Endo Smart Endo Motor

INSTRUCTION MANUAL

Please read this manual before operating

CE 0197

ZMN-SM-075 V1.7 - 20220912

GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.

Contents

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

Endo Smart is mainly used in Endodontic treatment. During root canal preparation procedure, it is used to mold and clean the root canal.

Features:

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

b) Wireless handpiece enables more convenient operation.

c) Wireless charging avoids poor contact problem of traditional contact charging.

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

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

1.2 Model and specification

Endo Smart

Please refer to packing list for device configurations.

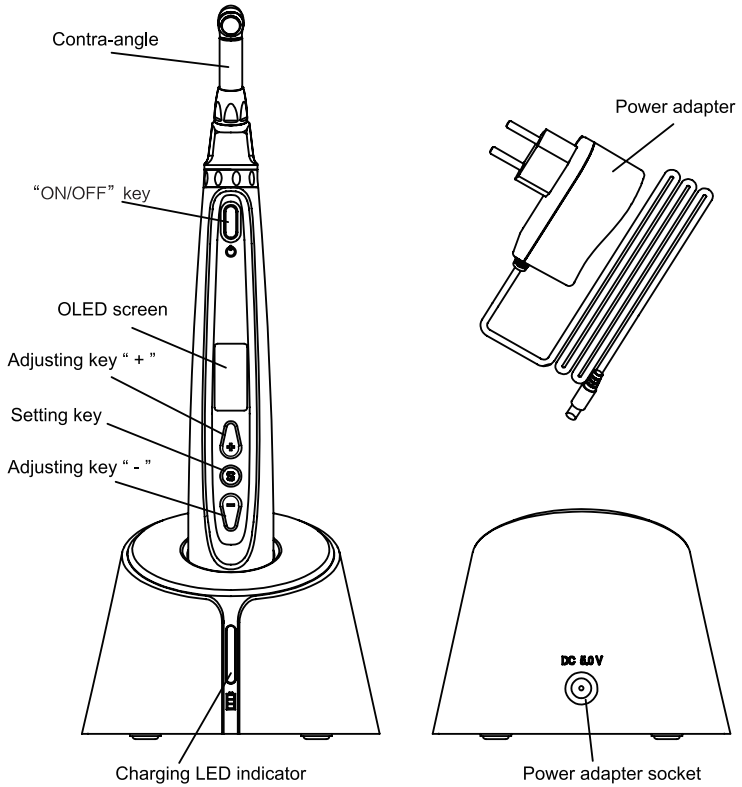
1.3 Scope of application

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.



The version of software is displayed on the OLED screen when starting up.

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.

1.6.16 Error in replacing lithium batteries can lead to unacceptable risks, so use the original lithium battery and replace the lithium battery according to the correct steps in the instructions.

1.6.17 Not to position equipment to make it difficult to operate the disconnection device.

1.6.18 Please remove the battery if the motor handpiece is not likely to be used for some time.

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 0.4A Max

Output: DC5V/1A

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

1.8.4 Rotate speed: 100rpm~1000rpm

1.9 Environment parameters

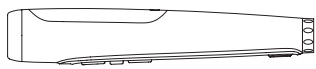
1.9.1 Environment temperature: +5℃ ~ +40℃

1.9.2 Relative humidity: 30% ~ 75%

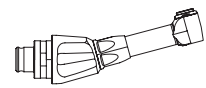
1.9.3 Atmospheric pressure: 70kPa ~ 106kPa

2 Installation

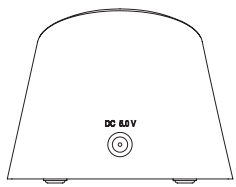
2.1 Basic accessories of product



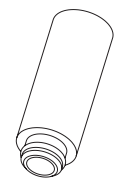
Motor handpiece



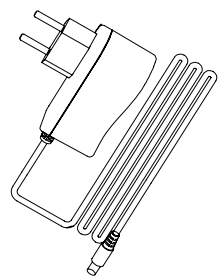
Contra-angle



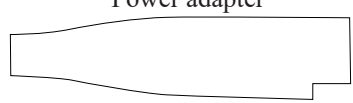
Charging base



Lubricator



Power adapter



Disposable insulation sleeves

2.2 Instructions for contra-angle

2.2.1 The contra-angle 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 motor handpiece and the contra-angle will be damaged.

