Endo Motor Instruction Manual

Please read this User Manual carefully before use for operating instructions, care and maintenance.

CE 0197

www.glwoodpecker.com

GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD.

Contents

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

1 Product introduction

1.1 Preface

Guilin Woodpecker Medical Instrument Co., Ltd is a professional manufacturing company that produces a wide range of dental products. It devotes a lot of time and resources to the research and development of innovative dental products with a robust quality control mechanism. Guilin Woodpecker Medical Instrument Co., Ltd has two brands, Woodpecker and DTE. Its main products include Ultrasonic Scalers, Curing light, Apex locators, Ultrasurgery equipment, Endo Motors, etc.

1.2 Product description

Endo Motor (model: Ai-Motor MotoPex) is used in Endodontic treatment. It is a cordless endo motor with an integrated apex locator. It can be used as an endo motor to prepare and enlarge root canals or as a device for measuring canal length. It can be used to enlarge the canals while monitoring the position of the file tip inside the canal.

Features:

a) Efficient brushless motor, low noise, long service life.
b) Cordless portable endo motor with integrated apex locator
c) 360 degrees rotation of the contra-angle
d) Adapt real-time feedback technology and dynamic torque control effectively preventing file separation.

1.3 Model and specification

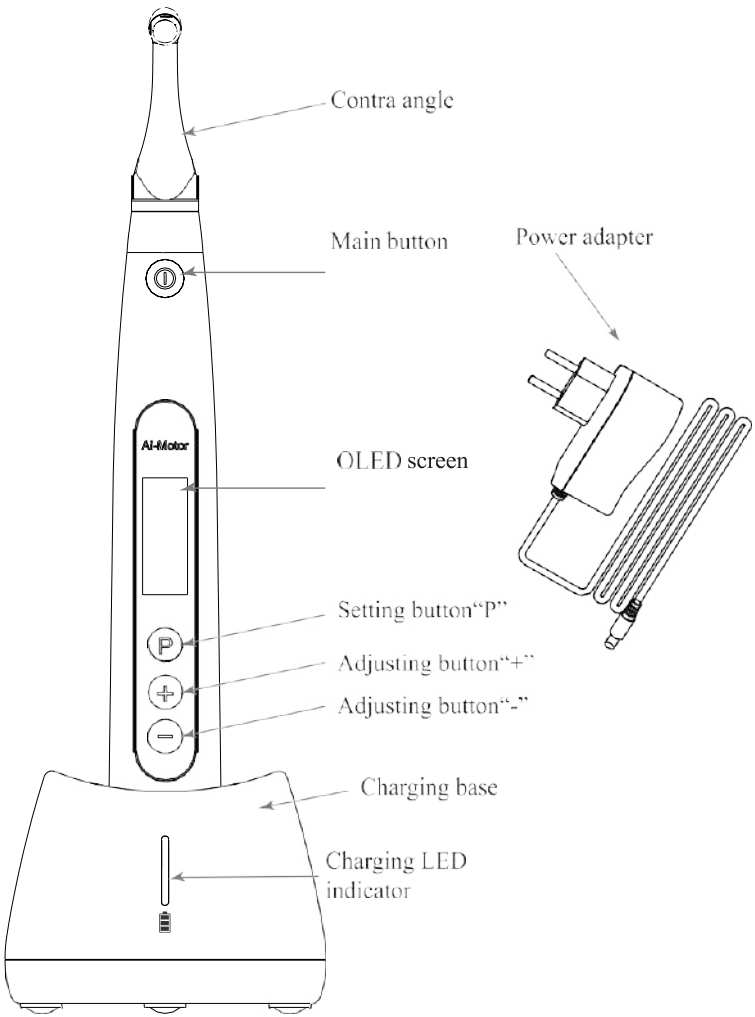
Ai-Motor, MotoPex

Please refer to packing list for device configurations.

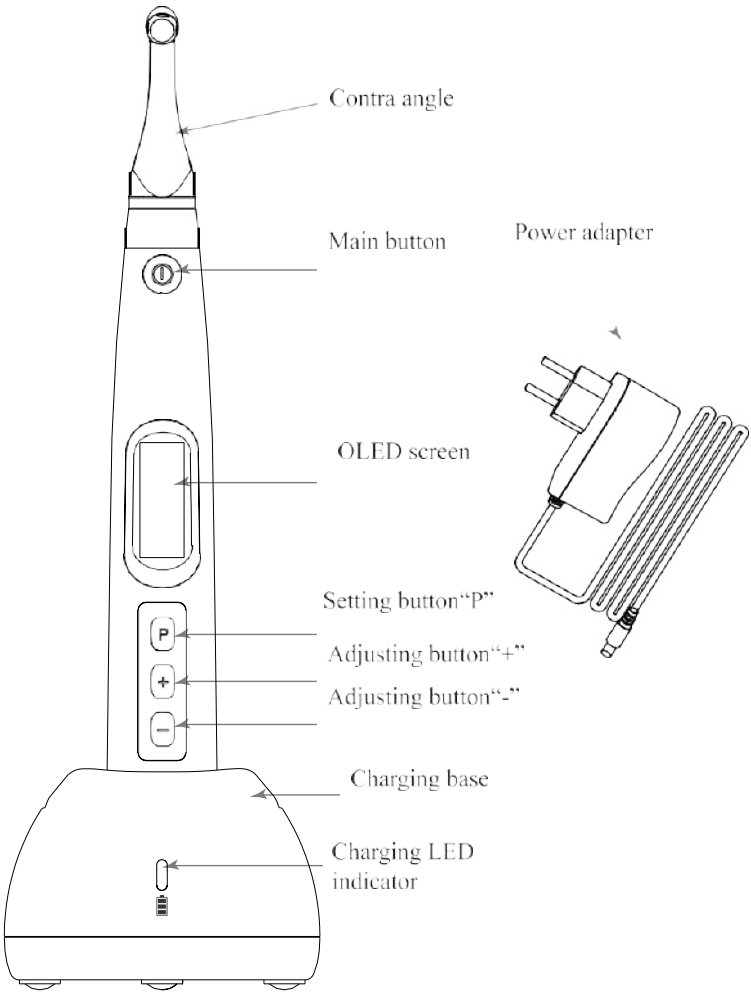
1.4 Performance and composition

The device is composed of a charging base, motor handpiece, contra-angle, measuring wire, lip hook, file clip, power adapter, protective silicon cover, etc.

Ai-Motor


Contra angle
Main button
Power adapter
Ai-Motor
OLED screen
Setting button"P"
Adjusting button"+"
Adjusting button"-"
Charging base
Charging LED
indicator

MotoPex


Contra angle
Main button
Power adapter
OLED screen
Setting button"P"
Adjusting button"+"
Adjusting button"-"
Charging base
Charging LED indicator

1.5 Scope of application

1.5.1 The device can be used for preparation and enlargement of root canals, or device for measuring canal length.

1.5.2 This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel

1.6 Contraindication

a) This endo motor with an integrated apex locator should be used with caution in patients with a cardiac pacemaker.

b) Contraindicated to use in Hemophilia patients.

c) Use with caution in patients with heart disease, pregnant women and young children.

