MORITA

Apex Locator

DENTA PORT ZX

Canal Measurement Module

INSTRUCTIONS FOR USE

* This is the Canal Measurement Module. The Canal Preparation and Light Cure Module (sold separately) can be easily connected to this module so that preparation can be performed while measuring the canal and the light cure can be applied.

CE
0197

2024-05-21 Pub. No.: K093-80002-505 (en)

■ Thank you for purchasing the DENTAPORT ZX Canal Measurement Module.

■ For optimum safety and performance, read this manual thoroughly before using the device and pay close attention to warnings and notes. Keep this manual in a readily accessible place for quick and easy reference. This manual contains essential safety information.

To access the warranty information for this product, scan the following QR code and visit our website.

- The useful life of the DENTAPORT ZX is 6 years from the date of installation provided it is regularly and properly inspected and maintained.
- J. MORITA MFG. CORP. will supply replacement parts and be able to repair the product for a period of 10 years after the manufacture of the product has been discontinued. For the duration of this period, we will supply replacement parts and be able to repair the product.

Table of Contents

1. Prevent Accidents

Most operation and reprocessing problems result from insufficient attention 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 device in accordance with the manufacturer's recommendations.

First thoroughly read all precautions and instructions pertaining to safety and accident prevention; then, operate the device with the utmost caution to prevent either damaging the device itself or causing bodily injury.

Note the meaning of the following symbols and expressions:

⚠WARNING	This warns that it may result serious injury of the patient or operator if the instructions are not followed properly.
⚠PROHIBITION	The user can not use in such a way that may result in serious injury of the patient or operator.
⚠CAUTION	This alerts the user to the possibility of damage to the device, potential injury of the patient or operator, or important points concerning operation and performance.
(Mandatory Action)	This alerts the user of important points concerning operation or the risk of device damage.

The user (e.g., healthcare facility, clinic, hospital etc.) is responsible for the management, maintenance and use of medical device.

This device must only be used by dentists and other legally licensed professionals.

Do not use this device for anything other than its specified purpose.

⚠WARNING

- *This devicet must not be connected to or used in combination with any other apparatus or system. It must not be used as an integral component of any other apparatus or system.*
  J. MORITA MFG. CORP. will not be responsible for accidents, device damage, bodily injury or any other trouble which results from ignoring this prohibition.
- *Accurate canal measurement is not always possible depending on the shape and condition of the tooth as well as a decline in the device's performance.*
- *Do not use damaged file holders; an accurate measurement can not be made with a damaged file holder.*
- *When continuous tone is heard while the main power switch is on and without any operation, some electrical part may be malfunction. Do not use the device and send it to J. MORITA OFFICE for repairing.*
- *A rubber dam should be used when performing endodontic treatment.*
- *Caution: US Federal law restricts this device to sale by or on the order of a dentist in U.S.A.*
- *The DENTAPORT ZX needs special precaution regarding EMC and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents.*
- *Portable and mobile RF communications device can affect the DENTAPORT ZX.*
- *Use of the parts other than those accompanied or specified by J. MORITA MFG. CORP. may result in increased EMC emissions or decreased EMC immunity of the DENTAPORT ZX.*
- *The DENTAPORT ZX should not be used adjacent to or stacked with other device and that if adjacent or stacked use is necessary, the DENTAPORT ZX should be observed to verify normal operation in the configuration in which it will be used.*
- *No modification of this device is allowed.*
- *Always wear personal protective equipment (PPE) such as safety glasses, gloves, a mask, etc. when using and reprocessing the DENTAPORT ZX.*

⚠PROHIBITION

- *Do not use this device in conjunction with an electric scalpel or on patients who have a pacemaker.*
- *Do not use this device in the medical operation room.*
- *Blocked canals cannot be accurately measured.*
- *This device must not be connected to or used in combination with any other apparatus or system. It must not be used as an integral component of any other apparatus or system.*
  J. MORITA MFG. CORP. will not be responsible for accidents, device damage, bodily injury or any other trouble which results from ignoring this prohibition.
- *Illumination devices such as fluorescent lights and the Film viewer which use an inverter can cause the DENTAPORT ZX to operate erratically. Do not use the DENTAPORT ZX near devices such as these.*
- *Electromagnetic wave interference could cause this device to operate in an abnormal, random and possibly dangerous manner. Mobile terminals, smart devices, transceivers, remote controls and all other devices which transmit electromagnetic waves located inside the building should be turned off.*
- *Do not perform maintenance while using the instrument for treatment.*

In Case of Accident

If an accident occurs, the DENTAPORT ZX must not be used until repairs have been completed by a qualified and trained technician authorized by the manufacturer.

For customers who use the DENTAPORT ZX in the EU:
If any serious incident occurs in relation to the device, report it to a competent authority of your country, as well as the manufacturer through your regional distributor. Observe relevant national regulations for detailed procedures.

Intended Operator Profile

This device must only be used by dentists and other legally licensed professionals.

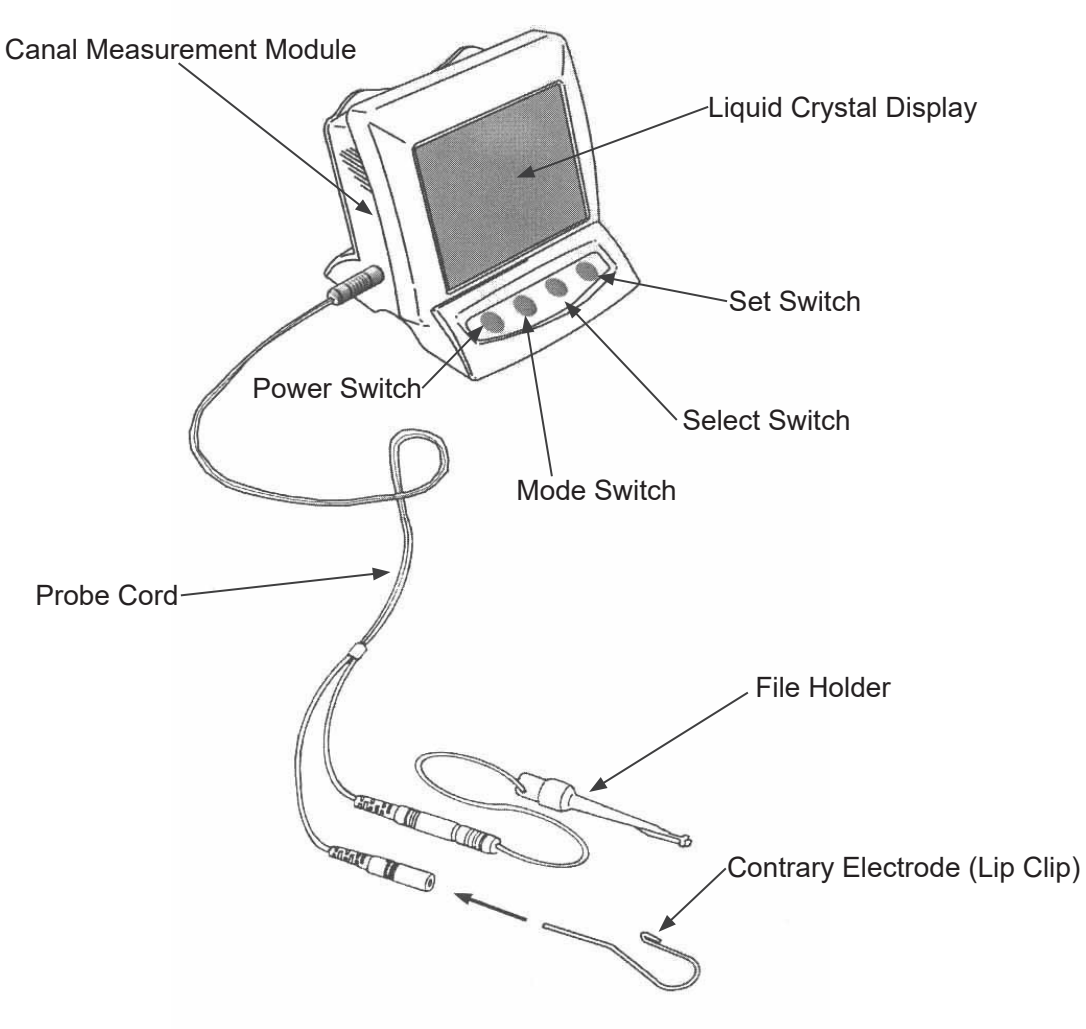
Patient Population

Age:	Child to Elderly
Weight:	N/A
Nationality:	N/A
Sex:	N/A
Health:	It is not intended for use on patients wearing pacemakers or ICDs.
Condition:	Conscious and mentally alert person. (Person who can stay still during treatment.)

