APEXPILOT® **G1**

Endo Motor

Instruction for Use





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1. Product introduction

1.1 Features

- Cordless
- Low noise
- 9 memory setting
- Auto apical reverse/stop

1.2 Intended use

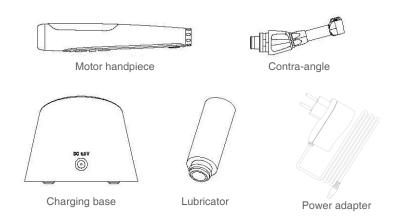
- 1.2.1 The device can be used for preparation and enlargement of root canals.
- 1.2.2 The device must be only operated by licensed dental professionals.

ApexPilot G1 is mainly used in Endodontic treatment. It can be used for preparation and enlargement of root canals, or measuring canal length.

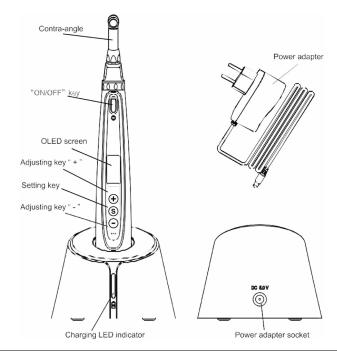
1.3 Contraindication

- Patient or doctor with a pacemaker
- Patient with hemophilia
- Patient with heart disease
- Pregnant women or young

1.4 Package includes



1.5 Diagram of components and control buttons



3

2. Warning and Safety



Warning

- Before operating this device, thoroughly read this instruction manual.
- This device should be operated only by licensed dental professionals.
- Do not directly or indirectly place this device near heat source.
- Operate and store this device in reliable environment.
- This device requires special precautions regarding electromagnetic compatibility (EMC) and must be in strict accordance with the EMC information for installation and use. Do not use this equipment especially in the vicinity of fluorescent lamps, radio transmitting devices, remote control devices, handheld and mobile highfrequency communication devices.
- Extended use in Reciprocating Mode may result in motor overheat
- · Only use the original contra angle
- Do not make any changes to the device. Any changes may violate safety regulations, causing harm to the patient
- Only use original power adapter. Other power adapter will result in damage to lithium battery and control circuit.
- The motor handpiece cannot be autoclaved. Use disinfectant of neutral pH value or ethyl alcohol to wipe its surface.
- Do not remove contra angle before motor stops. Doing so may cause damage to handpiece and contra angle.
- Secure the file before starting.
- Set torque and speed as per the recommended specifications of file manufacturer.
- Follow instruction in this manual to replace battery. And only replace with original lithium battery.
- Remove battery from the handpiece for long-term storage.
- Heat builds up while charging. Do not touch the handpiece or charging base for more than 10 sec during charging.



Safety

- Do not use device in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- Do not continuously use contra angle with patient for longer than 10 minutes. The temperature of contra angle may reach 46.6°C. Allow time to cool down before further use.

3. Installation

3.1 Battery

Handpiece has built-in lithium battery. It charges wirelessly through the base.

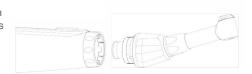
- Plug in power adapter and connect it to the charging base
- Seat handpiece on the charging base
- Flashing yellow light indicates device charging.
- When fully charged, yellow light will stay on.

3.2 Contra angle

- The contra angle adopts precision gear transmission, and the transmission ratio is 1:1.
- Clean and disinfect with disinfectant of neutral PH value before the first use.
- · Clean and disinfect after usage on each patient
- Sterilize under 134°C, 2.0~2.3bar (0.20~0.23MPa).
- Contra angle in this package only fits ApexPilot G1. This will not fit other handpieces.

Installation of contra angle

- Align the pin of the contraangle with one of the holes on the motor handpiece, and push in the contra-angle until there is an audible click
- A "click" sound indicates that the installation is in place.



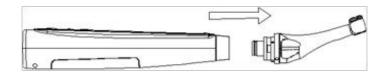
Note:

There are 6 holes on the motor handpiece which allows different orientations and rotational range to set the contra angle at

Once chosen orientation is set, orientation is fixed. Contra angle cannot rotate.

Removal of contra angle

Pull out the contra angle horizontally when the motor handpiece is off.





Warning

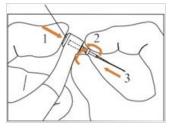
After installation, give the contra angle a light tug to make sure that it is securely attached before starting motor.