1.7 Warnings ⚠

1.7.1 Please carefully read this Instruction Manual before using for the first time.

1.7.2 This device should be operated only by a qualified dentist or professional in a registered hospital or clinic.

1.7.3 Do not place this device near the heat source directly or indirectly. Operate and store this device in a safe and protected environment.

1.7.4 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.

1.7.5 Reciprocating mode usage for a long time may result in overheating of the device. The device should be switched off for some time to allow cooling down. If the motor handpiece is overheated frequently, please contact the local distributor.

1.7.6 Please use the original contra angle head to avoid adverse consequences.

1.7.7 Please do not make any alterations to this device. Any changes made may violate safety regulations, that can cause harm to the patient.

1.7.8 Please use the original power adapter. Other power adapters may result in damage to the lithium battery and control circuit.

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

1.7.10 Do not activate the push button on the contra-angle head during operation or slow down This leads to damage of the head or instrument separation.

1.7.11 Do not remove the contra-angle head when the handpiece is rotating. If removed may result in the damage of the gear inside the motor handpiece

1.7.12 Please confirm whether the file is well inserted and locked before starting the motor handpiece.

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

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

1.7.15 Do not place the equipment in a difficult position to avoid difficulty in disconnection after use,

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

7.17 Wireless charging will generate heat, and the surface temperature of the charging base and motor handpiece will rise. It is recommended that the time of contact between the motor handpiece and charging base during wireless charging should not exceed 10 seconds (only for Ai- Motor).

1.8 Device safety classification

1.8.1 Type of operation mode: Continuous operating device

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

1.8.3 Degree of protection against electric shock: B type applied part

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

1.8.5 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.

1.8.6 Applied part: contra angle, lip hook, file clip, touch probe.

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

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

1.9 Primary technical specifications

1.9.1 Battery

Lithium battery in motor handpiece: 3.7V /2000mAh

1.9.2 Power adapter (Model: DJ-0500100-A5)

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

Output: DC5V/1A

1.9.3 Torque rang: 0.4Ncm-5.0Ncm（4mNm ~ 50mNm）

1.9.4 Speed rang: 100rpm~1200rpm

1.9.5 Wireless charging (only for Ai-Motor)

Frequency range: 112-205KHz

Maximum RF output power of the product: 9.46dBuA/m@3m

1.10 Environment parameters

1.10.1 Environment temperature: +5℃ ~ +40℃

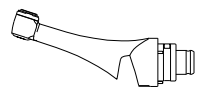
1.10.2 Relative humidity: 30% ~ 75%

1.10.3 Atmospheric pressure: 70kPa ~ 106kPa

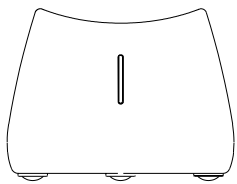
2 Installation

2.1 Basic accessories of product

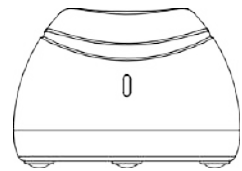
Motor handpiece



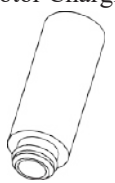
Contra angle



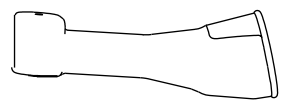
Ai-Motor Charging base



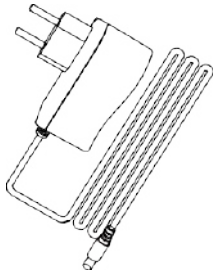
MotoPex Charging base



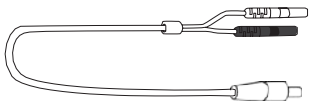
Nozzle



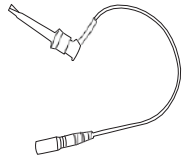
Protective silicon cover



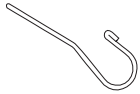
Power adapter



Measuring wire

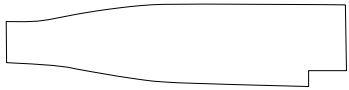


File clip



Lip hook

Touch probe



Disposable insulation sleeves

2.2 Display Screens

2.2.1 Display Screens for 5 Operation Modes and Standby

2.2.1.1 EAL Mode

This mode is for canal measurement. The motor handpiece does not run in this mode.

2.2.1.2 CW Mode

The motor handpiece rotates forward 360º, clockwise direction. It is used for rotary files such as WOODPECKER W3-Pro.

2.2.1.3 CCW Mode

The motor handpiece rotates in a counterclockwise direction only. This mode is used to inject calcium hydroxide or any other intracanal medicament. When this mode is used, a double-beep sound will be heard continuously.

2.2.1.4 REC Mode

Reciprocating mode.

F: Forward angle, R: Reverse angle

It is suggested that the difference between the forward angle and reverse angle should be greater than or equal to 120 degrees, otherwise, root canals cannot be prepared effectively.

Forward Angle<Reverse Angle, such as F:30/R:150, the effective cutting angle is Reverse Angle, it is suitable for use of the reciprocating files such as WOODPECKER W3-ONE.

Forward Angle>Reverse Angle, such as F:180/R:30, the effective cutting angle is Forward Angle, it is suitable for use of the reciprocating files such as SENDONELINE S1.

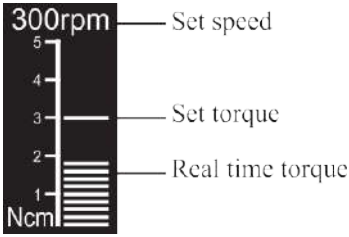
2.2.1.5 ATR Mode

ATR: Adaptive Torque Reverse function.

When the load on the file is greater than the set torque limit, the file will start to rotate alternately at the set angle.

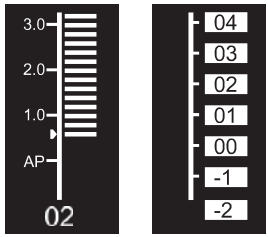
2.2.2 Torque Display

This appears when the device is operating. Display shows the torque load on the file.



2.2.3 Canal Measurement Display

This appears when a file is inside the canal and the lip hook is in contact with the patient's lip. Bars on the display show the location of the file tip in the root canal. In the EAL Mode, If the length is less than 1.0, the display will be enlarged.



The numbers displayed such as 1.0, 2.0, 3.0 and digital numbers 00-16 do not represent the actual length from the apical foramen. It indicates the file progression towards the apex. The digital numbers -1 and -2 indicate that the file extended beyond the apical foramen. The digital number "00" indicates that the file has reached the apical foramen. Subtract 0.5-1mm from the measured file length as the working length. These numbers are used to estimate the canal's working length.

