

ACCURATOR® A2

Apex Locator

Instruction for Use



Beyes[®]
CANADA

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1. Product Introduction

1.1 Foreword

Beyes Dental Canada Inc. is a dental equipment manufacturer involved in researching, developing and producing dental equipment with a wholesome quality assurance system.

Beyes products includes dental handpieces, ultrasonic scalers, curing lights, apex locators, endodontic motors and much more.

1.2 Features

- Advance multiple frequency network impedance measurement technology
- Auto calibration
- Clear LCD display
- Rechargeable battery

1.3 Intended use

Apex locator is a supporting device for endodontic treatments. Through determining the position of apical constriction and the length of the root canal space, will help dentists complete endodontic treatments.

This equipment applies to the measurements below:

- Measurement of pulpitis, pulp necrosis, periapical periodontitis and tooth length.
- Measurement of the tooth length before restoration of post crown.
- Measurement of the tooth length of transplantation and retransplantation.

This device must only be operated by qualified and licensed dental professionals.

1.4 Contraindication

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

1.5 Package includes



Measuring wire



File clip



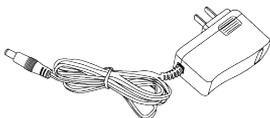
Lip hook



Touch probe



Battery

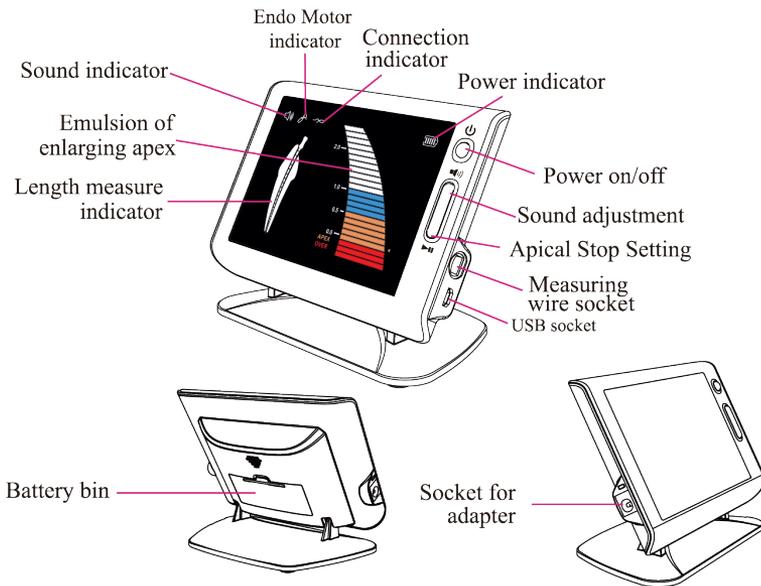


Adapter



Tester

Diagram of components and control buttons



2. Warnings and Precautions

Warnings

- First read this instruction manual before beginning to operate this device
- This device should only be operated by qualified and 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 high- frequency communication devices.
- Do not make any changes to the device. Any changes may violate safety regulations, causing harm to the patient
- Use original power adapter for charging the device
- Do not charge and operate the device at the same time. The device should be operated with battery only. Detach adapter from the device for operation.
- Remove battery from device for long term storage
- The device cannot be autoclaved. Use disinfectant of neutral pH value or ethyl alcohol to wipe its surface.
- Follow instruction in this manual to replace battery and only replace with original lithium battery.

Precautions

- Avoid any contact of the file or lip clip with metals. Be particularly careful with patients fitted with metallic crowns, bridges or large metallic fillings. Contact with metal can impair the measurements.
- High concentrations of sodium hypochlorite may result in a lower accuracy of the measurements. It is recommended to use sodium hypochlorite solution at maximum 3% concentration.
- Make sure that the canal is wet enough to ensure reliability of the measurement. But avoid excessive liquids inside the tooth cavity to prevent overflow and incorrect measurements.
- Apex locator may not be able to provide correct measurements in all conditions. In any case, it is recommended to take an X-Ray prior to device use and to compare the results obtained by both methods.

3. Installation

3.1 Battery

This device has built-in lithium battery.

