file tip and apical hole, the smaller the value, the closer to the apical hole)
С	Complete root canal image Shows file entering the root canal opening
D	Set the apex position

7.2 Measurement



/!\ WARNING:

- Do not allow lip hook, file clip and test wire to contact with power sources, such as power outlets
- · Make sure that all connectors are securely locked in place.