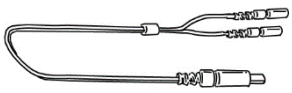
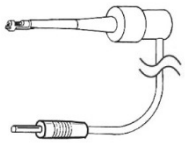
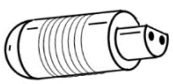
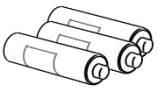
⚠CAUTION

- ***This device is not recommended for use in children under 12 years of age.***

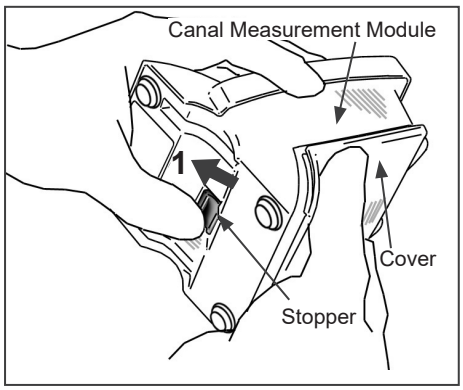
2. Parts Identification

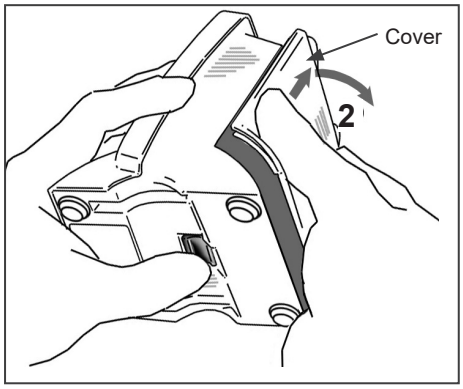


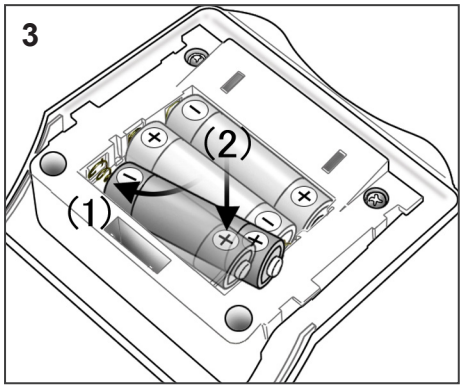
Accessories

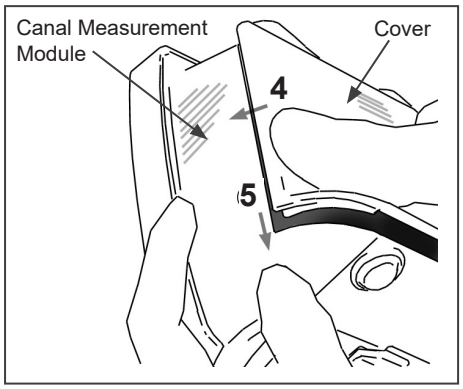
Probe Cord	File Holder	Contray Electrode
Code No.7503661 	Code No.7503670 	Code No.7503680 
Tester	**AA Battery**	**Long File Holder (option)**
Code No.7503910 		Code No.7503673 

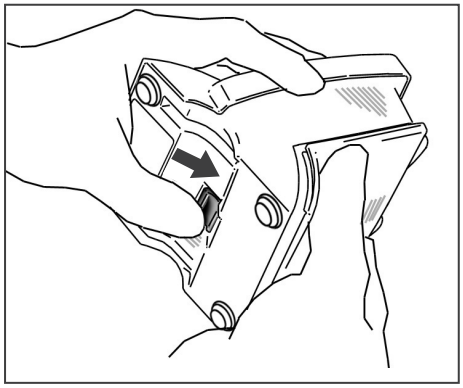
3. Assembling the Unit











Placing the Batteries

⚠CAUTION

- ***Canal Measurement Module is shipped without the batteries installed. Remove the cover and install the 3 AA batteries.***

1. Hold the cover and slide the stopper on the bottom towards the liquid crystal display.

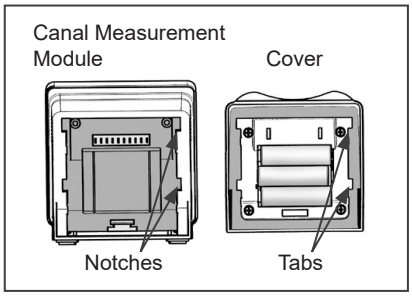
2. Slide the cover in the direction indicated by the arrow in the illustration and remove it from the Canal Measurement Module.

3. Place the 3 AA batteries included in the package as indicated on the device.
   (1) Insert the batteries by first pressing center of the minus end against its spring contact and then sliding the plus end down into place.
   (2) Make sure the contacts are not bent or damaged.

⚠CAUTION

- ***Do not reverse the plus and minus poles.***
- ***Never allow the spring contact to push against the edge of the battery. This could damage the outer cover causing a short or a leakage of battery liquid.***

4. Line up the tabs on the cover with the notches on the Canal Measurement Module and slide the cover on.
5. Slide the cover all the way down until it is securely attached.



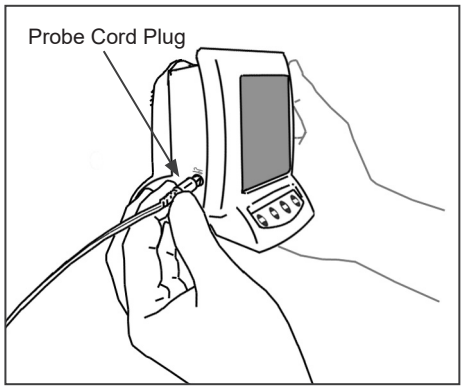
⚠CAUTION

- ***If the catch on the bottom is not back in its original place after attachment, push it in the direction shown by the arrow in the illustration.***
- ***After installation, give the cover a light tug to confirm it is securely attached***

4. Before Using the Unit

Be sure to perform reprocessing on the respective parts before using them for the first time.

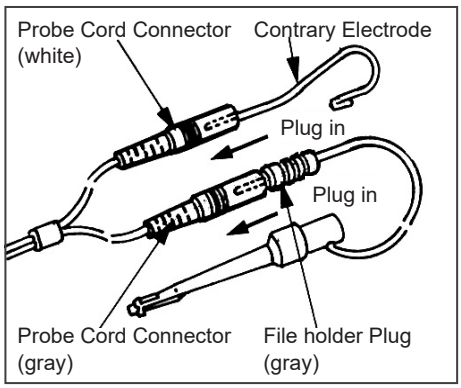
Connecting the Probe Cord



1. Insert the probe cord completely into the jack on the left side of the Canal Measurement Module.

⚠CAUTION

- ***Handle the Canal Measurement Module carefully; do not drop, bump or expose the device to other kinds of impacts or shocks. Rough handling could cause damage.***
- ***Make sure the plug is securely plugged into the jack. A poor connection can prevent measurement.***
- ***Do not drop anything on or bang the plug after it has been inserted into the jack.***



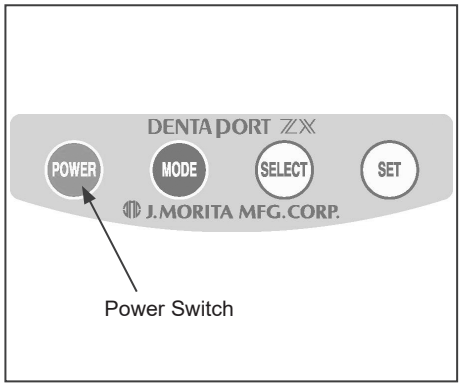
2. Insert the file holder's gray male plug into the gray female connector on the probe cord. Insert the contrary electrode into the white female connector on the probe cord.

⚠CAUTION

- ***Make sure to match colors of the file holder and contrary electrode to the probe cord.***
  Measurements cannot be made if these connections are reversed.

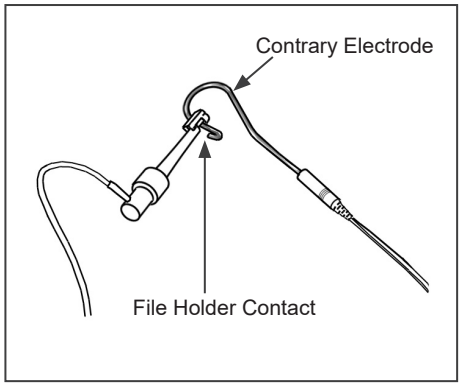
Checking the Function

This checking procedure should be followed at the beginning of every day.

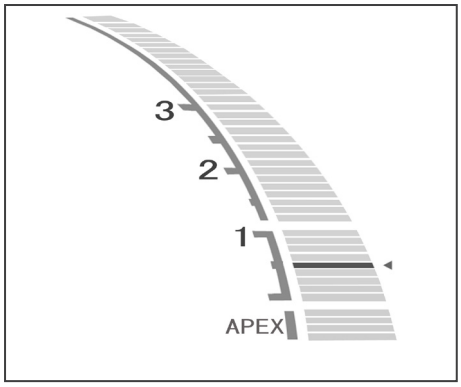


1. Press the Power switch to turn the unit on. The measurement display will appear.

   * The instrument turns itself off if it is not used for five minutes.



2. Check that the probe cord is properly plugged into the jack.
3. Check that the file holder and contrary electrode are properly connected to the probe cord.
4. Contact metal part of the file holder with contrary electrode.



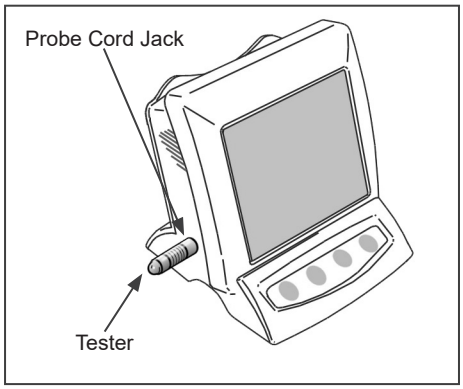
5. Check that all the meter indicator bars on the display are lit, the word “APEX” flashes and audible beep becomes continuous.

⚠WARNING

- ***Check the DENTAPORT ZX’s operation before each patient. If the indicators in the display do not all appear normally, the instrument may not be able to make an accurate measurement. In this case, stop using the instrument and have it repaired.***

Checking the Function with the Tester

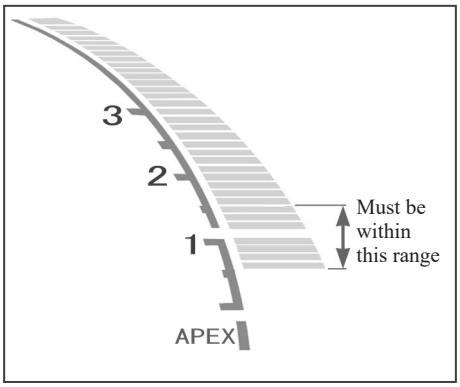
Check Canal Measurement Module’s performance with the tester once a week.