2.3 Instructions for contra angle

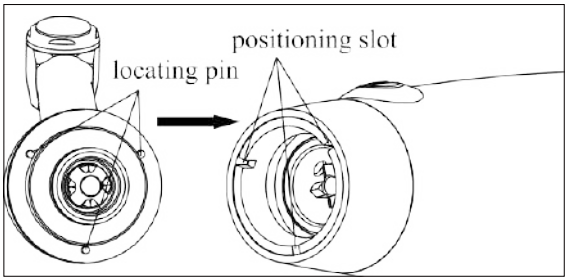
2.3.1 The contra angle adapts precision gear transmission, and the transmission ratio is 6:1

2.3.2 Before the first use and after the treatment, please clean and disinfect the contra-angle head with the disinfectant of neutral PH value. After disinfection, lubricate it with recommended cleaning oil. Finally, sterilize it under high temperature and high pressure (134℃, 2.0bar~2.3bar (0.20MPa~0.23MPa)). The contra angle should be used only with this device. The contra angle will be damaged if there is a mismatch with the device.

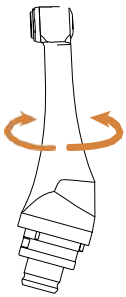
2.4 Installation and removal of contra angle.

2.4.1 Installation

Align one of the locating pins of the contra-angle with the positioning slot on the motor handpiece and push the contra-angle horizontally. When the three locating pins on the contra-angle are inserted into the corresponding three positioning holes on the motor handpiece a “click” sound indicates that the installation is achieved. The contra-angle can be



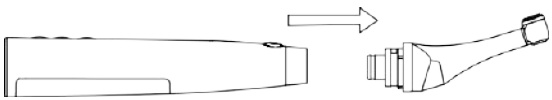
rotated 360° freely.



The contra-angle is free to rotate, adapting to the root canal in different positions, and it is convenient to watch the display on the device when operating by adjusting the position of the contra angle head.

2.4.2 Removal

Pull out the contra angle ahead away from the hand piece only after the device is switched off.



Warnings:

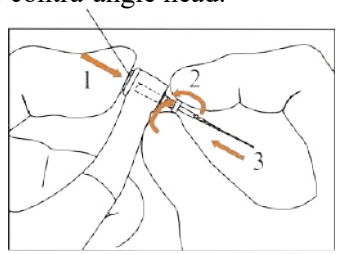
a) Before plugging in or pulling out contra angle head, please make sure the device is not in function.

b) Please ensure Contra angle is inserted properly into the hand piece before use.

2.5 Insertion and removal of file

2.5.1 Insertion of file

The file should be inserted into the contra- angle head before starting the hand piece. Press the push button on the contra-angle and insert the file. Tease the file back and forth until it is oriented with an interior latch groove and slips into place. Release the push button to make sure the file is engaged properly in the contra-angle head.



Warnings:

After plugging the file into contra-angle, release the push button and assure that the file cannot be taken out by gently pulling it.

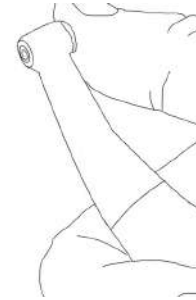
Be careful when inserting files to avoid injury to fingers.

Inserting and removing files without holding the push button may damage the chuck of the contra-angle.

Please use files with shanks that are in compliance with ISO standards. (ISO standard: Ø2.334 – 2.350 mm)

2.5.2 Removal of file

Press the push button and then pull the file gently out of the contra-angle



Warnings:

Before Inserting and removing the file, the motor handpiece should not be in function.

Be careful when removing files to prevent injury to fingers.

Removing files without pressing the push button will damage the chuck of the contra-angle.

2.6 Working length measurement Assembly

Working Length Measurement Connection.

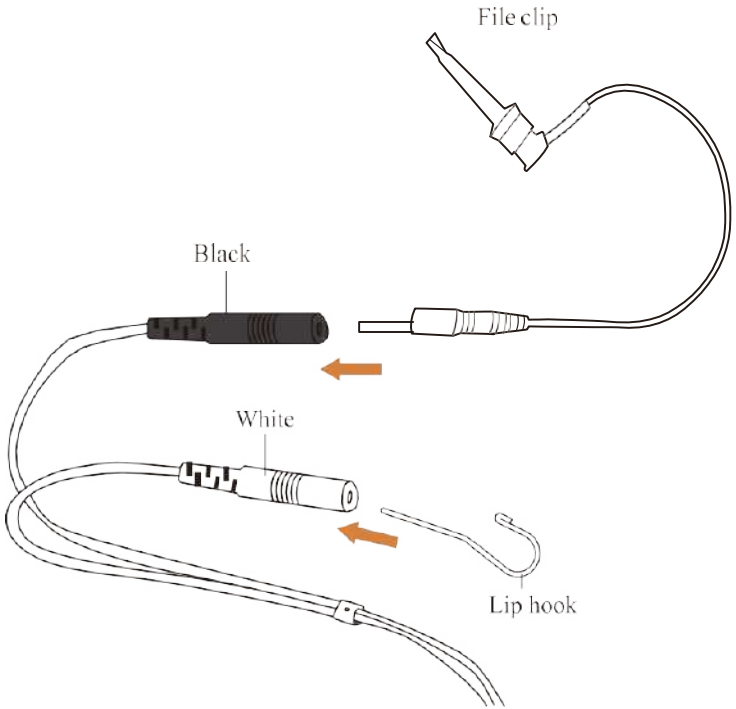
This assembly is required only when the working length is measured or to simultaneously monitor the working length during canal preparation.

Connect the measurement cable to the motor handpiece.

. Connect the measurement cable and turn on the device. Connect the metal part of the connection hook to the lip clip. Make sure that the accessories are cleaned properly before the test.

Orient measurement cable plug with the notch on the back of the motor and secure it firmly.

Connect the file clip plug into the socket (black) on the measurement cable Connect the lip hook to the socket (white) on the measuring wire.



Warnings:

Connect the lip hook to the socket (white) on the measurement cable io monitor working length during the root canal preparation

Installation and removal of disposable insulation sleeves

2.7.1 Installation

Before each use of the handpiece and after the handpiece is cleaned and disinfected, a disposable isolation sleeve should be used to cover the handpiece. Take the isolation sleeve out of the isolation sleeve box,and cover the motor handpiece from the thin end without any obvious wrinkle.

After covering the handpiece with the disposable isolation sleeve, wrap the barrier film around the handpiece surface, clean and disinfect the surface of the handpiece.

Refer to Chapter 6.3 for cleaning and disinfection procedures.