Stop the motor before plugging in or pulling out the contra angle.

3.3 File

Installation of file

- 1. Insert file into the chuck
- 2. Push button
- 3. Rotate file to fit the latch groove and slip in
- 4. Release push button to lock file
- 5. Pull file to ensure security



Note:

Use files with shanks that meet the ISO standard. (ISO standard: \emptyset 2.334 – 2.350 mm)



Warning

Do not insert or remove files without holding down the push button; this will damage the chuck.

Removal of file

- 1. Press the push button
- 2. Pull out the file



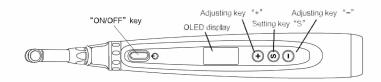


Warning

Stop motor before plugging and pulling out the file.

Removing files without holding the push button may damage contra angle chuck.

4. Operation



4.1 Turn on and off device

Press ON/OFF to turn on device Press and hold "S" and "+" for 2 seconds to turn off device

4.2 Start and stop operation

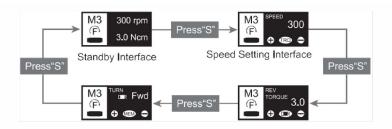
Press ON/OFF to start and stop motor



4.3 Store setting on M1-9

M1-M9 is a memory program used to store Operation mode and parameter settings.

Press +/- to change standby screen to select memory location between M1 to M9 (press and hold "+/-" to speed up screen selection change)



Standby Interface

Press "S" to enter parameter setting

Standby Interface Press "S" to enter parameter setting

Speed Setting Interface

Press "+/-" to change Speed Press "S" for next parameter

Press "+/-" to change Rev Torque Press "S" to mode selection

Press"+/-"- to select mode: Fwd. R and F+R

Change parameter and operating mode

Press"+/-" on each screen to change the parameter Press "S" to next parameter

Note:

Only available parameters for the operating mode can be changed. Example, Forward mode, Speed and Rev Torque can be changed.

Keep pressing "S" to cycle the display screen to different setting options. The display screen will go back to Standby display, when 5 seconds elapses without a switch being pressed.

4.4 Contra-angle calibration

Before using right after purchase, whenever the motor handpiece or contra angle has been replaced, or if the motor alternates between forward and reverse rotation outside the canal, calibrate the unit in the following way:

Press "S" and "-" and hold for 2 seconds to start calibration



After calibration is complete, the display screen will show "succeed" and will then return back to Standby Display (initial display).

Note:

Plug in original contra angle without file.

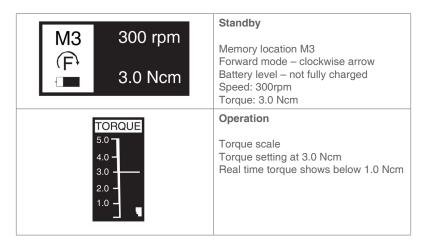


Warning:

- Use original contra angle only.
- Any load applied to contra angle will be offset and calibration will not be correct.
- Use caution when inserting and removing files to avoid injury to fingers

5. Screen Display

5.1 Standby and operation



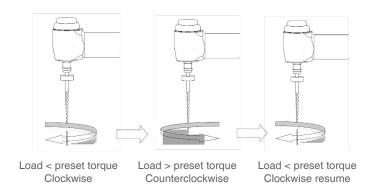
5.2 Mode and parameter setting

There are 3 operation modes:

	CW	CCW	F+R
	M3 TURN DR FWd	M3 rumi Rev (R) ⊕	M3
Mode	Clockwise	Counterclockwise	Reciprocating
Motor direction	Clockwise only	Counterclockwise only	Clockwise and counterclockwise
Applied file	Rotary	Special inject calcium hydroxide and other solutions	Reciprocating path rotary
Setting	M3 STEED 300 (P) 100 − 1000 (P) 100 −	M3 ROW 3.0	
Note	•	Device beeping	

6. Automatic Reverse Function

- Automatic reverse function is only available in CW mode.
- During operation, the motor is in clockwise rotation.
- If the load at file exceeds the preset torque, motor will automatically reverse to counterclockwise.
- Motor will resume clockwise rotation when torque is below preset torque.





Warning:

In low battery, motor cannot execute automatic reverse. It is advised that the handpiece should always be charged.

If automatic reverse is triggered frequently in the same operation, motor will overload and stop. If this occurs, please turn off device and allow motor to cool down.

