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Endo Motors  
Model: C-Smart-I

Pilot

# User 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 power of transmitter (W)                                                                                                                                                                                                                                                                                                                                                                                              | Separation distance according to frequency of transmitter |                                             |                                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                            | 150 kHz to 80 MHz<br>$d=1.2 \times P^{1/2}$               | 80 MHz to 800 MHz<br>$d=1.2 \times P^{1/2}$ | 80 MHz to 800 MHz<br>$d=2.3 \times$ |
| 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 test                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | IEC 60601 test level                                                                                                                          | Compliance level                                                                                                                             | Electromagnetic environment - guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Conducted<br>RF<br>IEC61000-4<br>-6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 3 Vrms<br>150 kHz to 80 MHz<br>6 Vrms in ISM and amateur radio bands 3 V/m, 10 V/m<br>80 MHz to 2.7 GHz                                       | 3 Vrms<br>150 kHz to 80 MHz<br>6 Vrms in ISM and amateur radio bands 3 V/m, 10 V/m<br>80 MHz to 2.7 GHz                                      | 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.<br><br>Recommended separation distance<br>$d=[3,5/V^{1/2}]\times P^{1/2}$ 80 MHz to 800 MHz<br>$d=1.2\times P^{1/2}$ 800 MHz to 2,7 GHz<br><br>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).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup><br><br>Interference may occur in the vicinity of instrument marked with the following symbol:  |
| Radiated<br>RF<br>IEC<br>61000-4-3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 385MHz-5785M Hz Test specifications for ENCLOSUREPORT IMMUNITY to RF wireless communication instrument(Refer to table 9of IEC 60601-1-2:2014) | 385MHz-5785MHz Test specifications for ENCLOSUREPORT IMMUNITY to RF wireless communication instrument(Refer to table 9 of IEC60601-1-2:2014) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| NOTE 1At 80 MHz and 800 MHz, the higher frequency range applies.<br>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.<br><br>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than3 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 test                                                                                                                                                                       | IEC 60601 test level                                                                                                                                               | Compliance level                                                                                                                                                   | Electromagnetic environment - guidance                                                                                                                                                                                                                                            |
| Electrostatic discharge (ESD) IEC 61000-4-2                                                                                                                                         | ±8 kV contact<br>±2 kV, ±4 kV, ±8kV, ±15 kV air                                                                                                                    | ±8 kV contact<br>±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<br>±1 kV for Input/output lines                                                                                                        | ±2kV for power supply lines<br>±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<br>±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 variations on power supply input lines IEC 61000-4-11                                                                                 | <5 % UT (>95% dip in UT.) for 0.5 cycle<br><5 % UT (>95% dip in UT) for 1 cycle<br>70% UT (30% dip in UT) for 25/30 cycles<br><5% UT (>95 % dip in UT) for 5/6 sec | <5 % UT (>95% dip in UT.) for 0.5 cycle<br><5 % UT (>95% dip in UT) for 1 cycle<br>70% UT (30% dip in UT) for 25/30 cycles<br><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 erupible 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.                                                                                                                                         |
| <b>NOTE:</b> $U_T$ 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:



#### **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% to 80%

Atmospheric pressure: 86kPa to 106kPa

#### Transport and Storage:

Temperature: -10°C to 55°C

Humidity: ≤ 93% (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.

## 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 instrument should assure that it is used in such an environment. |            |                                                                                                                                                                                          |
| Emission test                                                                                                                                                                           | Compliance | Electromagnetic environment – guidance                                                                                                                                                   |
| RF emissions<br>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<br>CISPR 11                                                                                                                                                                 | Class B    |                                                                                                                                                                                          |
| Harmonic emissions<br>IEC 61000-3-2                                                                                                                                                     | Class A    |                                                                                                                                                                                          |
| Voltage<br>fluctuations/flicker<br>emissions<br>IEC 61000-3-3                                                                                                                           | Complies   | 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. |

## 13. Symbols

|                                                                                     |                                                                                       |                                                                                     |                            |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|----------------------------|
|    | Warning/ Caution                                                                      |    | Note                       |
|    | Autoclave                                                                             |    | Manufacturer               |
|    | European union agent                                                                  |    | Serial number              |
|    | Type B applied part                                                                   |    | Keep dry                   |
|    | CE marked product                                                                     |    | Fragile                    |
|    | Vertical up                                                                           |    | Direct current             |
|    | Special disposal of waste electrical and electronic equipment (Directive 2002/96/EEC) |    | Follow instruction for use |
|    | Class II product                                                                      |    | Thermo-disinfector         |
|    | Start/Stop button                                                                     |    | Apex indicator             |
|    | Battery indicator                                                                     |    | Bluetooth indicator        |
|   | Handpiece power button                                                                |   | Catalogue number           |
|  | Batch code                                                                            |  | Indoor use                 |
|  | Alternating Current                                                                   |                                                                                     |                            |

## 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 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.

## 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 canal measurement function**".

### 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 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 " <b>7.3EMR</b> "                                                                                   |
| 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                   | Auto reverse is not set                                              | Turn on the auto 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                                                                                           |
| Calibration failed                          | The motor is under resistance                                        | Reconnect the contra-angle                                                                                   |
|                                             | Contra-angle is damaged                                              | Contact the dealer                                                                                           |

