



Root ZX3

INSTRUCTIONS FOR USE

Apex Locator Module



Thinking ahead. Focused on life.

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Thank you for purchasing the Root ZX3.

For optimum safety and performance as well as to avoid causing harm to people, read this user manual thoroughly before using the device and pay close attention to warnings and cautions. Keep this user manual in a readily accessible place for quick and easy reference.

* The device is the apex locator module dedicated to the Root ZX3. This device can add a HF module (sold separately) for high-frequency current treatment in addition to the apex location function.



Instructions for Use in Electronic Format (eIFU)

The electronic data (PDF document) of the Instructions for Use is available. Scan the following QR code and visit our website.



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1 Introduction

1.1 Customers

Make sure to obtain clear instructions concerning the various ways to use this device described in this accompanying user manual. Fill out and sign the warranty and give a copy to the dealer from whom you purchased the instrument.

1.2 Dealers

Be sure to give clear instructions concerning the various ways to use this device as described in this accompanying user manual. After instructing the customer in the operation of the device, have the customer fill out and sign the warranty. Then fill in your own section of the warranty and give the customer their copy. Be sure to send the manufacturer's copy to J. MORITA OFFICE.

1.3 Preventing Accidents

Most operation and reprocessing problems result from insufficient attention to basic safety precautions and not being able to foresee potential accidents. Problems and accidents are best avoided by foreseeing the possibility of danger and operating the unit 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.

Do not use the Root ZX3 for purposes other than its specified intended use in dental treatment.

The following symbols and expressions indicate the degree of danger and harm that could result from ignoring the corresponding instructions:

This indicates contraindications, related descriptions with operation and usage, as well as patients to whom this should not be applied due to their symptoms, underlying conditions, complications, anamnestic history, family history, or diathesis.

MWARNING

This alerts the user of the possibility of extremely serious injury or complete destruction of the device, as well as other property damage including the possibility of fire.

This alerts the user of the possibility of minor or moderate injury or damage to the device.



This informs 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 devices.

This device must not be used by anyone other than dentists, doctors, or other legally licensed professionals.

1.4 Disclaimer

J. MORITA MFG. CORP. will not be responsible for accidents, product damage, or bodily injury resulting from:

- (1) Repairs made by personnel not authorized by J. MORITA MFG. CORP.
- (2) Any changes, modifications, or alterations of its products.
- (3) The use of products made by other manufacturers, except for those produced by J. MORITA MFG. CORP.
- (4) Maintenance or repairs using parts or components other than those specified by J. MORITA MFG. CORP. and other than in their original condition.
- (5) Operating the device in a manner other than described in the operating procedures in this user manual or in a manner inconsistent with the safety precautions and warnings in this user manual.
- (6) Workplace, environmental, or installation conditions that do not conform to those stated in this user manual, such as an improper electrical power supply.
- (7) Fires, earthquakes, floods, lightning, natural disasters, or forces majeure.

1.5 In Case of Accident

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

2 Precautions

APROHIBITION

- Do not use this device on patient who has implanted a pacemaker or ICD (Implantable Cardiac Defibrillator). (May cause pacemakers and ICDs to malfunction.)
- Do not use this device simultaneously with any other electrosurgical unit (hereafter "high-frequency treatment device"). Otherwise, it may result in burns due to high-frequency leakage, or malfunction by mutual interference.

WARNING

- · No modification of this device is allowed.
- Do not add in or connect this device to any other devices or systems except products designated by J. MORITA MFG. CORP.
- Do not use the wireless transmission devices listed below in the patient examination area. Electromagnetic interference from such devices could cause the Root ZX3 to malfunction.
 - (1) Mobile phones and smart devices
 - (2) Wireless transmitting devices such as ham radios, walkie-talkies, and transceivers
 - (3) Personal Handy-phone System (PHS)
 - (4) Routers for intra-building paging systems, wireless LANs, analog cordless telephones, and other electric wireless devices
- Electromagnetic emissions produced by electric scalpels, lighting equipment, or other devices being used nearby could adversely affect the Root ZX3 operation.
- Do not perform maintenance while using this device for treatment.
- Always wear personal protective equipment (PPE) such as safety glasses, gloves, a mask, etc. when using and reprocessing this device.

