E-COM Endo Motor

INSTRUCTION MANUAL

CE 0197

Please read this manual before operating

GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.

Contents

⚠ Note: the description on reciprocating mode is only applicable for the device that has reciprocating mode.

Preface

Guilin Woodpecker Medical Instrument Co., Ltd is a professional manufacturer researching, developing, and producing dental products. Woodpecker owns a sound quality control system. Guilin Woodpecker Medical Instrument Co., Ltd has two brands, Woodpecker and DTE. Its main products include Ultrasonic Scaler, Curing light, Apex locator, Ultrasurgery, Endo Motor, etc.

1 Product introduction

1.1 Product description

E-COM is mainly used in Endodontic treatment. During root canal preparation procedure, it is used to mold and clean the root canal.

Features:

a) Wireless handpiece enables more convenient operation.

b) Adopt real-time feedback technology and dynamic torque control, effectively preventing needle breakage.

c) Wireless handpiece enables more convenient operation.

d) Storage of 9 user-defined modes allows invocation at any time.

Under each mode, Continuous Rotation Mode, Reciprocating Motion Mode, and Reverse Rotation are for options.

1.2 Model and specification

E-COM

Please refer to packing list for device configurations.

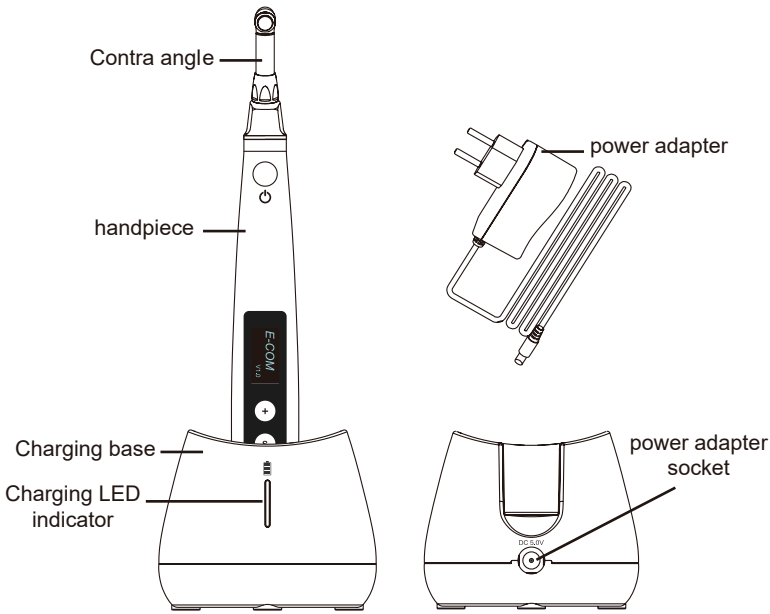
1.3 Scope of application

1.3.1 The device is suitable for root canal molding and cleaning in endodontic treatment.

1.3.2 The device must be operated in hospital and clinic by the qualified dentists.

1.4 Performance and composition

The device is composed of charging base, handpiece, contra-angle, and power adapter, etc.



1.5 Contraindication

Patients with implanted pacemakers (or other electrical equipment) who are warned not to use household appliances such as electric razors, hair dryers, etc. are not recommended to use this device.

1.6 ⚠ Warnings

1.6.1 Please carefully read this Instruction Manual before first operation.

1.6.2 This device should be operated by professional and qualified dentist in qualified hospital or clinic.

1.6.3 Do not directly or indirectly place this device near heat source. Operate and store this device in reliable environment.

1.6.4 This device requires special precautions regarding electromagnetic

compatibility (EMC) and must be in strict accordance with the EMC information for installation and use. Do not use this equipment especially in the vicinity of fluorescent lamps, radio transmitting devices, remote control devices, handheld and mobile high-frequency communication devices.

1.6.5 Long time use of Reciprocating Motion Mode may result in handpiece overheat, thus it should be left to cool for use. If the handpiece is overheated frequently, please contact local distributor.

1.6.6 Please use the original contra-angle. Otherwise it will not be used or cause adverse consequences.

1.6.7 Please do not make any changes to the device. Any changes may violate safety regulations, causing harm to the patient. There will be no promises of any modification.

1.6.8 Please use original power adapter. Other power adapter will result in damage to lithium battery and control circuit.

1.6.9 The handpiece cannot be autoclaved. Use disinfectant of neutral pH value or ethyl alcohol to wipe its surface.

1.6.10 Before the contra-angle stopping rotating, do not press the push cover of contra-angle. Otherwise the contra-angle will be broken.

1.6.11 Before the handpiece stopping rotating, do not remove the contra-angle. Otherwise the contra-angle and the gear inside handpiece will be broken.