1. Plug in power adapter
2. Connect power adapter to the device
3. Device will show a black screen with a battery icon and moving bars
4. When the device is fully charged, the screen will display battery icon with full bars

 **Warning:** Do not use device on patient while charging

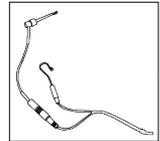
3.2 Lip hook and file clip

The measuring wire has a plug at one end and two jacks on the other end.

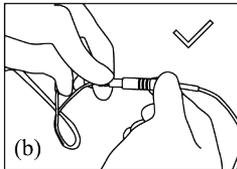
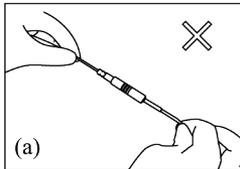
- Plug in the measuring wire to the device
- Plug in the lip hook to the white jack
- Plug in the file clip to the gray jack

Note:

When the device is connected to an endo motor, the file clip is not needed.



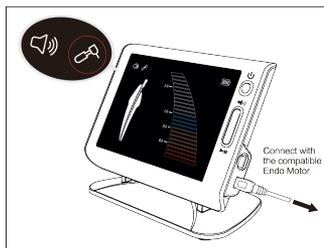
To remove lip hook or file clip, hold the jack and pull apart. Do not pull the wires.



3.3 Connect to endo motor (Optional)

Accurator A2 can be connected to Beyes ApexPilot G2. During operation, as the file at G2 reaches canal nerve, A2 alarm will be activated and G2 will stop or reverse motor according to its setting. This feature will help dentist to perform more accurate procedures.

Plug in the connecting wire from ApexPilot G2. The screen on A2 will show icon connecting the endo motor. For detail setting and functions, refer to ApexPilot G2 manual (Apex Locator section)



4. Device Operation

4.1 Turn on and off

Press power button to turn on/off device

Note: Device will shut down after 5 min of idling

4.2 Adjust volume

Press the sound adjustment to adjust the volume

After reaching the highest sound level, continuing to press the sound adjustment button will start back at lowest (mute) sound level.

4.3 Test connection



Always test before doing operation

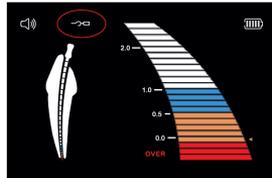
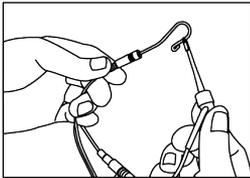
Install lip hook and file clip. See installation.

Touch the lip hook and the clip.

The display screen shows a bar ranging from all white and advances to blue, orange, and then red.

Icon at the top shows the hook and clip are touching

If the hook and clip are touching, there will be continuous beeping from the device



4.4 Set Apical Stop

Press lower part of the long button to move the pointer to the position of the between 0.0 and 1.0.



During operation when the file reaches the Apical Stop, the device will beep continually.

Note:

If ApexPilot G2 is connected with this device, the endo motor will respond according to defined action.

4.5 Operating screen

When the file reaches inside the canal, the display screen shows the tooth and the file extending to the bottom.

White zone

When the file reaches near the bottom, the enlarged display of apical foramen starts to light up the white bar and the device will start beeping.

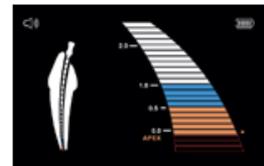
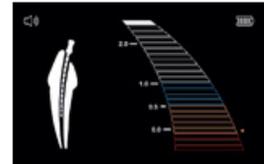
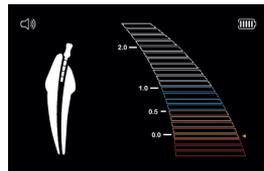
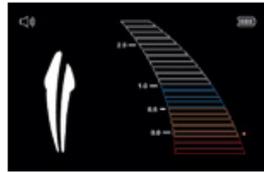
Blue and orange zone

As the file goes further down, the bar advances to blue and orange color with faster beeping.

Position 0.0

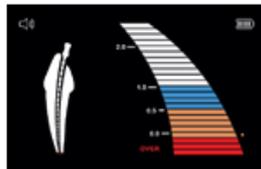
The location of anatomical apical foramen
“APEX”

Orange zone indicates when the file reaches the apical foramen



“OVER”

Red Zone indicates when the file has exceeded the apical foramen



⚠ Warning

The scale of reading does not indicate the actual distance. It indicates how close or far away the file is from the apical foramen.

