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Endo Smart Endo Motor

INSTRUCTION MANUAL

Please read this manual before operating

CE 0197



GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.

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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.

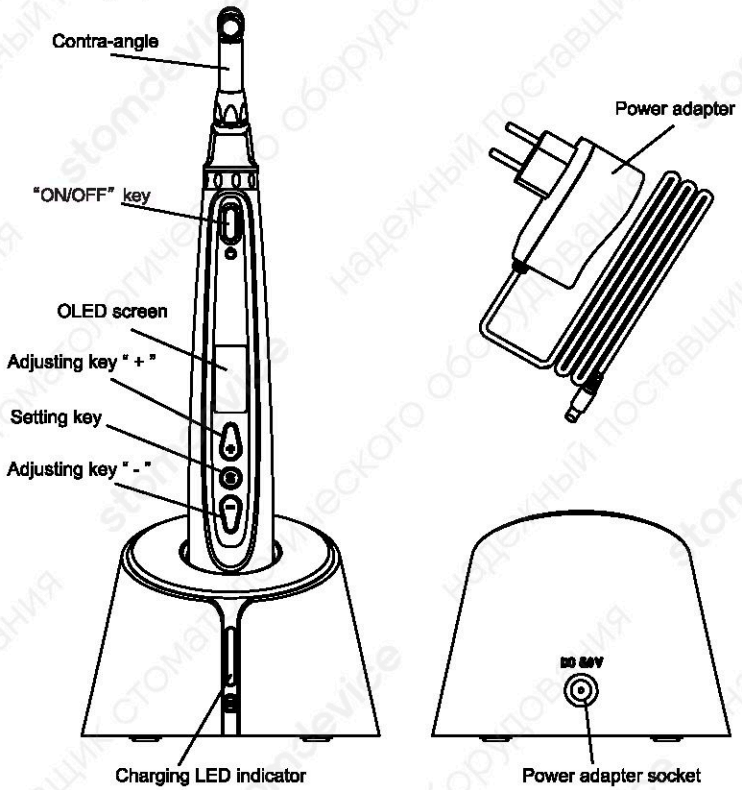
1.3.2 The device must be operated in hospital and clinic by the qualified dentists.

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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

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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

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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

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Output: DC5V/1A

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

1.8.4 Rotate speed: 100rpm~1000rpm

1.9 Environment parameters

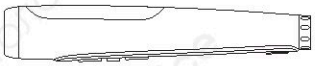
1.9.1 Environment temperature: +5℃ ~ +40℃

1.9.2 Relative humidity: 30% ~ 75%

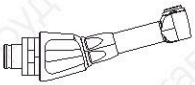
1.9.3 Atmospheric pressure: 70kPa ~ 106kPa

2 Installation

2.1 Basic accessories of product



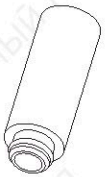
Motor handpiece



Contra-angle



Charging base



Lubricator



Power adapter

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.

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(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.

2.2.4 The service life of contra-angle is ONE year. But as a result of different use frequency, operating time, and the treatment complexity, the real service lives are different.

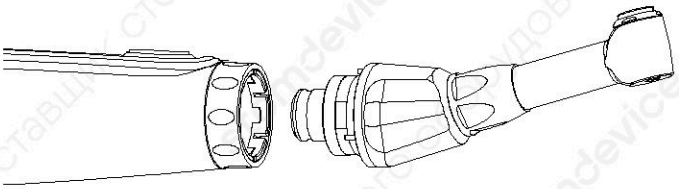
2.3 Installation and removal of contra-angle

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.

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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.

