文件名/NAME	大客户 05 Ai Motor(改型号为 CanalPro X-Move) 根管预备机英文说明书	代码/CODE	71.05.03.006
尺寸/SIZE	130×190mm，出血 6mm	版本/REV.	V1.2
材质/MATERIAL	120g 铜版纸		
工艺/PROCESS	/		
装订&注释/ bind (books etc) &NOTES	骑马订	印刷颜色/COLORS	4X4 CMYK
修订日期/DATE	2024 年 06 月 24 日		

请勿打印此页，仅供参考。/DO NOT PRINT THIS PAGE,REFERENCE ONLY.

CanalPro X-Move

Instructions for Use – User Manual

EN

CE 0197

COLTENE

Please carefully read this User Manual before first operation.

The device must be operated in a healthcare facility, hospital or clinic by legally qualified dentists.
It is assumed that the operator is familiar with a root canal apex locator.

Intended use

The CanalPro X-Move is an endodontic motor, an electro-medical device designed to drive mechanical instruments intended for dental root canal treatment (endodontic files).
In addition, it is intended to determine the working length (apex locator functionality).

United States federal law authorises the sale of this device only by a physician or by a prescription of the latter [21CFR801.109(b)(1)].

End user are invited to register CanalPro X-Move motor on mycoltene.com

mycoltene.com provides :

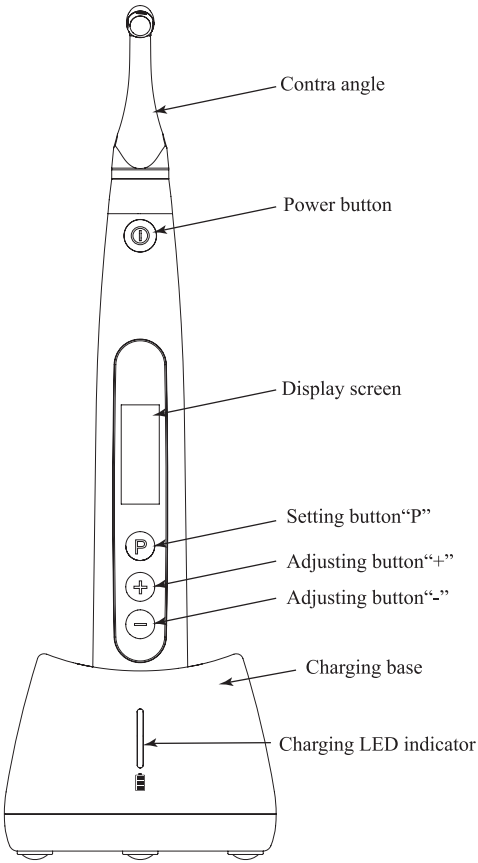
- **User Manuals**
- **Troubleshooting guides**
- **Service points and contacts**

Table of Contents

1. Product introduction

1.1 Description of the device

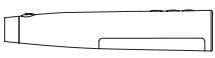
The CanalPro X-Move is a cordless endodontic motor with an integrated root canal apex locator. It can be used as an endodontic motor for preparation of root canals and as an apex locator device to determine the root canal working length. It can also be used to prepare the canals while monitoring the relative position of the endodontic instrument tip inside the canal (combined Motor and Apex locator mode).

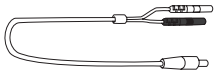


1.2 Components and accessories

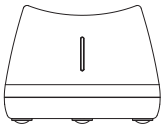
#	Designation	Quantity	Weight (g)	Reference COLTENE

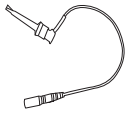
1	Motor handpiece	1	137	65002742
2	Charging base	1	155	65002743
3	Contra-angle	1	20	65002744
4	Spray nozzle	1	2	65002745
5	Measuring wire	1	22	65002747
6	File holder	4	8	65002748
7	Lip clip	2	2.6	65002749
8	Touch probe	2	2.4	65002750
9	"O"-ring	4	< 1	65002751
10	Universal AC-Adapter	1	96	65002746
11	Disposable insulation sleeves	10	1.9	65002841
12	Battery	1	37.5	65002752
-	User manual	1	-	-
-	Apex locator troubleshooting card	1	-	-
-	Package content list	1	-	-

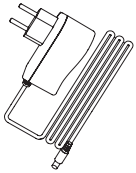

1. Motor handpiece


5. Measuring wire


9. O-ring

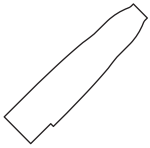

2. Charging base

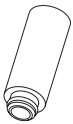

6. File holder


10. Universal AC-Adapter


3. Contra angle


7. Lip clip


11. Disposable insulation sleeves


4. Spray Nozzle


8. Touch probe

1.3 Technical specifications

a) Motor handpiece lithium battery specification
3.7V / 2000mAh

b) Power adapter specification
Input: ~100V-240V 50Hz/60Hz 0.4A max
Output: DC5V/1A
Plugs: type C, type A, type G and type I
c) Motor handpiece mechanical specification
Torque range: 0.4N.cm-5.0N.cm
Speed range: 100rpm-2500rpm
d) Wireless charging specification
Frequency range: 112-205kHz
Maximum RF output power of the product: 9.46dBuA/m@3m