1.6.12 Please confirm whether the file is well installed and locked before starting the handpiece.

1.6.13 The file of Continuous Rotation Mode shall not be used under Reciprocating Motion Mode and vice versa.

1.6.14 Please set torque and speed as per the recommended specifications of file manufacturer.

1.6.15 The Continuous Rotation Mode matches continuous rotating files; the Reciprocating Motion Mode matches reciprocating files (i.e. WAVE ONE); the Reverse Rotation Mode is adopted to pick the continuous rotating files out while the file accidentally gets stuck in the root canal.

1.7 Device safety classification

1.7.1 Type of operation mode: Continuous operating device

1.7.2 Type of protection against electric shock: Class II equipment with internal power supply

1.7.3 Degree of protection against electric shock: BF type applied part

1.7.4 Degree of protection against harmful ingress of water: Ordinary equipment (IPX0)

1.7.5 Degree of safety application in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide: Equipment cannot be used in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

1.7.6 Applied part: contra-angle.

1.7.7 The contact duration of applied part: 1 to 10 minutes.

1.7.8 The temperature of the surface of applied part may reach 46.6℃.

1.8 Primary technical specifications

1.8.1 Battery

Lithium battery in handpiece: 3.6V /750mAh

1.8.2 Power adapter

Input: ~100V-240V 50Hz/60Hz 0.5-0.2A

Output: DC5V/1A

1.8.3 Torque: 0.6Ncm-5.0Ncm(6mNm ~ 50mNm)

1.8.4 Rotate speed: 100rpm~1000rpm

1.9 Environment parameters

1.9.1 Environment temperature: +5℃ ~ +40℃

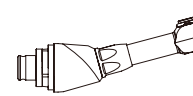
1.9.2 Relative humidity: 30% ~ 75%

1.9.3 Atmospheric pressure: 70kPa ~ 106kPa

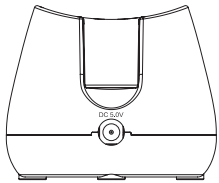
2 Installation

2.1 Basic accessories of product

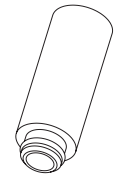
Motor handpiece



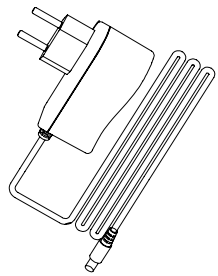
Contra-angle



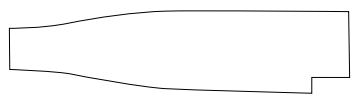
Charging base



Lubricator



Power adapter



Disposable insulation sleeves

2.2 Instructions for contra-angle

2.2.1 The contra-antgle adopts precision gear transmission, and the transmission ratio is 1: 1. The material for contra-angle is copper. (Model:CA001)

2.2.2 Before the first use and after treatments, please clean and disinfect contra-angle with disinfectant of neutral PH value. After disinfection, lubricate it with specific cleaning oil. Finally, sterilize it under high temperature and high pressure (134℃, 2.0bar~2.3bar (0.20MPa~0.23MPa)).

2.2.3 The contra-angle can only be used cooperatively with this device. Otherwise the contra-angle will be damaged.

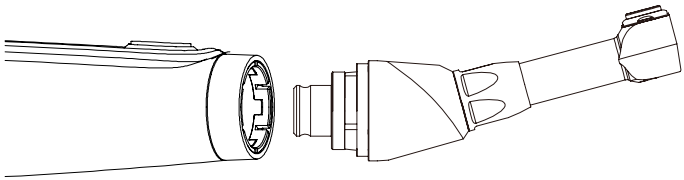
2.3 Installation and removal of contra-angle

2.3.1 Installation

Align the positioning pin of contra-angle with the positioning hole of handpiece, horizontally pushing the contra-angle. A click sound indicates that it is well installed. By aligning those three pins on contra-angle with those six holes on handpiece, the contra-angle can be installed in different angle. (As shown below)

2.3.2 Removal

Pull out the contra-angle horizontally when the motor handpiece does not start.



⚠ Warnings

a) Before plugging in or pulling out contra-angle, please first stop the handpiece motor.

b) After installation, please check and confirm that the contra-angle has been well installed.

2.4 Installation and removal of file

2.4.1 Installation of file

Before starting the device, plug the file into the hole of contra-angle head. While plugging, slightly screw the file with one hand, and press the push cover of contra-angle with another hand.

⚠ Warnings

Please use standard file. The maximum length of the file is 31mm. And the appropriate minimum length of file handle is 11mm with 2.334-2.35 mm handle diameter, which meet the requirements on Class Ihandle in ISO 1797-1 Standard.

After plugging the file into contra-angle, let go the hand on push cover to assure that the file cannot be taken out.

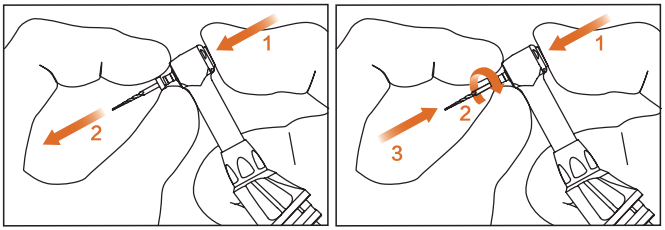
2.4.2 Removal of file

Pressing the push cover, and then directly pull out the file.