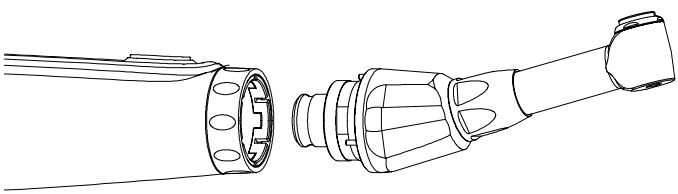
2.3 Installation and removal of contra-angle

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

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

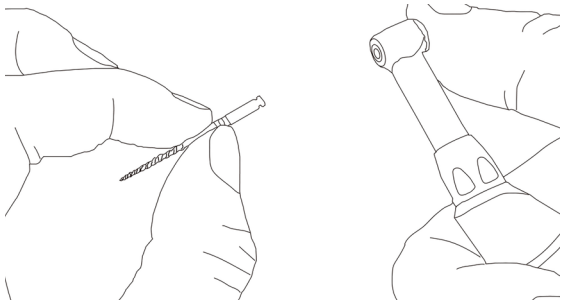
2.4.2 Removal of file

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.

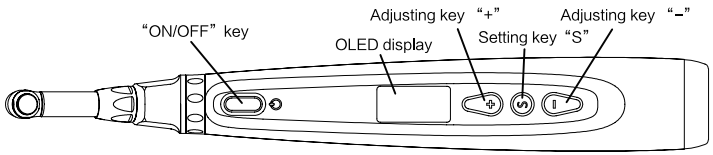
2.5.2 Removing

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.

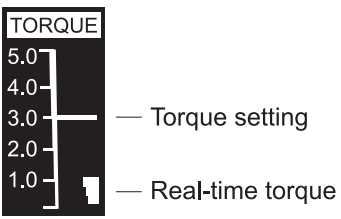
3 Function and operation of product

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

4 Operation instruction

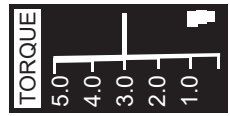
4.1 Starting and Stopping

4.1.1 Starting and stopping of handpiece

a) Under the power off state of handpiece, press "ON/OFF" key, and then the handpiece will enter Standby mode. The interface displays are as follow:

Standby interface

b) Under Standby mode, press “ON/OFF” key, and then the handpiece will enter Operating mode. The interface displays are as follow:

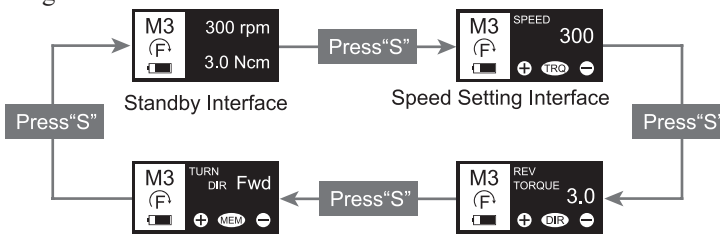


Continuous Rotation Mode interface

c) Press the “ON/OFF” key again, and then the handpiece backs to Standby mode.

4.2 Speed setting, torque setting, and operation mode setting

Schematic drawing of speed setting, torque setting, and operation mode setting interfaces



Standby Interface

Speed Setting Interface

Operation Mode Setting Interface

Torque Setting Interface

In setting interface, it will automatically back to Standby interface after 5s without operation. Press “ON/OFF” key to directly enter operating interface.

a) 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.

b) 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.

c) Operation Mode Setting

In the Operation Mode Setting Interface, press “+” or press “-” button to select Continuous Rotation Mode, Reciprocating Motion Mode or

Reverse Rotation Mode. There will be tick indication while setting to Reverse Rotation Mode. Long press to realize fast modes handover.

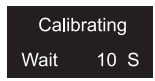
Continuous Rotation Mode　　Reverse Rotation Mode　　Reciprocating Motion Mode

4.3 Customized program handover setting

In Standby interface, shortly press adjusting key "+" and adjusting key "-" to realize handovers among different customized programs. Long press adjusting key "+" and adjusting key "-" to realize cyclic handover.

4.4 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 "S" 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

4.5 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 "S", and then long press Adjusting key "+", finally the device will automatically shut down 2s later.

4.6 Standby interface and operating state interface of three different Operation Modes.

a) Standby interface and operating state interface of continuous Rotation Mode

Standby Interface　　Operating State Interface

b) Standby interface and operating state interface of Reverse Rotation Mode

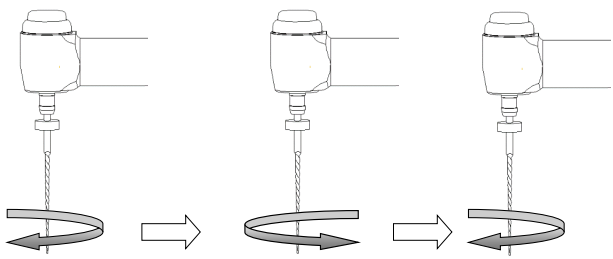
Standby Interface Operating State Interface

c) Standby interface and operating state interface of Reciprocating Motion Mode

Standby Interface Operating State Interface

4.6 Protective function of automatic reverse

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

4.7 Battery Charging

When charging the battery, leave approximately 10cm around the charging base for easy access to inlet and the power cord.
The handpiece has built-in rechargeable lithium battery, and is equipped with wireless sensor charging.
After the handpiece is inserted into the charging base, the three yellow LED indicators of the charging base are lights flashing, indicating that the handpiece is normally charged. After the handpiece is fully charged, those three yellow LED lights would be on.