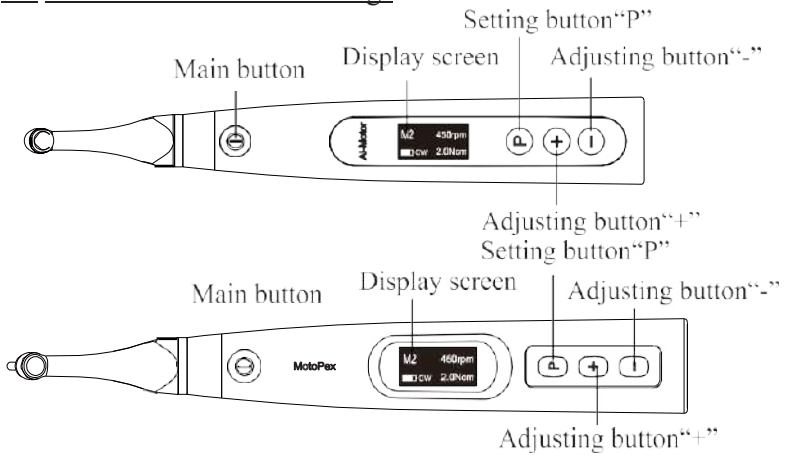
2.7.2 Removing

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 Button definition and settings



a. Power on

Press the Main button to turn on the motor handpiece.

b. Power off

Hold down the Setting button "P", then press the Main button to turn off motor handpiece.

c. Customized program change

Press Adjusting button "+"/ "-" during standby sate.

d. Parameter setting

Press Setting button "P" till target parameters, press Adjusting button "+"/ "-" to change, then press Main button or wait 5 seconds to confirm.

e. Preset program selection

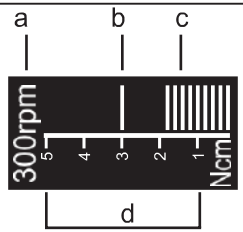
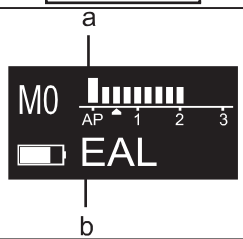
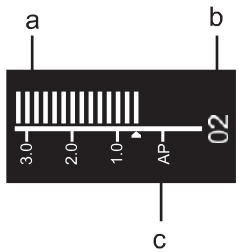
Long press Setting button "P" to enter the preset program during standby state, press Adjusting button "+"/ "-" to select file system, press Setting button "P" to enter the select file number, press Adjusting button "+"/"-" to select file number, then press the Main button to confirm.

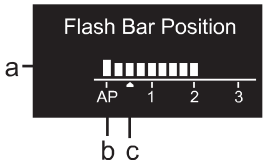
f. Handpiece functions setting

With the motor handpiece turned off, hold down the Setting button "P"

and press Main button to entry handpiece functions setting, press Setting button “P” till target setting, press Adjusting button “+”/“-” to adjust, then press the Main button to confirm.

3.2 Screen display

	Standby interface a. Customized program sequence number 0-9, total 10 programs. b. Battery level c. Set speed d. Set torque e. Operation mode
	Working interface a. Set speed b. Set torque c. Real time torque d. Torque display scale
	Working length measurement mode interface a. Apical reference point flash bar b. EAL: Electronic apex locator
	Working Length measurement state interface a. Canal length indicator bar b. Indication number Digital numbers 00-16 do not represent the actual length from the apical foramen. It simply indicates the file progression towards the apex. Number “00” indicate that the file has reached the apical foramen.
	c. Apical foramen.

	Apical reference point setting interface a. Apical reference point flash bar b. Apical foramen c. Digital “02” meter reading, very close to the apical foramen.

3.3 Terms and definition

CW	Clockwise rotation, forward ration applicable to rotary file
CCW	Counterclockwise rotation, reverse rotation applicable to special files / lentilospirals to inject calcium hydroxide or any other intracanal medicaments or root canal sealers
REC	Reciprocating motion Applicable to reciprocating file, path file and to prevent rotary file separation by setting some special angle.
ATR	Adaptive torque reverse Up on setting torque, the motor will function in reciprocating ATR mode; as the torque reduces to normal value, the motor will function in rotation mode.
Forward Angle	Angle of clockwise rotation of the file.
Reverse Angle	Angle of counterclockwise rotation of the file.
EAL	Electronic apex locator In this mode, the device functions as a stand-alone apex locator
AP	Apical foramen.
Apical Action	The file action when file tip reaches the flash bar point.
Flash Bar Position	Shows the point inside the canal where specified apical action is triggered.
Auto Start	The file starts rotating automatically when the file is inserted in the canal.
Auto Stop	The file stops rotating automatically when the file is of the canal.

Apical Slow Down	The file slows down automatically as it approaches the apex. Activating in CW and CCW operation mode.
Operation Mode	5 operation modes for canal shaping and measurement. Such as CW, CCW, REC, ATR and EAL.
Speed	File rotation speed.
Torque (Torque Limit / Trigger Torque)	For CW and CCW modes, the torque value (Torque Limit) that triggers reverse rotation. For ATR mode, the torque value (Trigger Torque) that triggers ATR action.

4 Operation instruction

4.1 Power on and power off

4.1.1 Starting and stopping of the motor handpiece

a) In the power off state of the motor handpiece when the main button is pressed, the motor handpiece will enter Standby interface. The interface displays are shown below

b) : Under Standby interface, press the Main button, and then the motor handpiece will enter Working interface. The interface displays are as follow

c) When you press the main button again the motor handpiece will Working interface displays are as follow:

Working interface

d) Press the Main button again, and then the motor handpiece backs to Standby interface.

e) Hold down the Setting button “P” and then press the Main button to turn off the motor handpiece. In Standby Interface, the motor handpiece automatically shuts down after 3 minutes if no button is pressed to operate. The motor handpiece automatically shuts down when placed in the charging

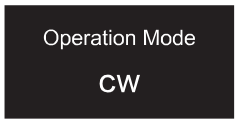
base.

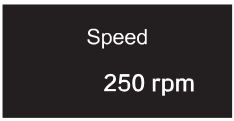
4.2 Selecting customized program sequence number

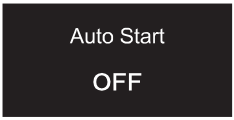
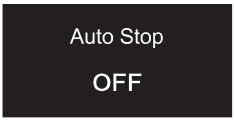
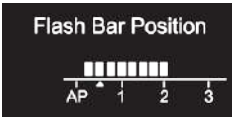
The motor handpiece has 10 memory programs(M0-M9) and 5 preset programs, press the adjusting button “+”/“-” to change the customized program sequence number during the standby state.

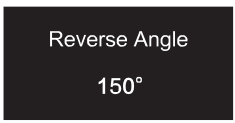
M0-M9 is a memory program for canal shaping and measurement, every memory program has its own parameters such as Operation mode, speed and torque, all these parameters can be changed if required.

Parameter setting

	Before starting the motor handpiece, please check the operation mode is correct and all the parameters must be set according to the file system intended to use, to prevent the file separation in the canal.
	It has 5 operation modes for canal shaping and measurement: CW, CCW, REC, ATR and EAL (See chapter 3.3 Terms and definition to get the explanations of these modes.) Press Setting button “P” once during standby state, press Adjusting button “+”/“-” to select the correct Operation mode. Counterclockwise rotation, reverse rotation applicable to special files / lentilospirals to, inject calcium hydroxide or any other intracanal medicaments or root canal sealers
Repeatedly press the Setting button “P” to check all the next level parameters of this operation mode are acceptable, press Adjusting button “+”/“-” to select if not.	