1.4 Warnings

a) Do not use this device for anything else than its intended use.
b) Use original components and accessories only.
c) Always set torque and speed following the recommendations of the file manufacturer.
d) Make sure the contra-angle is well connected before starting the motor handpiece (refer to Chapter 2.1.)
e) Make sure the instrument is well connected and locked before starting the motor handpiece (refer to Chapter 2.2).
f) Do not connect or disconnect the contra-angle while the motor is running.
g) Do not disconnect the instrument while the motor is running.
h) Be sure to be able to power OFF the device at any time.
i) Operate and store the device in reliable environment (refer to Chapter 1.7 and Chapter 8).
j) Do not use the device near fluorescent lamps, radio transmitting devices, remote control devices, handheld, and mobile high-frequency communication devices, due to EMC (Electro Magnetic Compatibility) interferences.
k) The motor handpiece, power adapter and charging base are not autoclavable (refer to Chapter 6).
l) Replace the battery according to the instructions (refer to Chapter 7.4).
m) Do not make any changes or modifications to the device. Any change, modification or any other alteration of the device may violate safety regulations, causing harm to the patient.
n) In case of motor handpiece frequent overheating, contact a local distributor.
o) Do not directly or indirectly place the device near heat sources.
p) Do not cover the device.
q) Remove the battery from the device if storing for a long period of time.

1.5 Contraindications

a) Do not use this device on patients who have implanted pacemakers, defibrillators, or any other implantable devices.

b) Do not use this device on patients with hemophilia.
c) Use with caution on patients with heart disease, pregnant women, and young children.

1.6 Device safety classification

a) Type of Operation mode: Continuous operating electromedical device
b) Type of protection against electric shock: Class II equipment with internal power supply
c) Degree of protection against electric shock: B type applied part
d) Degree of protection against harmful ingress of water: Ordinary equipment (IPX0)
e) 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.
f) Applied part: contra-angle, lip clip, file holder, touch probe. The contact duration of applied part: 1 to 10 minutes. Maximum temperature of applied part: 46.6°C (115.88°F).

1.7 Environmental parameters

a) Operating ambient temperature: +5°C ~ +40°C (+41°F ~+104°F)
b) Operating relative humidity: 30% ~ 75%
c) Operating atmospheric pressure: 70kPa ~ 106kPa

1.8 User qualification

a) The device must be operated in a healthcare facility, hospital or clinic by legally qualified dentists.
b) It is assumed that the operator is familiar with a root canal apex locator.

1.9 Intended use

a) The CanalPro X-Move is an endodontic motor, an electro-medical device designed to drive mechanical instruments intended for dental root canal treatment (endodontic files).
b) In addition, it is intended to determine the working length (apex locator functionality).

2. Device setup instructions

2.1 Contra-angle setup

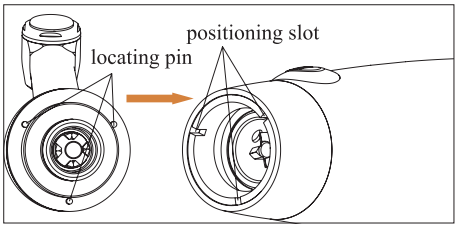
2.1.1 Before the first use and after each treatment
a) Clean and disinfect the contra-angle (refer to Chapter 6).
b) Lubricate the contra-angle (refer to Chapter 7.2).
c) Sterilize the contra-angle (refer to Chapter 6).

2.1.2 Warnings

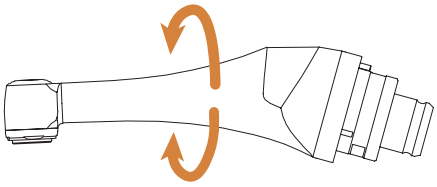
a) Use original contra-angle only.
b) Make sure the contra-angle is well connected before starting the motor handpiece.
c) Do not connect or disconnect the contra-angle while the motor is running.

2.1.3 Connecting the contra-angle

1. Align the three pins of the contra-angle with the positioning slots of the motor handpiece.
2. Push the contra-angle horizontally. A "click" sound indicates that the installation is in place.

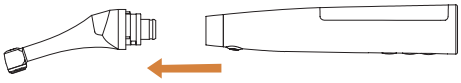


3. The contra-angle must rotate 360° freely.



2.1.4 Disconnecting the contra-angle

Pull out the contra-angle horizontally.



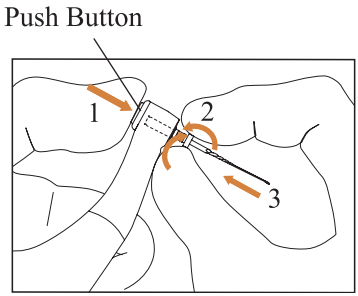
2.2 File setup

2.2.1 Warnings

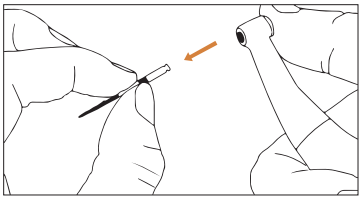
a) Make sure the instruments are compliant to ISO1797 standard (Shanks for

rotary and oscillating instruments).
b) Connecting and disconnecting files without holding down the Push button may damage the chuck of the contra-angle.
c) Be careful when manipulating files to avoid injury to fingers.
d) Make sure the file is well connected and locked before starting the motor handpiece.
e) Do not disconnect the file while the motor is running.