⚠ Cautions

The front of the handpiece must be inserted in the same direction as the front of the charging base. Otherwise it may cause charging failure as a result of induction failure.

4.8 Replacing Battery

Replace the battery if it seems to be running out of power sooner than it should. Please use the original lithium battery.
a) Turn the motor handpiece power off.
b) Use tweezers etc. to open the rubber cover and then remove the screw.
c) Remove the battery cover.
d) Remove the old battery and disconnect the connector.
e) Connect the new battery and put it in the motor handpiece.
f) Replace the cover and its screw.
It is recommended to contact local distributors or manufacturer to replace the battery.

4.9 Lubricating the contra-angle

Only the original oil lubricator nozzle can be used for oiling of contra-angle. After disinfection of contra-angle and before sterilization, oiling

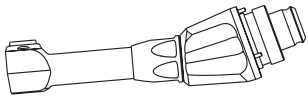
should be conducted under high pressure and high temperature.
a) Firstly, screw the lubricator nozzle into jet of oil bottle. (Around 10 circles)
b) Next, plug the nozzle into the end part of contra-angle, and then grease the contra-angle for 2-3s till the oil flow out of contra-angle head part.
c) Vertically place the end part of contra-angle or tilt the contra-angle to let go the redundant oil under gravity.

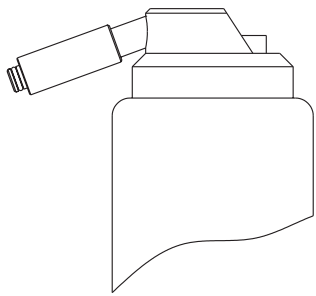
⚠ Warnings

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 lubricator. Swing lubricator can only be used for injection of gas, not for oiling.





5 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	Calibration failure caused by strong resistance of contra-angle	Clean the contra-angle, and recalibrate after oil injection.

Failure	Possible cause	Solutions
Handpiece heating	a) The bottom of handpiece is heating during wireless charging. b) Under Reciprocating Motion Mode, the using time is too long.	a) Normal phenomenon. b) Stop use. Use after the temperature of handpiece drops.
After plugging the handpiece into charging base, the wireless charging indicator does not lights flashing.	a) The handpiece is not in place. b) The handpiece is fully charged.	a) 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.

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:

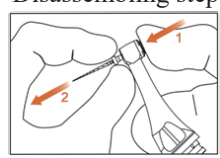
Tools: tray, soft brush, clean and dry soft cloth.

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.

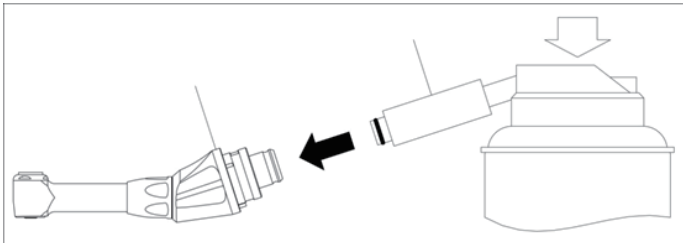
6.4.5 Drying

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 Storage, maintenance and transportation

7.1 Storage

7.1.1 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.
7.1.2 Avoid the storage in a too hot condition. High temperature will shorten the life of electronic components, damage battery, reshape or melt some plastic.
7.1.3 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.

7.2 Maintenance

7.2.1 This device do not include accessories for repair usage, the repair should be carried out by authorized person or authorized after service center.
7.2.2 Keep the equipment in a dry storage condition.
7.2.3 Do not throw, beat or shock the equipment.
7.2.4 Do not smear the equipment with pigments.

7.2.5 Calibration is recommended when using a new/other contra-angle or after an extend period of operation, as the running properties can change with usage, cleaning and sterilization.
7.2.6 Replace the battery if it seems to be running out of power sooner than it should.

7.3 Transportation

7.3.1 Excessive impact and shake should be prevented in transportation. Lay it carefully and lightly and don't invert it.
7.3.2 Don't put it together with dangerous goods during transportation.
7.3.3 Avoid solarization and getting wet in rain and snow during transportation.

8 Environmental protection

Please dispose according to the local laws.

9 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.

