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

8.3 Replacing File Electrode

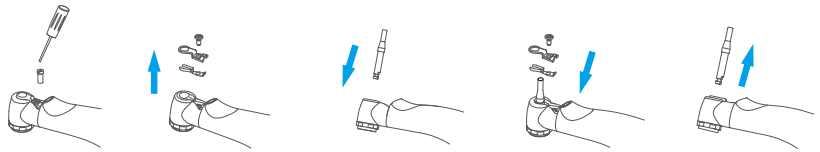
In the multi-function mode, the root canal indicator bar flashes or the indicator bar does not light up when the file touches the opposite electrode, and the problem cannot be solved after cleaning the rotor axle and the built-in electrode. The built-in electrode is worn out and the following steps must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

- 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.

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

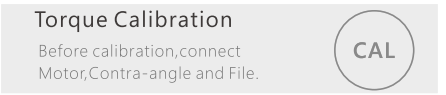


8.4 Calibration and Factory Reset

8.4.1 Calibration

Calibration is required to ensure the motor parameters are accurate.

- Press to enter setup state and then press CAL to prepare the calibration;



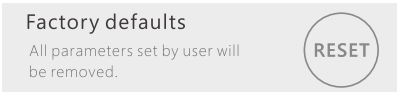
- Follow the prompt step by step
- During calibration, the icon mean:

CAL Calibrating OK Calibration complete Falut Calibration failed

CAUTION :
Calibration is required after disinfection, sterilization, replacement of a new contra-angle or priro to use.

8.4.2 Factory Reset

- Press to enter setup state and then press RESET to prepare to factory reset;



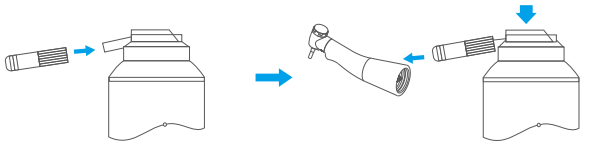
- Follow the prompt step by step
- During calibration, the icon mean:

RESET Reseting OK Factory reset is complete

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

8.5 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.



CAUTION:
- 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.

9. 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, Lip hook.
ADVICE:	Reprocessing procedures have only limited implications to a surgical instrumert. 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 Instructions	
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 decontaminaton is possible!
Decontamination of other parts than Contra-angle , File clip ,Lip hook :	After operation, take out the Motor Handpiece and AC adapter on thework 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 sterilisation 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:	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) • 5 min washing with a mild alkaline cleaner at 55°C • 3 min neutralising with warm water (>40°C) • 5 min intermediate rinsing with warm water (>40°C)
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.
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.
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.	

10. Troubleshooting

Malfunction	Cause	Remedy
Cannot turn on the power	The battery is low	Please charge in time
	Battery failure	Replace the battery
Cannot charge the battery	The adapter is not reliably connected	Check that the adapter connection is reliable
	Battery failure	Replacement battery
Apex locator imprecise/ not sensitive	Test wire connection unreliable	Reconnect the test wire or you can contact the file clip to lip hook directly to check the connection status
	The test wire has an open circuit or a short circuit	Replace test wire
	The root canal is in poor condition	Refer to 7
Cannot start the motor/ motor does not work	Low voltage protection	Please charge in time
	Contra-angle stuck	Clean or replace the contra-angle
	Handpiece failure	Replace handpiece
	Control unit failure	Contact the dealer
Motor stops automatically	Torque reverse is not set	Turn on the Torque reverse
	The load is too large to exceed the maximum output of the instrument	Manually release the load
Handpiece LED is not light	LED light is not turned on	Turn on the LED light on the settings page
	LED light is damaged	Contact the dealer

11. Symbols

	Caution		Manufacturer
EC REP	European Union agent	SN	Serial number
	Type B applied part		Keep dry
CE 0197	CE(0197) Marking		Fragile
	Vertical up		Direct current
	Special disposal of waste electrical and electronic equipment (Directive2002/96/EEC)		Follow instruction for use
	Class II product		Alternating Current
134°C	Autoclave		Thermo-Disinfector

12. 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. can be affected by portable and mobile RF The control unit is 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.

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

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 test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD)IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV,±8kV,±15 kV air	±8 kV contact ±2 kV, ±4 kV,±8kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/output lines	±2kV for power supply lines ±1 kV for Input/output lines	Mains power quality should be that of atypical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line	Mains power quality should be that of a 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 unit eruptible power supply or a battery.
Power frequency(50/60 Hz)magnetic 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 hospital environment.
NOTE: U_T is the a.C mains voltage prior to application of the test level.			

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 test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands 3 V/m, 10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSUREPORT IMMUNITY to RF wireless communication instrument(Refer to table 9of IEC 60601-1-2:2014)	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands 3 V/m, 10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSUREPORT IMMUNITY to RF wireless communication instrument(Refer to table 9 of IEC60601-1-2:2014)	Portable and mobile RF communications instrument should be used no closer to any part of the instrument, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=[3,5/V1]×P1/2 $d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=1.2\times P^{1/2}$ 800 MHz to 2,7 GHz Where the maximum is output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of 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 propagation is affected by absorption and reflection from structures, objects and people.			
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 than3 V/m.			

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 power of transmitter (W)	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz $d=1.2\times P^{1/2}$	80 MHz to 800 MHZ $d=1.2\times P^{1/2}$	80 MHz to 800 MHz $d=2.3\times P^{1/2}$
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 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.			