2.2.2 Connecting a file
Plug the file into the hole of the contra-angle head.
1. Hold down the Push button on the contra-angle and push the file.
2. While pushing, rotate the file clockwise and counterclockwise until its shank is aligned with the contra-angle latch groove.
3. When the shank is aligned and slips into place, release the Push button to lock the file into the contra-angle.



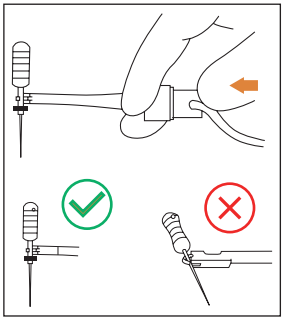
2.2.3 Disconnecting a file
Hold down the Push button and pull out the file.



2.3 Apex locator setup

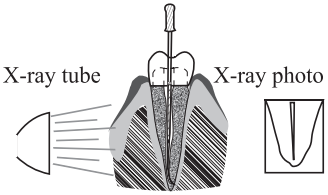
2.3.1 Warnings
a) In Apex locator mode, the file holder must properly hold the file.

b) In case of bad or wrong connection signal, replace the measuring wire.



c) In apex locator mode it is suggested to install the motor handpiece in the charging base to get better visual angle.

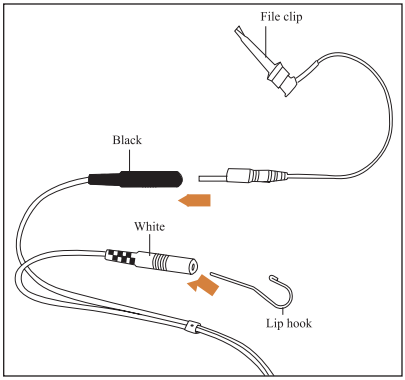
d) The Apex locator detects the canal apical foramen, not the tooth anatomical apex. This could explain some differences between the apex locator signal and an X-ray image.



e) Not all conditions are ideal for working length determination. To be informed about the Apex locator limitations, refer to Chapter 4.7.

2.3.2 Connecting apex locator wires

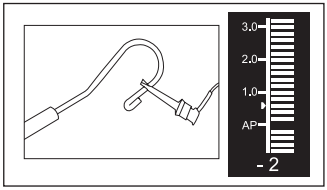
1. Connect the measuring wire to the motor handpiece (USB socket at the back).
2. Connect the lip clip to the white socket of the measuring wire.
3. Connect the file holder plug to the black socket of the measuring wire (this is not required in combined Motor and Apex locator mode).



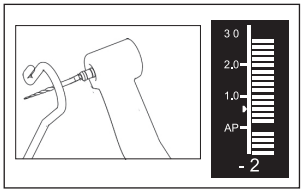
2.3.3 Connection testing

It is strongly recommended to check the connection quality before every use.

1. In Apex locator mode, clip the holder on lip clip and check that all the indicator bars light up, as shown below:



2. In combined Motor and Apex locator mode, touch the lip clip with the file and check that all the indicator bars light up, as shown below:



3. Device Operation modes and display interface

3.1 Motor modes

3.1.1 CW Operation Mode (Clockwise continuous rotation mode)

In this mode, the motor handpiece rotates in clockwise direction only (forward direction).

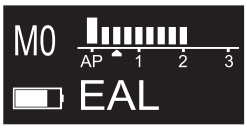
3.1.2 CCW Operation Mode (Counterclockwise continuous rotation mode)
In this mode, the motor handpiece rotates in counterclockwise direction only (reverse direction). In this mode, a double beep sounds continuously.

3.1.3 REC Operation Mode (Reciprocating motion mode)
In this mode, the motor handpiece generates reciprocating motion only (F: Forward angle, R: Reverse angle).

3.1.4 ATR Operation Mode (Adaptive Torque Reverse mode)
In this mode, the motor handpiece rotates in clockwise direction and generates reciprocating motion when the torque load on the file is higher than the set torque limit.

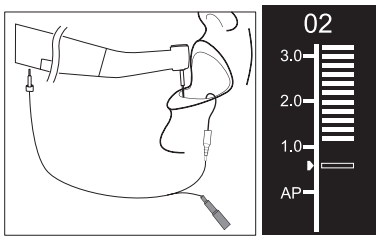
3.2 Apex locator Operation mode

EAL Operation Mode (Electronic Apex Locator)
This mode is intended for working length determination only.
In this mode, the motor handpiece does not run.