⚠ Warnings

a) Before plugging and pulling out the file, the handpiece must be stopped.

b) After the file is well installed, without pressing the push cover, the file should be firmly locked while slightly pulling the file.



2.5 Installation and removal of disposable insulation sleeves

2.5.1 Installation

Before each use of the handpiece and after the handpiece is cleaned and disinfected,put on a disposable isolation sleeve. Take the isolation sleeve out of the isolation sleeve box, then insert the isolation sleeve into the motor handpiece from the thin end of the handpiece, and install the isolation sleeve until there is no obvious wrinkle.

After installing the disposable isolation sleeve, wrap the barrier film around the handpiece surface. After that, clean and disinfect the surface of the handpiece. Refer to Chapter 6.3 for cleaning and disinfection procedures.

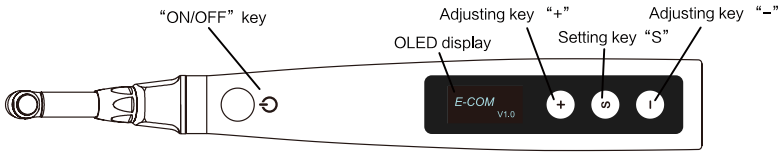
2.5.2 Removing

After each use, remove the barrier film and slowly pull the isolation sleeve from the thin end of the handpiece.

⚠ Warming: Isolation sleeves are not reusable.

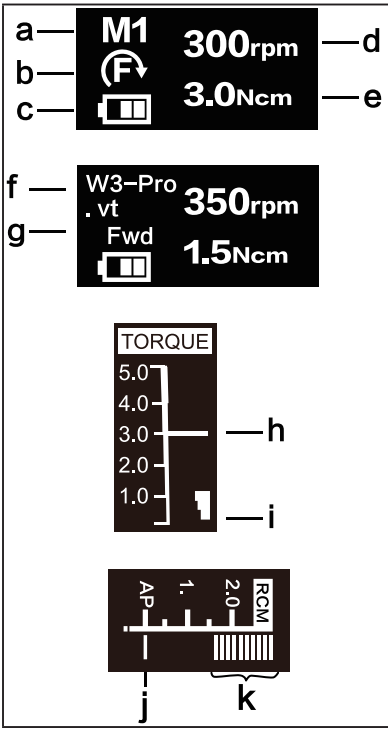
3 Function and operation of product

3.1 Schematic drawing of handpiece



Schematic drawing of handpiece

3.2 OLED display



a) Customized program sequence number 1-9, totally 9 programs

b) Operation mode

c) Battery consumption

d) Set speed

e) Set torque

f) File system

g) Operation mode

h) Torque setting

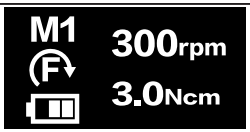
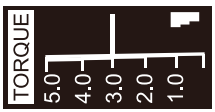
i) Real-time torque

j) Set apical stop

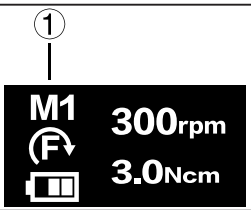
k) File position

4 Operation instruction

4.1 Starting and Stopping

a) Under the power off state of handpiece, press key, and then the handpiece will enter Standby mode.	 Standby interface
b) Under Standby mode, press key, and then the handpiece will enter Operating mode. **Note** The handpiece motor cannot enter working state while it is in the base. c) Press the key again, and then the handpiece backs to Standby mode.	 Continuous Rotation Mode interface

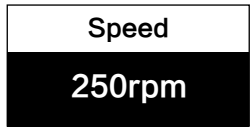
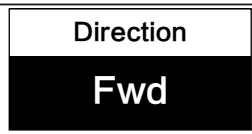
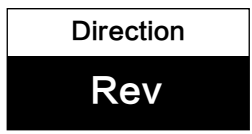
4.2 Selecting memory

a) E-COM allows 9 memorizing programs. Under standby state, please press key or to switchover those memorizing programs. And the serial number will change correspondingly.	

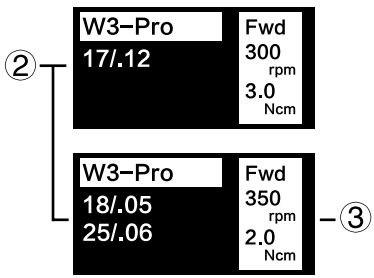
4.3 Speed setting, torque setting, and operation mode setting

Under standby state, short press key to enter speed setting, torque setting, and operation mode setting interfaces.

In setting interface, it will automatically back to Standby interface after 5s without operation. Press key to enter Standby interface.

