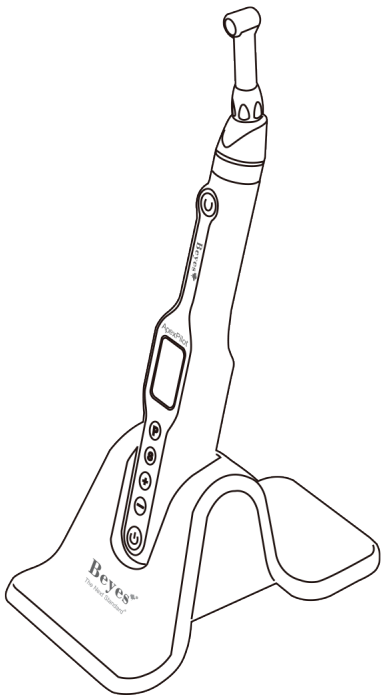
ApexPilot All-In-One

Cordless Endodontic Handpiece, Built-in Apex Locator

Instruction for Use



Beyes®

The Next Standard

Thank you for purchasing ApexPilot All-In-One (Built-in Apex Locator). Please read this Operation Manual carefully before use for operation instructions and care and maintenance guidelines, and keep this Operation Manual for future reference.

Please do not hesitate to contact Beyes Dental Canada Inc. for helps with any doubts or problems that may arise during consultation of this manual.

Consult accompanying documents (user manual)
This symbol, found on the labels of the unit and accessories, reminds the user to consult this User Manual.

Intended use

ApexPilot All-In-One is a cordless micro-motor used primarily for mechanical root canal preparation with integrated apex locator for endodontic treatment. While root canal preparation is made, the length determination can be simultaneously carried out. Alternatively, the stand alone measurement is possible, using the separate file clamp for measuring file.

User

Only qualified personnel is allowed to use the unit only in dentistry.

Prohibition

- Do not use ApexPilot Endo-Motor for formation of an extremely bent root canal.
- Do not use ApexPilot Endo-Motor for implants other than endodontic treatment or other dental treatment.

Classification of Devices

- Classification by type of protection against electric shock
  — Class II devices
- Classification by degree of protection against electric shock
  — Applied part type B
- Classification by sterilization or disinfection method allowed by the manufacturer
  — Refer to "5. Cleaning, desinfection, and sterilizing"
- Classification by mode of operation
  — Continuously operating device

Symbols

CE 0197 This conforms to CE European Directive of “Medical equipment directive 93/42/EEC.”


Follow the Waste Electrical and Electronic Equipment (WEEE) Directive


Class II equipment
Double insulated, fulfilling legal requirements of IEC-60601-1


Type B
Particular protections against electric shock


Refer to the Operation Manual


Consult accompanying documents (user manual)


Manufacturer

SN Serial Number


Date of manufacture

Direct current

EC REP Authorized representative in the European Community

Table of Contents

1. General Precautions

Most operational and maintenance problems are resulted from insufficient attentions being paid to basic safety precautions and not being able to foresee the possibilities of accidents.

Problems and accidents are best avoided by foreseeing the possibility of danger and operating the unit in accordance with the manufacturer's recommendations.

Warning

If the instructions are not being followed properly, operation may result in hazards for the product or the user/patient.

Note

Additional information, explanation on operation and performance.

1.1. General Warnings and Conditions for Operation

Warning

CONTRAINDICATION

Use of ApexPilot is contraindicated in patients and in users with pacemaker!

General Warning

- Use the specified battery for this product. Never use any batteries other than Beyes specified.
- High external pressure will cause a liquid leakage or explosion
- Keep the central unit away from water, high-temperature and chemical solution which may cause short circuit, fire, and other dangerous environment.
- Sterilize the motor by heat or steam which may cause a liquid leakage or explosion.
- Do not disassemble the central unit.
- The product is being used for dental treatment only by qualified personnel.

Conditions for Operation

- This equipment is for indoor use only.
- Ambient temperature.
- Relative humidity.
- The accuracy of the torque, rotation speed and apical position are guaranteed only when the original contra angle is used which is supplied by Beyes
- Do not sterilize the central unit, nor place it into autoclave or ultrasonic tank.
- Do not use the system in the presence of free oxygen or flammable gas mixtures.
- Portable and mobile RF communications equipment can affect Medical Electrical equipment. Do not use RF equipment outskirts for the product.
- Follow the instructions to set the rotation and speed of the motor.
- If the Central unit has not been used for a long time, check it before uses.
- There is electric circuit that controls the torque (TORQUE LIMITER Function) to prevent files from breaking; however, files may still break due to metal fatigue if the torque is conditioned to be higher. Please check the working instructions of file before use.
- The battery charger must be supplied at a voltage in the range: 100V-240V (+/-10%), 47-63Hz. Use only original parts.
- Should any anomalies arise during operation, suspend work and contact your technical service center.

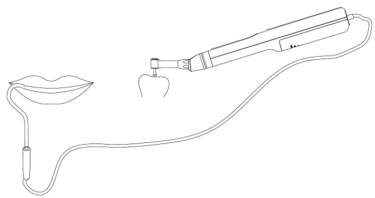
1.2. Undesired Effects

Except the contraindication of not using the unit on patients with a pacemaker, up to now no serious adverse events have been reported during the correct clinical use in a clinical setting.