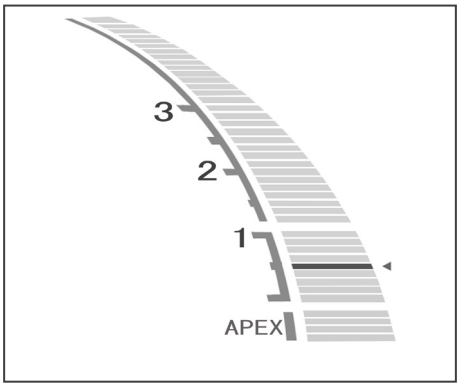
1. Press the Power switch to turn the unit on.
2. Insert the tester into the probe cord jack.
   Check that the meter indicates within ±3 bars away from (above or below) 1.

* The meter may jump when the tester is inserted. If it does, wait for about one second until the meter stabilizes and then check the reading.

* If the reading is 4 or more bars away from 1, the unit will not make accurate measurement. In this case, contact your local dealer or J. MORITA OFFICE.



3. Remove the tester and connect the probe cord.
4. Connect the file holder and contrary electrode to the probe cord.



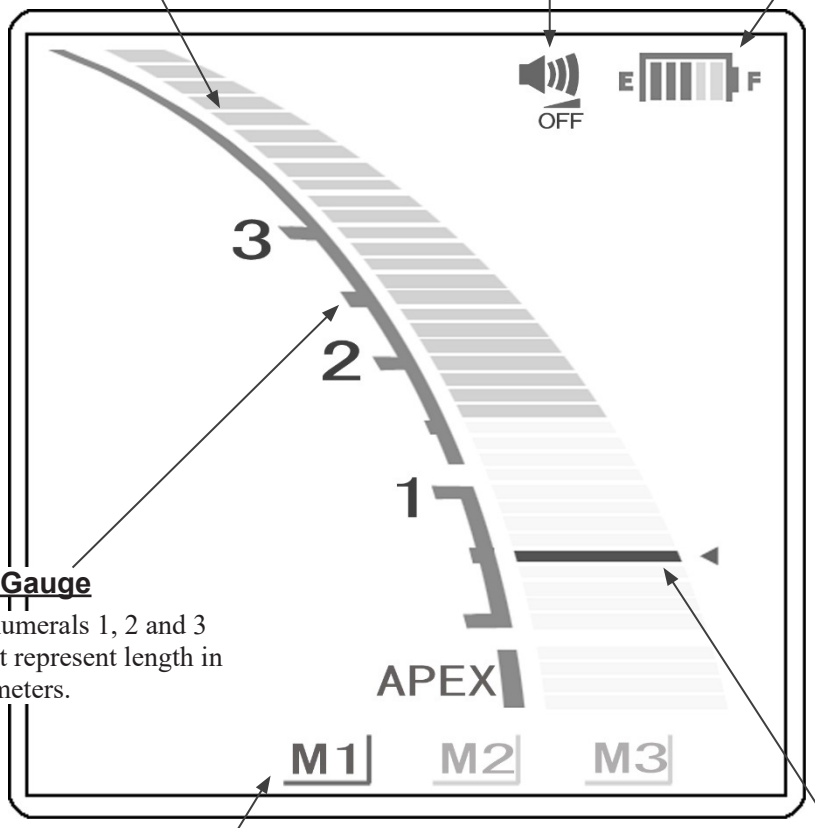
5. Touch the contrary electrode with the file holder’s contact tip.
   Check that all the canal length indicator bar on the display are lit, the word “APEX” flashes and audible beep becomes continuous.

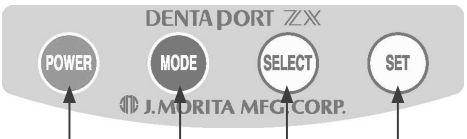
5. Operating the Unit

Operating Environments

Temperature: +10°C to +35°C (+50°F to +95°F)
Humidity: 30% to 80% (without condensation)
Atmospheric Pressure: 70 kPa to 106 kPa

Operation Panel Display and Switches





Sound Volume

Off, Low, High

Canal Length Indicator Bar

Battery Power Indicator

This bar graph indicates remaining battery power. Replace the batteries when this indicator begins flashing.

⚠ WARNING

- ***Never use the unit if the battery power indicator is flashing on and off. The unit will not function properly if the battery power is low.***

* **Battery power indicator also appears when the Canal Preparation and Light Cure Module is connected.**

Meter Gauge

* The numerals 1, 2 and 3 do not represent length in millimeters.

Apical Line

Use this point as an estimate for root canal measurement. It can be set anywhere between 2 and Apex.

Power Switch

Mode Switch

Select Switch

Set Switch

Memory (M1, M2, and M3)

For details, see "Setting and Changing Memory" on page 9.

Setting and Changing Memory

Use the Mode Switch to select M1, M2 or M3. Use the Select switch to select sound volume and Apical Line. Use the Set Switch to set the memory content.

Press Mode to select the memory.	Press Select to select the item.	Press Set to set the memory content.	
MODE Press	SELECT Press (The display will briefly flash on and off.)	SET Press	
M1 (Memory 1) → Root Canal Measurement Mode 1 M2 (Memory 2) → Root Canal Measurement Mode 2 M3 (Memory 3) → Root Canal Measurement Mode 3	Sound volume selected Flashes	OFF Turn the sound off. Set the sound volume low. Set the sound volume high.	
	Apical Line selected. Flashes	Apical Line	The apical line can be set anywhere between 2 and Apex.

* All memory settings will be retained even after the unit is turned off. Simply select M1, M2, or M3 to use those memory settings.

⚠WARNING

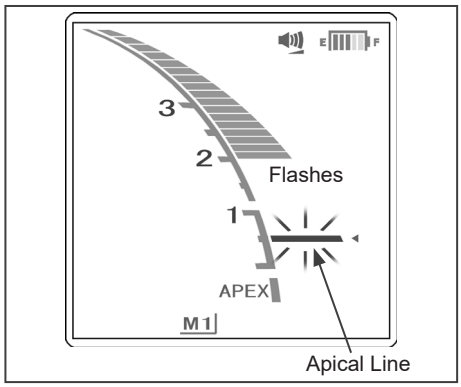
- ***Check the settings displayed after selecting memories.***

Alarm Sound Selection

In case 2 or more units are being used, there are two different sounds for the alarm so that you can tell one from the other. To change the sound, hold down the Set switch and turn the unit on.

* The sound that signals switch operation will also change.
* The sound cannot be memorized separately by the three memories (M1, M2 and M3).
* Turn the unit off to save the selection.

Meter Display



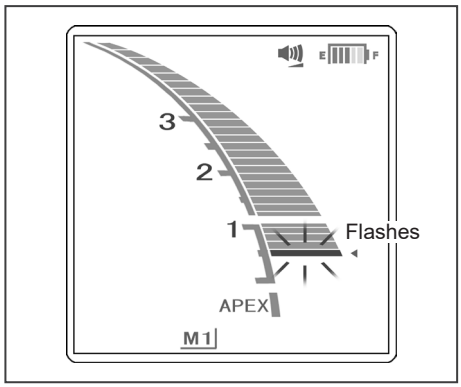
■ The position of the file tip is shown by the canal length indicator bar on the display. The apical line flashes on and off once file is inserted into the root canal.

⚠CAUTION

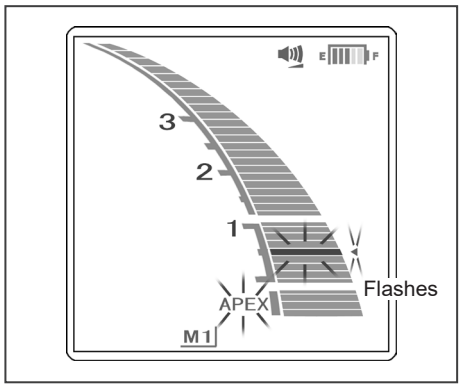
- ***Do not let the file touch the gums. This will cause the meter to jump to Apex.***
- ***If the canal is extremely dry, the meter may not move until it is quite close to the apex.***
  If the meter does not move, try moistening the canal with oxydol or saline.
- ***Occasionally the canal length indicator bar will make a sudden and large movement as soon as the file is inserted into the root canal, but it will return to normal as the file is advanced down towards the apex.***

⚠WARNING

- ***In some cases such as a blocked canal, a measurement cannot be made. (For details, see "Root Canals Not Suitable for Electic Apex Location" on page 13.)***
- ***Always check the measurement with an X-ray. In some cases, an accurate measurement cannot be made because of the canal shape, unusual cases, or poor performance of the instrument.***
- ***Stop using the instrument immediately if you sense something odd or abnormal while taking a measurement.***

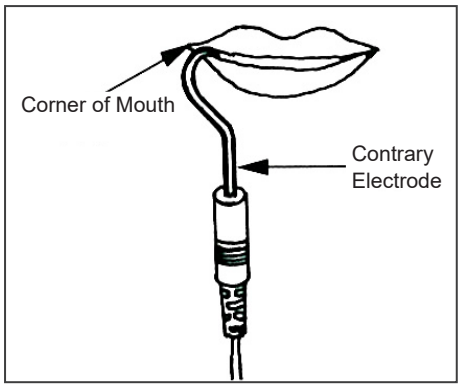


■ 0.5 Meter Reading
The meter's 0.5 reading indicates that the file tip is located very near the physiological apical foramen. Use this position as a reference to determine the working length depending on the individual case. The exact working length depends on the shape and condition of the canal, and a clinical judgment must be made by the dentist.
∗The numerals 1, 2, and 3 do not represent length in millimeters from the apex. These numbers are used to as a reference to determine the working length.



■ If the file tip reaches the major foramen, the alarm sound will sustain beep, and the word "APEX" and the little triangle next to the apical line will start to flash.