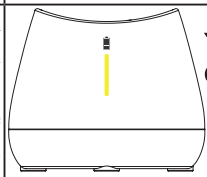
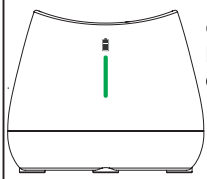
Speed setting: In the Speed Setting Interface, press ⊕ to increase speed, press ⊖ to decrease speed, and long press to fast increase or fast decrease speed.	
Torque setting: In the Torque Setting Interface, press ⊕ to increase torque, press ⊖ to decrease torque, and long press to fast increase or fast decrease torque.	
Operation Mode Setting: In the Operation Mode Setting Interface, press ⊕ key or ⊖ key to switch operation mode. Continuous Rotation Mode, Reverse Rotation Mode and Reciprocating Motion Mode are for options. There will be a tick indication while setting to Reverse Rotation Mode. Long press to realize fast modes handover. ⚠ **Note** The speed and torque cannot be adjusted under Reciprocating Motion Mode.	 Continuous Rotation Mode  Reverse Rotation Mode  Reciprocating Motion Mode

4.4 Preset programs

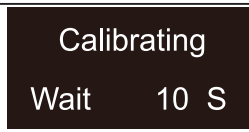
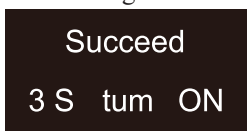
Select the self-defining program that need to be replaced.	
Long press key S to get into the interface of file system. Press key ⊕ or key ⊖ to select needed file system. Press the key S to confirm, and press the ⏻ key to log out.	
Press key S to get into the interface of corresponding file system. Press key ⊕ or key ⊖ to select needed file model (②), the corresponding rotation direction, speed, and torque value (③). Press the key S to confirm, and press the ⏻ key to log out.	
After selecting the file system, the selected one will replace the former program.	

4.5 Battery Charging

If the battery icon turns into display that as the picture shown, it indicates that the battery capacity is very low. Please charge.	

When the battery capacity is the too low, the device may indicate “Low Battery!” and automatically power off.	
Connect the power adapter with the base. Confirm that it is well connected, and then place the handpiece into the base. If the indicator light on base turns yellow, it indicates that it is charging. If the indicator light on base turns green, it indicates that the battery capacity is enough, and there is no need to charge. After charging, please unplug the power adapter. ⚠ **Note** Please use the original power adapter for charging.	 

4.6 Contra-angle calibration setting

After replacement of contra-angle, the contra-angle shall be calibrated before use. In Standby Interface, first long press setting key and then long press for 2s to enter Calibration Interface of contra-angle. After 15s’s countdown, the interface of successful calibration will appear. Five more seconds later, it will switch to Standby Interface.	 Calibration Interface of Contra-angle  Interface of Successful Calibration

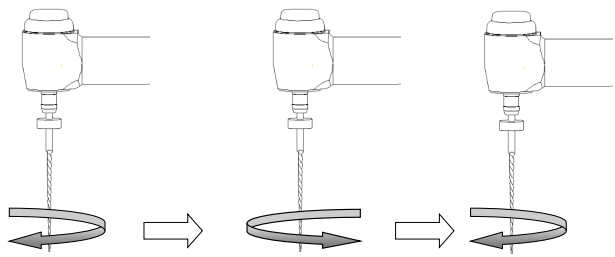
4.7 Power-off

In Standby Interface, the handpiece would automatically shut down

after 3 minutes without any button-pressing operation. The handpiece will also automatically shut down while it is put into the charging base. In Standby Interface, long press setting key ⊖ , and then long press Adjusting key ⊕ , finally the device will automatically shut down 2s later.

4.8 Protective function of automatic reverse

During operation, if the load value exceeds the preset torque value, the file rotation mode will automatically change to Reverse Mode. And the file would return to normal rotation mode when the load is below the preset torque value again.



a) b) c)

a) Clockwise rotation
Load value is lower than preset torque value
b) Counterclockwise rotation
Load value is higher than preset torque value
c) Clockwise rotation
Load value is lower than preset torque value again

⚠ Note

a) Protective function of automatic reverse is ONLY suitable for Continuous Rotation Mode.
b) This function is forbidden under Reciprocating Motion Mode and Reverse Rotation Mode.
c) When the handpiece battery indicator indicates a low battery capacity, the low battery capacity is insufficient to support the handpiece to reach the limit torque value, that is, the auto-reverse function will not work properly. Please charge it in time.
d) If the motor is under load all the time, the machine may stop automatically as a result of overheat protection. If it happens, turn off

the handpiece for a while until the temperature drops.

5 Oiling of contra-angle

Only the original oil injection nozzle can be used for oiling of contra-angle. After disinfection of contra-angle and before sterilization, oiling should be conducted under high pressure and high temperature.

1.Firstly, screw the injecting nozzle into jet of oil bottle. (Around 10 circles)

2.Next, plug the nozzle into the end part of contra-angle, and then grease the contra-angle for 2-3s till the oil flow out of contra-angle head part.

3.Vertically place the end part of contra-angle or tilt the contra-angle to let go the redundant oil under gravity.