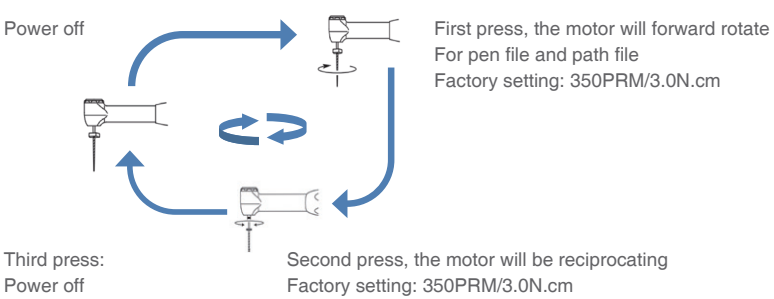
2. Getting Started

2.1 Description of Functions and Installation (please refer picture 4.2 for detailed operation)

- **Collaborative working function of Apex locator and Endo motor**
  Automatically rotate when entering the root canal
  Automatically slow down when approaching to the apical
  Automatically reverse when reaching the apical
  Automatically stop when exiting the root canal

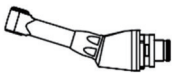


- Automatically start of apex locator to control motor mode without user setting
- ApexPilot All-In-One automatically identifies whether the measuring line is inserted
- Insertion of the measuring line and that means that the user needs to measure and expand the length of the root canal at the same time
- **Endo motor function**
  Quick start
  User program
  Auto reverse
  Reciprocating



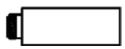
2.2 Name of each part and its accessories

Central Unit



16:1 contra angle
(ALP101)

Silicone Sleeve
(ALP 119)



Spray nozzle
(ALP 111)

Adaptor
(ALP 107)

Battery
(ALP 104)

Lip hook
(ALP 003)

Charging base
(ALP 121)

Charging wire
(ALP 108)

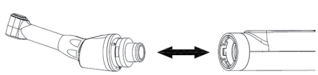
Measuring line
(ALP 110)

The ApexPilot All-In-One (Code: AL2020)
system is made up of the components listed below:

- Central Unit and Battery-Built-In Central Unit
- Contra-angle
- Battery Charger
- Adaptor and USB cord
- Accessories:
  Lip hook, Contra angle sleeve, Spray nozzle, adjust the font size

2.3 Installation contra angle

The contra angle can be connected with the central unit at 6 adjustable head positions. Align the positioning pins of the contra angle with the positioning slots of the central unit and insert the head until it click. When removing the contra angle head, pull it out axially.

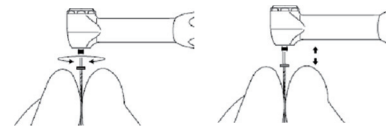


Warning

Turn off the power to remove or attach the contra angle
Do not use the contra angle other than Beyes'
Check that the contra angle is securely connected to the central unit

2.4 Mounting and Moving File

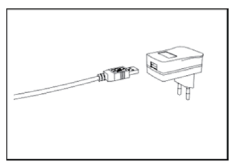
File Insertion:
Lightly turn the file until it engages with the latch mechanism, then push inward until it click.

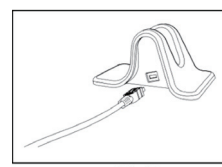


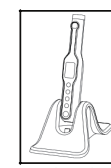
File Removal:
Depress the push key and pull out the file.

2.5 Battery

a) Insert the power cord jack into the inlet at the back of the battery charger. (Fig. a)
b) Insert the power cord and plug in. Make sure you have the correct model. (Fig. b)
c) Turn on the power switch. Meanwhile, check if the power lamp lights up.
d) Insert the central unit into the battery charge. Charging starts with the charge mark flashing on LCD. (Fig. c) When the buzzer sounds and is played on the LCD, charging is completed.


(Fig.a)


(Fig.b)


(Fig.c)

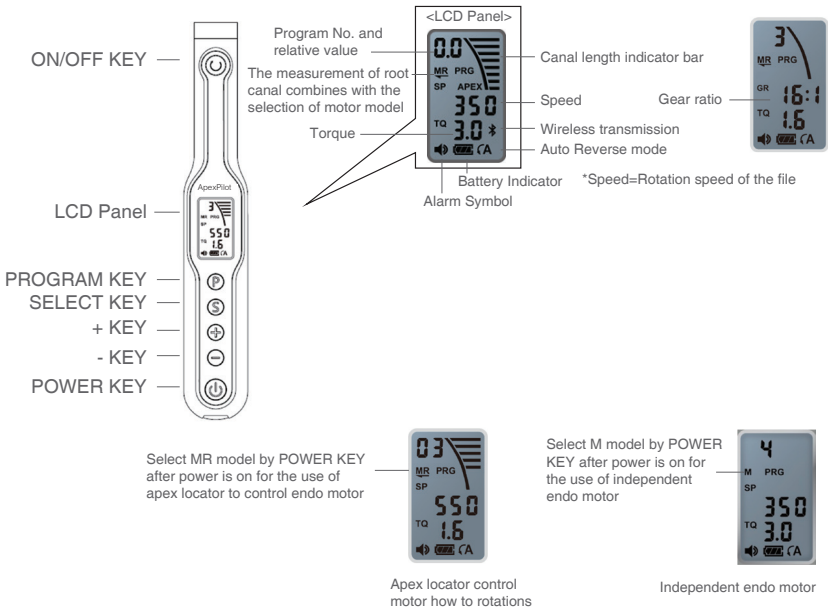
- The central unit can be charged directly by USB cable.
- Please ensure that the central unit and the battery charger are placed in dry and clean condition.
- Never use the battery charger for anything other than ApexPilot All-In-One from Beyes.
- The charging normally takes approx. 90 minutes, but it depends on battery use conditions, battery freshness, and ambient temperature, etc.
- Under the charging condition, the central unit is not allowed to rotate.
- The completely discharging will cause damages of the battery. The user should charge the battery completely once a month, or once bi-monthly, if the central unit will not be used for a long term.
- Pull out the central unit from the charger base up straightly after the battery fully charged.