3 Intended Use

3.1 Intended Purpose

Locate the apex inside the canal.

3.2 Indications for Use

The Root ZX3 device is a dental device with an apex locating function and an optional electrosurgical function and is composed of the aforementioned corresponding modules.

The apex locating function of Root ZX3 device is used for root canal measurement and working length determination.

3.3 User Qualifications (Intended Operator Profile)

a) Qualification:

Legally qualified person such as dentists for endodontic device operation (it may differ among countries).

b) Education and Knowledge:

Have a good understanding of risks associated with root canal treatment.

It is also assumed the user is thoroughly familiar with root canal treatment including the prevention of cross-infection.

c) Language Understanding:

English and local language (Intended for professional use as described above.)

d) Experience:

Person with experience operating endodontic devices.

No special training is required except in cases where this is required by legal regulations of the relevant country or region.

3.4 Patient Population

ACAUTION

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

· Pay close attention to the patient during treatment with this device.

Age : Child (12 or older) to Elderly

Weight : Not applicable

- Nationality : Not applicable
- Sex : Not applicable

Condition : Conscious and mentally alert person. (Person who can stay still during treatment.)

3.5 Intended Environment

This device is used in general dental clinics and hospitals (= Professional healthcare facility environment), and the following environment is assumed:

Non-sterile environment

- Normal room lighting
- · Low-noise environment in which the sound emitted by this device is audible

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

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

Do not expose the device to direct sunlight for an extended period of time.

If the device has not been used for some time, make sure it works properly before using it again.

Always remove the dry batteries prior to storing or shipping the device.

3.6 Contraindications, Warnings, and Considerations

• Do not use this device on patient who has implanted a pacemaker, ICD (Implantable Cardiac Defibrillator), or artificial cochlear.

3.7 Supposed Useful Life

The useful life of the Root ZX3 is 6 years from the date of installation provided it is regularly and properly inspected and maintained.

4 Parts Identification and Display Screens

4.1 Parts Identification



Components



Optional Items (sold separately)



4.2 LCD Display and Switches

LCD Display





5 Usage

5.1 Set Up

Check the followings before using the Root ZX3.

- Have the autoclavable parts been autoclaved? For details of autoclavable parts; 🗊 p. 28 "5.4.1 Parts to be Sterilized"
- Have the disinfectable parts been disinfected? For details of disinfectable parts; [p. 31 "5.4.2 Parts to be Disinfected"
- Does the battery power indicator show sufficient remaining power?

5.1.1 Install the Dry Batteries.

- Do not leave the power on when installing or replacing dry batteries.
- Always observe the following points. Otherwise, dry battery may generate abnormal heat.
- When the battery power indicator displays only one bar, replace all the dry batteries with new ones.
- Use alkaline dry batteries (AA size). Zinc–carbon batteries and nickel-metal hydride batteries can be used, but the device available time will be shortened compared to the alkaline dry batteries. Do not use any other type of batteries.
- When replacing dry batteries, change all four batteries with new ones of the same manufacture and model.
- When replacing dry batteries, make sure that the polarity direction (positive/negative) is correct.
- Do not use any defective (i.e., leaky, deformed, discolored, etc.) dry batteries.
- If a battery leaks, wipe the liquid thoroughly from the dry battery housing and replace all the dry batteries with new ones.

Dispose of the used dry batteries in accordance with the regulation of your local government.

Do not drop the Root ZX3 or give a strong impact on it. These could result in malfunction or damage to the device. * Dry batteries are removed from the device prior to shipment.

Install accompanied four alkaline dry batteries (AA size).

* Normal device available time with four alkaline dry batteries (AA size) is approximately six months. However, higher LCD brightness settings may drain battery power faster.

When dry batteries run out, a beep sounds, the message "LOW BATTERY" displays, and the device will turn off automatically.

Replace all the dry batteries with new ones immediately.