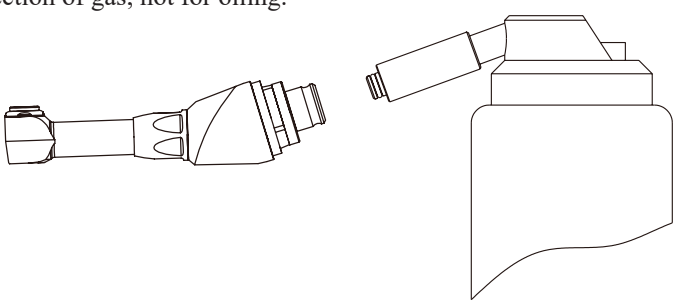
⚠ Warnings

Handpiece cannot be filled with oil.

⚠ Cautions

a.To avoid the contra-angle from flying out for the pressure, use hand to safely hold the contra-angle while greasing.

b.Do not use a swirling nozzle. Swing nozzle can only be used for injection of gas, not for oiling.



6 Cleaning, Disinfection and Sterilization

6.1 Foreword

For hygiene and sanitary safety purposes,the contra-angle and the protective silicon cover must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use, as well as all subsequent uses.

6.2 General recommendations

6.2.1 Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA and Health Canada approval) and in accordance with the DFU of the disinfecting solution manufacturer.
6.2.2 Do not place the contra-angle in a disinfectant solution or in an ultrasonic bath.
Do not use chloride detergent materials.
6.2.3 Do not use bleach or chloride disinfectant materials.
6.2.4 For your own safety, please wear personal protective equipment (gloves, glasses, mask).
6.2.5 The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments where applicable after sterility.
6.2.6 The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.
6.2.7 To sterilize the endodontic files, refer to the manufacturer's instructions for use.
6.2.8 The contra-angle needs to be lubricated after cleaning and disinfection, but before sterilization.

6.3 Cleaning and disinfection steps for the motor handpiece, the AC adapter and the base.

Before and After each use, all the objects that were in contact with infectious agents should be cleaned using towels impregnated with a disinfecting and detergent solution (a bactericidal, fungicidal and aldehyde free solution) approved by VAH/DGHM-listing, CE marking, FDA and Health Canada.

⚠ Warning: Do not sterilize the motor handpiece, the AC adapter and the base.

6.3.1 Pre-Op processing

Before each use, the handpiece, charger, and base must be cleaned and disinfected. The specific steps are as follows:

⚠ Warning: The handpiece, charger, and base cannot be cleaned and disinfected with automatic equipment. Manual cleaning and disinfection is required.

6.3.1.1 Manual cleaning steps:

1. Take out the handpiece, charger, and base on the workbench.
2. Wet the soft cloth completely with distilled water or deionized water, and then wipe all the surfaces of the components such as the handpiece, charger, base, etc. until the surface of the component is not stained.
3. Wipe the surface of the component with a dry soft nap-free cloth.
4. Repeat the above steps at least 3 times.

Note:

a)Use distilled water or deionized water for cleaning at room temperature.

6.3.1.2 Manual disinfection steps:

1. Soak the dry soft cloth with 75% alcohol.
2. Wipe all surfaces of headpiece, charger, base and other components with a wet soft cloth for at least 3 minutes.
3. Wipe the surface of the component with a dry soft nap-free cloth.

Note:

a) The cleaning and disinfection must be performed within 10min before use.

b) The disinfectant used must be used immediately, no foaming is allowed.

c) In addition to 75% alcohol, you can use non-residue disinfectants such as Oxytech from Germany, but you must respect the concentration, temperature and time specified by the disinfectant manufacturer.

d) After cleaning and disinfecting the handpiece, you must install a disposable isolation sleeve before use and repeat steps 1, 2 and 3 to clean the disposable isolation sleeve(For detailed installation steps, see section 2.5).

6.3.2 Post-Op processing

After each use, clean and disinfect the handpiece, charger, and base within 30 minutes. The specific steps are as follows:

Tools: Nap-free soft cloth, tray

1. Remove the contra-angle from the handpiece, place it in a clean tray, and then remove the disposable isolation sleeve from the handpiece.
2. Soak the nap-free soft cloth with distilled water or deionized water, and then wipe all the surfaces of the components such as the handpiece, charger, base, etc. until the surface of the component is not stained.
3. Wet the dry soft cloth with 75% alcohol, and then wipe all surfaces of the handpiece, charger, base and other components for 3 minutes.
4. Put the handpiece, charger, base and other components back into the clean storage area.
Note:
a) The cleaning and disinfection must be performed within 10min before use.
b) The disinfectant used must be used immediately, no foaming is allowed.
c) In addition to 75% alcohol, you can use non-residue disinfectants such as Oxytech from Germany, but you must respect the concentration, temperature and time specified by the disinfectant manufacturer.

6.4 The cleaning, disinfection and sterilization of contra-angle,protective silicon cover as follow.

Unless otherwise stated, they will be hereinafter referred to as “products”.