Operating the Unit



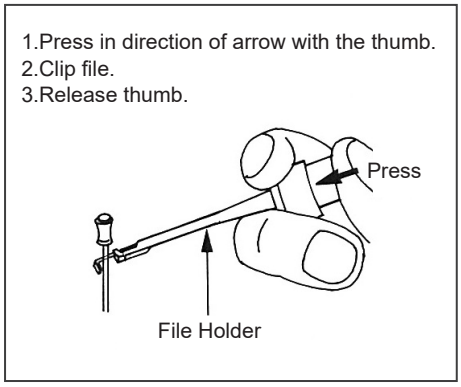
1. Turn the unit on.
2. Hook the contrary electrode in the corner of the patient's mouth.

⚠ WARNING

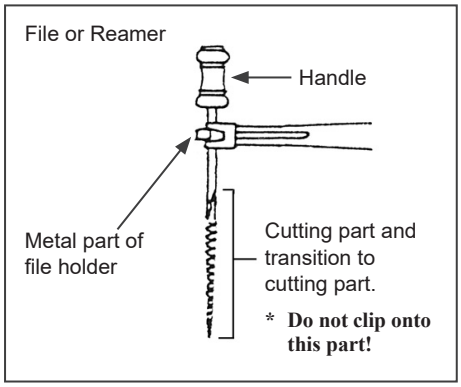
- ***Do not use an ultra sonic scaler with the contrary electrode attached to the patient.***
  Electrical noise from the scaler could interfere with canal measurements.
- ***Make sure that the contrary electrode, file holder etc. do not come into contact with an electric power source such as an electrical socket. This could result in a severe electrical shock.***

⚠ CAUTION

- ***The contrary electrode could cause an adverse reaction if the patient has an allergy to metals. Ask the patient about this before using the contrary electrode.***
- ***Take care that medicinal solutions such as formalin cresol (FC) or sodium hypochlorite do not get on the contrary electrode or the file holder. These could cause an adverse reaction such as inflammation.***



3. Clip the file holder to the metal shaft of the file.

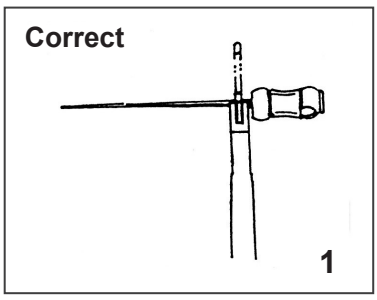


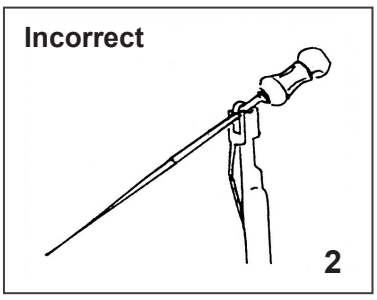
⚠ CAUTION

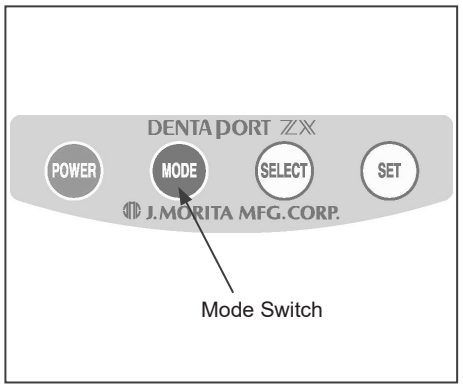
- ***Always clip the file holder to the upper part of file shaft, near the handle. The metal and plastic part of the file holder can be damaged if they are attached to the file's cutting part or the transition to the cutting part.***

⚠CAUTION

- ***Use files and reamers with plastic handles only. If the file has a metal handle, electrical leakage will occur when the handle is touched by fingers and it will prevent an accurate root canal measurement. Even if the file handle is made of plastic, make sure not to touch the metal part of the file with finger.***
- ***Do not use damaged file holders. An accurate measurement cannot be made using a damaged file holder.***
- ***Clip the file as shown in illustration #1 below. If the file is forced into the position shown in illustration #2, it may not make a correct measurement and the file holder could be damaged.***



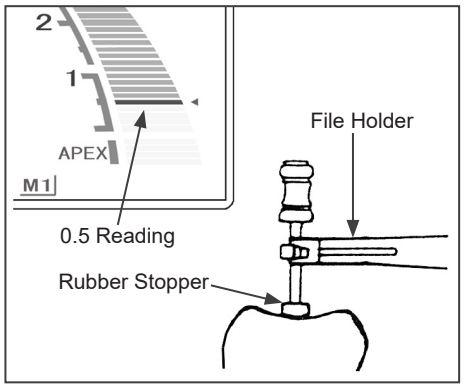




4. Press the mode switch to select memory 1, 2 or 3 (M1, M2 or M3).

* See “Setting and Changing Memory", on page 9 for how to set the memory contents.

* While an actual measurement is being made, none of the switches, except the power switch, will work.



5. Insert the file (in most case size 10) until the meter reads 0.5 (this point can be recognized by the change in the alarm sound as well). Then advance the file with slow clockwise turns until the word “APEX” begins to flash. When the apex is reached, turn the file with slow counter clockwise turns until meter reads 0.5 again. Since some canals have multiple constrictions, it is essential that the file be taken to the apex then returned to the apical constriction (0.5 reading). Position the rubber stopper on the tooth surface as a reference point to determine the root canal’s working length.
6. Determine the working length

■ <u>0.5 Meter Reading</u>
The meter’s 0.5 reading indicates that the file tip is located very near the physiological apical foramen. Use this position as a reference to determine the working length depending on the individual case. The exact working length depends on the shape and condition of the canal, and a clinical judgment must be made by the dentist.

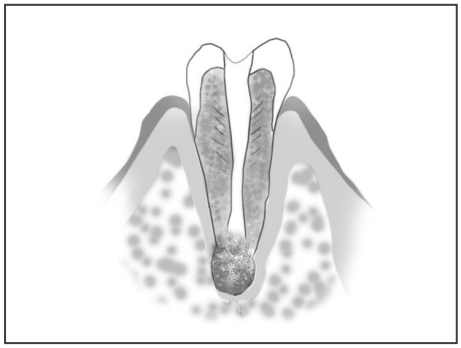
∗The numerals 1, 2, and 3 do not represent length in millimeters from the apex. These numbers are used to as a reference to determine the working length.

⚠CAUTION

- ***Make sure to take an X-ray to check the results.***

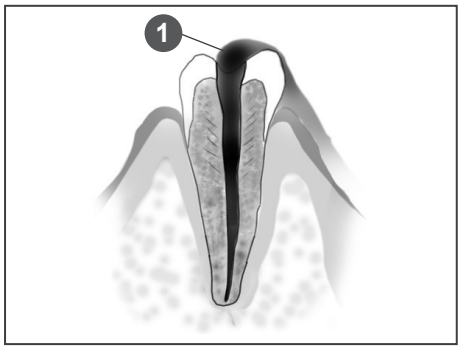
Root Canals Not Suitable for Electic Apex Location

Accurate apex location cannot be obtained with the root canal conditions shown below.



Root Canal with a large apical foramen

Tooth with incomplete root canal (e.g., root resorbed tooth and primary tooth).

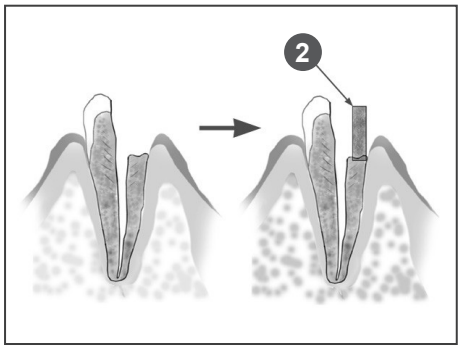


Root canal with blood overflowing from the opening

If blood overflows from the opening of the root canal and contacts the gums, this will result in electrical leakage and an accurate apex location cannot be obtained. Wait for bleeding to stop completely. Clean the inside and opening of the canal (❶) throughly to get rid of all blood, and then check the apex location again.

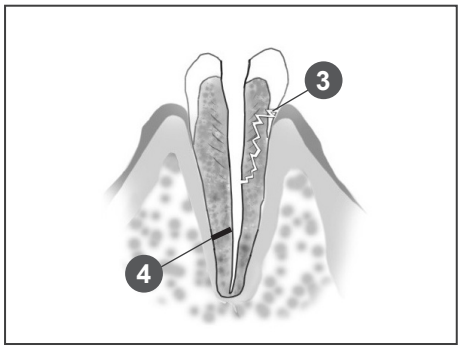
Root canal with a chemical solution overflowing from the opening

An accurate apex location cannot be obtained if a chemical solution is overflowing from the canal opening. In this case, clean the canal and its opening, and the perform apex location. It is important to remove any solution overflowing the opening.



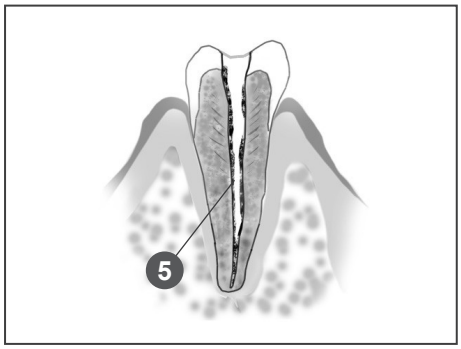
Broken crown

If the crown is broken and a section of the gingival tissue is contacting caries surrounding the canal opening, the DENTAPORT ZX may malfunction due to electrical leakage between the gingival tissue and the root canal. In this case, build up the tooth with a suitable material such as cement (❷), to insulate the gingival tissue.