Warning

When the central unit is charging, but the buzzer does not sound and the charging animation is not displayed, please take the central unit out from the battery charger, and check the“ERROR CODE” to find out the problem.

3. Description of user-interface

3.1 Keypad and Display



POWER Key (⏻)

- The POWER key
- Apex locator controls motor working mode option (turn on the power, press this key to circle options)

ON/OFF (⏻)

- Normal rotation: when the power is on.

— Press this key to rotate the motor and then release. Press this key again to stop the motor.

- Temporary rotation: when the power is on.

— Press and hold down the key to rotate the motor. Release this key to stop the motor.

- QS (Quick Start Key): when the power is off

SELECT Key (Ⓢ) (When the motor is running, the key is invalid, setting would be saved automatically)

- Speed, torque and gear ratio setting.
- Rotation Mode selection setting.
- Apex locator DEMO and self-checking: when the power is off, long press this key to enter apex locator DEMO, and start the self-checking at the same time. (The details to see “4.2.4 Root apex locator Demo and self-checking”)

PROGRAM Key (Ⓟ) (When the motor is running, the key will be invalid, and the setting will be auto-saved)

- A program can be selected
- QS (Quick Start Key) setting (The details to see “ 4.1.2 The QS quick start key setting”)
- Turn on the Bluetooth to connect the external display (For the product with wireless display module only)

+/- Key (⊕⊖)

- Use these keys to increase or reduce the speed of the motor.
- Adjust the values as other functions.

LCD panel

Root canal length measurement display: displayed as the picture on the right.

- Apex locator control motor working mode option: Turn on the power, press to select

— **‘M’** Motor only, apex locator will not work

— **‘MR’** Motor working for the root canal preparation and apex locator working for the measurement of the root canal length at the same time, apex locator will control the preparation of motor.

— **‘MR’** Motor working for the root canal preparation and apex locator working for the measurement of the root canal length at the same time, apex locator will not control the preparation of motor

— **‘R’** Apex locator only, motor will not work

- Root canal depth scale:

— displayed the files into the root canal narrow area, there are in a total of 8 scales, full scale means that the apical is reached.

— **APEX:** "APEX" icon is appeared when the apical is reached, flashing of this icon means it is beyond the apical.

— **Digital display:** Relative value of root canal length, 0 means the apical is reached, -1 means it is beyond the apical.

- Auto Reverse

  : If the load is removed after auto-reverse rotation, it returns to the normal rotation again.

  : If the load is removed after auto-reverse rotation, it stops.

  : Auto-reverse rotation is not activated. (There will be no symbol displayed)

  : Rotation is in anti-clockwise motion.

  : Rotation in reciprocating mode

- Battery Symbol

The symbol indicates the capacity of battery. The symbol will be animated when the battery is being charged

  : The battery is full or nearly full

  : About 30-80 % remaining

  : Less than about 30% remaining

  : Battery are drained or the symbol flashing with alarm. Please charge the battery at once

The symbol indicates the remaining capacity of the battery. When load is applied to the file, the symbol that indicates the remaining capacity of the battery appears to become lower.

- Alarm Symbol (The details to see “4.5.4 Alarm Sound Setting”)

  : MAX

  : MIDDIUM

  : OFF

4. Operations

4.1 QS (Quick Start ON/OFF KEY function)

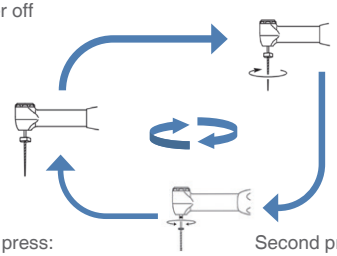
4.1.1 QS quick start key using

In order to make maximum imitation of dentists' operation habits, we develop this quick start function, The doctor can set the most commonly used parameters to this function. Such as speed, torque, and rotation mode.

There are 3 steps cycle:

1. Forward rotate 350PRM/3.0N.cm
2. Reciprocating 350PRM/3.0N.cm
3. Off

Power off



First press, the motor will forward rotate
For pen file and path file
Factory setting: 350PRM/3.0N.cm

Third press:
Power off

Second press, the motor will be reciprocating
Factory setting: 350PRM/3.0N.cm

Quick Start factory setting:
Rotation speed: 350PRM (forward rotate and reciprocating)
torque: 3.0N.cm (forward rotate and reciprocating)
Auto Reverse: Factory setting auto-reverse mode
Reciprocating mode rotation direction: forward (forward about 270 degrees, reverse about 30 degrees)
Working mode: apex locator controls working mode (connect the measurement cable and lip hook file, when the file approaches the apical foramen, the motor will automatically slow down, when it reaches the apical foramen, the motor will auto-reverse. Working as independent motor without measurement cable)

4.1.2 QS quick start key setting

Press this key for long time

First step: Enter the setting:

- Long press “P” to enter Quick Start Key mode setting when the power is off.