|                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|--------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Cleaning:</b>                                 | <p>Regarding cleaning/disinfection, rinsing and drying, it is to distinguish between manual and automated reprocessing methods. Preference is to be given to automated reprocessing methods, especially due to the better standardizing potential and industrial safety.</p> <p>Automated Cleaning:<br/>Use a washer-disinfector meeting the requirements of the ISO 15883 series.<br/>Put the instrument into the machine on a tray. Connect the instrument with the WD by using suitable adapter and start the program:</p> <ul style="list-style-type: none"> <li>• 4 min pre-washing with cold water (&lt;40°C)</li> <li>• emptying</li> <li>• 5 min washing with a mild alkaline cleaner at 55°C</li> <li>• emptying</li> <li>• 3 min neutralising with warm water (&gt;40°C)</li> <li>• emptying</li> <li>• 5 min intermediate rinsing with warm water (&gt;40°C)</li> <li>• Emptying</li> </ul> <p>The automated cleaning processes have been validated by using 0.5% 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</p> |
| <b>Disinfection:</b>                             | <p>Automated Disinfection:<br/>Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0-Value (see EN 15883).<br/>A disinfection cycle of 5 min disinfection at 93°C has been validated for the device to achieve an A0 value of 3000.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Drying:</b>                                   | <p>Automated Drying:<br/>Drying of outside of instrument through drying cycle of washer/disinfector. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Functional Testing, Maintenance:</b>          | <p>Visual inspection for cleanliness of the instruments and reassembling. Functional testing according to instructions of use.<br/>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</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Packaging:</b>                                | <p>Pack the instruments in an appropriate packaging material for sterilization. The packaging material and system refer to EN ISO 11607.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Sterilization:</b>                            | <p>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.<br/>Minimal requirements: 3 min at 134 °C In EU, 5 min at 134 °C is required.<br/>Maximal sterilization temperature: 137°C</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Storage:</b>                                  | <p>Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures refer to label and instructions for use.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Reprocessing validation study information</b> | <p>The above-mentioned reprocessing process (cleaning, disinfection sterilization) has been successfully validated.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

- 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 pulpitis 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



Control Unit



Motor Handpiece



Contra-angle



File Clip



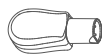
Root Apex Wire



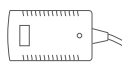
Lip Hook Wire



Lip Hook



Tester



Adaptor

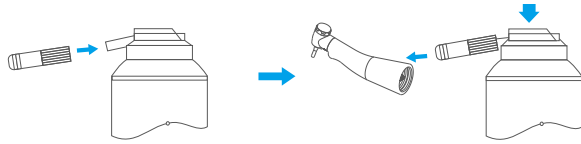


#### CAUTION:

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

### 11. Cleaning, Disinfection and Sterilization

|                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Device:</b>                                                                 | 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>ADVICE:</b>                                                                 | 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.<br>In case of damage the device should be reprocessed before sending back to the manufacturer for repair.                                                                                                                                                                                                                                                                                                                               |
| <b>Reprocessing Instructions</b>                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Preparation at the Point of Use:</b>                                        | 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.<br>Store the instruments in a humid surrounding.                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Transportation:</b>                                                         | Safe storage and transportation to the reprocessing area to avoid any damage and contamination to the environment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Preparation for Decontamination:</b>                                        | The devices must be reprocessed in a disassembled state.<br>Only Contra-angle, File clip and Lip hook can be cleaned and disinfected with automated methods and sterilized with steam sterilization process.<br>Do not sterilize the Motor handpiece and AC adapter.<br>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!                                                                                                                                                                                                                                                                                                                                                     |
| <b>Decontamination of other parts than Contra-angle, File clip, Lip hook :</b> | 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.<br>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:<br>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. Wipe the surface of the component with a dry soft lint-free cloth. |
| <b>Pre-Cleaning:</b>                                                           | <b>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!</b><br>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.<br>Clean the surface with a soft bristle brush.                                                                                                                                                                                                                                                                                              |



#### ⚠ 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

### 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.

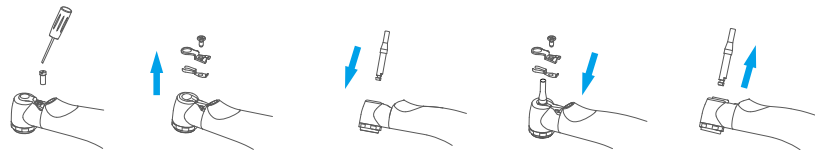
#### ⚠ CAUTION:

- 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

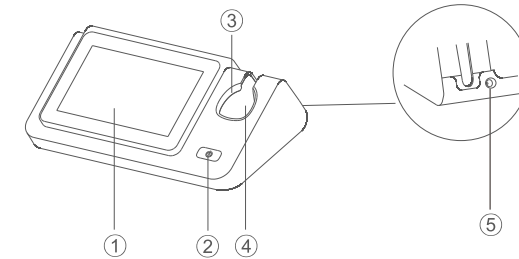
- Slide the built-in electrode onto the guide bar and line up the screw whole.
- Slowly turn the screw and make sure the built-in electrode goes into the head properly.
- Tighten the screw securely and then hold down the push button and pull out the guide bar.

#### ⚠ 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

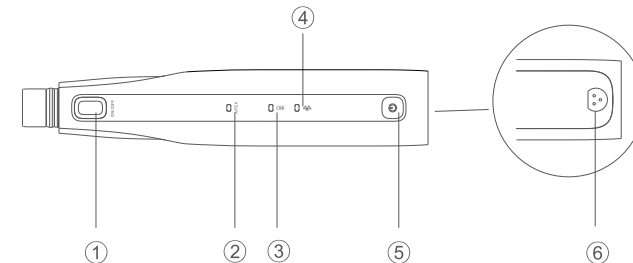


### 3.3.2 Control unit



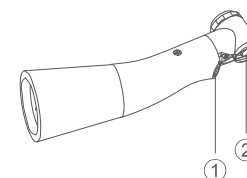
- ① Touch screen
- ② ON/OFF Button, short press to turn on, long press to turn off
- ③ Handpiece charging light, refer to “5.5 charging”
- ④ Handpiece charger
- ⑤ Power supply Jack, refer to “5.5 charging”

### 3.3.3 Handpiece



- ① ON/OFF Button, refer to “8.Root canal preparation” and “9.Smart pilot”
- ② Apex locator Indicator, refer to “7.Canal length measurement”
- ③ Battery indicator, refer to “5.4 Battery of control unit and handpiece”
- ④ Bluetooth indicator, refer to “4.3 Bluetooth 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