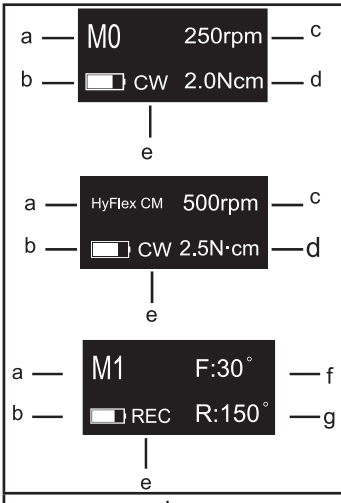


3.3 Combined Motor and Apex locator Operation mode

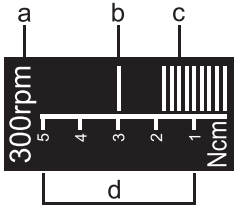
When a file is inside the canal and the lip clip is in contact with patient's lip, the device enters automatically in the combined Motor and Apex locator mode.



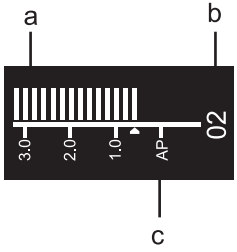
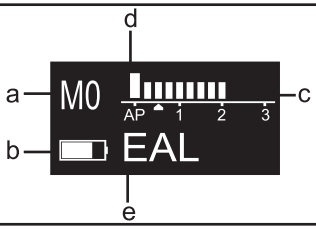
3.4 Display interface



Stand-by interfaces
While the motor is not running, the display shows the actual settings of the motor.
a. User Program (M0-M9) or
COLTENE preset program (refer to Chapter 4.2)
b. Battery level
c. Set speed (rpm)
d. Set torque limit (N.cm)
e. Motor Operation mode
f. Set forward angle (°deg)
g. Set reverse angle (°deg)

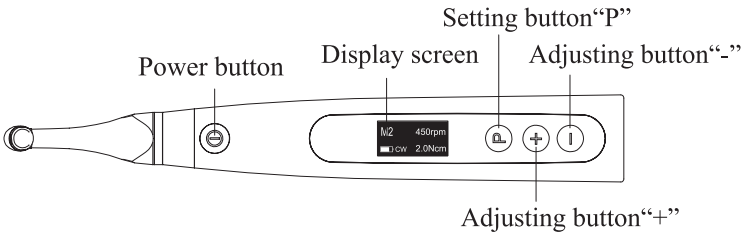


Motor Operation interface
While the motor is running, the display shows the torque load on the file.
a. Set speed (rpm)
b. Set torque limit (N.cm)
c. Real time torque (N.cm)
d. Torque display scale (N.cm)

	Combined Motor and Apex locator Operation interface a. File progression indication bar b. File progression indication number The numbers 1.0, 2.0, 3.0 (a) and numbers "00"-"16" (b) do not represent an absolute length. It simply indicates the relative file position towards the apical foramen. These numbers are used to help the determination of the working length. c. Apical foramen (AP) The digital number "00" (b) indicates that the file has reached the apical foramen. The digital numbers "-1" and "-2" (b) indicate that the file has passed the apical foramen.
	Apex locator Operation interface (EAL mode) a. User Program (M0-M9) b. Battery level c. File position indication bar d. Apical reference point e. Motor Operation mode

4. Device operating instructions

4.1 Setting interface and button description



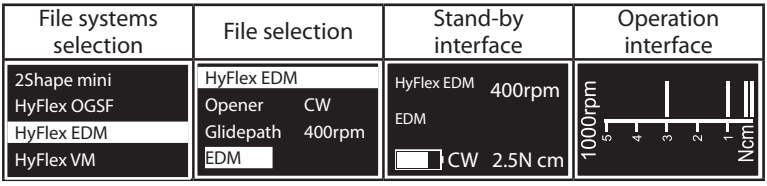
4.2 Power ON and power OFF the device

1. To power ON the device, press the Power button. The device enters directly in the Coltene File Systems.
The Coltene File Systems are already preset in the device, in order to assist and facilitate the use, with pre-settings parameters according to Coltene recommendations.

Coltene files can only be used if they are registered in the country. The fact that they are pre-programmed in this endo motor does not prejudge their registration.

2. To select the desired Coltene File System, press the Adjusting button "+"/"-" and press the Setting button "P" to confirm.
3. To select a file, press the Adjusting button "+"/"-" and press the Power button to confirm.

For example, for HyFlex EDM



4. In stand-by state. The display shows the stand-by interface of the last program used. For example:

5. To replace one of the five "favorite" registered Coltene File System with another one, press the Adjusting button "+"/"-" to select the program to replace, and hold down the Setting button "P" during about 3 seconds.
5 favorites programs can be selected (refer to Chapter 4.4.2).

6. To start the motor from the stand-by state, press the Power button.
The display shows the working interface according to the program used.
For example:

7. To stop the motor, press the Power button again. The device goes back in stand-by state.

8. To power OFF the device, hold down the Setting button "P", and press the Pow-

er button. In stand-by state, the device will automatically shut down after 5 minutes.

4.3 Select User Programs

The device contains 10 memorized User Programs (M0-M9) and 5 preset/favorite Coltene File Systems available directly from the stand-by state.

1. Press the Setting button "P" to select a program from Coltene File Systems list
2. To select a program from the stand-by state, press the Adjusting button "+"/"-".