— There are 6 parameters for setting, to press “P” can change the parameters from 6 to 1, and cycle

Second step: set the speed and torque for the forward rotate

- Press “P” to select parameters 6, speed coruscate, press +/- to select clockwise rotation speed
- Press “P” to select parameters 5, torque coruscate, press +/- to select clockwise torque

Third step: set the speed and torque for reciprocating

- Press “P” to select parameters 4, speed coruscate, press +/- to select reciprocating rotation speed
- Press “P” to select parameters 3, torque coruscate, press +/- to select reciprocating torque

Forth step: set direction of reciprocating mode

- Press “P” to select parameters 2
- Press +/- to select arrow direction

Fifth step: apex locator control motor

- Press “P” to select parameters 1
- press +/- to select MR

A↻	Reciprocating mode, rotate clockwise 300°,anti-clockwise 30
↺A	Reciprocating mode, rotate anti-clockwise 300°, clockwise 30
MR	Apex locator control motor
MR	Apex locator and motor working independently
M	Only motor

Exit setup: Setting parameters will be saved automatically
When setting, Press ON/OFF to enter Quick Start mode, and work with parameter settings above: Press POWER to enter traditional working mode.

4.2 Integrated Apex Locator

ApexPilot All-In-One is equipped with an integrated apex locator. It can be used in the following two ways: Combined length determination by using the contra angle and lip clip (determination with the rotating file) and the stand alone determination using the separate file clamp and lip clip, which excludes the contra angle and is recommended with manual files.

Warning

- Combined length determination by using the given contra angle and lip clip only accurate results when using the original contra angle by Beyes supplied
- Use only endodontic NiTi files with a metal handle for this type of length determination.
- In some clinical cases accurate length determination is impossible! (for details see chapter x “Troubleshooting”)
- Electrical length determination uses minimal auxiliary current. The values used in the ApexPilot All-In-One are far below the values required in IEC 60601-1-1. Nevertheless, in rare cases electrical sensation during the length determination can occur. In this case, do not continue the treatment with this patient.

4.2.1 Modes of Root apex locator Control Endo-motor mode

- There are two types of work mode related to Root Apex Locator.
  M Mode, Independent Endo motor, Apex locator is invalid.
  MR Mode, Apex locator controls motor for rotations
- Can be made by the **Power** key to select one of the above work mode after power on.

M Mode
Independent
Endo motor

MR Mode
Apex locator controls
motor for rotations

NOTICE

- In MR working mode, the motor will automatically rotate, stop, reverse depends on the length of the root canal measured by the apex locator.

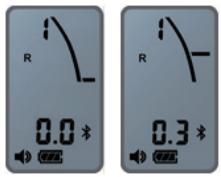
4.2.2 Useful tips for accurate length determination

- Gloves and rubber dam are recommended in order to isolate the tooth.
- Dry the access cavity with the suction pump or a cotton-pellet.
- Avoid any direct contact between the contra angle file and mucosa. Use the silicone sleeve for the contra angle.

4.2.3 Optional Apical Line

- This feature is convenient for users to make marks of the relative distance from apical point
- The range of markers is 5 scales, from 0.0 to 0.5

According to user-labeled apical scale, when reaching marker position, better visual and sound cues



Set the apical line to 0.3

Complete the following steps to change the marks of apical point

- Turn on the power of main unit
- Choose apex locator only for the working mode
- Press “+/-“ to change the marks

As shown on the right, when it is in use, at the relative value of 0.3 from the point of the root tip, it has been displayed as the point of root tip and it would be automatically reversed and exited.

Notice

- Save settings automatically
- This mark for the apical is available in all working modes, including QS mode and the working mode of motor controlled by the apex locator once set.
- Sound cue prompts all apical lines as vertices

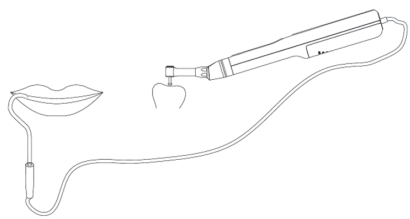
4.2.4 Operation of Apex Locator—Auto-Start, Auto-Stop, and Auto-Exit

We are committed to produce safe and reliable medical equipment for the doctors, so we recommend doctors to use the apex locator to control the motor mode.

4.2.4.1 Connecting

Use the contra angle that covered by the silicone sleeves for combined length determination.

- Connect the lip clip cable to the Micro USB port at the bottom of the central unit. Insert the lip clip into the connector at the end of the cable. Ensure the connection is solid.
- Put the pip clip in the patient's mouth (we recommend positioning it on the opposite side of the tooth undergoing therapy).



For combined length determination

4.2.4.2 Application steps

- Press "POWER" to turn on the machine
- Press POWER key to select the mode of endo motor controlled by the Root Apex Locator or stand-alone Apex Locator

*The relative parameters can be changed in accordance to the user's manual, such as speed and torque

- Measurement loop detection:

For combined length determination

For combined length determination
Contact with the lip clip and file

- File will rotate in anti-clockwise
- The warning will sound rapidly
- Display on the screen: Root canal indicator scale full grid, the root canal indicator data: APEX, -1 non-stop flashing

The apex locator cannot be worked on due to malfunction as the above state.
Possible causes are:

- One of the connecting cables might be damaged or improperly connected.
- Unsolid connection between the apex locator cable and the unit.
- Too quick or improper contact between either the lip clip and file inserted into the contra angle or between lip clip and file in the file clamp.
- Operation: After setting the above parameters, connecting measuring line, detecting measurement loop, hang the lip hook on the patient's lip, the treatment can be started

The response of motor:

- Putting the file into the root canal, the file will self-acting rotate as setting speed, torque. Or press ON/OFF to drive the file to rotate
- when the file approaching the apical foramen, the root canal relative value will be shown as 0.2, then the motor will automatically slow down, the root canal relative value which will be slower and the minimum speed will be 140 PRM. When it reaches to the apical foramen, the motor will be auto-reversed.
- When the file reverse and the root canal relative value will be shown as 0.5, the motor will rotate as the setting speed, torque, direction and cycle.