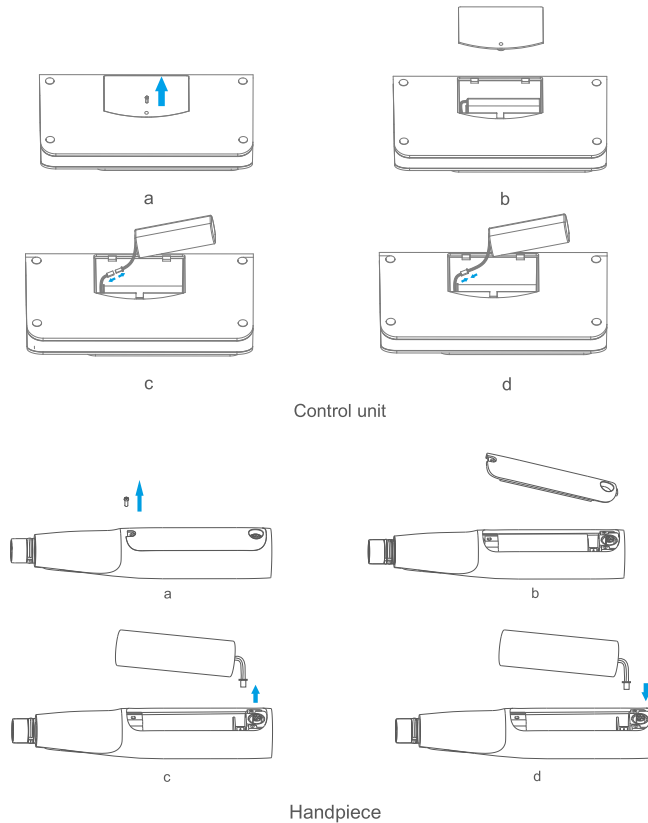
### 3.3.4 Contra-Angle



- 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 )                                                                                                                                                              |
| Control unit's input power                          | 35VA                                                                                                                                                                              |
| Operation mode                                      | Non-continuous                                                                                                                                                                    |
| Gear ratio                                          | 1.9 : 1                                                                                                                                                                           |
| File of contra-angle                                | ISO1797-1Type1 diameter:2.35mm,minum fitting length:11mm,overall length:max23mm,working diameter: max 2mm                                                                         |
| File of file clip                                   | File of root apex locators meet the ISO 3630-1 Type 1<br>Neck diameter (d16): min 0.52mm, max 1.72mm<br>Head diameter (D): min 0.20mm, max 1.40mm<br>Working length ( I16 ): 16mm |
| Applied part                                        | Contra-angle, File clip, Lip hook                                                                                                                                                 |
| Measurement accuracy                                | ±0.5mm                                                                                                                                                                            |
| Degree of protection(IEC 60529)                     | IPX0                                                                                                                                                                              |



#### 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.

## 10. Maintenance

### 10.1 Bluetooth re-pair

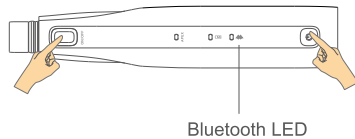
This operation is only required after replacing control unit or handpiece.

#### Pairing:

- Press  to pair Bluetooth.



- Press  and  at the same time, until Bluetooth LED solid.



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



#### NOTE:

- 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.

#### Disconnecting:

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

### 10.2 Replacement battery

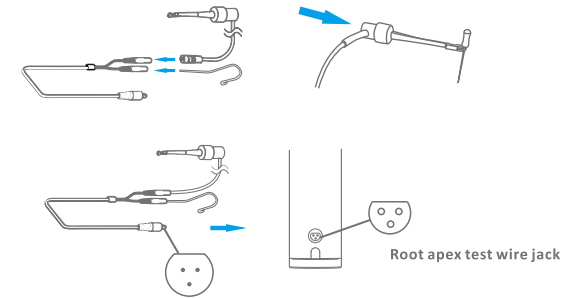
- Open the rubber cover or remove the screw.
- Remove the battery cover as shown in the illustration.
- Remove the old battery.
- Connect the new battery.
- Install the cover and its screw or rubber cover.

## 4. Preparation

### 4.1 Connection

#### A: Used for single canal length measurement.

Connect lip hook, file clip, root apex test wire and handpiece as below:

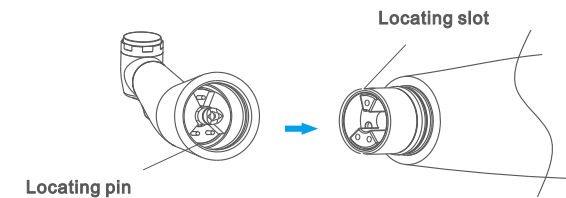


#### B: Used for single root canal preparation.

##### B.1 contra-angle

Align and connect the locating slot and the locating pin.

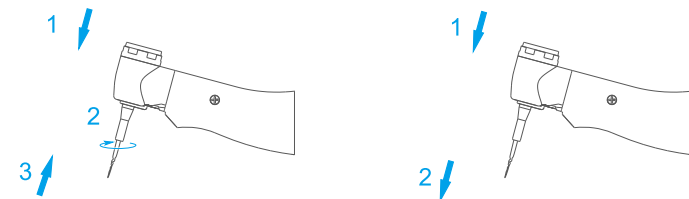
**Disconnecting:** Pull it straight out.



##### 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.



### ⚠ WARNING:

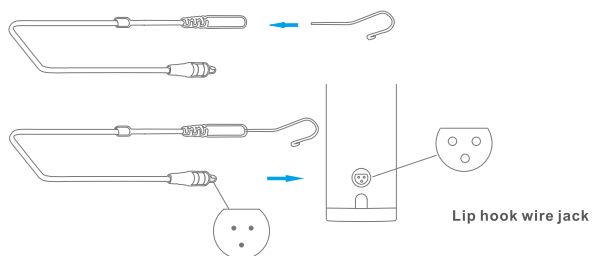
- Make sure the connection is not damaged
- Never use stretched, deformed or damaged files

### ⚠ CAUTION:

- 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 wire(used for root canal measurement and preparation )

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 connection

- 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:

### i Note:

- Torque auto reverse function is available
- Suitable files:
  - Nickel-Titanium :# 20
  - larger shaping files