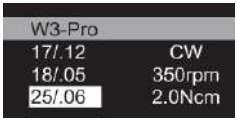
	The speed setting can be adjusted from 100 rpm to1200 rpm. Press the Adjusting button “+”/“-” to increase or decrease the speed. Press the button for a long time to increase or decrease the speed. In ATR mode, speeds of 100~500rpm are available. In REC mode, speeds of 100~500rpm are available.
	The torque setting can be adjusted from 0.4Ncm to 5Ncm. Press the Adjusting button “+”/“-” to increase or decrease the torque. . Press the button for a long time to increase or decrease the toque. In ATR mode, the Trigger Torque of 0.4Ncm~4.0Ncm is available. In REC mode, the torque of 2.0Ncm~5.0Ncm is available.
	Actions that happen automatically when the file tip reaches the point inside the canal determined by the Flash Bar setting. This action is due to the integration of the working length determination function, when the file reaches the reference point, the motor will respond according to the setting, it can either be Reverse /Stop or OFF. Press the Adjusting button “+”/“-” to change. OFF: It disables the apical Action function, and the file rotates as usual even on reaching the reference point. Stop: The rotation stops automatically when the file reaches the reference point, if moved away from the reference point the file rotates again. Reverse: The file automatically rotates in reverse motion when it reaches the reference point, if moved away from the reference point the file rotates again in the forward motion.

	The file starts rotating automatically as soon as the file is inserted into the canal and the canal length indicator bar lights up more than 2 bars. Press the Adjusting button “+”/“-” to change. OFF: The file does not start rotating on inserting the file into the canal. The main button should be used to start and stop the motor handpiece. ON: Motor starts automatically.
	T The file stops rotating automatically when the file is taken out of the canal and the canal length indicator bar lights up less than 2 bars before the file is taken out. Press the Adjusting button “+”/ “-” to change. OFF: Motor does not stop when the file is taken out of the canal. The Main button should be used to start and stop the motor handpiece.
	This is the reference point where various apical actions are triggered. Press the Adjusting button “+”/ “-” to select a reference point by change the flash bar. The meter’s 0.5 reading indicates that the file tip is located very near the physiological apical foramen. The reference point (flash bar) can be set from 2to AP (Apex) on the meter.
	The file rotation automatically slows down as the file tip approaches the reference point. Press the Adjusting button “+”/ “-” to change. OFF: Disable Apical Slow Down function. ON: Rotation automatically slows down as the file tip approaches the reference point.

  	Only activating in REC and ATR operation mode. F: Forward Angle. In the REC mode, the Forward Angle of 20°~400° is available. In the ATR mode, the Forward Angle of 60°~400° is available. R: Reverse Angle In the REC mode, the Reverse Angle of 20°~400° is available. In the ATR mode, the reverse Angle cannot be greater than the forward Angle. Press Adjusting button “+”/ “-” to change the angle, adjustable every 10 degrees. It is suggested that the difference between the forward angle and reverse angle should be greater than or equal to 120 degrees, root to prepare root canals effectively. Forward Angle<Reverse Angle, such as F: 30º/R: 150º, the effective cutting angle is Reverse Angle, is suitable for the reciprocating files such as WOODPECKER W3-ONE. Forward Angle>Reverse Angle, such as F: 180º/ R: 30º, the effective cutting angle is Forward Angle, is suitable for the reciprocating files such as SENDONELINE S1.

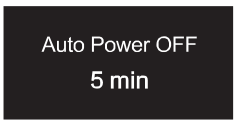
4.3 Preset program selection

	For convenience, some file systems are preset. Press the Adjusting button “+”/ “-” to switch to the preset program (M0-M9, preset program 1-5), the interface will be displayed as depicted on the left side of the row.
	press Setting button “P” for a long time to enter the preset program during standby state, the interface will be displayed as depicted on the left side of the row. Press the Adjusting button “+”/ “-” to select the filesystem.

	After selecting the file system, press the Setting button “P” to enter the select file number, press the adjusting button “+”/“-” to select the file number. Press the main button to confirm.
	The parameters of "W3-Pro" can also be changed from the default setting. To return to the default setting, press the Setting button “P” for a long time to enter the preset program during standby state, select "W3-Pro" and press the "main" button to confirm, the default setting will be reloaded, Turn off the motor handpiece and subsequently turn on the power to restore the default setting. Changing the preset program default setting is not recommended to prevent file separation.

4.4 Handpiece functions setting

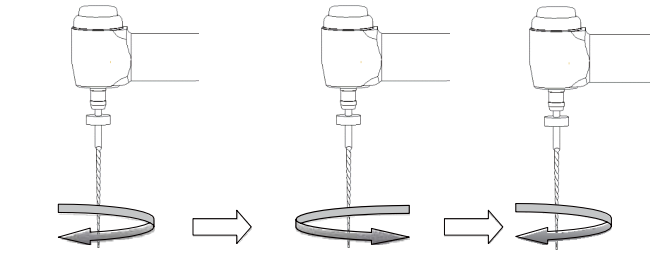
4.5 With the motor handpiece turned off, hold down the Setting button “P” and press the main button to enter handpiece functions setting, press Setting button “P” till target setting, press the Adjusting button “+”/“-” to adjust, then press the main button to confirm.

	With the motor handpiece turned off when the Setting button “P” held down and pressing the main button to enter the handpiece functions setting, the software version number will appear on the display screen.
	After 3 seconds of displaying the version number on the screen, the "Auto Power OFF “time setting can be changed by, pressing the adjusting button “+”/“-” and then press the "Main" button to confirm. If no buttons are pressed, the auto power-off time of motor, the handpiece can be set from 3 to 30 minutes in 1-minute increments

	Press the Setting button “P” again, the “Auto Standby Scr” can be changed, press Adjusting button “+”/“-” to adjust the time , and then press "Main" button to confirm. If no buttons are pressed, auto return to standby display of the motor handpiece can be set from 3to 30 seconds in 1 second increments.
	Press the Setting button “P” again, the "Dominant Hand" can be changed, press Adjusting button “+”/“-” to adjust, then press the “Main” button to confirm. The right hand or the left hand can be set.
	Press the Setting button “P” again, the “Calibration” can be changed, press the Adjusting button “+”/“-” to select “ON”, then press the “Main" button to calibrate. Before calibrating, make sure the original contra-angle is installed before inserting any file. The torque set will not be correct if calibration is done without the original contra-angle or any load is applied on the contra-angle chuck and may result in file separation. After replacement of the contra-angle, the contra-angle should be calibrated before use.
	Press the Setting button “P” again, the "Beeper Volume" can be changed, press the Adjusting button “+”/“-” to adjust, then press the "main" button to confirm. The “Beeper Volume “can be set from 0-3. Vol.0: Mute.
	Press the Setting button “P” again, the "Restore Defaults" can be changed, press adjusting button “+”/“-” to select “ON”, then press the main button to restore defaults.