Response of alarm:
With the file depth, alarm sound from slow to fast, and then to APEX. The alarm sound remain constant, however, the alarm sounds rapidly when it is over the apical, over apical the alarm sound rapidly changes

Screen display:
The root canal relative value changes with the file depth.

APEX icon will appear when it reaches the apical, the root canal scale will be full, and the root canal relative value will be 0;

APEX icon will flash when it reaches over the apical, the root canal scale will be full, and the root canal relative value will be -1.

The file is entering the root canal

Close to the arrow area, The relative value to the apical is 0.5

Reached the APEX
The motor auto-stops

Over the APEX auto-exit when the file tip reaches APEX

4.2.5 Root apex locator Demo and self-checking

- In order to reduce the user's key operation, DEMO and the internal detective apex locator will be processed in parallel.
- ApexPilot All-In-One embedded calibration circuit, and there is no need to ration calibration modules.
- Demo animation is the whole process to measure the length of Apex Pilot All-In-One apex locator. Simulation shows that the file enters the root canal, reaches the apical, beyond the apical, the change of display and warning of ApexPilot All-In-One at each stage.

Steps for DEMO and internal detection:

- Turn off power of ApexPilot All-In-One
- Connect measuring line with the main unit
- Put the file clamp into two interfaces of measuring line
- Insert the file into the contra angle
- Connect the two file clamps with the file
- Long press "S" to enter DEMO and internal detection, then wait for the test results
  After the test result is produced:
  a. If there is no operation, it will shutdown in 10 minutes
  b. Press“ON/OFF” to enter QS quick start mode
  c. Press“POWER” to enter normal mode

Instructions of test and calibration results:

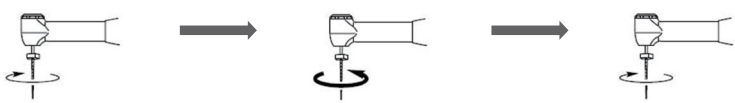
- The number above represent (from left to right)
  Self-checking result: apex locator testing result, apex locator combined with motor testing results
- Self-checking result: 1 represent internal detecting result normal, 0 represent error, (please contact with local dealer)
- apex locator testing result: 1 represent normal, 0 represent error
- apex locator combined with motor testing results: 1 represent normal, 0 represent error

4.3 Running in different modes of rotations and settings

4.3.1 Running in different modes of rotations

CA Auto Reverse

When it continues on a load and it exceeds the torque limit value, it will automatically turn to AUTO-REVERSE mode, the file will rotate reversely.



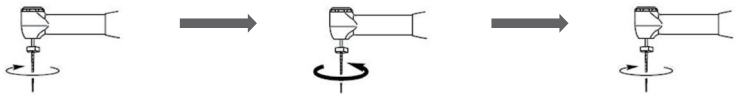
Load lower than the set torque limit value

Load higher than the set torque limit value, anti-clockwise

It will reversely rotates when the load continues; it will stop and return to clockwise rotation when the load is removed.

A Auto-Stop

The motor handpiece starts in reversely. When a load is removed, the motor handpiece will stop. If you want (forward-rotate) again, re-press the ON/OFF Key or repeat the steps.



Load lower than the set torque limit value

Load higher than the set torque limit value, anti-clockwise

Rotate reversely when the load continues, stop when the load is removed.

No Display Auto-Reverse Off

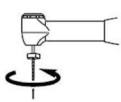
The motor handpiece stops without reverse rotation. If you want it to rotate (forward-rotate) again, re-press the ON/OFF Key or repeat the steps.

The load is lower than the set torque limit value

The load is higher than the set torque limit value, handpiece will then stop.

Anti-clockwise Rotation

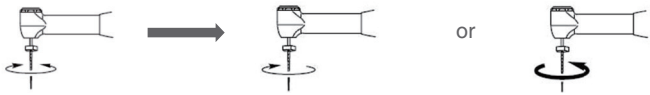
In general condition, the Endo Motor that rotates in counter-clockwise is so-called as reverse motion. The traditional rotary files withdraw from the canal by reverse motion. Therefore, beep will sound when using this function.



Notice

There will be no TORQUE CONTROL when the motor rotates counter-clockwise

Reciprocating



The load is lower than the torque limit value clockwise and anticlockwise (reciprocating).

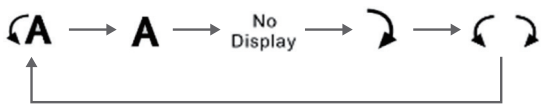
The load is higher than the set torque limit value, motor will exit the root canal automatically, The exiting direction is opposite to the direction of reciprocating cutting: if reciprocating is 270 clockwise, 30 anticlockwise, exiting direction is opposite. Vice versa

Notice

- Under the reciprocating mode, only 16:1 or 20:1 is supported. The setting must be according to the actual contra angle.
- To set the reciprocating rotation/direction, please see 5.1 QS (Quick Start) function settings.