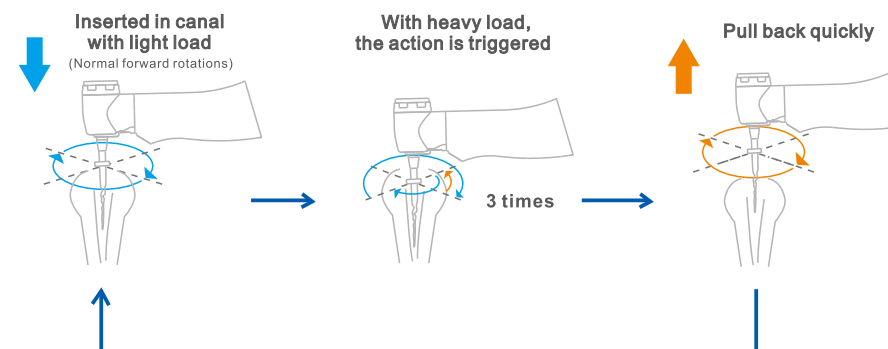
### ● Stop

During operation, press the button on handpiece again:

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

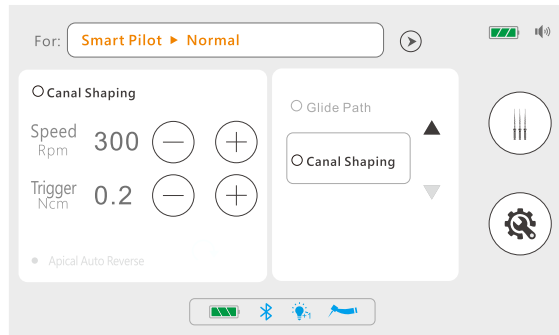
### ● Operating

- The file will alternate between forward and reverse rotation when the set trigger torque is reached.
- Advance the file slowly to start canal shaping, pull the file up quickly every three reverse rotation ,repeat the sequence as below:

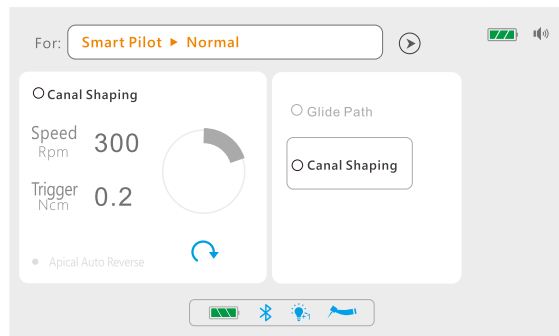


## 9.5 Canal Shaping

- **Stand-by**



- **Working**

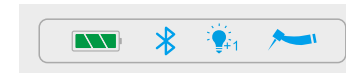


- **Start working**

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 canal length measurement 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.

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



**Note:**

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

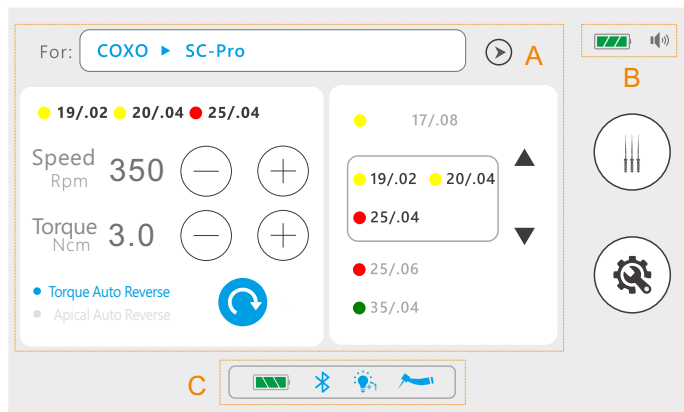
### 5.1 Mode

**Canal length measurement:** Single canal length measurement, refer to “**7. Canal length measurement**”.

**Root canal preparation:** Single root canal preparation or root canal measurement and preparation; refer to “**8. Root canal preparation**”.

**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 “ <b>5.4 Battery</b> ”  |
|  | Control unit volume , refer to “ <b>6.1 Setting</b> ” |

C: Handpiece

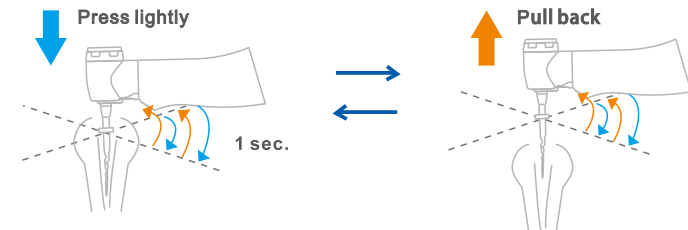
### Note:

- Torque auto reverse function is available
- Suitable files:
  - Nickel-Titanium : # 10-20 ( t02 )
  - Stainless Steel : # 10-15 ( t02 )
  - Glide path files

### Stop

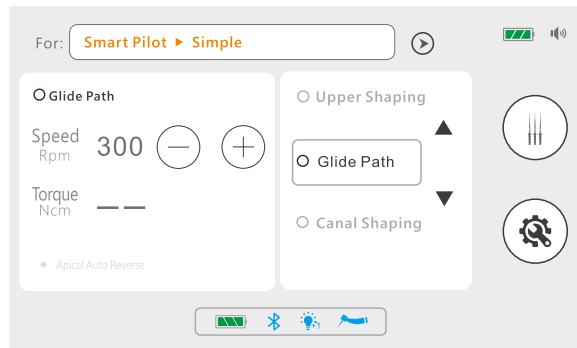
During operation, press the button on handpiece again:

- 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 dentist.
  - Press down for approximately 1 second then pull it up. Repeat the sequence as below:

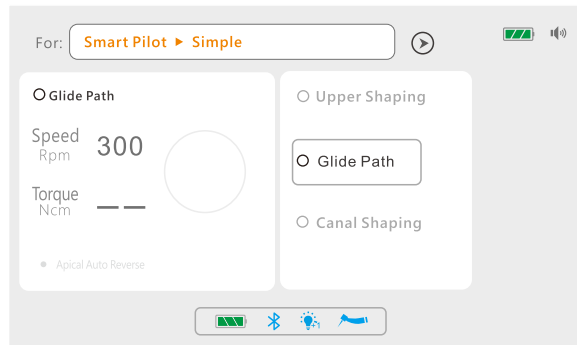


## 9.4 Patency/Glide Path

### ● Stand-by



### ● Working



### ● 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 canal length measurement 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.