3. To come back to Coltene File Systems list press the Power button.

4.4 Set User Program parameters

4.4.1 Warnings

a) Make sure the Operation Mode is adequate before starting the motor.
b) All the parameters must be set according to the file manufacturer recommendations.
c) Make sure all the parameters are verified before starting the motor handpiece.
d) M0-M9 User Program parameters modified by the user are memorized.
e) Coltene File Systems parameters cannot be modified by the user (refer to Chapter 4.2).

4.4.2 Parameter setting

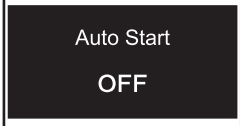
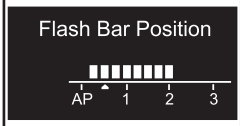
To modify User Program parameters from the stand-by state:

1. To select the desired parameter, press the Setting button "P".
2. To modify the parameter setting, press the Adjusting button "+"/"-".
3. Press the Power button or wait 5 seconds to confirm.

4.4.3 User Program parameters list

Operation Mode **CW**	Set Operation Mode Operation modes list: CW, CCW, REC, ATR, EAL (refer to Chapter 3 for modes description)

Speed 250rpm	Set Working Speed In continuous rotation modes (CW and CCW), the working speed can be adjusted from 100rpm to 2500rpm (50rpm increments). In REC mode, the working speed can be adjusted for 100rpm to 500rpm (50rpm increments). In ATR mode, the working speed can be adjusted for 100rpm to 500rpm (50rpm increments). In REC and ATR modes, the working speed represents the mean speed of one single angle movement (speed set for both Forward and Reverse angles).
Torque Limit 1.0Ncm	Set Torque Limit In CW continuous rotation mode, the torque limit can be adjusted from 0.4N.cm to 5.0N.cm depending on the set speed: • 100-350rpm Max torque limit : 5.0N.cm • 400-500rpm Max torque limit : 4.5N.cm • 550-650rpm Max torque limit : 4.0N.cm • 700-1200rpm Max torque limit : 3.0N.cm • 1250-1500rpm Max torque limit : 2.0N.cm • 1550-2000rpm Max torque limit : 1.5N.cm • 2050-2500rpm Max torque limit : 1.0N.cm In REC mode, the torque limit can be adjusted from 2.0N.cm to 5.0N.cm depending on the set speed: • 100-350rpm Trigger Torque between 2.0N.cm and 5.0N.cm • 400-500rpm Trigger Torque between 2.0N.cm and 4.5N.cm In ATR mode, the Trigger Torque can be adjusted from 0.4N.cm to 4.0N.cm. In CCW continuous rotation mode, the torque limit cannot be set.

	Set Apical Action The Apical action applies when the file reaches the set apical reference point (refer to **Flash Bar Position** below) OFF: Disable Apical Action STOP: The motor stops automatically when the file reaches the reference point. The motor restarts automatically when the file is pulled away from the reference point. REVERSE: The motor automatically reverses the rotation direction when the file reaches the reference point. The motor goes back automatically to initial rotation direction when the file is pulled away from the reference point.
	Set Auto Start OFF: Disable Auto Start (the Main button is needed to start the motor handpiece). ON: The motor starts automatically when the file is inserted into the canal (from when the file progression indicator shows 2 bars).
	Set Auto Stop OFF: Disable Auto Stop (the Main button is needed to stop the motor handpiece). ON: The motor stops automatically when the file is taken out the canal.
	Set Flash Bar Position (Apical reference point) The apical reference point (flash bar) can be set from 2 to AP (Apical foramen). (0.5 indicates that the file tip is located very near the physiological apical foramen) **Apical Action** and **Apical Slow Down** are triggered by the apical reference point.

Apical Slow Down OFF Apical Slow Down 200rpm	Set Apical Slow Down When the Apical Slow Down is activated, the motor slows down to a set final speed as the file tips approaches the apical reference point. The motor speed decreases starting from the position "3.0" of the file progression indication bar. OFF: Disable Apical Slow Down In CW continuous rotation mode, the final speed can be adjusted from 100rpm to the current set speed (50rpm increments). The Apical Slow Down function is available for CW & CCW continuous rotation mode only. The final speed must be lower than the nominal speed.
Forward Angle 30°	Forward Angle In REC mode, the Forward Angle can be adjusted from 20° to 400° (10° increments) In ATR mode, the Forward Angle can be adjusted from 60° to 400° (10° increments).
Reverse Angle 150°	Reverse Angle In REC mode, the Reverse Angle can be adjusted from 20° to 400° (10° increments) In ATR mode, the Reverse Angle can be adjusted from 20° to the Forward Angle (10° increments).