4.3.2 Differences in modes of rotation settings

- Press and hold the SELECT Key for 1 second or longer
- Enter the Rotation Mode selection: the sequence will be, Auto-Reverse, Auto-Stop, Auto- Reverse off, and finally Reverse-Reciprocating, in circle: adjust the value by press + or -.
- To quit the 'Rotation Mode selection';
  1. Press "S";
  2. Press "ON/OFF";
  3. Press "P" to quit.



4.4 Speed, Torque and Gear rate Settings by the key Ⓢ

- The key will be invalid while the motor is running
- Start setting
  First press 'S', rotation speed flashing, press '+/-' to set the speed
  Second press 'S', gear reduction ratio flashing, press'+/-'to set the ratio
  Thrid press 'S', torque flashing, press '+/-' to set the torque
  Press 'S' again to exit, or press 'P', 'ON/OFF', 'POWER' can exit
- All the parameter setting are auto-saved

4.5 Convenient function

4.5.1 Program while the motor is running, the Ⓟ key will be invalid

- ApexPilot All-In-One supplies 5 memory programs. Press Ⓟ to select different programs; press "P" to program cycle from 1-5.
- Users can set the speed, torque, rotate direction, working mode by according to personal habits or the order of files.
- all parameters will be saved automatically

we recommended users to save the parameters into program 1-5 by according to the conventional order of file, more convenient to call.

4.5.2 Factory-Default Parameters

- The program can return to the original state that is configured at the time of factory shipment, if setup becomes confusing.
- Turn off the power if the power is on.
- Press PROGRAM, and then press the POWER key for more than one second. Release the keys when the LCD panel indicates "RES". The machine is on hold.
- Re-press the PROGRAM key, the LCD displays "FIN".
- After the long beep, the reset would be successful.

Caution

If this function is used, all programs will disappear and return to the original set values. Record details of the present program if it is required prior to carrying out this operation.

4.5.3 Calibration

It functions as to decrease fluctuation in the rotation speeds of the motor central unit and the differences in torque by the contra angle.

- Lubricate the contra angle head (Refer to Section 7 (1) Lubricating Contra Angle.")
- Turn off the power. (If the motor power is on)
- Press PROGRAM, and press the POWER key for more than one second.Release the keys when the LCD panel indicates “RES” And then press “+” key three times.
- The LCD panel displays “CAL” with the alarm sound.
- Attach the lubricated contra angle to the motor.
- Put the central unit into the charger, and then press ON/OFF key.
- If the motor central unit begins to rotate, leave it as it is until it stops.
- This process ends if the rotation stops and the LCD panel display returns to its original state.
- If you want to stop this process, turn off the power key for more than 1 second.

Caution

- This function does not work unless the remaining battery capacity is sufficient.
- Perform calibration after cleaning the contra angle. Residuals will affect the calibration.
- Do not attach any rotary files or other when performing calibration.
- Do not shake the motor when performing calibration.
- This function can achieve the perfectly match between the central unit with contra angle. However it cannot match more than 1 different contra angle.

4.5.4 Alarm Sound Setting

- Turn off the power.
- Press the S key, and then keep pressing the POWER key for one second or longer. Release the keys when the alarm symbol on the LCD panel.
- Press the SELECT key to select OFF, MIDDIUM or MAX for the volume of the alarm.
- The setting memorized automatically
- Display on the LCD would return to the original state if there is no operation performed in awhile.

4.5.5 Wireless Transmission Display (Optional)

We designed the product from the point of view of doctors, ApexPilot All-In-One is a safe, accurate, compact and convenient product, but it cannot meet other users who like big screen, The auto-reverse and -exit functions of ApexPilot All-In-One is actually very intelligent, there is no need for the users to stare at the screen during operation. In order to best meet the user needs, we also provide an optional wireless display solutions.

There's built-in wireless transmission module in ApexPilot All-In-One, wireless connection with our apex locator, reflect the work information of ApexPilot All-In-One on the big screen of apex locator.

- ApexPilot All-In-One wireless transmission uses Bluetooth transmission technology to meet the requirements of various radiation indicators.
- There is no more than 5 meters for the transmission distance.
- Display the transmission information in milliseconds to avoid any delays.

Wireless transmission connection:

- Wireless transmission display features start and off

while the power is on; long press "P" to turn on wireless transmission module, long press "P" again to turn off wireless transmission module

- Successful connection

The wireless transmission sign on the screen of ApexPilot All-In-One isn't flashing anymore

The connecting device display ApexPilot All-In-One

If the connection is not successful or being connected, then the wireless transmission sign on the screen of ApexPilot All-In-One would flash.

If the connection is not successful in 2 minutes, the wireless transmission module will be turned off automatically. Restart the function to connect again.

ApexPilot All-In-One
wireless transmission note

Apex Locator
wireless transmission key

The first wireless connection of two wireless transmission equipment: (such as first wireless connection of ApexPilot All-In-One and ApexPilot)

- Turn on the power for two equipment
- As mentioned above, start the wireless transmission display function of ApexPilot All-In-One ——long press “P”, then the wireless transmission sign would flash on the screen
- To initialize the wireless transmission module of connected device. (for ApexPilot C is to long press“wireless transmission key”)
- Wait for successful connection, as mentioned above

Caution

- The wireless transmission function is designed for one connection, does not support multipoint connection
- When there are multiple devices automatically connected at the same time, the connection error may occur. Please connect one by one as required
- The wireless transmission will save automatically once it starts; this function is off under factory settings.

5. Cleaning, Disinfection, Sterilizing

Notice

None of the ApexPilot All-In-One components are delivered under disinfected or sterilized conditions.