It is recommended to check the position with an x-ray.

Note:

- The recommended working length is between 0.5 and 1.0 mm (blue zone). But it varies across different teeth. Dentist should make professional judgement during operation.
- Use the right file size for the root canal diameter. If file size selected is too small for the canal, this may affect accuracy of the reading.
- Keep the access cavity dry. Excessive liquid will affect the accuracy of the reading.

5. Dental Operation with Device (for reference)

5.1 Requirements

Warning:

This device should be operated by a qualified and licensed dental professional.
Read this manual before operation

- A fully exposed access cavity to show the pulpal cabin.
- An X-ray photo to show the whole length and root canal of the teeth.
- The endo file should not be too big nor too small to avoid cutting through the apical foramen.
- Mark an anatomized symbol on the diseased tooth and memorize it on the case history.
This symbol should be marked on the health bridge or on the tooth filled integrated. The position of the mark should be on the incisal edge of the anterior tooth or on the spire of the molars. For those bridge that's broken obviously, this symbol should be on the tooth surface supported by the dentin instead of on the suspended enamel.
- The acute inflammation surrounding the apex has been gone and the infected material has been cleaned. It is also necessary to get rid of the pulp and necrosis tissue.

5.2 Cases not suited for normal measurement

Case 1

The size of the root is similar to the size of apical foramen.

In this case, the measurement result of the length of the root canal will be shorter than its real length because of the hypoplasia of the root.



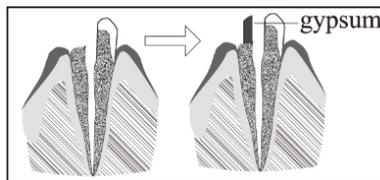
Case 2

Bleeding or blood overflows from the apical foramen. In this case, the blood will overflow from the root canal and reaches gingival. The blood and the gingival will be on a conducting state which will cause an inaccurate result while measuring. The measurement can be continued when the bleeding stops



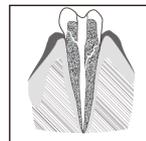
Case 3

The tooth crown is broken. The tissue of the gingiva may reach the cavity of the endo hole at the broken point which will cause inaccuracy because of the electronic conduction. The measurement can be continued when the crown is fixed by gypsum or other insulators



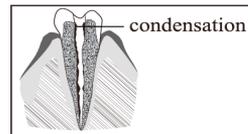
Case 4

There is a crack on the tooth root. In this case, the crack may cause electric leakage which will affect the accuracy of measurement



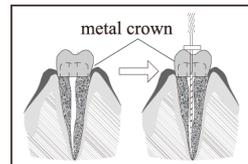
Case 5

A retreatment to a root canal which was filled with gutta-percha. Clean the remaining material in the root canal and fill it with little normal saline before a measurement



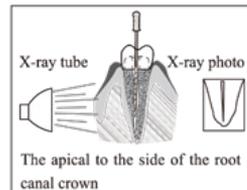
Case 6

There is a metal crown which has connected to the gingival. It will cause inaccuracy when the endo file touches metal crown



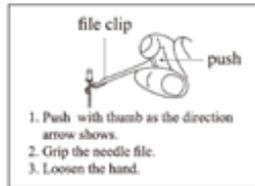
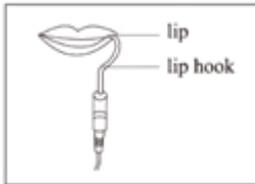
Case 7

Sometimes, the results of the Apex Locator may not match the X-ray reading. This does not necessarily mean that the machine is not normal or that the photo was taken incorrectly. The actual position of the apical foramen is different from the anatomical one. It is very common that the apical foramen is slightly to the side of the root canal crown. In this case, according to the shooting angle, it may create an illusion that the front tip of the root canal haven't reached the canal tip. (Due to the limiting angles of X-rays, sometimes the photo taken may not show the accurate position of the apical foramen.)