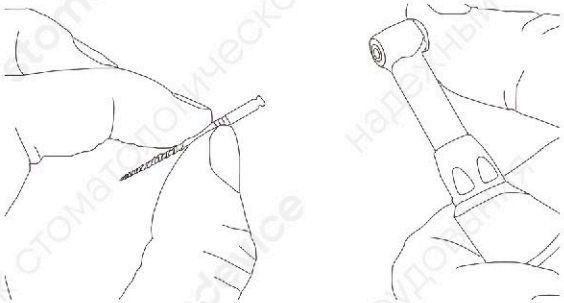
2.4.2 Removal of file

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

⚠ Warnings

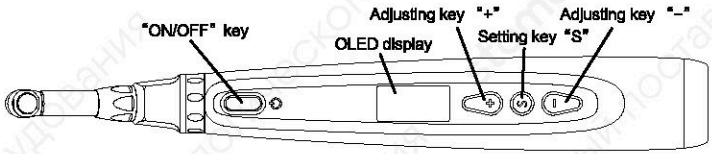
a) Before plugging and pulling out the file, the handpiece must be stopped.

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



3 Function and operation of product

3.1 Schematic drawing of handpiece



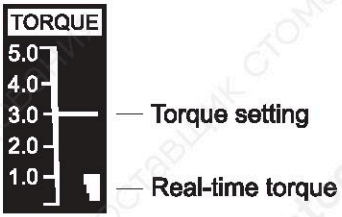
Schematic drawing of handpiece

3.2 OLED display

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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

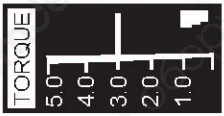
4.1.1 Starting and stopping of handpiece

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:



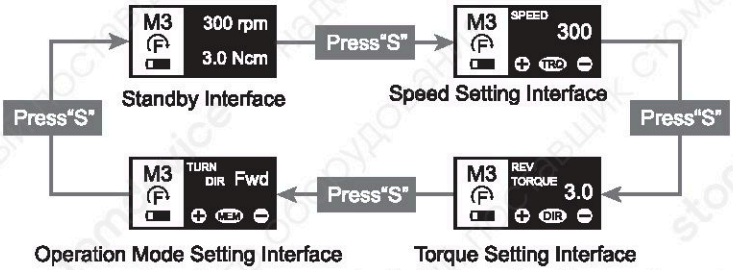
Continuous Rotation Mode interface

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

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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

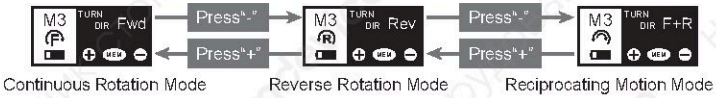
In the Speed Setting Interface, press "+" to increase speed, press "-" to decrease speed, and long press to fast increase or fast decrease speed.

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.



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

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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

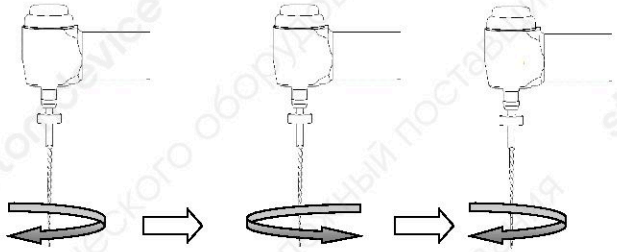
4.6 Protective function of automatic reverse

During operation, if the load value exceeds the preset torque value, the file continuous rotation mode will automatically change to Reverse

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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

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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.

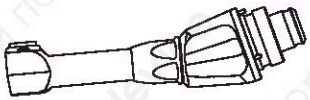
⚠ Cautions

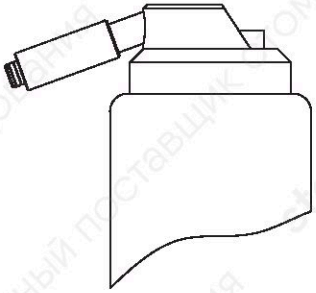
a) To avoid the contra-angle from flying out for the pressure, use hand to safely hold the contra-angle while greasing.

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

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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.
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.

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Failure	Possible cause	Solutions
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 and Sterilization

6.1 Foreword

For hygiene and sanitary safety purposes, the contra-anglemust be cleanedand 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 Medical multienzyme detergent(Protease, phospholipase, etc.) which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA and Health Canada approval) and in accordance with the DFU of the detergent manufacturer.

6.2.3 Do not place the contra-angle in a disinfectant solution or in an ultrasonic bath.

Do not use chloride detergent materials.