Warnings:

The use of strong detergent and disinfectant (alkaline pH>9 or acid pH <5) will reduce the life span of products. And in such cases, the manufacturer takes no responsibility.

The products may not be exposed to temperature above 138℃.

Processing limit

The products have been designed for a large number of sterilization cycles. The materials used in manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. The maximum number of sterilizations for products is 250 times.

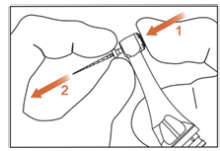
6.4.1 Initial processing

6.4.1.1 Processing principles

It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product-specific procedures are used for

cleaning/disinfection and sterilization, and that the validated parameters are adhered to during every cycle.
Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic, especially with regard to the additional requirements for the inactivation of prions.
6.4.1.2Post-operative treatment
The post-operative treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows:
1. Remove the products from the base, and rinse away the dirt on the surface of handpiece with pure water (or distilled water/deionized water);
2. Dry the products with a clean, soft cloth and place it in a clean tray.
Notes:
a) The water used here must be pure water, distilled water or deionized water.
6.4.2 Preparation before cleaning
Steps:
Tools: tray, soft brush, clean and dry soft cloth.
1. Remove the shanks/files.
2. Remove the isolation sleeve and Contra-angle from the handpiece, and then put them into a clean tray;
3. Use a clean soft brush to carefully brush connecting protective silicon cover, head and back cover of the contra-angle until the dirt on surface is not visible. Then use soft cloth to dry the products and put them into a clean tray. The cleaning agent can be pure water, distilled water or deionized water.

Disassembling steps



(a)

(b)

(c)

a) Press the push-button and pull out the shank/file.

b) When removing the protective silicon cover, pull it straight out slowly.

c) When inserting and removing the contra-angle, turn thehandpiece power off beforehand.

6.4.3 Cleaning

The cleaning should be performed no later than 24 hours after the operation.

The cleaning can be divided into automated cleaning and manual cleaning. Automated cleaning is preferred if conditions permit.

6.4.3.1Automated cleaning

•The cleaner is proved to be valid by CE certification in accordance with EN ISO 15883.

▪There should be a flushing connector connected to the inner cavity of the product.

▪The cleaning procedure is suitable for the product, and the irrigating period is sufficient.

It is recommended to use a washer-disinfector in accordance with EN ISO 15883. For the specific procedure, please refer to the automated disinfection section in the next section "Disinfection".

Notes:

a) The cleaning agent does not have to be pure water.It can be distilled

water, deionized water or multi-enzyme. But please ensure that the selected cleaning agent is compatible with the product.
b) In washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it would be difficult to remove.
c) After cleaning, the chemical residue should be less than 10mg / L.
6.4.4 Disinfection
Disinfection must be performed no later than 2 hours after the cleaning phase. Automated disinfection is preferred if conditions permit.
6.4.4.1Automated disinfection-Washer-disinfector
·The washer-disinfector is proved to be valid by CE certification in accordance with EN ISO 15883.
·Use high temperature disinfection function. The temperature does not exceed 134 ° C, and the disinfection under the temperature cannot exceed 20 minutes.
·The disinfection cycle is in accordance with the disinfection cycle in EN ISO 15883.
Cleaning and disinfecting steps by using Washer-disinfector
1. Carefully place the product into the disinfection basket. Fixation of product is neededonly when the product is removable in the device. The products are not allowed to contact each other.
2. Use a suitable rinsing adaptor, and connect the internal water lines to the rinsing connection of the washer-disinfector.
3. Start the program.
4. After the program is finished, remove theproductfrom the washer-disinfector, inspect (refer to section "Inspection and Maintenance") and packaging (refer to chapter "Packaging"). Dry the productrepeatedly if necessary (refer to section "Drying").
Notes:
a) Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.
b) With this equipment, cleaning, disinfection and drying will be carried out together.
c) Cleaning: (c1) The cleaning procedure should be suitable for the product to be treated. The flushing period should be sufficient (5-10 minutes). Pre-wash for 3 minutes, wash for another 5 minutes, and rinse it for twice with each rinse lasting for 1 minute. (c2) In the washing stage, the water temperature should not exceed 45 °C, otherwise the

protein will solidify and it is difficult to remove. (c3) The solution used can be pure water, distilled water, deionized water or multi-enzyme solution, etc., and only freshly prepared solutions can be used. (c4) During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed. The used cleaner is neodisher MediZym (Dr. Weigert).

d) Disinfection: (d1) Direct use after disinfection: temperature ≥ 90 ° C, time ≥ 5 min or A0 ≥ 3000;

Sterilize it after disinfection and use: temperature ≥ 90 ° C, time ≥ 1 min or A0 ≥ 600

(d2) For the disinfection here,the temperature is 93 ° C, the time is 2.5 min, and A0>3000

e) Only distilled or deionized water with a small amount of microorganisms (<10 cfu/ml) can be used for all rinsing steps. (For example, pure water that is in accordance with the European Pharmacopoeia or the United States Pharmacopoeia).

f) After cleaning, the chemical residue should be less than 10mg / L.

g)The air used for drying must be filtered by HEPA.

h) Regularly repair and inspect the disinfector.