Warning

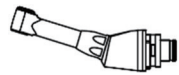
- Do not immerse the central unit into ultrasonic cleaners.
- The central unit can only be wiped off with cotton cloth is that moistened with alcohol.
- The battery charger can only be wiped off with cotton cloth that is with alcohol.

Items that can be sterilized

The lip clip, the file clamp, the contra angle sleeve and contra angle have biocompatible properties (in compliance with EN 10993-1) and can be sterilized in the autoclave (put the item in special plastic bag prior to sterilization) for 20 minutes at 121 ^{0}C or for 5 minutes at 132/134 ^{0}C . Use steam autoclaves that are in compliance with the standard of EN 13060.

Lip clip

Contra angle sleeve



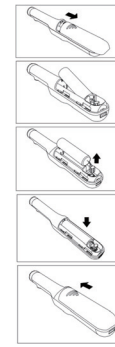
Contra angle

Warning

Except lip clip, file clamp, contra angle sleeve and contra angle mentioned above, all other parts for ApexPilot All-In-One can't be sterilized with high temperature and pressure.

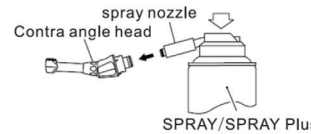
6. Maintenance

6.1 Change battery



- Remove the battery cover:
  Remove the battery cover by sliding it toward the charging terminal.
- Remove the old battery:
  Pull out the battery a little part, and then pull out the battery plug from central unit by hand carefully.
- Replace with new battery:
  Put in the new battery.
- Close the battery cover:
  Slide the cover from the button to the top with a little force by the finger.

6.2 Lubricating contra angle



Insert the spray nozzle into the contra angle head (insert to the part that connects to the central unit)

Insert the lubricants spray nozzle to the provided spray nozzle loop, inject the lubricants for 1-2 seconds till the outlet liquid from the head of the contra angle is cleaned.

WARNING

- Do not lubricate the micromotor in the central unit for any reason, because lubricant contamination of the micromotor can have a strong negative effect on its safe operation.
- When lubricating the contra angle, check if there is no lubricant penetrates the micromtor.
- Never introduce any foreign objects into the micromotor.
- Do not disassemble or alter the central unit.

7. Technical Specification

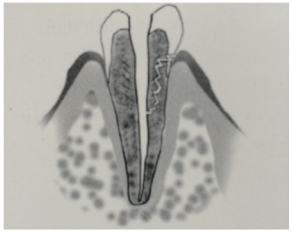
MANUFACTURER:	Beyes Dental Canada Inc.
MODEL:	ApexPilot All-In-One
METERIAL:	280 x 25 x 26mm(central unit include contra angle) 123 x 61 x81mm (battery charger)
WEIGHT:	780g
POWER TYPE:	Battery powered, 750mAh/3.7VDC
BATTERY CHARGER VOLTAGE SUPPLY:	100-240VAC
VOLTAGE FLUCTUATIONS:	Max.±10%
FREQUENCY:	47-63Hz
BATTERY CHARGER POWER RATING:	0.5A
TORQUE VARIATION:	0.1-4.0 N.cm
SPEED VARIATION TO MOTOR SHAFT:	2000-9000prm
ELECTRIC SAFETY:	CLASS II
APPLIED COMPONENT TYPE:	TYPE B
LEVEL OF SAFETY IN PRESENCE OF INFLAMMABLE ANAESTHETIC MIXTURE OR OXYGEN:	NOT SUITABLE FOR USE IN PRESENCE OF INFLAMMABLE ANAESTHETIC MIXTURES OR OXYGEN
OPERATING MODE:	CONTINUOUS
ENVIRONMENT CONDITIONS FOR USE:	+10--+40ºC, RH: <70% (Non condensing), 1000h Pa
PROTECTION AGAINST LIQUID PENETRATION:	ORDINARY
CLASSIFICATION AS MEDICAL DEVICE:	II Rule IX 93/42/EEC
TRANSPORT AND STORING CONDITIONS	-10--+50ºC, RH: 10-80% (Non condensing), 500-1000h Pa

8. Troubleshooting

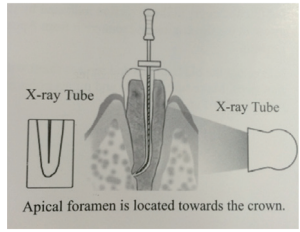
If your ApexPilot All-In-One does not seem to work properly, it does not necessarily mean that the central unit does not work correctly. Please first review the below checklist in order to exclude any user error or anatomic/other peculiarities before contacting your dealer.

If the problem persists, please contact either your local dealer or Beyes Dental Canada Inc.