7. Troubleshooting

Failure	Possible cause	Solutions
Continuous beeping after starting the handpiece	The continuous beeping indicates that the hand-piece is under reverse rotation state.	Stop the handpiece and change the operating mode to Continuous Rotation Mode.
Contra-angle calibration failure	Calibration failure caused by strong resistance of contra-angle	Calibration failure caused by strong resistance of contra-angle Clean the contra-angle, and recalibrate after oil injection.
Handpiece heating	Extended usage in Reciprocating Motion Mode	a) Normal phenomenon. b) Stop use. Use after the temperature of handpiece drops.
After plugging the handpiece into charging base, the wireless charging indicator light does flash	a) The handpiece is not seated in place.b) The handpiece is fully charged.	Reseat the handpiece in place
The time of endurance becomes shorter after charging	Battery capacity is reduced	Please contact local distributor or manufacturer.
The continuously rotating file is stuck at the root canal	Incorrect specification setting. Too high load torque of file.	Choose Reverse Rotation Mode, start the handpiece, and take the file out.

8. Cleaning, Disinfection and Sterilization

8.1 Foreword

For hygiene and sanitary safety purposes, the contra angle must be cleaned, disinfected and sterilized before each usage to prevent any contamination. This concerns the first use, as well as all subsequent uses.

8.2 General recommendations

8.2.1 Use only a disinfecting solution which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA and Health Canada approval) and in accordance with the DFU of the disinfecting solution manufacturer.

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

8.2.3 Do not use chloride detergent materials.

8.2.4 Do not use bleach or chloride disinfectant materials.

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

8.2.6 The user is responsible for the sterility of the product for the first cycle and each further usage as well as for the usage of damaged or dirty instruments where applicable after sterility.

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

8.2.8 Do not sterilize the motor handpiece, the AC adapter or the base. After each use, all the objects that were in contact with infectious agents should be cleaned using towels impregnated with a disinfecting and detergent solution (a bactericidal, fungicidal and aldehyde free solution) approved by VAH/DGHM-listing, CE marking, FDA and Health Canada.

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

8.2.10 The contra angle needs to be lubricated after cleaning and disinfection, but before sterilization.

8.3 Step-by-Step Procedure

#	Operation	Operating Mode	Warning <u></u>
1	Preparation	Remove the contra- angle from handpiece and charging base.	

2	Manual cleaning (Contra-angle, etc.)	For 5 minutes, rinse and brush under running deionized water (DI), or water that has this degree of purity (<38°C (100.4°F)). Remove any liquid residues (ultra- absorbent cloth, particle-free compressed air).	Use a cleaning tool (brush). In order to clean faster and more effective, use only a Medical multienzyme detergent (Protease, phospholipase, etc.) which is approved for its efficacy (VAH/DGHM-listing, CE marking, FDA and Health Canada approval) and follow instructions and observe concentrations given by the detergent manufacturer.
3	Automated Cleaning with washer- disinfector	Put the contra- angle into the washer disinfector (Ao value >3000 or, at least 5 min at 90°C/194°F)	- Avoid any contact between the contra-angle and any instruments, kits, supports or container Follow instructions and observe concentrations given by the manufacturer (see also general recommendations) Use only approved washerdisinfector according to EN ISO 15883, maintain and calibrate it regularly Make sure contra-angle, is dry before moving to the next step.
4	Inspection	Inspect the contra- angle and sort out those with defects.	- Dirty contra-angle must be cleaned - Lubricate the contra-angle with an adequate spray before packaging.
5	Packaging	Pack the contra- angle in "Sterilization pouches".	- Check the validity period of the pouch given by the manufacturer to determine the shelf life Use packaging which is resistant to a temperature up to 141°C (286°F) and in accordance with EN ISO 11607.

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

9. Maintenance

9.1 General

- This device do not include accessories for repair usage, the repair should be carried out by an authorized person or authorized after service center.
- Keep the equipment in a dry storage condition.
- Do not throw, beat or shock the equipment.
- Do not smear the equipment with pigments.
- Calibration is recommended when using a new/other contra angle or after an extend period of operation, as the running properties can change with usage, cleaning and sterilization.
- Replace the battery if it seems to be running out of power sooner than it should.