6.4.5 Drying

If your cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.

Methods:

1. Spread a clean white paper (white cloth) on the flat table, point the product against the white paper (white cloth), and then dry the product with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the productdrying is completed.

2. It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is 80℃~120℃ and the time should be 15~40 minutes.

Notes:

a) The drying of product must be performed in a clean place.

b) The drying temperature should not exceed 138 °C;

c) The equipment used should be inspected and maintained regularly.

6.4.6 Inspection and maintenance

6.4.6.1 Inspection

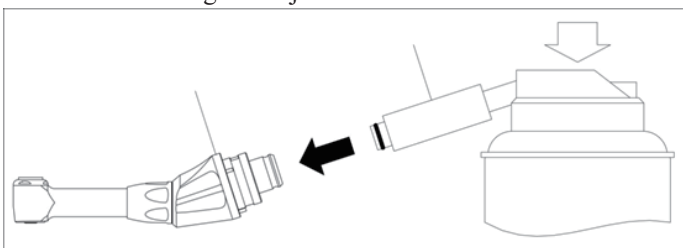
In this chapter, we only check the appearance of the product.

1. Check the product. If there is still visible stain on the product after cleaning/disinfection, the entire cleaning/disinfection process must be repeated.
2. Check the product. If it is obviously damaged, smashed, detached, corroded or bent, it must be scrapped and not allowed to continue to be used.
3. Check the product. If the accessories are found to be damaged, please replace it before use. And the new accessories for replacement must be cleaned, disinfected and dried.
4. If the service time (number of times) of the product reaches the specified service life (number of times), please replace it in time.

6.4.6.2Maintenance

Oil lubrication of sterilized and dried products.

The nozzle of cleaning lubricant is aligned with the air intake hole at the end of thecontra angle to inject oil for 1-2 seconds.



6.4.7 Packaging

Install the disinfected and dried product and quickly package it in a medical sterilization bag (or special holder, sterile box).

Notes:

a) The package used conforms to ISO 11607;

b) It can withstand high temperature of 138 °C and has sufficient steam permeability;

c) The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants;

d) Avoid contact with parts of different metals when packaging.

6.4.8 Sterilization

Use only the following steam sterilization procedures (fractional pre-vacuum procedure*) for sterilization, and other sterilization procedures are prohibited:

·The steam sterilizer complies with EN13060 or is certified according to EN 285 to comply with EN ISO 17665;
·The highest sterilization temperature is 138 ° C;
·The sterilization time is at least 4 minutes at a temperature of 132 ° C / 134 ° C and a pressure of 2.0 bar ~ 2.3 bars.
·Allow a maximum sterilization time of 20 minutes at 134 °C.
Verification of the fundamental suitability of the products for effective steam sterilization was provided by a verified testing laboratory.
Notes:
a) Only products that have been effectively cleaned and disinfected are allowed to be sterilized;
b) Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.
c) Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;
d) Please use the recommended sterilization procedures for sterilization. It is not recommended to sterilize with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended. If you use the sterilization procedures that have not been recommended, please adhere to related effective standards and verify the suitability and effectiveness.
* Fractional pre-vacuum procedure = steam sterilization with repetitive pre-vacuum.The procedure used here is to perform steam sterilization through three pre-vacuums.
6.4.9 Storage
1.Store in a clean, dry, ventilated, non-corrosive atmosphere with a relative humidity of 10% to 93%, an atmospheric pressure of 70KPa to 106KPa, and a temperature of -20 °C to +55 °C;
2. After sterilization,the product should be packaged in a medical sterilization bag or a clean sealing container, and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.
Notes:
a) The storage environment should be clean and must be disinfected regularly;
b) Product storage must be batched and marked and recorded.

6.4.10 Transportation

1. Prevent excessive shock and vibration during transportation, and handle with care;
2. It should not be mixed with dangerous goods during transportation.
3. Avoid exposure to sun or rain or snow during transportation.

7 Troubleshooting

Failure	Possible cause	Solutions
There is continuous beep sounds after starting the handpiece.	The continuous beep sound is indicating that the handpiece is under reverse rotation state.	Stop the handpiece and change the operating mode to Continuous Rotation Mode.
Contra-angle calibration failure.	1.Calibration failure caused by strong resistance of contra-angle.	1.Recalibration. 2.Clean the contra-angle, and recalibrate after oil injection.
After plugging the handpiece into charging base, the charging indicator does not light.	The power adapter is not well connected.	Check whether the power adapter is well connected.
After plugging the handpiece into charging base, the charging indicator does not turn to yellow.	1.The handpiece is not in place. 2.The handpiece is fully charged.	Plug the handpiece in place.
The time of endurance becomes shorter after charging.	Battery capacity becomes smaller.	Please contact local distributor or manufacturer.
The continuously rotating file is stuck at the root canal.	Incorrect specification setting. Too high load torque of file.	Choose Reverse Rotation Mode, start the handpiece, and take the file out.