5.3 Instruction

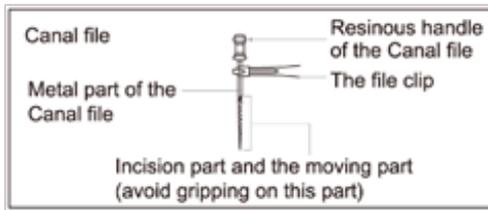
1. Connect the measuring wire to the device
2. Plug in lip hook and file clip
3. Adjust the volume
4. Test connection by touching the lip hook and the file clip
5. Hang the lip hook on the lip, make sure it makes contact with the oral mucosa as a reference electrode



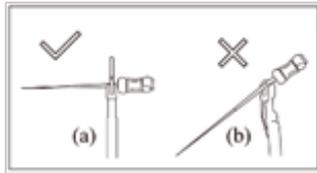
6. Clip the file with file clip, approach to the apex, then there will be continuous alarm when the distance is less than 2mm

Note:

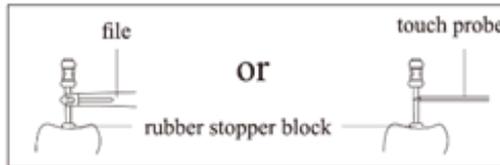
1. Clip the upper metal part of file. Clipping the blade or moving part wears the resin of the file



2. Use resin needle when measuring the length of root canal and wear gloves to prevent leakage which causes inaccurate measurement.
3. Do not use worn file clip
4. Clip the file perpendicular as shown



5. When the file reaches the apex, adjust the rubber piece set on the endo file to the reference point (incisal edge or fossa edge), then pull out the endo file, measure the length between the top of the file and the rubber piece, and this is the working length of the tooth. It also can be used with the touch probe instead of file clip, when it is inconvenient to measure the back teeth



6. Autoclave the lip hook, file clip or touch probe after use
7. Clean the device and measuring wire with 75% alcohol

6. Trouble Shooting

Problems	Possible causes	Solutions
No power and no signal on the screen after pressing power on	<ol style="list-style-type: none">1. The battery is placed incorrectly2. The battery has been depleted	<ol style="list-style-type: none">1. Re-install the battery.2. Recharge the battery.
The length of the root canal cannot be measured.	<ol style="list-style-type: none">1. The connection of the measuring wire is loose2. The measuring wire is broken	Confirm the measuring wire is plugged firmly, link the lip hook with the file clip to check if the measuring wire is broken.
No sound of alarm.	Volume is set at "mute"	Adjust the sound level.
The charging LED indicator goes out.	<ol style="list-style-type: none">1.The adapter is not connected properly2. A faulty adapter with excessive output is being used.3. The battery is not installed well.4. The battery has been damaged.	<ol style="list-style-type: none">1.Reconnect the adapter.2.Change the adapter. Only the original adapter should be used.3.Reinsert the battery and then reconnect the adapter.4.Change the battery and then reconnect the adapter.

Problems	Possible causes	Solutions
<p>Display not steady while measuring: the measurement result is rather longer or shorter; numerical display irregular. The length of the root canal cannot be measured. No sound of alarm. The charging LED indicator goes out.</p>	<p>The connection between the lip hook and the oral mucosa is not making contact</p>	<p>Make sure the lip hook has contacted the oral mucosa at a good position.</p>
	<p>Blood/saliva is overflowing or glued to the crown</p>	<p>Blood, liquid overflow from the root canal, glued to the crown or the tooth neck, will cause short circuit then cause the abnormal phenomena. Clean the blood and the liquid.</p>
	<p>The root canal is filled with blood or other liquid</p>	<p>Once the endo needle contact the surface of the root canal which is filled with blood, liquid, it will display "OVER" immediately. In this case, push the needle to the apical root canal, then the display will be normal, you can measure the length of the root canal correctly.</p>
	<ol style="list-style-type: none"> 1. The adapter is not connected well. 2. A faulty adapter with excessive output is being used output. 3. The battery is not installed well. 4. The battery has been damaged. 	<ol style="list-style-type: none"> 1. Reconnect the adapter. 2. Change the adapter, must use the original adapter. 3. Reinsert the battery and then reconnect the adapter. 4. Change the battery and then reconnect the adapter.
	<p>There is liquid or scrap on the tooth surface</p>	<p>Clean the tooth surface.</p>
<p>The endo needle is coming into contact with the gums</p>	<p>The LCD will display "OVER" if the endo needle contact the gums.</p>	