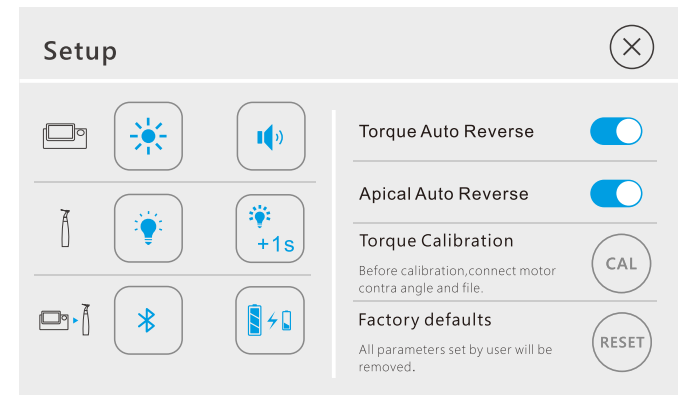
|  |                                                                                                                |
|--|----------------------------------------------------------------------------------------------------------------|
|  | Handpiece power, refer to "5.4 Battery "                                                                       |
|  | Bluetooth, refer to "4.3 Bluetooth connection"                                                                 |
|  | LED and delay times, refer to "6.1 Setting "                                                                   |
|  | Root canal preparation, not suitable for Single canal length measurement                                       |
|  | Canal length measurement, include Single canal length measurement and canal length measurement and preparation |

### Other

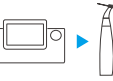
|  |                                                |
|--|------------------------------------------------|
|  | NITI system button, refer to "6.2 File system" |
|  | Setup button                                   |

## 5.3 Setup interface

Press to enter setup interface, press to exit.

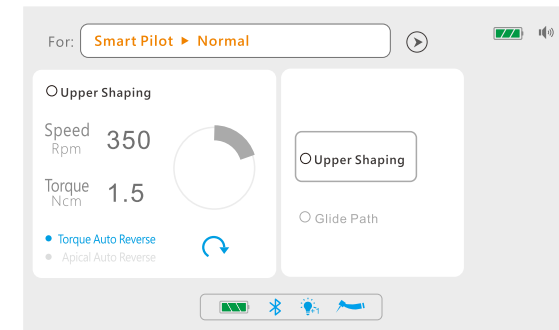


|  |                                                   |
|--|---------------------------------------------------|
|  | Control unit                                      |
|  | Adjust screen brightness , refer to "6.1 Setting" |

|                                                                                              |                                                                                    |
|----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
|             | Adjust button sound , refer to“ <b>6.1 Setting</b> ”                               |
|             | Handpiece                                                                          |
|             | Adjust handpiece brightness , refer to“ <b>6.1 Setting</b> ”                       |
|             | LED delay times , refer to“ <b>6.1 Setting</b> ”                                   |
|             | Connect control unit and handpiece                                                 |
|             | Disconnect or repair Bluetooth button , refer to “ <b>10.1 Bluetooth re-pair</b> ” |
|             | Internal charging , refer to “ <b>5.5 Charging</b> ”                               |
| Torque Auto Reverse                                                                          | Torque Auto Reverse function , refer to “ <b>6.6 Torque auto reverse</b> ”         |
| Apical Auto Reverse                                                                          | Apical Auto Reverse function , refer to “ <b>6.7 Apical auto reverse</b> ”         |
| Torque Calibration<br><small>Before calibration,connect motor contra angle and file.</small> | Torque Calibration function , refer to “ <b>6.3 Calibration</b> ”                  |
| Factory defaults<br><small>All parameters set by user will be removed.</small>               | Factory Defaults function , refer to “ <b>6.8 Factory Reset</b> ”                  |

## 5.4 Battery

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



### ● 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 canal length measurement 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.

### ● Stop

**During operation, press the button on handpiece again:**

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

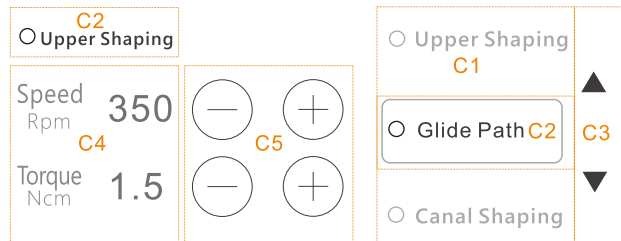
- **Upper Shaping:** Enlarge the upper part of the canal to make treatment easier.
- **Glide Path:** Use a thin file to make the glide path needed for shaping.
- **Canal Shaping:** Change file sizes as you shape the canal.



#### Note:

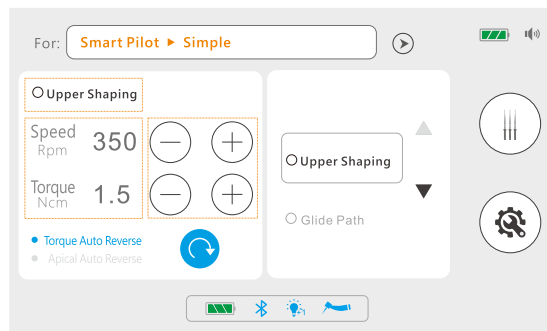
Canal length measurement refers to “**7. Canal length measurement**”

- Press ▲ / ▼ to select step, screen will display corresponding parameters , charge parameters refer to “**6.2.3 Parameter adjustment**”.



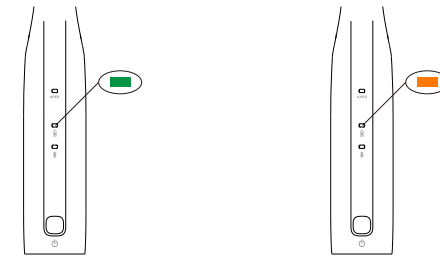
### 9.3 Upper Shaping

- Refer to “**8. Root canal preparation**” to use.
- **Stand-by**



- **Working**

- Battery indicator of handpiece



Constant green

Flashing orange

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



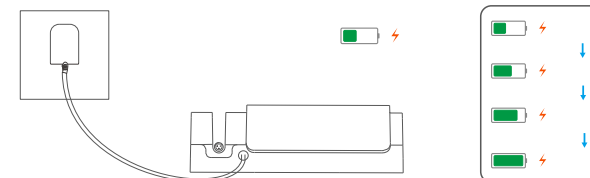
#### CAUTION:

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:

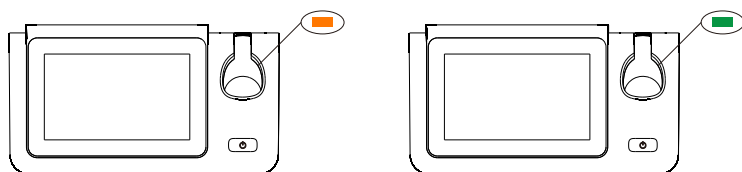
- **External charging:** Connect handpiece and adapter, and place handpiece on handpiece charger to charge.
- **Internal charging:** Control unit can charges handpiece without external input.
- Press to enter setup state and then press to turn on/ off internal charging.