Problem	Cause	Solution
The power is unable to turn on.	Battery has fully discharged.	Recharge the battery.
	No battery inserted.	Insert battery.
	The internal fuse has burnt.	Contact your dealer.
Charge failure	Battery has been completely discharged.	Replace with new battery.
	The power cord plug is not inserted into the outlet	Plug the power cord or adaptor properly
	The motor handpiece is not correctly set to the charger	Insert the power cord plug into the outlet.
	There is some residual contamination on the charger base	Remove the residual contamination
	An error code is displayed.	Refer to No. 10 Error Code.
	Nothing is displayed on the panel of the handpiece even when it is set to the charger	Contact your dealer.
	The charger out of service	Charge the motor by cable, then contact your dealer
The motor hand piece does not rotate.	The contra angle has been blocked	Clean or reset the contra angle
The alarm sounds when the motor is working	The contra angle head has jammedup.	Clean the contra angle head
alarm sounds when the motor is working.	Set to Auto Reverse mode, take off contra angle, there is NO click sound when working	Contact your dealer.
	set to Auto Reverse mode, take off contra angle, there is click sound	Clean the contra angle head
	There is some residual contamination on the rotating shaft of the contra angle	Clean the contra angle head
Apex locator no response	measuring line, lip clip, file clamp loose contact.	Reconnect
	measuring line, file clamp is aging	Changes measuring, file clamp
Apex locator can not control the motor working	Check if control working mode setting is correct	Read instruction manual carefully, set the main unit in apex locator control motor working mode
	If the measuring line and lip clip connect correctly	Read instruction manual carefully, make sure the installation and connection is correct
	if the contra angle directly contacts with the human body	Read instruction manual carefully, put sleeve or rubber dam on the contra angle
	if contra angle is installed in place.	Read instruction manual carefully, make sure the installation and connection is correct
No warning sound	check if the sound is on	turn on the sound



In case of root fracture or perforation, it is impossible to take a precise length determination as the electric current leaks along the fracture gap.



The X-ray image of the canal curvature may show a shorter working length than with ApexPilot All-In-One when the bending direction of the root canal is in line with the direction of irradiation.

Electric Length Determination and X-Ray Technique

As that radiographs are only reproduced in a two-dimensional way in a three-dimensional root canal system, there are a few cases in which the X-ray image and the result obtained with electric length determination do not match. This does not mean that your ApexPilot All-In-One is not working properly or that the X-ray image is inaccurate.

These discrepancies indetermination occur due to the anatomical variation. The actual apical foramen may not be located at the radiographic apex.

9. Disposing Product

Please consult with the dealer from whom you purchased in regards to waste disposal.

The used Li-ion batteries are recyclable, but their disposal may sometimes not be permitted by the respective country. Return them to your dealer.

10. Certificates

This product is classified as a Class IIa product and it bears the CE marking CE 0197

Manufacturer: Beyes Dental Canada Inc.
30 Casebridge Court
Toronto, Ontario, M1B 3M5
Canada

The Declaration of Conformity is attached in the appendix.

11. Warranty

Manufacturer warrants its products to the original purchaser against defects in material and workmanship under normal practices of installation, use and servicing. Battery etc., are disposable components, and are not covered by this warranty.

Manufacture's information can be found in warranty card.

Appendix

Service Form
Declaration of Conformity

Electromagnetic emissions and immunity
The appliance is intended for use in the electromagnetic environment specified below. The user of the device should assure that it is used in such an enirvonment.

<table>
<tr><td colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</td></tr>
<tr><td colspan="3">The ApexPilot All-In-One is intended for use in the electromagnetic environment specified below. The customer or the user of the ApexPilot All-In-One should assure that is used in such an environment.</td></tr>
<tr><td>Emission test</td><td>Conformity</td><td>Emission test Conformity Electromagnetic Environment – guidance</td></tr>
<tr><td>RF Emissions CISPR11</td><td>Group 1</td><td>The appliance use 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.</td></tr>
<tr><td>RF Emissions CISPR11</td><td>Class B</td><td rowspan="3">The ApexPilot All-In-One 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.</td></tr>
<tr><td>Harmonic emissions IEC61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td><td>Conforms</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic emissions			
The ApexPilot All-In-One is intended for use in the electromagnetic environment specified below. The customer or the user of the ApexPilot All-In-One should assure that is used in such an environment.			
Immunity test	IEC60601 test level	Compliance Level	Electromagnetic environment - guide
Electrostatic discharge(ESD) EN 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV 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	± 2 kV for power supply lines ± 1 kV for input/ Output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode	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 cycles 40 % UT (60 % dip in UT) for 5 cycles < 5 % UT 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT < 5 % UT (> 95 % dip in UT) for 5 s	< 5 % UT (> 95 % dip in UT) for 0.5 cycles 40 % UT (60 % dip in UT) for 5 cycles < 5 % UT 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT < 5 % UT (> 95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ApexPilot All-In-One requires continued operation during power mains interruptions, it is recommended that the ApexPilot All-In-One be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/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.			

Guidance and manufacturer's declaration – electromagnetic emissions			
The ApexPilot All-In-One is intended for use in the electromagnetic environment specified below. The customer or the user of the ApexPilot All-In-One should assure that is used in such an environment.			
Immunity test	level EN 60601-1-2	Compliance Level	Electromagnetic environment - guide
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ApexPilot All-In-One, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz-800 MHz $d = 2.3 \sqrt{P}$ 800 MHz-2.5 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following 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 propagation is affected by absorption and reflection from structures objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ApexPilot All-In-One is used exceeds the applicable RF compliance level above, the ApexPilot All-In-One should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ApexPilot All-In-One b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the ApexPilot All-In-One

The ApexPilot All-In-One is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ApexPilot All-In-One can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter Watts [W]	Separation distance according to frequency of transmitter (in meters) Meters [m]		
	150 kHz-80 MHz $d = 1.2 \sqrt{P}$	80 MHz-800 MHz $d = 1.2 \sqrt{P}$	800 MHz-2.5 GHz $d = 2.3 \sqrt{P}$
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 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.

Beyes®

The Next Standard

Federal law restricts this device to sale by or on the order of a dentist, physician, or any other practitioner licensed by the law of the states in which he or she practices to use or order the use of this device. Beyes Dental Canada Inc is not responsible for any typographical errors. *All brands are holders of their respective trademarks.

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