Problems	Possible causes	Solutions
Display not steady while measuring: the measurement result is rather longer or shorter; numerical display irregular.	There is still pulp in the root canal	If there is much pulp left in the root canal, the root canal length can't be measured correctly.
	Needle touched the metal repaired material	Once the needle touched the metal repaired material, current measurement from the gums to the periodontal tissue loss, the screen will display "OVER".
	Adjacent surface has caries	Current measurement flow from caries of the adjacent surface to gums, then the root canal length can't be measured correctly.
	There is collateral or the tooth root is broken	Once the needle reached the collateral or the broken part of the tooth root, current measurement will overflow from periodontal ligament, it displays "OVER".
	Is it because in addition to the top pulp chamber, low tooth crown? Or there are residues left?	Use rubber dam to prevent the current flow to gums.

Problems	Possible causes	Solutions
Display not steady while measuring; the measurement result is rather longer or shorter; numerical display irregular.	There are apical cysts	If there has cysts, the length of root canal can't be measured accurately.
	The file clip is not clean or broken	Clean the file clip by alcohol, or replace it.
	The measuring wire is broken or has poor contact	Contact both ends of the measuring wire directly, it displays "-3".
The length measurement indicator only full display near narrow part of the apical.	The root canal is occlusive	The display will be normal after penetrating the narrow part of apical.
	The root canal is too dry	Wet the root canal with normal saline solution or sodium hypochlorite solution.
	The endo file is too small for the root canal	Replace the current endo file with a larger one.

* If all above measures do not work, please contact us.

7. Cleaning, Disinfection and Sterilization

The cleaning, disinfection and sterilization of lip hook, file clip and touch probe are as follows:

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



Warnings

The use of strong detergent and disinfectant (alkaline pH>9 or acid pH <5) will reduce the life span of products. In such cases, the manufacturer takes no responsibility.

This device shall not be exposed to high temperature above 138°C. Processing limit

The products have been designed for a large number of sterilization cycles. The materials used in manufacture were selected accordingly. However with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products. The maximum number of sterilizations for file clip is 200 times. For lip hook and touch probe, it is 1000 times.

7.1 Initial processing

7.1.1 Processing principles

It is only possible to carry out effective sterilization after the completion of effective cleaning and disinfection. Please ensure that, as part of your responsibility for the sterility of products during use, only sufficiently validated equipment and product- specific procedures are used for cleaning/disinfection and sterilization, and that the validated parameters are adhered to during every cycle.

Please also observe the applicable legal requirements in your country as well as the hygiene regulations of the hospital or clinic, especially with regard to the additional requirements for the inactivation of prions.

7.1.2 Post-operative treatment

The post-operative treatment must be carried out immediately, no later than 30 minutes after the completion of the operation. The steps are as follows: 1.Remove the measuring wire from the Apex Locator Device, and rinse away the dirt on the surface of product with pure water (or distilled water/deionized water); 2.Dry the product with a clean, soft cloth and place it in a clean tray.

Note:

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

7.2 Preparation before cleaning

Steps:

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

1. Remove lip hook, file clip and touch probe from the measuring wire, and then put them into a clean tray.
2. Use a clean soft brush to carefully brush the copper needle at the end of the file clip, the probe surface and the lip hook surface until no dirt can be seen on the surface, and put them into a clean tray. The cleaning agent can be pure water, distilled water or deionized water.

7.3 Cleaning

The cleaning should be performed no later than 24 hours after the operation. The cleaning can be divided into automated cleaning and manual cleaning. Automated cleaning is preferred if conditions permit.

Automated cleaning

- The cleaner is proved to be valid by CE certification in accordance with EN ISO 15883.
- There should be a flushing connector connected to the inner cavity of the product.
- The cleaning procedure is suitable for the product, and the irrigating period is sufficient.
- Do not clean the product with ultrasound.
- It is recommended to use a washer-disinfector in accordance with EN ISO 15883. For the specific procedure, please refer to the automated disinfection section in the next section "Disinfection".