### Note:

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.



### Note:

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

### WARNING:

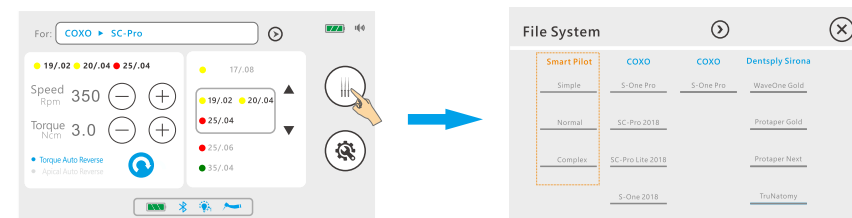
- Only use the adapter provided by manufacturer
- Do not charge in humid places

## 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

Simple, Normal: Upper Shaping ----- Glide Path ----- Canal Shaping

Complex: Upper Shaping ----- Patency ----- Glide Path ----- Canal Shaping

## 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:

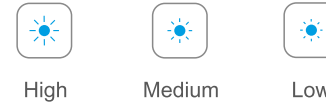
- When the motor reverses, there will be a buzzer prompt
- When the motor stops, the direction returns to clockwise

## 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.



### NOTE:

The change will be automatically saved

#### b) Handpiece

- **LED :** Press button to change the status as below:



### Note:

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.



### Note:

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.

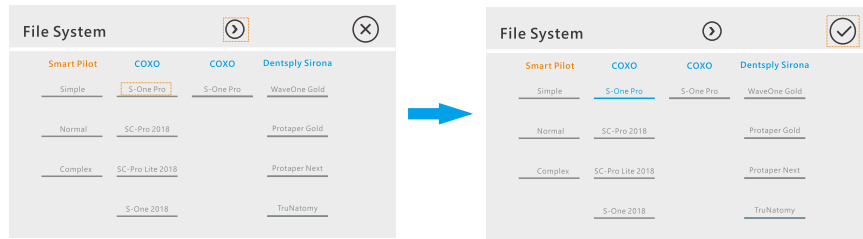
### Note:

Not available in single canal length measurement

### 6.2.1 File selection

#### a) Manufacturer and NITI system

- Press   to switch pages and press  to exit.

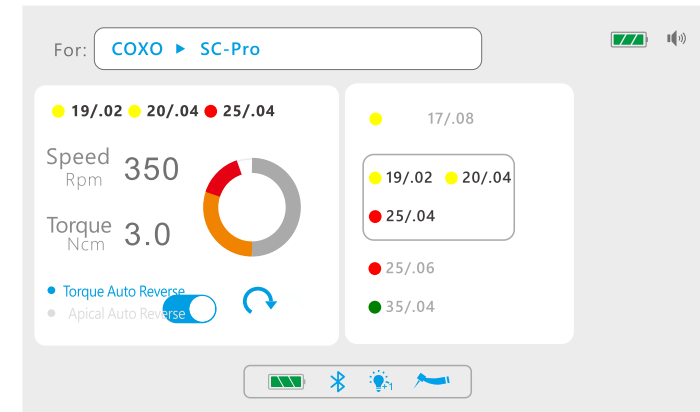
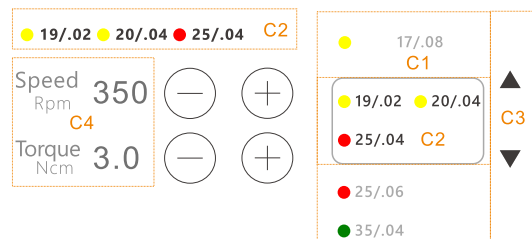


- After the selection is completed, the status bar of the main page displays the selected NITI system.

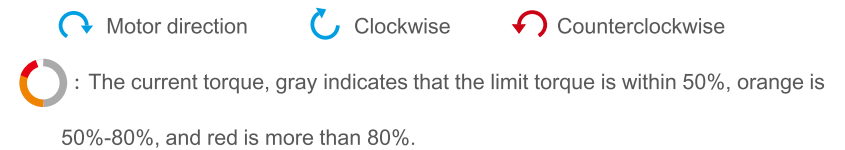


- B1File manufacturer
- B2NITI system name
- User can also press  (B3) to select different NITI system under the same manufacturer.

#### b) File selection



### Single root canal preparation



## 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 canal length measurement 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.

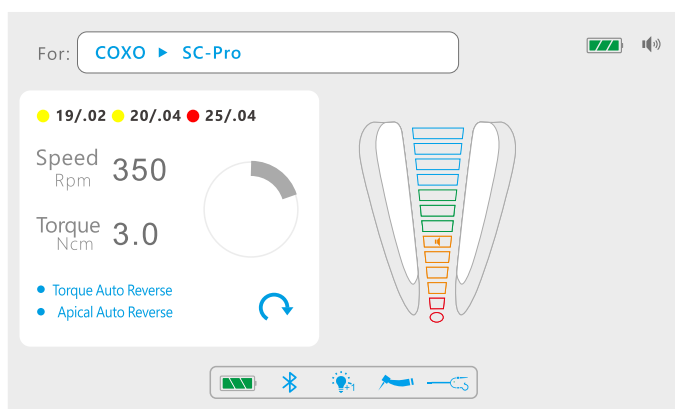
### CAUTION:

During operation, do not apply excessive force to the file

### Note:

- **Torque Auto Reverse** Depends on whether this function is turned on , refer to “**6.6 Torque auto reverse**”
- **Apical Auto Reverse** Depends on whether this function is turned on, Single root canal preparation is available. refer to “**6.7 Apical auto reverse**”
-  Depends on the set apex position , Single root canal preparation is available. refer to “**6.5 Set the apex position**”
-  Depends on whether LED is turned on and the delay times , refer to “**6.1 Setting**”

## 8.2 Working



Root canal measurement and preparation

- 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

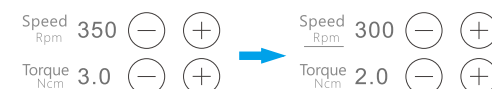
- The instrument contains two user's systems: Rotary File and Recipro File.
- Rotary File:There is 5 continuous rotary files in the system and user can set speed and torque as required.
- Recipro File:There is a reciprocation rotary file in the system and user can set speed and rotation angle as required.