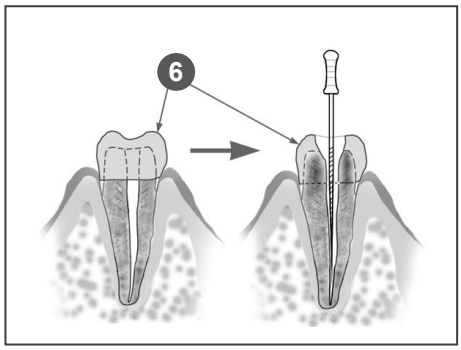
Fractured tooth Leakage through a branch canal

A fractured tooth (❸) will cause electrical leakage and accurate apex location cannot be obtained. A branch canal (❹) will also cause electrical leakage and accurate apex location cannot be obtained.



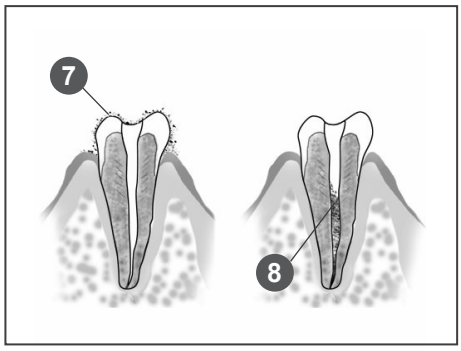
Re-treatment of a root filled with gutta-percha

The gutta-percha must be completely removed to eliminate its insulating effect. After removing the gutta-percha (❺), pass a small file all the way through the apical foramen, and then put a little saline in the canal, but do not let it overflow the canal opening.



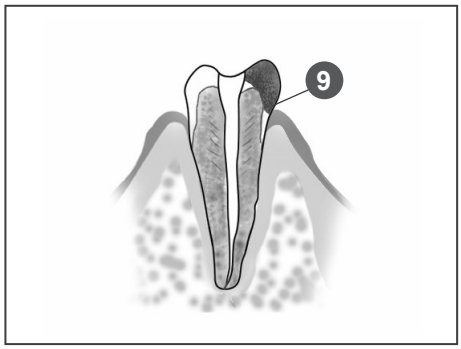
Crown or metal prosthesis touching gingival tissue

The DENTAPORT ZX will malfunction if the file or reamer touches a metal prosthesis that is touching gingival tissue. In this case, widen the opening at the top of the crown (❻) so that the file or reamer will not touch the metal prosthesis before performing the apex location.



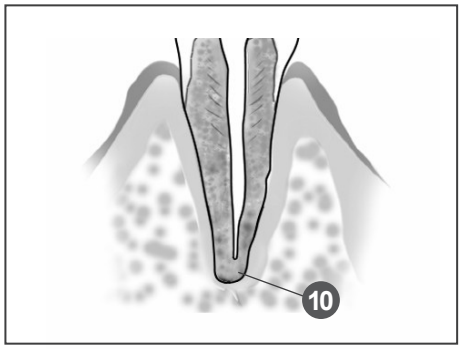
Cutting debris on tooth Pulp inside canal

Thoroughly remove all cutting debris (❼) from the tooth. Thoroughly remove all the pulp (❽) inside the canal. Otherwise accurate apex location cannot be obtained.



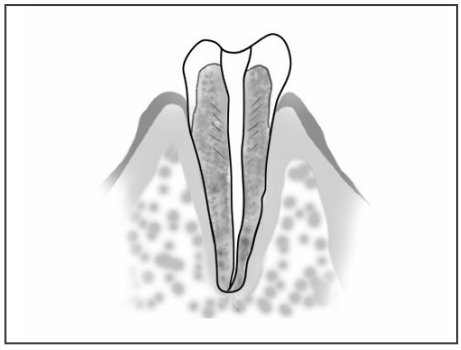
Caries touching the gums

In this case, electrical leakage through the caries infected area to the gums (❾) will make it impossible to obtain an accurate apex location.



Blocked canal

The meter will not move if the canal is blocked (❿).
In this case, open the canal all the way (penetration) to the apical constriction.

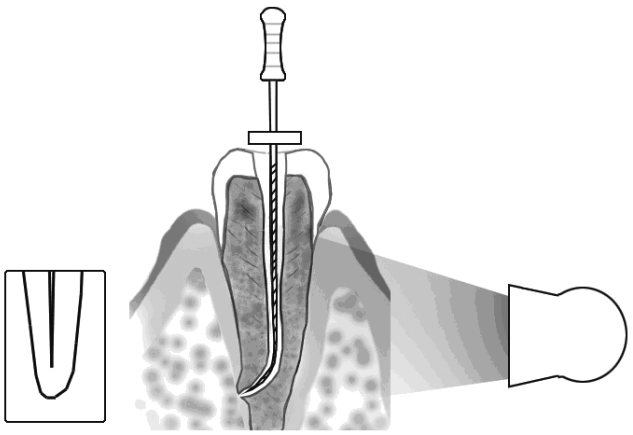


Extremely dry canal

If the canal is too dry, the meter may not move until the file is near the apex.
In this case, try moistening the canal with oxydol or saline.

DENTAPORT ZX Meter Reading and Radiography

Sometimes the DENTAPORT ZX meter reading and the X-ray image will not correspond.
This does not mean that the DENTAPORT ZX is not working properly or that the X-ray exposure is a failure.
An X-ray image might not show the apex correctly depending on the angle of the X-ray beam, and the location of the apex might seem to be other than it really is.



In the illustration above, the actual apex of the canal is not the same as the anatomical apex. There are frequently cases where the apical foramen is located up towards the crown.
In these cases, an X-ray might indicate that the file has not reached the apex even though it has actually reached the apical foramen.

6. After Using the Unit

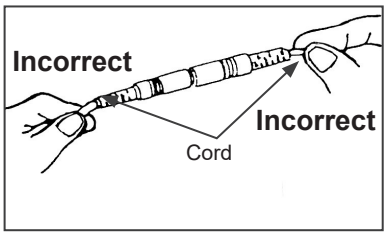
1. Turn the unit off.

   * The unit will automatically turn off after 10 minutes of non-use.

2. Disconnect the probe cord from the unit and remove the file holder and contrary electrode from the probe cord.

⚠CAUTION

- ***Do not pull directly on the cords when connecting or disconnecting the probe and file holder. Always grip the connectors to connect and disconnect cords.***
- ***Do not wrap the probe cord around the body of the unit.***



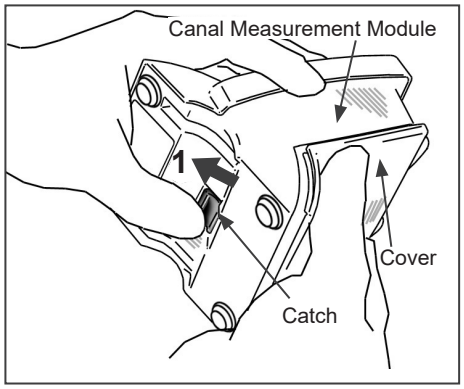
Replacing Batteries

Replace the batteries as soon as the battery power indicator starts flashing.

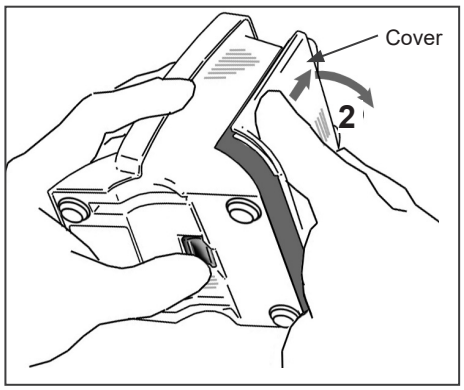
* To be on the safe side, replace the batteries when the battery power indicator displays two lines.

⚠WARNING

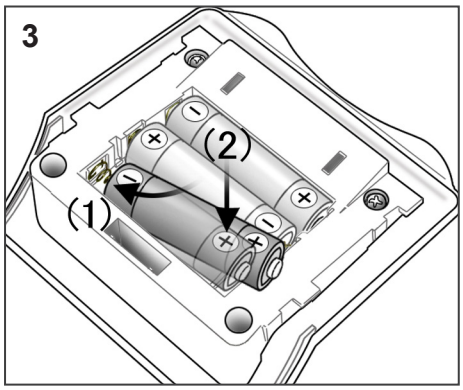
- ***Do not use the unit if the battery power display is flashing. The unit may not function properly if the battery power is low.***



1. Hold the cover and slide the catch on the bottom of the module towards the display to release it.



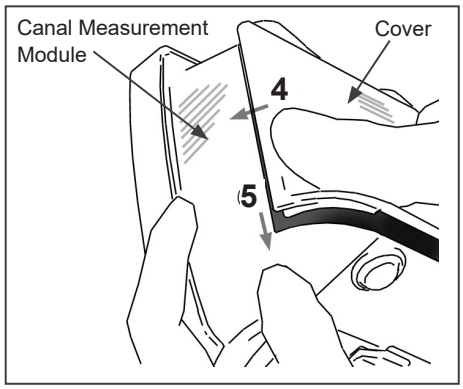
2. Slide the cover in the direction indicated by the arrow in the diagram to take it off.

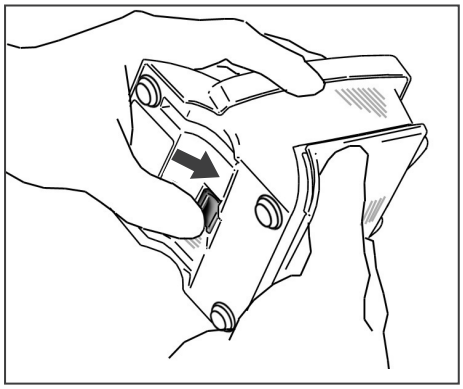


3. Take out the old batteries and replace them with new ones. Make sure the plus and minus poles are correctly lined up.
   (1) Insert the batteries by first pressing center of the minus end against its spring contact and then sliding the plus end down into place.
   (2) Make sure the contacts are not bent or damaged.