Note:

1. The cleaning agent does not have to be pure water. It can be distilled water, deionized water or multi-enzyme. But please ensure that the selected cleaning agent is compatible with the product.
2. In washing stage, the water temperature should not exceed 45 °C, otherwise the protein will solidify and it would be difficult to remove.
3. After cleaning, the chemical residue should be less than 10mg / L.

7.4 Disinfection

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

Automated disinfection-Washer-disinfector

- The washer-disinfector is proved to be valid by CE certification in accordance with EN ISO 15883.
- Use high temperature disinfection function. The temperature does not exceed 134°C, and the disinfection under the temperature cannot exceed 20 minutes.
- The disinfection cycle is in accordance with the disinfection cycle in EN ISO 15883.

Cleaning and disinfecting steps by using Washer-disinfector:

1. Carefully place the product into the disinfection basket. Fixation of product is needed only when the product is removable in the device. The products are not allowed to contact each other.
2. Use a suitable rinsing adaptor, and connect the internal water lines to the rinsing connection of the washer-disinfector.
3. Start the program.
4. After the program is finished, remove the product from the washer-disinfector, inspect (refer to section "Inspection and Maintenance") and packaging (refer to chapter "Packaging"). Dry the product repeatedly if necessary (refer to section "Drying").

Note:

1. Before use, you must carefully read the operating instructions provided by the equipment manufacturer to familiarize yourself with the disinfection process and precautions.
2. With this equipment, cleaning, disinfection and drying will be carried out together.
3. Cleaning: (a) The cleaning procedure should be suitable for the product to be treated. The flushing period should be sufficient (5-10 minutes). Pre-wash for 3 minutes, wash for another 5 minutes, and rinse it for twice with each rinse lasting for 1 minute. (b) In the washing stage, the water temperature should not exceed 45°C, otherwise the protein will solidify and it is difficult to remove. (c) The solution used can be pure water, distilled water, deionized water or multi-enzyme solution, etc., and only freshly prepared solutions can be used. (d) During the use of cleaner, the concentration and time provided by manufacturer shall be obeyed. The used cleaner is neodisher MediZym (Dr. Weigert).
4. Disinfection: (a) Direct use after disinfection: temperature $\geq 90^{\circ}\text{C}$, time $\geq 5\text{ min}$ or A0 ≥ 3000 ;

Sterilize it after disinfection and use: temperature $\geq 90^{\circ}\text{C}$, time ≥ 1 min or $A0 \geq 600$ (b) For the disinfection here, the temperature is 93°C , the time is 2.5 min, and $A0 > 3000$

5. Only distilled or deionized water with a small amount of microorganisms (<10 cfu/ml) can be used for all rinsing steps. (For example, pure water that is in accordance with the European Pharmacopoeia or the United States Pharmacopoeia).
6. After cleaning, the chemical residue should be less than 10mg / L.
7. The air used for drying must be filtered by HEPA.
8. Regularly repair and inspect the disinfectant.

7.5 Drying

If your cleaning and disinfection process does not have an automatic drying function, dry it after cleaning and disinfection.

Methods:

1. Spread a clean white paper (white cloth) on the flat table, point the product against the white paper (white cloth), and then dry the product with filtered dry compressed air (maximum pressure 3 bar). Until no liquid is sprayed onto the white paper (white cloth), the product drying is completed.
2. It can also be dried directly in a medical drying cabinet (or oven). The recommended drying temperature is $80^{\circ}\text{C}\sim 120^{\circ}\text{C}$ and the time should be 15~40 minutes.

Note:

1. The drying of product must be performed in a clean place.
2. The drying temperature should not exceed 138°C ;
3. The equipment used should be inspected and maintained regularly.

7.6 Inspection and maintenance

1. Check the product. If there is still visible stain on the product after cleaning/ disinfection, the entire cleaning/disinfection process must be repeated.
2. Check the product. If it is obviously damaged, smashed, detached, corroded or ruptured, it must be disposed and not allowed to continue to be used.
3. Check the product. If the accessories are found to be damaged, please replace it before use. The new accessories for replacement must be cleaned, disinfected and dried.
4. If the service time (number of times) of the product reaches the specified service life (number of times), please replace it in time.

7.7 Packaging

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

Note:

1. The package used conforms to ISO 11607;
2. It can withstand high temperature of 138 °C and has sufficient steam permeability;
3. The packaging environment and related tools must be cleaned regularly to ensure cleanliness and prevent the introduction of contaminants;
4. Avoid contact with parts of different metals when packaging.