9.2 Replacing Battery

Please use original lithium battery only

- 1. Turn the motor handpiece power off
- 2. Use tweezers to remove soft cover
- 3. Unscrew and remove the battery cover
- 4. Disconnect battery
- 5. Replace with new battery
- 6. Put cover back and screw in

Note: It is recommended for you to contact your local distributor or manufacturer to replace the battery.

9.3 Lubrication of contra angle

Use the oil injection nozzle in the package

The contra angle needs to be lubricated after cleaning and disinfection, but before sterilization

- 1. Screw injecting nozzle into jet of oil bottle. (Around 1 to 3 circles)
- 2. Plug nozzle into the end part of contra angle
- 3. Spray oil into the contra angle for 2-3 secs until the oil flows out of contra angle head
- 4. Purge excess oil from the end part of contra angle using air or keep contra angle in a vertical position for gravity draining.



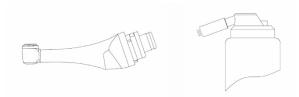
Warning

Motor handpiece cannot be filled with oil.



Caution

- Hold the contra angle head securely to prevent it from flying off from the air pressure of the spray
- Do not use a swirling nozzle
- · Hold the spray can upright.



10. Environmental Protection

Please dispose according to your local state regulations.

11. After service

Follow Instructions for Use

Date of manufacture



IPXO Ordinary equipment



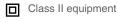








Manufacturer





Keep dry

Appliance compliance



SN Serial number

12. Statement

All rights of modifying the product are reserved to the manufacturer without further notice. The pictures are only for reference. The final interpretation rights belong to Beyes Dental Canada Inc. The industrial design, inner structure, etc, have claimed for several patents by Beyes, any copy or fake product must undertake legal responsibilities.

13. Beyes Limited Warranty Statement

From purchase date, based on warranty registration, we will repair this equipment free of charge if there are any quality issues experienced. Please refer to the warranty card for the warranty period.

13.1 SCOPE OF WARRANTY

BEYES Dental Canada Inc. warrants to the original retail purchaser that it will be at BEYES option to repair or replace components of the dental products manufactured by BEYES (except for components not warranted under 'Exclusions') that are defective in material or workmanship under normal use and service. BEYES' obligation under this limited warranty is limited to the repair or replacement of the applicable components. This limited warranty shall only apply to defects that are reported to BEYES within the applicable warranty period and which, upon examination by Beyes, prove to be defective. This warranty extends only to the first retail purchaser of a product and is not transferable or assignable. Replacement components or products may be used and/or refurbished components or products, provided they are of like quality and specifications as new components or products.

13.2 APPLICABLE WARRANTY PERIOD

The applicable warranty period, measured from the date of invoice to the original user, shall be as follows

ApexPilot G1 Endo Motor are warranted for a period of 12 months

13.3 EXCLUSIONS

This limited warranty does not cover and BEYES shall not be liable for the following; 1. Defects, damage or other conditions caused, in whole or in part, by misuse,

abuse, negligence, alteration, accident, freight damage, negligent storage, tampering or failure to seek and obtain repair or replacement in a timely manner;

- 2. Products which are not installed, used, and properly cleaned and maintained as required or recommended in the BEYES 'Installation' and/or 'Installation/Operation Manual' for the applicable product, including the specified structural and operational environment conditions and electrical power requirements;
- 3. Products considered to be of a consumable or sterile nature:
- 4. Accessories or parts not manufactured by BEYES:
- 5. Charges by anyone for adjustments, repairs, replacement parts, installation or other work performed upon or in connection with such products which are not expressly authorized in writing in advance by BEYES;
- 6. Costs and expenses of routine maintenance and cleaning;
- 7. Representations and warranties made by any person or entity other than BEYES;
- 8. Matching of color, grain or texture except to commercially acceptable standards;
- 9. Changes in color caused by natural or artificial light;
- 10. Custom manufactured products;
- 11. Alterations or modifications to the product by any person or entity other than BEYES:
- 12. Products that would otherwise by covered under Sections 1 and 2 of this limited warranty, but are acquired: (i) from a person or entity that is not BEYES or one of its authorized dealers; or (ii) from a BEYES dealer that is not authorized to sell the product at issue in the geographic territory where the purchaser is located, or is not authorized to sell the product at issue within the medical, animal health or dental market, as the case may be, in which purchaser intends to use the product.