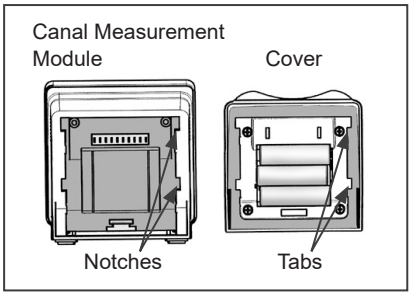
⚠CAUTION

- ***Do not reverse the plus and minus poles.***
- ***Never allow the spring contact to push against the edge of the battery. This could damage the outer cover causing a short or a leakage of battery liquid.***





4. Line up the projections on the cover with the notches in the module. Fit the cover onto the module and slide it down into place.
5. Slide the cover all the way down until it is snugly seated on the module.



⚠CAUTION

- ***If the catch on the bottom is not back in its original place after attachment, push it in the direction shown by the arrow in the illustration.***
- ***After installation, give the cover a light tug to make sure it is securely attached.***

⚠CAUTION

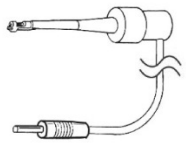
- ***Always use alkaline AA batteries.***
- ***Never use rechargeable nickel-hydrogen or nickel-cadmium batteries.***
- ***Replace all three batteries at the same time.***
- ***Make sure that the plus and minus poles are correctly aligned.***
- ***Never use batteries that are leaky, deformed, discolored or otherwise abnormal.***
- ***Dispose of old batteries according to local codes and regulations.***
- ***In case of battery leakage, carefully dry the battery terminals and remove all of the leaked liquid. Replace the battery with a new one.***

* Overheating could result if the above conditions are not adhered to.
* The three AA alkali dry cells used for this device will last for about 100 hours of use. (This equals 6 to 12 months at normal rates of usage.)

7. Reproccessing

There are two ways to perform reprocessing depending on the items.

Parts to be Sterilized

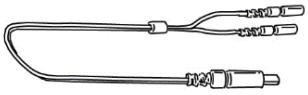


File Holder

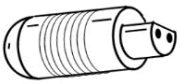
Contrary Electrode

Long File Holder (option)

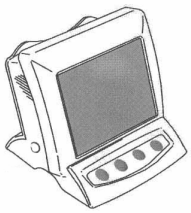
Parts to be Disinfected



Probe Cord



Tester



Canal Measurement Module

⚠WARNING

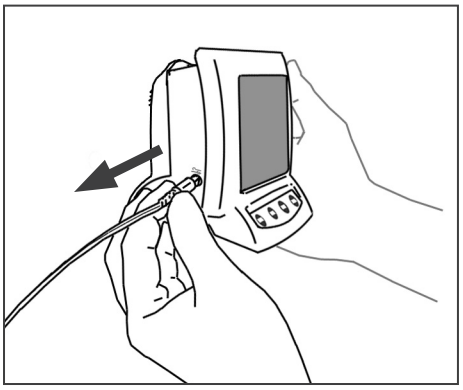
- ***Be careful to avoid cross infection when performing reprocessing.***
- ***Always wear personal protective equipment (PPE) such as safety glasses, gloves, a mask, etc. when performing the reprocessing procedures.***

⚠CAUTION

- ***When performing reprocessing, always turn off the device and make sure that the device will not operate.***
- ***Be careful when clipping and unclipping files to avoid injury to fingers.***

After use, perform reprocessing promptly.
Before reprocessing, make sure that all the parts (e.g., file, file holder, etc.) are separated individually.

■ Preparation

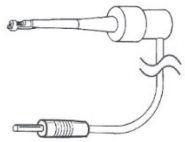


Turn off the power.
Disconnect all parts.

Parts to be Sterilized

∗Be sure to perform the reprocessing procedures in the following order promptly after use with each patient.

Pre-treatment → **Cleaning & Disinfection** → **Packaging** → **Sterilization**


File Holder


Contrary Electrode


Long File Holder (option)

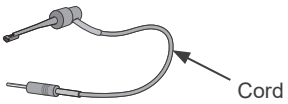
⚠WARNING

- ***To prevent the spread of infections, be sure to perform the reprocessing procedures after use with each patient.***

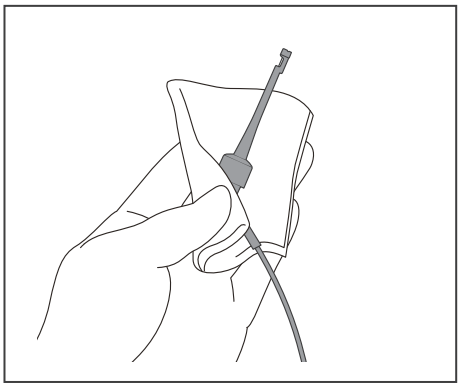
Pre-treatment

This must be performed after use with each patient.

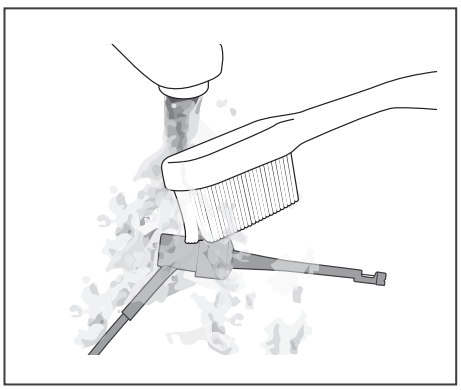
- ***After use, perform reprocessing promptly. If the parts are left contaminated with blood, it will be difficult to remove.***
- ***Do not use any chemicals that may coagulate proteins before cleaning.***
- ***If a medical agent being used for the treatment has adhered to the part, wash it off under tap water.***
- ***Be careful not to tug on the cord when you clean the file holder. This could cause the wire to break.***


Cord

- ***Do not clean the parts with an ultra sonic cleaning device.***



Wipe the parts with a piece of gauze or microfiber cloth (e.g., Toraysee for CE - Medical Equipment and Instruments Maintenance Cloth) that has been dampened with tap water to remove visible contaminants.



Alternatively, clean the parts in running water with a soft brush to remove visible contaminants.

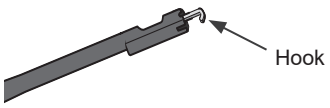
Cleaning & Disinfection

⚠ WARNING

- ***If any moisture is left inside the parts after cleaning, it could cause corrosion or poor sterilization. Also, the remaining water may come out during use. After cleaning, use a syringe or compressed air to expel remaining moisture.***

⚠ CAUTION

- ***Dust and other impurities adhering to the file holder's electrical contacts or hook can cause the device to malfunction.***

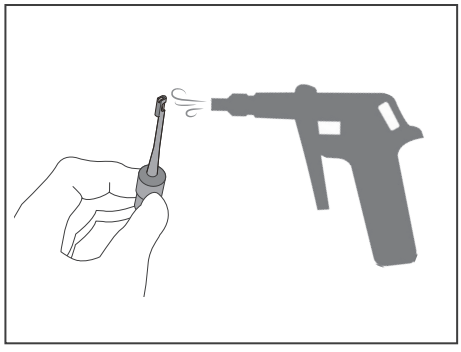


- ***Be sure to remove visible contaminants before this step.***
- ***Be sure to use washer-disinfectors that conform to ISO 15883-1 (must be capable of achieving disinfection values of not less than $A_0 = 3000$).***
- ***If your region is susceptible to hard water scale buildup, use deionized water (ion-exchanged water).***
- ***For details on handling detergents and neutralizers, concentration, water quality as well as parts washing baskets, refer to the accompanying user manual for the washer-disinfector.***
- ***Inappropriate cleaning methods and solutions may damage the parts.***
- ***Do not use strong acidic or alkaline chemicals that could cause the metal to corrode.***
- ***Do not start drying when the interior of the part is filled with water. Otherwise, this could result in corrosion of the part due to condensation of the rinsing solution.***
- ***After completing the cleaning process, expel remaining moisture inside the parts with compressed air.***
- ***Do not leave the parts in the washer-disinfector. This may cause corrosion or malfunction of the parts.***
- ***Parts' surface may get scratched and wear out during the cleaning process due to contact with the parts washing basket or other parts. Replace the parts as necessary depending on degree of scratches and wear.***

Recommended Conditions for Washer-Disinfectors

Unit Name	Miele G7881
Mode	Vario TD
Detergent (concentration)	neodisher MediClean (0.3% to 0.5%)
Rinse (concentration)	neodisher MediKlar (0.02% to 0.04%)

After cleaning there may be streaks or white spots on the parts. Use a neutralizer only if there are streaks or white spots.



Put parts in the parts washing basket.

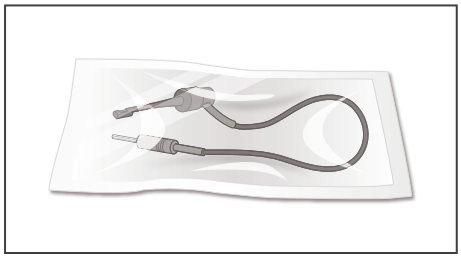
Select the washer-disinfector's mode as shown in the chart and start the process.

After completing the cleaning process, make sure the parts are thoroughly clean.

Expel remaining moisture on the surface or inside the parts with compressed air.

Packaging

- ***Use sterilization pouches that conform to ISO 11607.***
- ***Do not use any sterilization pouches that contain hydrosoluble adhesive ingredients such as PVA (polyvinyl alcohol). Note that even ISO 11607 conformable sterilization pouches may contain PVA.***
- ***When placing a part in a sterilization pouch, be sure not to put stress on the part (e.g., cord).***



Place the parts individually in a sterilization pouch.