### 6.2.3 Parameter adjustment

#### CAUTION:

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).



### NOTE:

- 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 symbol mean:



: Calibrating



: Calibration complete



: Calibration failed



**NOTE:**

Calibration failed refers to " 12 Troubleshooting"



**CAUTION:**

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

## 6.4 Check canal measurement function

Before canal length measurement or when the measurement is inaccurate, you can check the function as follow.

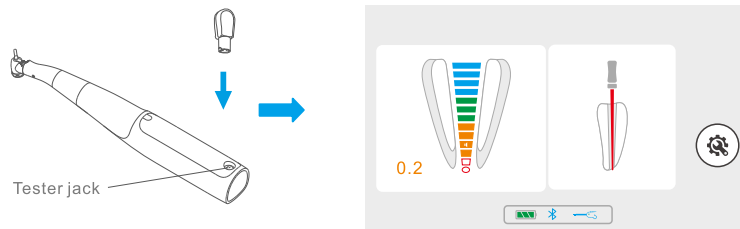


**NOTE:**

Suitable for root canal measurement, not only single root canal measurement but also root canal measurement and preparation

### 6.4.1 Check with tester

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



**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.

## 8. Root canal preparation

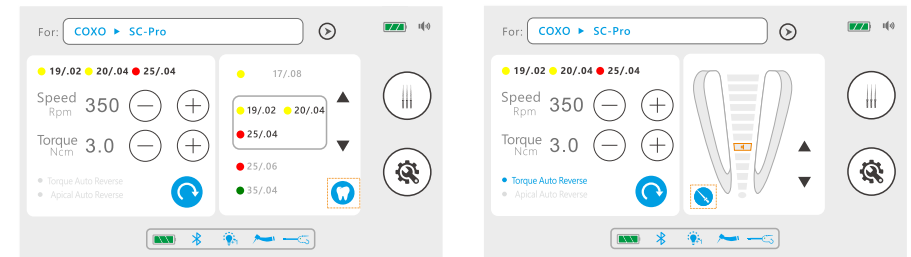
Refer to "4.1 B" to connect accessories to enter root canal preparation.



**Note:**

If the lip hook wire is not connected, there is only single root canal preparation, but no canal length measurement

### 8.1 Stand-by

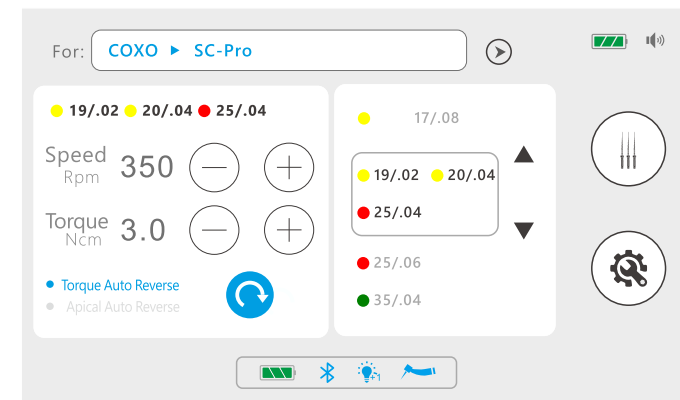


#### Root canal measurement and preparation

##### A: Root canal preparation

##### B: Canal length measurement

|                                                                                                                                                                         |                                                                                                                                                                                                                            |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | Button to switch page A/B                                                                                                                                                                                                  |
|                                                                                      | Motor reverse button<br> Clockwise  Counterclockwise |



#### Single root canal preparation

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.

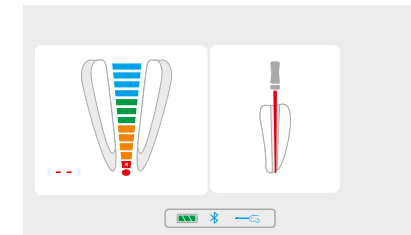
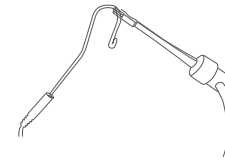
#### **Blocked canal**

The meter will not move if the canal is blocked.

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

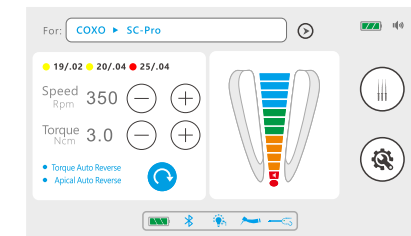
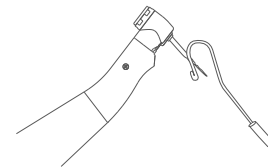
#### **Extremely dry canal**

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.



### **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**

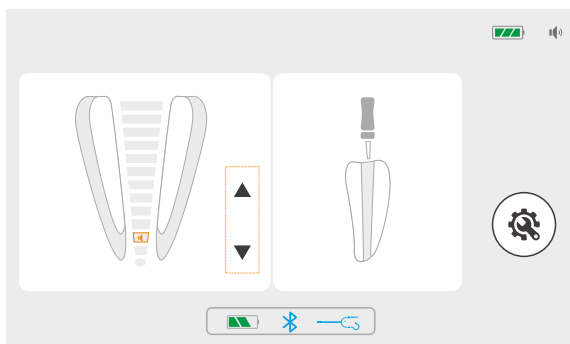
Set the apex position according to your need.