4.4.4 User Programs parameters availability table

Parameter / User Program Operation Mode	Set Working Speed	Set Torque Limit	Set Apical Action	Set Auto Start	Set Auto Stop	Set Flash Bar Position	Set Apical Slow Down	Set Forward Angle	Set Reverse Angle
CW	YES	YES	YES	YES	YES	YES	YES	n/a	n/a
CCW	YES	NO	NO	NO	NO	YES	YES	n/a	n/a
REC	YES	YES	YES	YES	YES	YES	NO	YES	YES
ATR	YES	YES	YES	YES	YES	YES	NO	YES	YES
EAL	n/a	n/a	n/a	n/a	n/a	YES	n/a	n/a	n/a

4.5 Set device parameters

To set the device parameters:

1. To access the device parameters from the power OFF state, hold down the Setting button "P" and press Power button.

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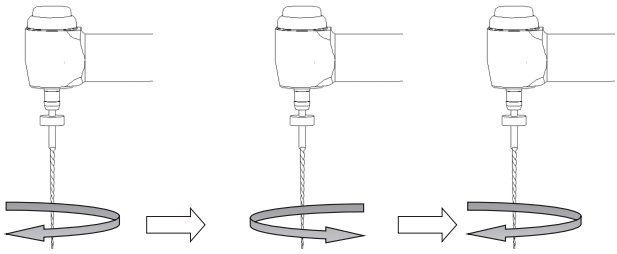
2. To select the desired parameter, press Setting button “P”
3. To set the parameter, press the Adjusting button “+”/“-” and the Power button to confirm.

4.5.1 Device parameters list

Auto Power OFF 5 min	Auto Power OFF In stand-by state, the device automatically turns OFF after the set timer. The timer can be adjusted from 3 minutes to 30 minutes (1 minute increments)
Auto Standby Scr 30 sec	Auto Standby Scr The display automatically switches back to the stand-by interface after the set timer. The timer can be adjusted from 3 seconds to 30 seconds (1 second increments)
Dominant Hand Right	Dominant Hand The device can be adjusted for left-handed or right-handed user (180° rotation of the display).
Calibration OFF	Calibration Make sure the original contra-angle is installed before starting the motor calibration. OFF: No action. ON: Start motor calibration The motor must be calibrated before the first use and after lubrification.
Beeper Volume Vol.3	Beeper volume The device sound volume can be adjusted from Vol. 0 to Vol. 3. Vol. 0: Mute.
Restore Defaults OFF	Restore Defaults OFF: No action. ON: Device parameters return to original setting.

4.6 Torque overload protection

During operation, if the measured torque load exceeds the torque limit, the motor will automatically reverse the direction of rotation. The motor returns to initial Operation mode (CW) when the torque load goes back below the torque limit.

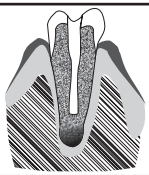
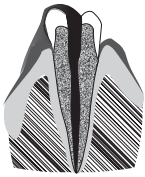


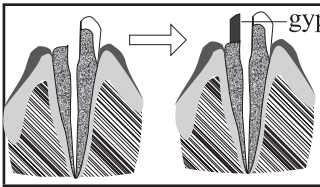
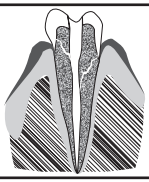
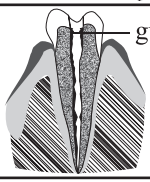
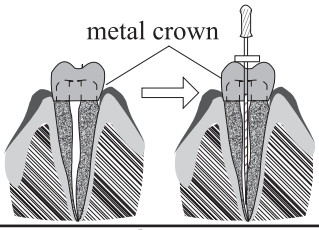
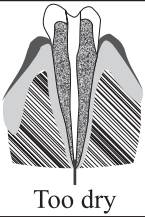
⚠ 4.6.1 Warnings

a) In reciprocation motion mode (REC), when the load value is higher than the torque limit:
i. if the Forward angle is greater than the Reverse angle, the motor automatically switches to counterclockwise rotation (reverse direction).
ii. if the Reverse angle is greater than the Forward angle, the motor automatically switches to clockwise rotation (forward direction).
b) The auto-reverse protection is not available for CCW and ATR modes.
c) The auto-reverse protection might not work properly in case of low battery level.
d) Under continuous load, the motor may stop automatically due to overheating. In that case, the device must be powered OFF long enough to allow the device to naturally cool down.

4.7 Apex locator limitations

Not all conditions are ideal for root canal length evaluation. Accurate signal cannot be obtained if the root canal shows the conditions listed below.

	Root canal with a large apical foramen Root canal with exceptionally large apical foramen due to a lesion or incomplete development might disturb the electrical signal.
	Root canal with liquid overflowing from the opening Root canal with blood or any other liquid overflowing from the opening and in contact with the gingival tissue might disturb the electrical signal.

	Broken crown If the crown is broken and a section of the gingival tissue intrudes into the cavity surrounding the canal opening, the contact between the gingival tissue and the file might disturb the electrical signal.
	Fractured tooth Fractured tooth might disturb the electrical signal.
	Re-treated root canal filled with gutta-percha Debris of gutta-percha might disturb the electrical signal.
	Crown or metal prosthesis touching gingival tissue The contact between the prosthesis and the file might disturb the electrical signal.
	Extremely dry root canal A dry canal might disturb the electrical signal.

5. Troubleshooting

Failure	Possible cause	Solutions
The motor handpiece does not rotate.	Device in EAL mode EAL mode is only for canal measurement.	Changing to CW, CCW, REC or ATR mode.