6.2.4 Do not use bleach or chloride disinfectant materials.

6.2.5 For your own safety, please wear personal protective equipment (gloves, glasses, mask).

6.2.6 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.

6.2.7 The water quality has to be convenient to the local regulations especially for the last rinsing step or with a washer-disinfector.

6.2.8 Do not sterilize the motor handpiece, the AC adapter or the charding base. After each use, all the objects that were in contact with infectious agents should be cleaned using towels impregnated with a detergent solution (a bactericidal, fungicidal and aldehyde free solution)

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approved by VAH/DGHM-listing, CE marking, FDA and Health Canada.

6.2.9 To sterilize the endodontic files, refer to the manufacturer's instructions for use.

6.2.10 The contra-angle needs to be lubricated after cleaning but before sterilization.

6.3 Step-by-Step Procedure

#	Operation	Operating Mode	Warning
1	Preparation	Remove the contra-angle from handpiece and charging base.	
2	Manual cleaning(Contra-angle, etc.)	For 5 minutes, rinse and brush under running deionized water (DI), or water that has this degree of purity (<38°C (100.4°F)). Remove any liquid residues (ultra-absorbent cloth, particle-free compressed air).	Use a cleaning tool (brush). In order to clean faster and more effective,use only a Medical multienzyme detergent(Protease, phospholipase, etc.)which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA and Health Canada approval) and follow instructions and observe concentrations given by the detergent manufacturer.

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3	Automated Cleaning with washer-disinfector	Put the contra-angle into the washer disinfector (Ao value >3000 or, at least 5 min at 90°C/194°F)	- Avoid any contact between the contra-angle and any instruments, kits, supports or container. - Follow instructions and observe concentrations given by the manufacturer (see also general recommendations). - Use only approved washer-disinfector according to EN ISO 15883, maintain and calibrate it regularly. - Make sure contra-angle, is dry before moving to the next step.
4	Inspection	Inspect the contra-angle and sort out those with defects.	- Dirty contra-angle must be cleaned - Lubricate the contra-angle with an adequate spray before packaging.
5	Packaging	Pack the contra-angle in "Sterilization pouches".	- Check the validity period of the pouch given by the manufacturer to determine the shelf life. - Use packaging which is resistant to a temperature up to 141°C (286°F) and in accordance with EN ISO 11607.

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6	Sterilization	Steam sterilization at 134°C, 2.0bar-2.3bar(0.20Mpa-0.23MPa), for 4 minutes.	- Use only autoclaves that are matching the requirements of EN 13060, EN 285. - Use a validated sterilization procedure according to ISO 17665. - Respect the maintenance procedure of the autoclave device given by the manufacturer. - Use only this recommended sterilization procedure. - Control the efficiency (packaging integrity, no humidity, color change of sterilization indicators, physico-chemical integrators, digital records of cycles parameters). - Maintain traceability of procedure records.
7	Storage	Keep the contra-angle in sterilization packaging in a dry and clean environment.	- Sterility cannot be guaranteed if packaging is open, damaged or wet. - Check the packaging and the contra-angle before using it (packaging integrity, no humidity and validity period).

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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

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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 0197 CE marked product

SN serial number

 Date of manufacture

 Manufacturer

 Type BF applied part

 Class II equipment

IPX0 Ordinary equipment

 Recovery

 Used indoor only

 Keep dry

 Handle with care

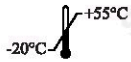
 Power on / off



Humidity limitation



Temperature limitation



Atmospheric pressure for storage

 Appliance compliance WEEE directive

 Consult the accompanying documents

EC REP Authorised Representative in the EUROPEAN COMMUNITY

 Follow instructions for use

11 European authorized representative

EC REP MedNet GmbH
Borkstrasse 10 · 48163 Muenster · Germany

12 Statement

All rights of modifying the product are reserved to the manufacturer

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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

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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) IEC 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 IEC 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.

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Power frequency (50/60 Hz) magnetic field IEC 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

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Conducted RF IEC 61000-4-6 Conducted RF IEC 61000-4-6 Radiated RF IEC 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.			

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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 3 V/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

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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.

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