13.4 EXCLUSIVE REMEDY; CONSEQUENTIAL DAMAGES DISCLAIMER

Beyes' obligation under this limited warranty is the repair or replacement of defective parts. Beyes shall not be liable for and hereby disclaims any direct, special, indirect, incidental, exemplary or consequential damages or delays, including, but not limited to, damages for loss of profits or income, loss of use, downtime, cover and employee or independent contractor wages, payments and benefits.

13.5 WARRANTY DISCLAIMER

This limited warranty is Beyes only warranty and is in lieu of all other warranties, express or implied. Beyes makes no implied warranties of any kind including any implied warranties of merchantability or fitness for a particular purpose. This warranty is limited to the repair or replacement of defective parts.

13.6 STATUE OF LIMITATIONS

No actions may be brought against Beyes for breach of this limited warranty, or implied warranty, if any, or for any other claims arising out of or relating to the products, more than ninety (90) days following expiration of the limited warranty period.

14. Technical Specification

Technical parameters

Device Classification	Class II Type B IPX	0
Device Classification	Class II Type B IF A	U
Applied part	Contra angle	
Power supply	Class II	
	Input	100V-240V 50Hz/60Hz
	Output	DC5V/1A
Battery capacity	3.6V 750mAh	
Torque	0.6 – 5 Ncm	
Speed	100 – 1000 rpm	

Environmental parameters

	Working	Storage
Temperature	+5°C~+40°C	-20°C~ +55°C
Humidity	30%~75%	10% ~ 93%
Air pressure	70kPa~106kPa	70kPa ~ 106kP



/ Warning:

Do not store device in extreme temperature and humidity.

15. 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 effected by electromagnetic interference Avoid using the device in high electromagnetic environment.

Technical Description Concerning Electromagnetic Emission Table 1: Declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions				
The model ApexPilot G1 is intended for use in the electromagnetic environment specified below. The customer or the user of the model ApexPilot G1 should assure that it is used in such an environment.				
Emissions test	Compliance	Electromagnetic environment - guidance		
RF emissions CISPR 11	Group 1	The model ApexPilot G1 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 ApexPilot G1 is suitable for used in all establishments, including		
Harmonic emissions IEC 61000-3-2	Class A	domestic establishments and those directly connected to the public low-voltage power		

Technical Description Concerning Electromagnetic Immunity Table 2: Guidance & Declaration - electromagnetic immunity

Guidance & Declaration — electromagnetic immunity				
The model ApexPilot G1 is intended for use in the electromagnetic environment specified below. The customer or the user of the model ApexPilot G1 should assure that It is used in such an environment.				
Immunity test IEC 60601 Compliance level Electromagnetic environment - guidance				

Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±2, ±4, ±8, ±15kV air	±8kV contact ±2, ±4, ±8, ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for Input/ output lines	±2kV for power supply lines	Voltage should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 , ± 1 kV line to line ± 0.5 , ± 1 , ± 2 kV line to earth	± 0.5 , ± 1 kV line to line ± 0.5 , ± 1 , ± 2 kV line to earth	Voltage 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	Voltage should be that of a typical commercial or hospital environment. If the user of the models ApexPilot G1 requires continued operation during power mains interruptions, it is recommended that the models ApexPilot G1 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.			

NOTE UT is the a.c. mains voltage prior to application of the test level.

Table 3: Guidance & Declaration - electromagnetic immunity concerning Conducted RF & Radiated RF

Guidance & Declaration - Electromagnetic immunity

The model ApexPilot G1 is intended for use in the electromagnetic environment specified below. The customer or the user of the models ApexPilot G1 should assure that it is used in such an environment

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 frequency band 3 V/m 80 MHz to 2.7 GHz	3V 6V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the models Endo Smart, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2×P1/2 d=2×P1/2 d=1.2×P1/2 d=0.2×P1/2 d=1.2×P1/2 d=0.2×P1/2 d=0.2×P1/2 d=0.2×P1/2 d=0.3×P1/2 d=0.3×P1/

NOTE I At 80 MHz end 800 MHz. the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the model ApexPilot G1 is used exceeds the applicable RF compliance level above, the model ApexPilot G1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model ApexPilot G1.

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 ApexPilot G1

Recommended separation distances between portable and mobile RF communications equipment and the model ApexPilot G1

The model ApexPilot G1 is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model ApexPilot G1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model ApexPilot G1 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz d=1.2×P1/2	80MHz to 800MHz d=1.2×P1/2	800MHz to 2,7GHz d=2.3×P1/2
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

NOTE I At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.





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.

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EU REP

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