7.8 Sterilization

Use only the following steam sterilization procedures (fractional pre-vacuum procedure*) for sterilization, and other sterilization procedures are prohibited:

1. The steam sterilizer complies with EN13060 or is certified according to EN 285 to comply with EN ISO 17665;
2. The highest sterilization temperature is 138°C;
3. The sterilization time is at least 4 minutes at a temperature of 132°C / 134°C and a pressure of 2.0 bar ~ 2.3 bars.
4. Allow a maximum sterilization time of 20 minutes at 134 °C.

Verification of the fundamental suitability of the products for effective steam sterilization was provided by a verified testing laboratory.

Note:

1. Only products that have been effectively cleaned and disinfected are allowed to be sterilized;
2. Before using the sterilizer for sterilization, read the Instruction Manual provided by the equipment manufacturer and follow the instructions.
3. Do not use hot air sterilization and radiation sterilization as this may result in damage to the product;
4. Please use the recommended sterilization procedures for sterilization. It is not recommended to sterilize with other sterilization procedures such as ethylene oxide, formaldehyde and low temperature plasma sterilization. The manufacturer assumes no responsibility for the procedures that have not been recommended. If you use the sterilization procedures that have not been recommended, please adhere to related effective standards

and verify the suitability and effectiveness. *Fractional pre-vacuum procedure = steam sterilization with repetitive prevacuum. The procedure used here is to perform steam sterilization through three prevacuums.

7.9 Storage

- Store in a clean, dry, ventilated, non-corrosive atmosphere with a relative humidity of 10% to 93%, an atmospheric pressure of 70 kPa to 106KPa, and a temperature of -20°C to +55°C;
- After sterilization, the product should be packaged in a medical sterilization bag and stored in a special storage cabinet. The storage time should not exceed 7 days. If it is exceeded, it should be reprocessed before use.

Notes:

1. The storage environment should be clean and must be disinfected regularly;
2. Product storage must be batched and marked and recorded.

7.10 Transportation

- Prevent excessive shock and vibration during transportation, and handle with care;
- It should not be mixed with dangerous goods during transportation.
- Avoid exposure to sun or rain or snow during transportation.
- The cleaning and disinfection of main unit and the measuring wire are as follows.
- Before each use, wipe the surface of the machine and the measuring wire with a soft cloth or paper towel soaked in 75% medical alcohol. Repeat the wipe for at least 3 times.
- After each use, wipe the surface of the device and the measuring wire with a soft cloth soaked in clean water (distilled or deionized water) or a clean disposable wipe. Repeat the wipe for at least 3 times.

8. Maintenance

- This device do not include accessories for repair usage, the repair should be carried out by 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.
- Replace the battery if it seems to be running out of power sooner than it should.

8.1 Replace battery

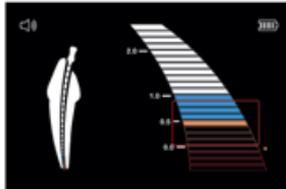
Please use the original lithium battery.

1. Turn off device
2. Remove the battery cover.
3. Remove the old battery and disconnect the connector.
4. Connect the new battery and put it in the Battery compartment.
5. Put back the battery cover

Note: It is recommended to contact you local distributors or dealers to replace the battery.

8.2 Test device (every two weeks)

Insert the tester to the measuring wire socket



Turn device on

The screen shows bars ± 3 bars away from the dial 0.5. It indicates the device functions normally. If the indicating bar is outside the range, contact authorized distributor or manufacturer for repair.

9. Environmental Protection

Please dispose according to your local state regulations

10. Symbol Instruction



Follow Instructions for Use



Appliance compliance
WEEE directive



Date of manufacture



Manufacturer



Type BF applied part



Class II equipment



Ordinary equipment



Recovery



Used indoor only



Keep dry



Power on/off



Handle with care



Sound adjustment



Serial number



Apical Stop Setting



Atmospheric pressure
for storage



Humidity limitation



Temperature limitation

11. 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.

12. 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

12.1 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.