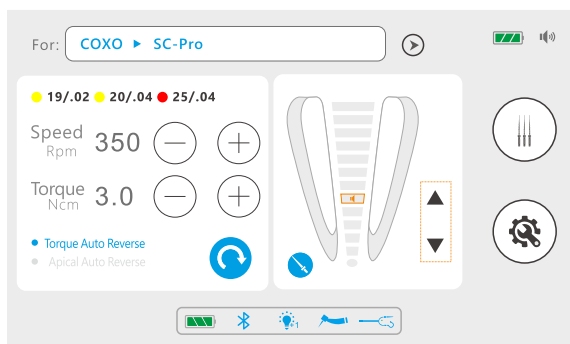
#### **Note:**

Suitable for root canal measurement, not only single root canal measurement but also root canal measurement and preparation

- 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).



Single canal length measurement



Root canal measurement and preparation

Press ▲ / ▼ 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.

### NOTE:

- Suitable for root canal preparation
- The function is unviable in some steps of Smart pilot, refer to "9. smart pilot"

- Press ☐ / ☒ to turn on/off the function.

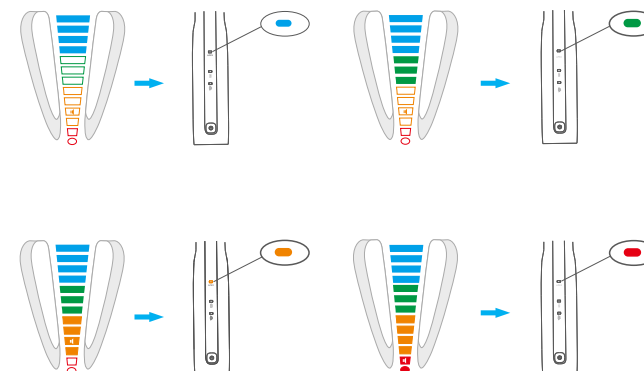
### ● Torque Auto Reverse

ON

### ● Torque Auto Reverse

OFF

- When the function is available it will disappear.



### NOTE:

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

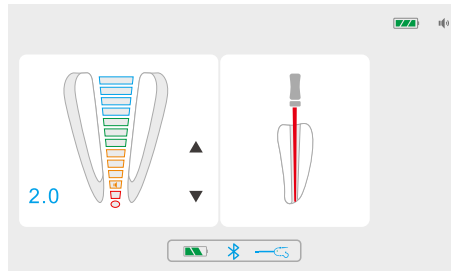
Fractured tooth will cause electrical leakage and an accurate measurement cannot be obtained.

A branch canal will also cause electrical leakage.

### Re-treatment of a root filled with gutta-percha

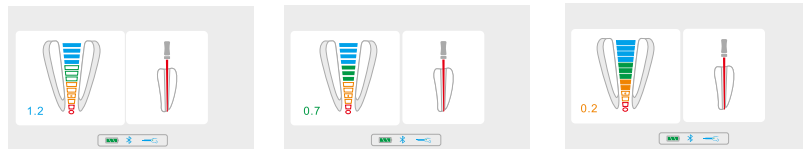
The gutta-percha must be completely removed to eliminate its insulating effect. After removing the gutta-percha, pass a small file all the way through the apical foramen and

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



Apex enlargement area:

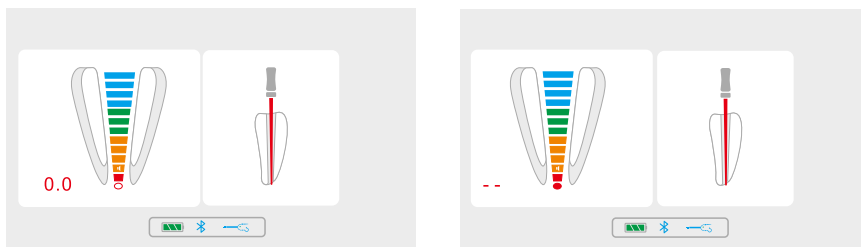
- Indicators indicates the exact position and changes accordingly from blue to green and then to yellow as shown below.



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)

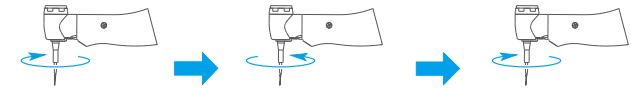
Red (Beyond apex foramen)

#### NOTE:

- 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.



Load within the torque limit value

Load beyond the torque limit value

When the load is reduced, the motor is automatically restored



#### CAUTION:

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.



#### Note:

- Suitable for root canal preparation and measurement
- The function is unviable in some steps of Smart pilot, refer to "9. Smartpilot"

- Press ☐ / ☒ to turn on/off the function.

#### Apical Auto Reverse

ON

#### Apical Auto Reverse

OFF

- 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



#### CAUTION:

During operation, do not apply excessive force to the file

### 6.8 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;

#### Factory defaults

All parameters set by user will be removed.

RESET

- Follow the prompt step by step.
- During factory reset, the symbol mean:

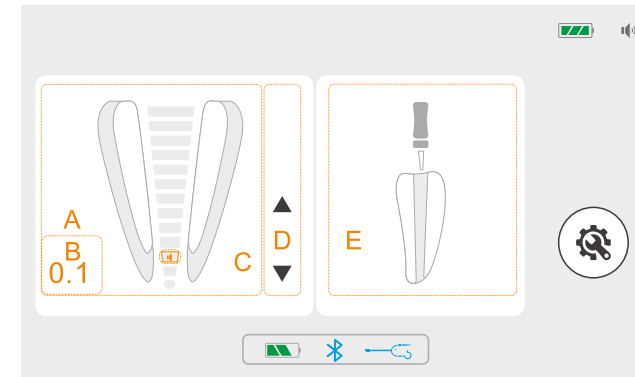
 : Resetting

 : Factory reset is complete

## 7. Canal length measurement

Refer to “4.1 A” to connect accessories to enter canal length measurement.

### 7.1 Stand-by



|     |                                                                                       |                                                                                                                                                          |
|-----|---------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| A   |    | Root apex area, shows the root apex area and indicate where file was reached                                                                             |
| B   |    | 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) |
| C、D |   | Set the apex position                                                                                                                                    |
| E   |  | Complete root canal image<br>Shows file entering the root canal opening                                                                                  |

### 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.