4.6 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. The file would return to normal rotation mode once the load is below the preset torque value again.

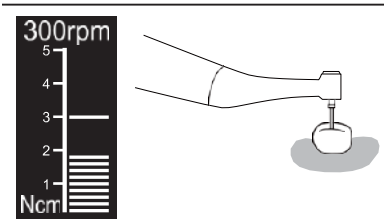


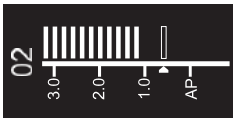
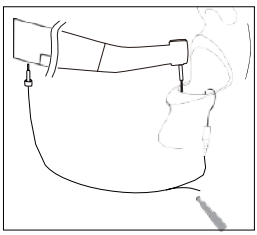
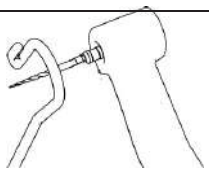
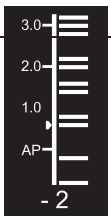
Cautions:

1. Protective function of automatic reverse is ONLY suitable for CW mode.
2. In REC mode, when the load value is higher than the preset torque value if the Forward angle is greater than the Reverse angle, the file rotation automatically changes to reverse rotation, and if the Forward angle is less than the Reverse angle, the file rotation automatically changes to forward rotation.
3. This function is not applicable for CCW mode and ATR mode.
4. If the motor handpiece battery indicator indicates a low battery capacity, it would be insufficient to support the motor handpiece to reach the preset torque value, which leads to improper auto-reverse function Please charge it in time.

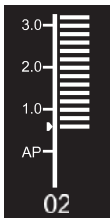
4.7 Motor operation

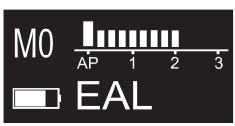
Please set operation mode, torque and speed as per the recommended specifications of file manufacturer.

	**Motor alone mode** When using as motor alone mode, the torque bar will show on the screen. (more information about torque bar, please see chapter 3. 2 Screen display)

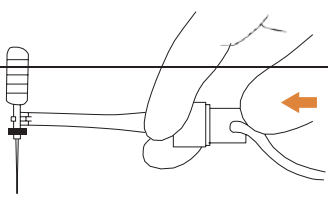
 	**Motor combined canal measurement function mode** When using the motor combined with the integrated apex locator function, connect the lip hook to the socket (white) on the measurement cable to monitor working length during the root canal preparation, keep the black socket idle. The canal length indicator bar will be displayed on the screen (more information about canal length indicator bar, please see chapter 3. 2 Screen display) Setting parameters of automatic functions as needed, such as Apical Action, Auto Start, etc (more information about automatic functions, please see chapter 4.3 Parameter setting)
 	**Connection testing** It is strongly recommended to check the connection testing every time before use. Touch the lip hook with the file inserted to the contra-angle and check that all the bars on the display on the screen light up, and the rotation should be reversed. The measurement cable or contra-angle should be replaced if these functions are not noticed.

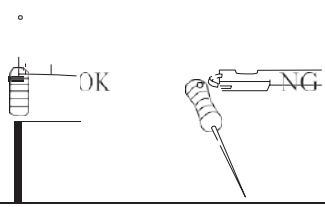
4.8 Canal measurement operation



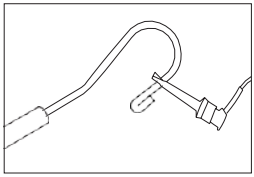


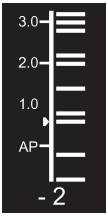
When using in the apex locator mode. the motor handpiece is suggested to be placed on the charging base to get a better visual angle.
Press Setting button “P” once in the standby state, press the adjusting button “+”/“-” to select EAL Operation mode, then press the Main button to confirm. (See chapter 3.3 Terms and definition to get the explanations of Operation modes.)
The measurement cable must be connected with the motor handpiece at the USB socket, the white socket connects with the patient’s lip by lip hook, and the black socket connects with the file clip.
The canal length indicator bar will be shown on the screen (more information about canal length indicator bar, please see chapter 3. 2 Screen display).





The file clip must hold the file correctly.
Push the button on the file clip with your thumb in the direction shown by the arrow. Clip the holder onto the metal upper part of the file and then release the button.



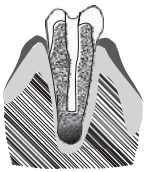


Connection testing

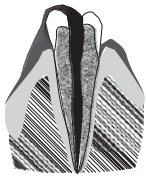
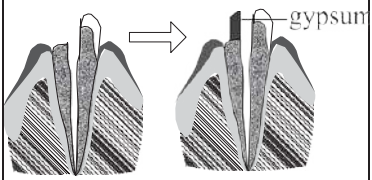
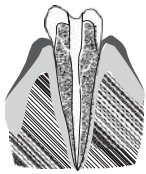
It is strongly recommended to check the connection testing every time before use. Clip the holder onto the lip hook and check that all the bars on the meter on the display light up, If this is not noticed, the measuring wire or file clip should be replaced.

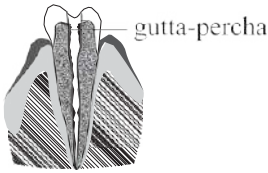
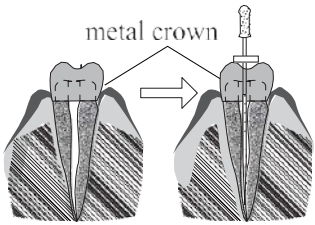
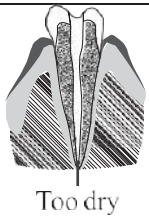
.

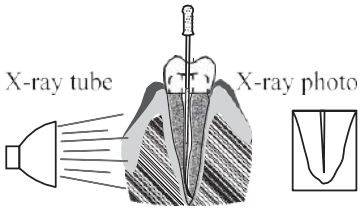
Root canal with a large apical foramen



A root canal that has an exceptionally large apical foramen due to a lesion or incomplete development cannot be accurately measured. The results may show a shorter measurement than the actual length.