10 Symbol instruction

CE marked product

serial number


Date of manufacture


Manufacturer


Type BF applied part


Class II equipment

Ordinary equipment


Recovery

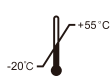

Used indoor only


Keep dry


Handle with care


Power on / off

Humidity limitation



Temperature limitation

Atmospheric pressure for storage

Appliance compliance WEEE directive

EC REP Authorised Representative in the EUROPEAN COMMUNITY

Follow instructions for use

11 European authorized representative

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

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 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 Endo Smart is intended for use in the electromagnetic environment specified below. The customer or the user of the model Endo Smart should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance

RF emissions CISPR 11	Group 1	The model Endo Smart 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 Endo Smart 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 Endo Smart is intended for use in the electromagnetic environment specified below. The customer or the user of the model Endo Smart 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 Endo Smart requires continued operation during power mains interruptions, it is recommended that the models Endo Smart 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 Endo Smart is intended for use in.the electromagnetic environment specified below. The customer or the user of the models Endo Smart 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 Endo Smart, 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 Endo Smart is used exceeds the applicable RF compliance level above, the model Endo Smart should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model Endo Smart.
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 Endo Smart

Recommended separation distances between portable and mobile RF communications equipment and the model Endo Smart			
The model Endo Smart is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model Endo Smart can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model Endo Smart 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×P1/2	80MHz to 800MHz d=1.2×P1/2	800MHz to 2,7GHz d=2.3×P1/2
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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Information Industrial Park, Guilin National High-Tech
Zone, Guilin, Guangxi, 541004 P. R. China
Sales Dept.: +86-773-5873196
Http://www.glwoodpecker.com
E-mail: woodpecker@glwoodpecker.com

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

Cut along the dashed line

Warranty Card

Name of Customer		(Ⅰ) For Distributor
Address Details		
Postal Code		
Tel		
Model		
Motor Handpiece No.		
Contra-angle No.		
Purchase Date		
Contact Person		
Date	Maintenance Record	Repairer

Guilin Woodpecker Medical Instrument Co., Ltd.
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Asia & Africa Sales Dept. Tel: +86-773-5855350, 2125896
Fax: +86-773-5822450
E-mail: woodpecker@glwoodpecker.com, sales@glwoodpecker.com
Website: http://www.glwoodpecker.com

Distributor:

Seal

Warranty Card

Name of Customer		(Ⅱ) Return to Manufacturer
Address Details		
Postal Code		
Tel		
Model		
Motor Handpiece No.		
Contra-angle No.		
Purchase Date		
Contact Person		
Date	Maintenance Record	Repairer

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Fax: +86-773-5822450
E-mail: woodpecker@glwoodpecker.com, sales@glwoodpecker.com
Website: http://www.glwoodpecker.com

Distributor:

Seal

Warranty Instruction

Ⅰ Period validity:

The base, handpiece, power adapter have two years warranty period from the date of purchase. The contra-angle has one year warranty period. Other spare parts have six months warranty period.

Ⅱ Range of warranty:

Within the warranty period of validity, we are responsible for any troubles caused by quality problems or products technique and structure.

Ⅲ The following are beyond our warranty:

1. The damage caused by disobeying the operation instruction or lack of the needed condition.
2. The damage caused by unsuitable operation or disassembly without authorization.
3. The damage on product that caused by users' unexpected drop or impact to product.
4. The damage caused by unadvisable transportation or preservation.
5. There isn’t the seal of distributor or the warranty card isn’t filled in completed.

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Harm of fake products

WOODPECKER and DTE are two brands of Guilin woodpecker medical instrument company. Recently, growing fake ultrasonic scaler handpieces, tips curing lights are produced and sold on the market, which do harm to users' interest.On this issue, We Woodpecker will crack down fake products and provide safe and secure medical instrument products.

1. Harm of fake ultrasonic scaler handpieces.

1.1 Fake handpieces with poor-designed inner structure can lead to frequent power leakage, which may cause medical accidents.
1.2 Material used on fake handpieces don' t pass biocompatible test, which can easily lead to irritability and poisoning.
1.3 Fake handpieces have quality problems of overheating, non-vibration and cracking, which cause ultrasonic scalers out of order.
1.4 Fake handpieces can' t be compatible with ultrasonic scalers, thus leading to circuit burn out.

2. Harm of fake scaler tips.

2.1 Fake tips are low in toughness, poor in resistance and easy to crack, thus easily cause medical accident.
2.2 Fake tips' screw threads are roughly processed, which can cause handpiece' s screw loosing and cracking.
2.3 Material used on fake tips is inferior and easily rusting, which can cause infection of patient.
2.4 Fake tips have used problem of poor water-spraying, bad screw-thread fit and water leaking, which leads ultrasonic scalers work wrongly.

3. Harm of fake curing light.

3.1 Fake curing light' s batteries can cause self-ignite, even explosion with poor-quality material and no complete charging management.
3.2 Light intensity of fake curing light is not constant, when battery level goes down under 60%, it would lead to incomplete solidification of resin, causing secondary dental caries.