8 Storage, maintenance and transportation

8.1 Storage

8.1.1 This equipment should be stored in a room where the relative humidity is 10% ~ 93%, atmospheric pressure is 70kPa to106kPa, and the temperature is -20°C ~ +55°C.

8.1.2 Avoid the storage in a too hot condition. High temperature will shorten the life of electronic components, damage battery, reshape or melt some plastic.

8.1.3 Avoid the storage in a too cold condition. Otherwise, when the temperature of the equipment increases to a normal level, there will be dew that will possibly damage PCB board.

8.2 Maintenance

8.2.1 This device do not include accessories for repair usage, the repair should be carried out by authorized person or authorized after service center.

8.2.2 Keep the equipment in a dry storage condition.

8.2.3 Do not throw, beat or shock the equipment.

8.2.4 Do not smear the equipment with pigments.

8.3 Transportation

8.3.1 Excessive impact and shake should be prevented in transportation. Lay it carefully and lightly and don't invert it.

8.3.2 Don't put it together with dangerous goods during transportation.

8.3.3 Avoid solarization and getting wet in rain and snow during transportation.

9 Environmental protection

Please dispose according to the local laws.

10 After service

From the date this equipment has been sold, based on the warranty card, we will repair this equipment free of charge if there are quality problems. Please refer to the warranty card for the warranty period.

11 Symbol instruction

CE 0197	CE marked product		Follow instructions for use
IPX0	Ordinary equipment	SN	serial number
	Date of manufacture		Manufacturer
	Type BF applied part		Class II equipment
	Used indoor only		Recovery
	Handle with care		Keep dry
93% 10%	Humidity limitation		Power on / off
106kPa 70kPa	Atmospheric pressure for storage	+55°C -20°C	Temperature limitation
	Appliance compliance WEEE directive		
EC REP	Authorised Representative in the EUROPEAN COMMUNITY		

12 Statement

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD. The industrial design, inner structure, etc, have claimed for several patents by WOODPECKER, any copy or fake product must undertake legal responsibilities.

13 European authorized representative

EC REP MedNet EC-Rep GmbH
Borkstrasse 10 · 48163 Muenster · Germany

14 EMC-Declaration of comformity

The device has been tested and homologated in accordance with EN 60601-1-2 for EMC. This does not guarantee in any way that this device will not be effected by electromagnetic interference Avoid using the device in high electromagnetic environment.

Technical Description Concerning Electromagnetic Emission

Table 1: Declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The model E-COM is intended for use in the electromagnetic environment specified below. The customer or the user of the model E-COM should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model E-COM uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The model E-COM is suitable for used in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions lEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions lEC 61000-3-3	Complies	

Technical Description Concerning Electromagnetic Immunity

Table 2: Guidance & Declaration - electromagnetic immunity

Guidance & Declaration — electromagnetic immunity			
The model E-COM is intended for use in the electromagnetic environment specified below. The customer or the user of the model E-COM should assure that It is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

Electrostatic discharge (ESD) lEC 61000-4-2	±8kV contact ±2, ±4, ±8, ±15kV air	±8kV contact ±2, ±4, ±8, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for Input/ output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge lEC 61000-4-5	±0.5, ±1kV line to line ±0.5, ±1, ±2kV line to earth	±0.5, ±1kV line to line ±0.5, ±1, ±2kV line to earth	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 <5 % UT (>95% dip in UT.) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 250 cycles	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT.) for 1 cycle 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models E-COM requires continued operation during power mains interruptions, it is recommended that the models E-COM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field lEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 3: Guidance & Declaration - electromagnetic immunity concerning Conducted RF & Radiated RF

Guidance & Declaration - Electromagnetic immunity

The model E-COM is intended for use in.the electromagnetic environment specified below. The customer or the user of the models E-COM should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF lEC 61000-4-6 Conducted RF lEC 61000-4-6 Radiated RF lEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM frequency band 3 V/m 80 MHz to 2.7 GHz	3V 6V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the models E-COM, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2×P1/2 d=2×P1/2 d=1.2×P1/2 80 MHz to 800 MHz d=2.3×P1/2 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacturer and d Is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur In the vicinity of equipment marked with the following symbol:
NOTE I At 80 MHz end 800 MHz. the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model E-COM is used exceeds the applicable RF compliance level above, the model E-COM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model E-COM.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the model E-COM

Recommended separation distances between portable and mobile RF communications equipment and the model E-COM			
The model E-COM is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model E-COM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model E-COM as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz $d=1.2\times P^{1/2}$	80MHz to 800MHz $d=1.2\times P^{1/2}$	800MHz to 2,7GHz $d=2.3\times P^{1/2}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.
NOTE I At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Scan and Login website
for more information

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