There is a continuous beep sound after starting the motor handpiece.	The continuous beep sound is indicating that the motor handpiece is under CCW mode.	Stop the motor handpiece and change the operating mode to CW Mode.
Contra-angle calibration failure	Calibration failure caused by strong resistance of contra- angle	Clean the contra-angle and recalibrate after oil injection.
Motor handpiece heating	Under Reciprocating Motion Mode, the time of use is too long.	Stop using. Resume use after the temperature of the motor handpiece drops.
The time of endurance becomes shorter after charging.	Battery capacity becomes smaller.	Contact local distributor.
No sound	Beeper Volume set to 0. Vol.0: Mute.	Set Beeper Volume to 1,2,3.
The continuously rotating file is stuck at the root canal.	Incorrect specification setting. Torque load is too high for the file being used.	Choose CCW Mode, start the motor handpiece, and take the file out.

6. Cleaning, Disinfection and Sterilization

6.1 Foreword

For hygiene and sanitary safety purposes, the contra-angle (including the O-ring), the lip clip, the file holder, and the touch probe must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use, as well as all subsequent uses.

6.2 General recommendations

a) After each use, all the objects that were in contact with infectious agents should be cleaned using towels impregnated with a disinfection agent.
b) Use OXYTECH® disinfecting solution or any other disinfection agent compliant with local national regulations (such as VAH/DGHM-listing, CE marking, FDA, and Health Canada approval) and in accordance with the IFU of the disinfecting solution manufacturer.
c) Do not immerge the contra-angle in a disinfectant solution or in an ultrasonic bath.
d) Do not use chloride detergent materials.
e) Do not use bleach or chloride disinfectant materials.
f) For your own safety, please wear personal protective equipment (gloves, glasses, mask).
g) The user is responsible for the sterility of the product and of the instruments.

h) The water quality must be compliant to the local regulations especially for the last rinsing step or with a washer-disinfector.
i) The contra-angle needs to be lubricated after cleaning and disinfection, but before sterilization (refer to Chapter 7.2).
j) To sterilize the endodontic files, refer to the manufacturer's instructions for use.

⚠ Do not sterilize the motor handpiece, the AC-Adapter, or the charging base.

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

6.3 Step-by-Step Procedure for the motor handpiece, the AC adapter and the base

#	Operation	Operating Mode	Warning
1	Preparation	Remove accessories (contra- angle, lip clip, file holder, touch probe) from handpiece and base.	
2	Manual Cleaning	Clean motor handpiece, AC adapter and base with a soft cloth and distilled or de-ionized water, and wipe all component surfaces with a dry soft nap-free cloth	
3	Manual disinfection	Disinfect motor handpiece, AC adapter and base with a soft cloth and 75% alcohol, and wipe all component surfaces with a dry soft nap-free cloth for at least 3 min In addition to 75% alcohol, you can use non-residue disinfectants such as OXY-TECH® from Germany	The cleaning and disinfection should be done within 10min before use.
4	Inspection	Inspect motor handpiece, AC adapter and base and sort out those with defects	Dirty components (motor handpiece, AC adapter and base) must be cleaned and disinfected again.
5	Storage	Put the handpiece, charger, base and other components back into the clean storage area	

6.4 Step-by-Step Procedure for accessories (contra-angle, lip clip, file holder,

touch probe)

#	Operation	Operating Mode	Warning
1	Preparation	Remove accessories (contra-angle, lip clip, file holder, touch probe) from handpiece and base.	
2	Automated Cleaning/ Desinfec-tion/Drying with washer-disinfector	Put the accessories (contra- angle, lip clip, file holder, touch probe) into the washer disinfector (Ao value >3000 or, at least 5 min at 90°C/194°F). The solution used can be pure water, distilled water, deionized water or multi-enzyme solution. The used multi-enzyme cleaner is Neodisher MediZym (Dr. Weigert).	- 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 wash-er-disinfector according to EN ISO 15883, maintain and calibrate it regularly. - Make sure accessories (con-tra-angle, lip clip, file holder, touch probe) are dry before moving to the next step.
3	Inspection	Inspect the accessories (contra- angle, lip clip, file holder, touch probe) and sort out those with defects.	- Dirty accessories (contra-an-gle, lip clip, file holder, touch probe) must be cleaned and disinfected again. - Lubricate the contra-angle with an adequate spray be-fore packaging.
4	Packaging	Pack the accessories (contra- angle, lip clip, file holder, touch probe) 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 11607-1.

5	Sterilization	Steam sterilization at 134°C (+273.2°F), 2.0bar- 2.3bar (0.20Mpa-0.23MPa), for at least 4 minutes. The highest sterilization temperature is 138 ° C. Allow a maximum sterilization time of 20 minutes at 134 °C. Cycle for French market : 134°C – 18 min	- Use only autoclaves that are matching the requirements of EN 13060, EN 285. - Use a validated sterilization procedure according to EN ISO 17665-1. - 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, physicochemical integrators, digital records of cycle parameters). - Control the absence of corrosion on the contra-angle - Maintain traceability of procedure records. - The maximum number of sterilizations for products is 250 times.
6	Storage	Keep the accessories (contra- angle, lip clip, file holder, touch probe) 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 use (packaging integrity, no humidity and validity period). - The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

7. Maintenance

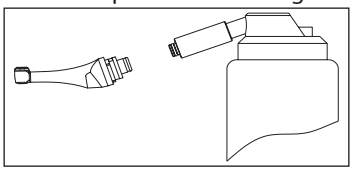
7.1 Calibration

Perform calibration after replacement or lubrification of the contra-angle (refer to Chapter 4.5).