12.2 APPLICABLE WARRANTY PERIOD

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

Accurator A2 Endo Motor are warranted for a period of 12 months

12.3 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 be 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.

12.4 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.

12.5 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.

12.6 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.

13. Technical Specification

Technical parameters

Device Classification	Class II Type B IPX0	
Applied part	touch probe, lip hook, file clip	
Power supply	Model	DJ-0500100-A5
	Input	100V-240V 50Hz/60Hz
	Output	DC5V/1A
Battery capacity	3.6V 750mAh (model:14500)	
Power consumption	≤0.5W	
Screen size	4.5" LCD	
Dimensions	138mm (L) × 77mm (W) × 107mm (H)	
Weight	385g	

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.

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

Guidance and manufacturer s declaration- electromagnetic emissions		
The model is intended for use in the electromagnetic environment specified below. The customer or the user of the model should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions	Group 1	The model 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	Glass B	The model is suitable for used in domestic establishments and in establishment directly connected to a low voltage power supply network which supplies buildings
Harmonic emissions IMC 61000-3-2	Glass A	

Guidance & Declaration - electromagnetic immunity

The model is intended for use in the electromagnetic environment specified below. The customer or the user of the model 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV 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 ±1 kV for Input/ output lines	±2kV for power supply lines ±1kV for interconnecting cable	Voltage should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line	Voltage should be that of a typical commercial or hospital environment.

<p>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</p>	<p><5 % Ur (>95% dip in UT for O5 cycle 40% Ur (60% dip in UT for 5 cycles 70% Ur (30% dip in UT for 25 cycles <5% Ur (>95 % dip in UT) for 5 sec</p>	<p><5% UT (>95% dip in UT.) for O5 cycle 40 % UT (60% dip in UT for 5 cycles 70%UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 sec</p>	<p>Voltage should be that of a typical commercial or hospital environment If the user of the model require continued operation during voltage interruptions, it is recommended that the model be powered from an uninterruptible power supply or a battery.</p>
<p>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</p>	<p>3A/m</p>	<p>3A/m</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p>
<p>NOTE UT is the ac. main voltage prior to application of the test level.</p>			

Guidance & Declaration - Electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V 3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the model, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the Transmitter</p> <p>Recommended separation distance $d = [3,5/V1]XP^{1/2}$ $d = 1.2 \times P^{1/2}$ 280 MHz to 800 MHz $d = 2.3 \times P^{1/2}$ 800 MHz to 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 b. Interference may occur In the vicinity of equipment marked with the following symbol:</p> 

NOTE 1 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 is used exceeds the applicable RF compliance level above, the model should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model .

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

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

The model is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the model can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment(transmitters)and the model is 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 $d=1.2XP^{1/2}$	80MHz to 800MHz $d=1.2XP^{1/2}$	800MHz to 2.5GHz $d=2.3XP^{1/2}$
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
<p>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.</p>			

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

Apex locator in the above specified electromagnetic environment, it will be safe, and can provide the basic properties such as article 1.6.1-1.6.3;

1. Measurement of pulpitis, pulp necrosis, periapical periodontitis and tooth length.
2. Measurement of the tooth length before restoration of post crown.
3. Measurement of the tooth length of transplantation and retransplantation.

Cautions:

1. User must regard EMC, please install and put in service the model according to the EMC information provided in the accompanying documents
2. Portable and mobile RF communications equipment can affect medical electrical equipment.
3. Use is not specified for the Apex locator the model of the adapter, measuring wire, file clip may increase the radiation quantity or reduce the interference ability of the Apex locator system. A list of all cables and maximum lengths of cables is as follows, transducers and other accessories with Beyes Dental Canada Inc. claims compliance with the requirements of Emission and Immunity. Please use original accessories.

Serial Number	Accessories name	Cable length	Whether shielding
1	adapter	1	No
2	measuring wire	1.7	No
3	file clip	0.2	No

4. The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Beyes Dental Canada Inc. as replacement parts for internal components, may result in increase Emissions or decreased Immunity of the model.
5. The model should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the model should be observed to verify normal operation in the configuration in which it will be used.
6. The accessories adapter, battery, measuring wire, file clip of Apex locator the model may affect the radiation quantity. The original accessories are in compliance with therequirements of the IEC 60601-1-2. Please use original accessories.



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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