	Excessive bleeding into the canal from apical foramen. This bleeding may contact the gingiva and the device shows inaccurate measurement. The bleeding should be arrested before measuring the working length. If Irrigating solutions used in the root canal are in contact with oral tissues, the measurement will be inaccurate. Please make sure no solution is in contact with oral tissues before measuring the working length.
	Fractured crown If the crown is fractured and gingival tissue overgrows into the access cavity, contact between the gingival tissue and the file will result in an inaccurate measurement. Pre endo buildup is recommended to avoid the contact tissue with the endodontic file.
	Fractured root Leakage through a fracture line in the root causes electrical leakage and lead to inaccurate measurement

	Re-treatment of a root canal obturated using gutta-percha. The gutta-percha must be completely removed to eliminate its inhibitory effect. After removing the gutta-percha, a small file should be used to establish patency through the apical foramen Place a small amount of saline in the canal and make sure saline does not overflow.
	Crown or metal prosthesis touching gingival tissue Accurate measurement cannot be obtained if the file touches a metal prosthesis touching gingival tissue. Widen the opening at the crown or wrap the shank portion of the file with Teflon so that the file is not in contact with the metal prosthesis while measuring the working length.
	Extremely dry canal If the canal is extremely dry, there will be no display of the file movement until it is very near to the apex. Moisten the canal with saline to avoid this problem.
Difference in working length measurement between the apex locator Radiograph. Sometimes the reading on the apex locator and the length on the X-ray image may not correspond. This does not mean the apex locator is not working properly or that the X-ray exposure is a failure. An X-ray image might not show the apex correctly depending on the angle of the X-ray beam, and the location of the apex might seem to be other than the actual location.	

 The apical to the side of the root canal crown	The actual apex for the canal is not the same as that for the radiographic apex. There are cases where the apical foramen is placed coronally compared to the radiographic apex. In these cases, an X-ray might indicate that the file has not reached the apex even though it has actually reached the apical foramen.

4.9 Battery Charging

The motor handpiece has a built-in rechargeable lithium battery.

When charging the battery, leave approximately 10cm around the charging base for easy access to the inlet and the power cord.

Connect the power adapter with the charging base. Confirm that it is well connected, place the motor handpiece on the charging base. The indicator light on the charging base turning blue indicates charging. The indicator light on the base turning green indicates the battery is fully charged. There is no need to charge further. (Only for MotoPex).

Insert the power adapter plug into the charging base power socket and confirm that they are correctly connected. Insert the motor handpiece into the charging base (the motor handpiece needs to be correctly aligned with the charging base in the same direction for charging). When the blue indicator on the charging base flashes, it is charging. When the motor handpiece is fully charged, the blue indicator on the charging base would be always on (Only for Ai-Motor).

After charging, please unplug the power adapter.

4.10 Replacing Battery

Replace the battery if it seems the battery recharging time becomes shorter. 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 place it in the motor handpiece.

f) Replace the cover and its screw.

It is recommended to contact local distributors or manufacturers to replace the battery.

4.11 Oiling of contra-angle

Only the original oil injection nozzle should be used for the oiling of the contra-angle. The contra-angle needs to be lubricated after cleaning and disinfection but before sterilization.

1. Firstly, insert in screwing motion to inject the nozzle into the jet of the oil bottle. (Around 1 to 3 circles)
2. Next, plug the nozzle into the end part of the contra-angle, and grease the contra-angle for 2-3s till the oil flows out of contra-angle head part.
3. Vertically place the end part of the contra-angle for more than 30 minutes to let go of the redundant oil under gravity.

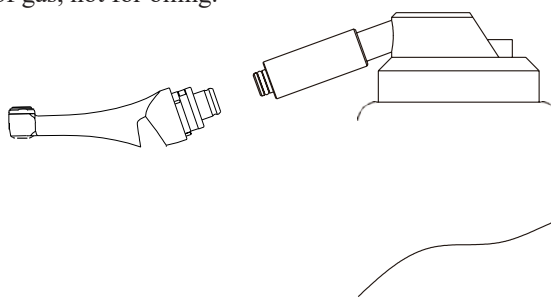
Warnings

Motor handpiece should not be filled with oil.

Cautions

a: To avoid the contra angle from flying out due to 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.



5 Troubleshooting

Failure	Possible cause	Solutions
The motor handpiece does not rotate.	Chose EAL mode, EAL mode is only for working length measurement.	Change to CW, CCW, REC or ATR mode.

There is a continuous beep sound after starting the motor handpiece.	The continuous beep sound indicates the motor handpiece is in CCW mode.	Stop the motor handpiece and change the operating mode to CW Mode.
Contra angle calibration failure	Calibration failure caused due to strong resistance in the contra angle	Clean the contra angle, and recalibrate after oil lubrication
Motor handpiece over heating	Used in reciprocating Motion mode for long time	Stop the motor till the handpiece cools down.
The time of endurance becomes shorter after charging.	Battery capacity reduced	Please contact local distributor or manufacturer.
No sound	Beeper Volume set to 0. Vol.0: Mute.	Set Beeper Volume to 1,2,3.
The file is stuck in the root canal when used in Continuous rotation mode.	Incorrect setting for the file used. High torque load on the file	Change to CCW Mode, start the motor handpiece, and remove the file from the contra angle. .

6 Cleaning, Disinfection and Sterilization

6.1 Foreword

For hygiene and sanitary safety purposes, the contra-angle, the lip hook, the file clip, the protective silicon cover and the touch probe must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This is applicable for the first use, as well as all subsequent uses.

6.2 General recommendations

. 6.2.1 Use only a disinfecting solution that 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.

6.2.3 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 during the first cycle and subsequently.

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

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

6.2.9 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 recommended.

6.3.1.1 Manual cleaning steps:

1. Place the handpiece, charger, and base on the workbench.

2. Wet a soft cloth completely with distilled water or deionized water, to wipe all the surfaces of the components such as handpiece, charger, base, etc. until the surface of the component is free of debris or stains.

3. Wipe the surface of each 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, non-residue disinfectants such as Oxytech from Germany can be used, but the concentration, temperature and time specified by the disinfectant manufacture must be followed.

d) After cleaning and disinfecting the handpiece, disposable isolation sleeve should be installed before use and repeat steps 1, 2 and 3 to clean the disposable isolation sleeve (For detailed installation steps, see section 2.7).

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. Wet nap-free soft cloth with distilled water or deionized water, should be used to wipe all the surfaces of the components such as handpiece, charger, base, etc. until the surface is free of debris or stains.

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. Place the handpiece, charger, base and other components back into a clean storage area.

Note:

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

b) The disinfectant should be sprayed immediately after the use but no foaming is allowed.

c) In addition to 75% alcohol, non-residue disinfectants such as Oxytech from Germany can be used, but the concentration, temperature and time specified by the disinfectant manufacture must be followed.

6.4 The cleaning, disinfection and sterilization of contra-angle, lip hook, file clip, protective silicon cover, touch probe are as follows.

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

Warnings:

The use of strong detergent or disinfectant (alkaline pH>9 or acid pH <5) will reduce the life span of products. The manufacturer takes no responsibility if the recommendations are not followed.

The products should 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 manufacturing process were selected accordingly. However, with every cycle 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

Effective sterilization is possible only after thorough cleaning and disinfection. Please ensure 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 adhere to legal requirements applicable 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.

6.4.1.2 Post-operative treatment

The post-operative sterilization must be carried out immediately, no later than 30 minutes after the completion of the procedure. The steps are as follows:

1. Remove the products from the base, and rinse away the dirt on the surface of the handpiece with pure water (or distilled water/deionized water);
2. Dry the products with a clean, soft cloth and place them in a clean tray.