7.2 Lubrification of the contra-angle

The contra-angle needs to be lubricated after cleaning and disinfection, but before sterilization.
Use oil intended for dental handpieces and contra-angles.

1. Screw the oil injection nozzle to the oil bottle (around 1 to 3 turns).
2. Plug the nozzle into the end part of contra-angle



3. Fill the contra-angle with oil until the oil flows out of contra-angle head part.
4. Position contra-angle vertically for at least 30 minutes to let go the redundant oil under gravity via the end part.

7.2.1 Warnings

a) Use original oil injection nozzle only.
b) Motor handpiece shall not be filled with oil.

7.3 Charging of the battery

1. Insert the power adapter plug into the charging base power socket and make sure they are correctly connected.
2. Leave approximately 10cm around the charging base for easy access to inlet and the power cord.
3. Insert the motor handpiece into the charging base (the motor handpiece must be correctly aligned with the charging base).
i. While the motor handpiece is charging the LED indicator on the charging base flashes.
ii. When the motor handpiece is fully charged, the LED indicator on the charging base is always on.
4. After charging, unplug the power adapter (full charge in about 4.5 hours).

7.4 Replacement of the battery

1. Power off the device.
2. Use a tweezer or a screwdriver to open the rubber cover and then remove the screw.
3. Remove the battery cover.
4. Remove the old battery and disconnect the connector.
5. Connect the new battery and put it in the motor handpiece.

6. Replace the cover and the screw.

7.4.1 Warnings

a) Use CanalPro X-Move battery only.
b) It is recommended to contact local distributors to replace the battery.

8. Storage

a) The device and accessories should be stored in a room where the relative humidity is 10%
~ 93%, atmospheric pressure is 70kPa ~ 106kPa, and the temperature is -20°C ~ +55°C (-4°F ~ 131°F).
b) Remove the battery from the device if storing for a long period of time.

9. Transportation

a) Avoid excessive shocks during transportation.
b) Don't store together with dangerous goods during transportation.
c) Avoid sun, rain and snow exposure during transportation.

10. Environmental protection

Please dispose of the product according to the local laws.
Follow the regulations and recycling procedures of the country for the disposal or recycling of components.

11. After sales service

a) This package does not include spare parts or accessories for repair servicing.
b) The after sales service should be carried out by admitted personnel only.

12. 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
93% 10%	Humidity limitation	+55 °C -20°C	Temperature limitation
106kPa 70kPa	Atmospheric pressure for storage	CE 0197	CE marked product
	Warning	MD	Medical Device
Rx Only	Caution: Federal law restricts this device to sale by or on the order		
EC REP	Authorised Representative in the EUROPEAN COMMUNITY		
CH REP	Authorised Representative in Switzerland		
UK REP	Authorised Representative in United Kingdom		

13. 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.

14. 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 high electromagnetic environment.

14.1 Technical Description Concerning Electromagnetic Emission

Table 1: Guidance & declaration - electromagnetic emissions

The model CanalPro X-Move is intended for use in the electromagnetic environment specified below. The customer or the user of the model CanalPro X-Move should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The model CanalPro X-Move 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 CanalPro X-Move 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 IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

14.2 Technical Description Concerning Electromagnetic Immunity

Table 2: Guidance & Declaration - electromagnetic immunity

The model CanalPro X-Move is intended for use in the electromagnetic environment specified below. The customer or the user of the model CanalPro X-Move 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 In-put/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 CanalPro X-Move requires continued operation during power mains interruptions, it is recommended that the models CanalPro X-Move be powered from an uninterruptible power supply or a battery.
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

The model CanalPro X-Move is intended for use in the electromagnetic environment specified below. The customer or the user of the model CanalPro X-Move should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

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 frequen- cy band 3 V/m 80 MHz to 2.7 GHz	3V 6V 3V/m	Portable and mobile RF communi- cations equipment should be used no closer to any part of the models CanalPro X-Move, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\times P^{1/2}$ $d=2\times P^{1/2}$ $d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=2.3\times P^{1/2}$ 800 MHz to 2.7 GHz where P is the maximum output pow- er rating of the transmitter in watts (W) according to the transmitter manu- facturer and d Is the recommended separation distance in meters (m). Field strengths from fixed RF transmit- ters, as determined by an electromag- netic 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 follow- ing symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic prop- agation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model CanalPro X-Move is used exceeds the applicable RF compliance level above, the model CanalPro X-Move should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model CanalPro X-Move.
[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 CanalPro X-Move

The model CanalPro X-Move is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model CanalPro X-Move can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model CanalPro X-Move as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz $d=1.2\times P^{1/2}$	80MHz to 800MHz $d=1.2\times P^{1/2}$	800MHz to 2,7GHz $d=2.3\times P^{1/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.
NOTE 1: 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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