Sterilization

⚠ WARNING

- ***To prevent the spread of infections, the parts must be autoclaved after each patient's treatment has been completed.***

⚠ CAUTION

- ***Parts are extremely hot right after autoclaving. Wait for them to cool off before touching.***

- ***Do not sterilize the parts by any method other than autoclaving.***
- ***If chemical solutions or foreign debris are not removed, autoclaving could damage or discolor the part. Thoroughly clean and disinfect the parts before autoclaving.***
- ***The setting temperature for sterilization and drying process must be +135°C (+275°F) or lower. If the temperature is set at beyond +135°C (+275°F), it may cause a malfunction owr stain on the parts.***
- ***Do not autoclave any parts other than the file holder, contrary electrode, and Long File Holder (option).***
- ***Take the file out of the file holder before autoclaving.***
- ***Follow the manufacturer's recommendations for autoclaving files.***
- ***After completing the autoclaving process, do not leave the parts in the autoclave.***

Recommended Autoclave Settings

Sterilizer Type	Temperature	Time	Drying Time after Sterilization
Dynamic Air Removal	+134°C (+273.2°F)	3 minutes	10 minutes
	+134°C (+273.2°F)	5 minutes	
Gravity	+134°C (+273.2°F)	min. 6 minutes	min.10 minutes
	+121°C (+249.8°F)	min. 60 minutes	

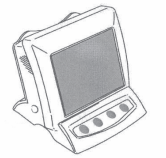
Autoclave the autoclavable parts.

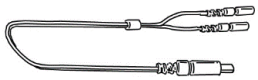
After autoclaving, store the parts in a clean and dry environment.

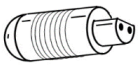
Parts to be Disinfected

∗Be sure to perform reprocessing procedures in the following order promptly after use with each patient.

Pre-treatment → **Cleaning & Disinfection**


Canal Measurement Module

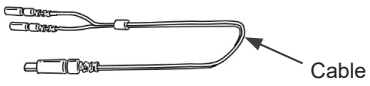

Probe Cord


Tester

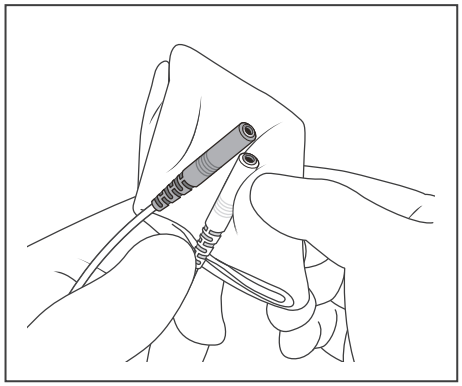
Pre-treatment

This must be performed after use with each patient.

- ***After use, perform reprocessing promptly. If the parts are left contaminated with blood, it will be difficult to remove.***
- ***Do not use any chemicals that may coagulate proteins before cleaning.***
- ***If a medical or adhesive agent being used for the treatment has adhered to the part, immediately remove it with a piece of gauze or microfiber cloth (e.g., Toraysee for CE - Medical Equipment and Instrument Maintenance Cloth) that has been dampened with tap water.***
- ***Be sure not to tug on the cable when you clean the parts. This could cause the wire to break.***



- ***Do not clean the parts with an ultra sonic cleaning device.***
- ***Do not wet the electrical contacts.***



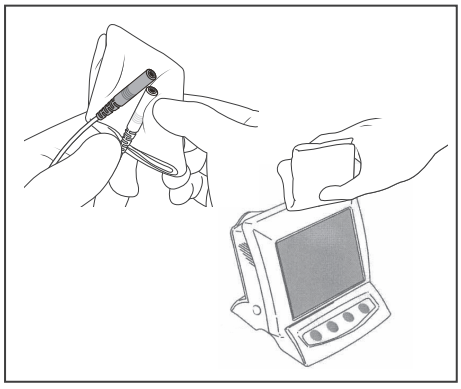
Wipe the parts with a piece of gauze or microfiber cloth (e.g., Toraysee for CE - Medical Equipment and Instruments Maintenance Cloth) that has been dampened with tap water to remove visible contaminants. Then wipe off moisture completely with a soft cloth.

Cleaning & Disinfection

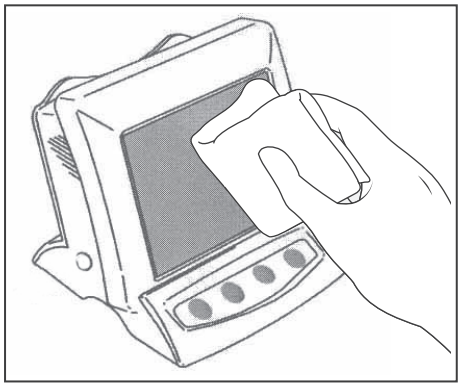
- ***Make sure that there is no visible moisture and contamination when wiping the parts.***
- ***Be sure not to tug on the cable when you clean the parts. This could cause the wire to break.***
- ***Do not use disinfectants other than those designated by J. MORITA MFG. CORP.***
- ***For details on handling disinfectants, refer to the accompanying user manual for each disinfectant.***
- ***If too much disinfectant is applied to the piece of gauze or microfiber cloth, it will seep into the part and cause a malfunction.***
- ***Do not immerse the parts in or wipe them with any of the following: functional water (acidic electrolyzed water, strong alkaline solution, and ozone water), medical agents (glutaral, etc.), or any other special types of water or commercial cleaning liquids. Such liquids may result in metal corrosion or adhesion of the residual medical agent to the parts.***
- ***Do not clean or immerse the parts with chemicals such as formalin cresol (FC) and sodium hypochlorite. These will damage the metal and plastic parts. Immediately wipe away any chemicals that are accidentally spilled on the parts.***

Disinfectants Approved by J. MORITA MFG. CORP.

Disifectant
FD333 forte (wipes)



Wipe the part’s surface with disinfectants approved by J. MORITA MFG. CORP.
(Except for the LCD display’s clear cover.)



How to Clean the LCD Display's Clear Cover

To avoid scratching the surface, gently wipe the cover with a soft microfiber cloth (e.g., eyeglass cloth).
If there is dirt that is hard to remove, use a soft cloth that has been dampened with water or lukewarm water and wrung out thoroughly. Then wipe off moisture completely.

8. Replacement Parts, Transport and Storage Environments

Replacement Parts

* Replace parts as necessary depending on degree of wear and length of use.
* Order replacement parts from your local dealer or J. MORITA OFFICE.

Transport and Storage Environments

Temperature: -10°C to +45°C (+14°F to +113°F)
Humidity: 10% to 85% (without condensation)
Atmospheric Pressure: 70 kPa to 106 kPa

* Store the unit where it will not be exposed to X-rays or direct sunlight.
* If the unit has not been used for a long time, make sure it works properly before use.
* Always remove the batteries prior to storing or shipping the unit.

9. Inspection

Regular Inspection

* This device should be inspected every 6 months in accordance with the following maintenance and inspection items.

Maintenance and Inspection Items

1. Check that the Power switch turns the device on and off properly.
2. Insert the Tester and check that the indicator is within ±3 lines of 1 on the meter.
3. Check that the Mode switch changes the memory from M1 to M2 to M3 etc.
4. Check that the Select and Set switches work properly.
5. Check that the probe cord can be properly plugged into its jack.
6. Check that the file holder's plug can be connected properly to the probe cord and that the file holder can be clipped onto a file. Check the contrary electrode can be plugged into its probe cord connector.

Parts Lists

Component	Description	When
Probe Cord	Probe Cord Assembly	Defective conductivity
File Holder		
Contrary Electrode		

10.Troubleshooting

If the device does not seem to be working properly, the user should first try to inspect and adjust it himself.

* If the user is unable to inspect the instrument himself or if the instrument fails to work properly after being adjusted or after parts are replaced, contact your local dealer or J. MORITA OFFICE.

Problem	Check Points	Response
No power	Check battery installation.	Install batteries properly.
	Check battery power.	Replace batteries.
Cannot make a Measurement.	Is the contrary electrode properly hooked in the corner of the patient's mouth?	Hook it in the corner of the patient's mouth.
	Check cord connections.	Check that all connections are properly secured.
	Check probe cord for broken wire.	Touch the contrary electrode to the file holder to check probe cord conductivity.
No alarm sound	Check if sound is turned off.	Turn the sound on.
Cannot switch memories	Is a measurement being performed?	Switches do not work during taking measurement.
Cannot change memory settings	Does the switch work?	Switch may be broken.
Display does not appear.	Is there a sound when the unit is turned on and off?	Replace batteries if there is no sound. Broken display if there is a sound.
Canal Length Indicator is unstable.	Is contrary electrode making good contact with oral mucosa?	Make sure the contrary electrode makes good contact with the oral mucosa.
	Is the file holder dirty?	Clean the file holder with disinfectant.
Canal Length Indicator overreacts or is too sensitive. (Measurements are too short. Poor accuracy. Erratic results.)	Is blood or saliva overflowing from the opening of the crown?	If blood or other fluids overflow the canal, the current will leak to the gums and the meter will jump to Apex. Clean the canal, canal opening and tooth crown thoroughly.
	Is the canal filled with blood, saliva or chemical solutions?	The canal length indicator bar may suddenly swing when it breaks the surface of fluids inside the canal, but it will return to normal as the file is advanced down toward the apex.
	Is the tooth surface covered with cutting debris or chemical solutions?	Clean entire tooth surface.
	Is the file touching the gingival tissue?	This will cause the canal length indicator bar to suddenly jump all the way to the "APEX".
	Is there pulp tissue left inside the root canal?	Accurate measurements cannot be obtained if a large amount of pulp tissue is left inside the root canal.
	Is the file touching a metal prosthesis?	Touching a metal prosthesis with the file allows a flow of current to the gingival tissue or periodontal pocket and will cause the meter to jump to the "APEX".
	Are proximal surfaces infected with caries?	Current can flow through the caries infected area to the gums and prevent an accurate measurement from being made.