Notes:

a) The water used here must be pure water, distilled water or deionized water.

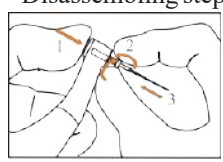
6.4.2 Preparation before cleaning Steps:

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

1. Remove the files from the contra-angle.
2. Remove the file clip, isolation sleeve, Contra-angle and connecting wire from the handpiece in sequence and place them in a clean tray.
3. Use a clean soft brush to carefully brush the lip hook, file clip, protective silicon cover, touch probe, head and back cover of the contra-angle until debris or stains on the surface are not visible.
4. Use a soft cloth to dry the products and place them in a clean tray.

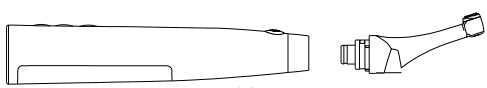
The cleaning agent can be pure water, distilled water or deionized water.

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 out slowly.
c) Make sure the handpiece is switched off before Inserting or removing

the contra-angle.

6.4.2 Cleaning

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

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

6.4.2.1Automated cleaning

•The cleaner must be approved 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 the 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.

6.4.3 Disinfection

Disinfection must be performed no later than 2 hours after the cleaning phase. Automated disinfection is preferred if possible.

6.4.3.1Automated disinfection-Washer-disinfector

·The washer-disinfector use should be approved by CE certification in

accordance with EN ISO 15883.

·Use high temperature disinfection function. The temperature should not exceed 134 ° C, and the disinfection under the temperature cannot be more than 20 minutes.

·The disinfection cycle must be 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. The product needs to be fixed only when the product is moving in the device. The products are not allowed to contact each other.

2. Use a suitable rinsing adaptor, and connect the internal water lines

t o the rinsing connection of the washer-disinfector.

3. Start the program.

4. After the program is finished, remove the product from the washer-disinfector, inspect (refer to the section "Inspection and Maintenance") and the packaging (refer to chapter "Packaging"). Repeat the process 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 can 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 twice with each rinse lasting for 1 minute. (c2) when washing, the water temperature should not exceed 45 °C, to prevent solidification of the protein which is difficult to remove. (c3) freshly prepared solutions such as pure water, distilled water, deionized water or multi-enzyme solution, etc. can be used. (c4) During the use of cleaner, the concentration and time provided by the manufacturer must be followed. 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 number 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.

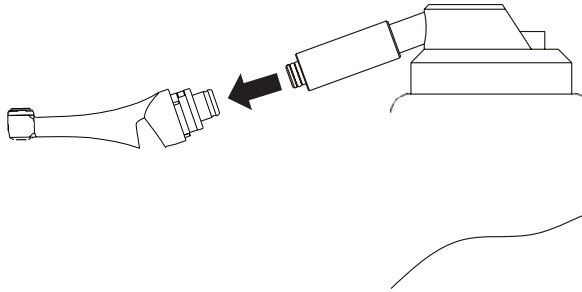
h) Regular maintenance and inspection of the disinfector should be performed.

6.4.4 Drying

If the 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, orient the product vertically on the white paper (white cloth), and then dry the product with filtered dry compressed air (maximum pressure 3 bar). No liquid oozing onto the white paper (white cloth), indicates the drying of the product is complete.
2. It can also be dried directly by placing it in a medical drying cabinet (or oven). The recommended drying temperature is 80℃~120℃ and the time is 15~40 minutes.
Notes:
a) The drying of the 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.

6.4.4 Inspection and maintenance
6.4.4.1 Inspection
In this chapter, we only check the appearance of the product.
1. Check the product. If any stain or debris is still visible 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 should not be used.
3. Check the product. If the accessories are found to be damaged, they must be replaced before use. Replaced new accessories must be cleaned, disinfected and dried before use.
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 the cleaning lubricant is aligned with the air intake hole at the end of the contra-angle to inject oil for 1-2 seconds.



6.4.4 Packaging

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

Notes:

a) The package used should conform to ISO 11607 standards

b) The packing should 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.

6.4.5 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 standards.

·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 should be provided by a verified testing laboratory.

Notes:

a) Only products that have been effectively cleaned and disinfected should 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 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.

6.4.6 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.

6.4.7 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 storage in too hot conditions. The high temperature will shorten the life of electronic components, damage batteries, reshape or melt some plastic.

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

7.1 Maintenance

7.2.1 This device does not include accessories for repair usage, the repair should be carried out by an authorized person or an 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 extended period of usage, 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 charge sooner than it should.

7.1 Transportation

7.3.1 Excessive impact and shaking should be prevented in transportation. Place the device carefully and lightly and don't invert it.

7.3.2 Don't place it together with dangerous goods during transportation.

7.3.3 Avoid exposure to sunlight, 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 purchase based on the warranty card, we will repair this equipment free of charge if there are any quality problems. Please refer to the warranty card for the warranty period.

10 European authorized representative

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

11 Symbol instruction


Follow Instructions for Use

Serial number


Date of manufacture


Manufacturer


Type B applied part


Class II equipment

IPX0 Ordinary equipment


Recovery

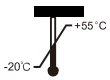

Used indoor only


Keep dry


Handle with care


Appliance compliance WEEE directive

Humidity limitation



Temperature limitation

Atmospheric pressure for storage

CE marked product

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 EMC-Declaration of conformity

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 affected by electromagnetic interference. Avoid using the device in a high electromagnetic environment.

Technical Description Concerning Electromagnetic Emission

Table 1: Declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The model Ai-Motor / MotoPex is intended for use in the electromagnetic environment specified below. The customer or the user of the model Ai-Motor、MotoPex should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model Ai-Motor、MotoPex 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 Ai-Motor /、MotoPex is suitable for use 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 Ai-Motor 、 MotoPex is intended for use in the electromagnetic environment specified below. The customer or the user of the model Ai-Motor、MotoPex 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 Ai-Motor、MotoPex requires continued operation during power mains interruptions, it is recommended that the models Ai-Motor、MotoPex 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 Ai-Motor、MotoPex is intended for use in the electromagnetic environment specified below. The customer or the user of the models Ai-Motor、MotoPex should ensure 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 Ai-Motor、MotoPex, including cables, then 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 strength 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 Ai-Motor、MotoPex is used exceeds the applicable RF compliance level above, the model Ai-Motor、MotoPex should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model Ai-Motor、MotoPex.
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 Ai-Motor、MotoPex

Recommended separation distances between portable and mobile RF communications equipment and the model Ai-Motor、MotoPex			
The model Ai-Motor MotoPex is intended for use in electromagnetic environment in which radiated RF disturbance is controlled. The customer or the user of the model Ai-Motor 、 MotoPex can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model Ai-Motor、MotoPex 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) according 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

Guilin Woodpecker Medical Instrument Co., Ltd.
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

ZMN-SM-034 V1.9-20210430