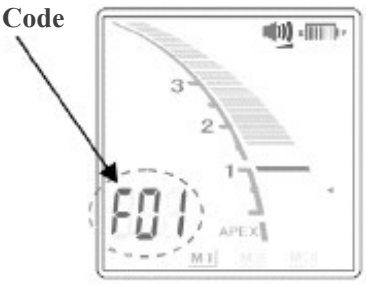
Problem	Check Points	Response
Canal Length Indicator overreacts or is too sensitive. (Measurements are too short, poor accuracy or erratic results.)	Are there lateral canals or is the tooth fractured?	The canal length indicator bar may jump to “APEX” when it reaches the opening of a lateral canal or the opening of a fractured tooth that allows the current to flow to the gingival tissue.
	Does a broken crown allow leakage of electric current?	Build up an insulating barrier to stop the leakage.
	Is there a lesion at the apex?	A lesion can destroy the apical foramen through absorption and an accurate measurement cannot be obtained.
	Is the file holder broken or dirty?	Replace or clean the file holder.
Canal Length Indicator does not move at all or only when the file tip is close to the apical foramen.	Is the canal blocked?	Open the passage all the way through the apical constriction first and then take the measurement.
	Is the apical foramen very large and open?	If the apical foramen is large or wide open and not completely formed, the canal length indicator bar will suddenly jump when the file tip gets close to the apex.
	Is the canal extremely dry?	Moisten the canal with oxydol or a saline solution.

■ **Error Code**

There may be something wrong with the instrument if any of the following error codes appear. If any of these appear repeatedly, contact your local dealer or J. MORITA OFFICE for repairs.

Code*	Cause	Module	
		Measurement	Preparation and Light
F01	Defective canal measurement circuit	○	
F02	Defective off relay for the AC adapter		○
F03	Defective EEPROM	○	○
F04	Transmission Defect	○	○
F07	Defective Thermistor (Open / Short)		○[*1]
F08	LED broken lead		○[*1]

***Error Code**



[*1]: Mainly a problem for the light cure handpiece.

11.Technical Specifications

Specifications

* Specifications may be changed without notice due to improvements.

Model	DP-ZX
Type	RCM-EX
Intended Use	The DP-ZX is intended to detect the apex of the root canal.
Operating Principle	The impedance in the root canal is measured by measuring at two frequencies and the position of the treatment instrument in the root canal is detected.
Degree of Protection	IPX0
Protection against Electric Shock	Internal powered ME equipment / Type BF Applied part
Essential Performance	None (There is no unacceptable risk.)
Rated Input Voltage	DC 4.5 V (three alkaline dry cells [LR6 “AA size” batteries])
Dimensions	Approx. Height 115 × Width 105 × Length 105 mm
Weight	Approx. 370 g
Applied Part	File holder, Contrary electrode
Expected Service Life	6 years

Symbols

* Some symbols may not be used.

UDI — Unique device identifier

MD — Medical device

Attention, consult accompanying documents.

SN — Serial Number

GS1 DataMatrix

Type BF applied part

Manufacturer

Date of manufacture

Direct current

Marking of electrical equipment in accordance with the European Directive 2012/19/EU (WEEE)

EU

Battery

This symbol is affixed to fulfill the requirements of EU Directive 2006/66/EC Article 21. Batteries provided with this equipment cannot be disposed of as unsorted municipal waste within the European Union. Follow local regulations for disposal.

CE 0197

CE(0197) marking

Conforms with the European Directive, 93/42/EEC.

CE marking

Conforms with the European Directive, 2011/65/EU.

135 ℃

Autoclavable up to +135°C (+275°F)

Refer to instructions for use

EC REP

EU Authorized Representative under the European Directive 93/42/EEC

Keep away from rain

This way up

Fragile

Temperature limitation

Atmospheric pressure limitation

Humidity limitation

CH REP

Authorized representative in Switzerland

Importer

Distributor

USA

EU

(Examples)

Country or region

(Country Names: Conforming to the ISO 3166-1 alpha-3 codes and EU for European Union)
Description noted next to the code is an indication that conforms to the regulations valid only for the relevant country or region.

12-3-4-5-6789012

Registration number of medical device in Thailand

(The 12-digit sample number shown is for demonstration purposes only.)

Disposal

The battery should be recycled. Metal parts of the device are disposed as scrap metal. Synthetic materials, electrical components, and printed circuit boards are disposed as electrical scrap. Material must be disposed according to the relevant national legal regulations. Consult specialized disposal companies for this purpose. Please inquire of the local administration concerning local disposal companies.

* For disposal of batteries in EU countries, refer to the above remarks concerning batteries. Inquire with the local dealer where the batteries or device were purchased for details concerning battery disposal.

Service

The DP-ZX may be repaired and serviced by:

- The technicians of J. MORITA's subsidiaries all over the world.
- Technicians employed by authorized J. MORITA dealers and specially trained by J. MORITA.
- Independent technicians specially trained and authorized by J. MORITA.

Electromagnetic Disturbances (EMD)

The DENTAPORT ZX (hereafter "this device") conforms to IEC 60601-1-2:2014 Ed. 4.0, the relevant international standard for electromagnetic disturbances (EMD).
The following is the “Guidance and Manufacturer's Declaration” which is required by IEC 60601-1-2:2014 Ed. 4.0, the relevant international standard for electromagnetic disturbances.

This is a Group 1, Class B product according to EN 55011 (CISPR 11).
This means that this device does not generate and/or use internationally radio-frequency energy, in the form of electromagnetic radiation, inductive and/or capacitive coupling, for the treatment of material or inspection/analysis purpose and that it is suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings use for domestic purposes.

<table>
<tr><th colspan="3">Guidance and Manufacturer’s Declaration – Electromagnetic Emissions</th></tr>
<tr><td colspan="3">This device is intended for use in the electromagnetic environment specified below.
The customer or the user of this device should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic Environment – Guidance</th></tr>
<tr><td>Conducted disturbance
CISPR 11</td><td>Group 1
Class B</td><td>This device 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.</td></tr>
<tr><td>Radiated disturbance
CISPR 11</td><td>Group 1
Class B</td><td rowspan="3">This device 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 current [*1]
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations and flicker
IEC 61000-3-3</td><td>Clause 5</td></tr>
</table>

[*1]: Although this device is not applicable to Harmonics test since the rated power is less than 75 W, it has been tested as a reference according to limits for Class A

⚠ WARNING

- ***The use environment of this device is the Home healthcare environment.***
- ***This device needs special precautions regarding EMD and needs to be installed and put into service according to the EMD information provided in the ACCOMPANYING DOCUMENTS.***
- ***Use of parts other than those accompanied or specified by J. MORITA MFG. CORP. could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.***
- ***Do not use this device as adjacent or stacked as possible with other.***
  When adjoining or stacking is necessary, use it after observing whether this device and other device work properly.
- ***Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the DP-ZX, including cables specified by the manufacturer.***

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device 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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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 transients/bursts IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines *1 ±1 kV for input/output line *1	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	AC/DC power ±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth Signal input/output ±2 kV line(s) to earth	AC/DC power ±0.5 kV, ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV, ±2 kV line(s) to earth Signal input/output *2 ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	dips 0% U_T: 0.5 cycle (at 0, 45, 90, 135, 180, 225, 270, 315°) 0% U_T: 1 cycle (at 0°) 70% U_T: 25/30 cycles (at 0°) 25 (50 Hz)/30 (60 Hz) short interruptions 0% U_T: 250/300 cycles 250 (50 Hz)/300 (60 Hz)	dips 0% U_T: 0.5 cycle (at 0, 45, 90, 135, 180, 225, 270, 315°) 0% U_T: 1 cycle (at 0°) 70% U_T: 25/30 cycles (at 0°) 25 (50 Hz)/30 (60 Hz) short interruptions 0% U_T: 250/300 cycles 250 (50 Hz)/300 (60 Hz)	Mains power quality should be that of a typical commercial or hospital environment. If user of this device requires continued operation during power mains interruptions, it is recommended that this device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (r.m.s.) 50 Hz or 60 Hz	30 A/m (r.m.s.) 50 Hz or 60 Hz	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE 1: U_T is the a.c. mains voltage prior to application of the test level. NOTE 2: r.m.s.: root mean square			

*[1]: This test is not applicable since the EUT signal cable is less than 3 m.

*[2]: Not applicable because it does not connect directly to outdoor cable.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
This device is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V ISM[c] / amateur radio frequency band: 6 V 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz 27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930, MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 5785 MHz	3 V ISM[c] / amateur radio frequency band: 6 V 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz 27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710, 745, 780 MHz 28 V/m 810, 870, 930, MHz 28 V/m 1720, 1845, 1970 MHz 28 V/m 2450 MHz 9 V/m 5240, 5500, 5785 MHz	Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distances $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 0.4\sqrt{P}$ 80 MHz to 800 MHz $d = 0.7\sqrt{P}$ 800 MHz to 2.7 GHz $d = \frac{6}{E}\sqrt{P}$ Portable wireless RF communication equipment Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, E is the compliance level in V/m and d is the recommended separation distance in meters (m). Field strengths from field RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 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 ratio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicated 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 this device is used exceeds the applicable RF compliance level above, this device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting of relocating this device. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. [c] The ISM (Industrial, Scientific and Medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.			

Essential Performance

None

Cable List

No.	Interface(s):	Max. Cable Length, Shielding	Cable Classification
1.	AC Power Cable (TR-EX)	1.5 m, Un-shielded	AC Power Line
2.	DC Power Cable (TR-EX)	2.0 m, Un-shielded	DC Power Line
3.	Handpiece Cord (TR-EX)	1.5 m, Un-shielded	Signal Line (Patient-Coupled cable)
4.	Foot Pedal Cable (TR-EX)	1.9 m, Un-shielded	Signal Line
5.	Probe Cord (RCM-EX)	1.6 m, Un-shielded	Signal Line (Patient-Coupled cable)

Diagnostic and Imaging Equipment

Treatment Units

Handpieces and Instruments

Endodontic Systems

Laser Equipment

Laboratory Devices

Educational and Training Systems

Auxiliaries

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