Battery Power Indication



1 Remove the Dry Battery Housing.



2 Install the Dry Batteries.

Do not reverse the polarity direction (positive/negative).



3 Reinstall the Dry Battery Housing.



5.1.2 Probe Cord Connection

Connect the probe cord to the device.

ACAUTION

• Make sure that the plug is inserted all the way. If the plug is improperly connected, the device may not work correctly.

Avoid strong impacts to the connection.





1 Plug

2 Connection Port

3 Probe Cord

Connect the file holder and contrary electrode. 2

ACAUTION

• Connect the file holder and contrary electrode onto the probe connectors correctly. Accurate apex location cannot be obtained if there are reversed.









5.1.3 Operation Check

· Check the Root ZX3's functionality before use with each patient.





2 Turn on the device.

() When only one bar (🛄) is displayed, replace all the dry batteries with new ones.



Touch the contrary electrode with the file holder contact. 3



Check the LCD display. Δ

• If all the apex location indicator bars do not light up, accurate canal location cannot be obtained. Stop using the device immediately and have it professionally repaired.



Confirm the following points:

- All the apex location indicator bars are lit up.
- "Over", "Apex", and "
- · A continuous beep sounds.

5.2 Usage

* Example of operation with setting the flashing bar at 0.5 meter reading.

5.2.1 Apex Location

- Do not use the Root ZX3 together in conjunction with an ultrasonic scaler. Otherwise, the apex location might not be accurate.
- While using the device, if the LCD display is unstable or the device turns off on its own (except the auto power off function), stop using the device immediately and have it professionally repaired.

Turn on the device.

p. 17 "2 Turn on the device."

2 Select a memory number.

ACAUTION

• Always check the settings of the selected memory before use.



* For more details on memory settings: [Solar p. 33 "How to Modify Various Settings"

3 Hook the contrary electrode.

MWARNING

• Never place the contrary electrode, file holder, or other connection parts in contact with a power source (e.g., power outlet). You could get an electric shock.

- 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 or sodium hypochlorite do not get on the contrary electrode or the file holder. These could cause inflammation of tissues.
- If connections are not securely plugged in the device, it may not accurately locate the apex. If the meter does not change as the file goes down the canal, stop using the device immediately and make sure all the connections are securely inserted.



* Make sure that the contrary electrode touches patient's oral mucosa.

4 Clip the file.

WARNING

- · Do not use worn or bent files or reamers.
- Make sure that the file or reamer is properly clipped. If it is loose, the file or reamer could come off and injure the patient.
- Always use a rubber dam to prevent accidental swallowing of files, reamers, etc.

ACAUTION

- · Files and reamers are sharp; handle with care.
- Use a file or reamer with a plastic handle and be sure not to touch its metal part. If you do not wear gloves, electricity flows through the metal part to your fingers and accurate apex location cannot be obtained.
- Do not use damaged file holders. Otherwise, accurate apex location cannot be obtained.

Clip the file holder onto the metal upper part of the file or reamer (close to the handle). Do not clip it onto the cutting part or transition part of the file or reamer. This will cause the file holder contact and plastic to wear out very quickly.



O Push Button

2 File Holder4 Cutting and Transition Parts

• Do not clip a file or reamer as shown in figure 2. Otherwise, an accurate apex location cannot be obtained and the tip of the file holder will be damaged.



D Perform apex location.

MARNING

- Stop using the device immediately if it does not seem to be working properly.
- Since files and reamers can easily break due to metal fatigue and excessive load, do not use excessive force to insert them. It may result in digging into the canal and breaking the file or reamer.

- Accurate apex location may not always possible, it depends on tooth condition, case complexity, as well as degradation of the device. Make sure to take an X-ray to check the results.
- Est p. 24 "5.2.3 Root Canals Not Suitable for Electric Apex Location"
- If none of the apex location indicator bars appear even when the file is inserted, the device may be malfunctioning. Stop using the device immediately and contact your local dealer or J. MORITA OFFICE.
- Do not touch the gums with the file. Otherwise, an accurate apex location cannot be obtained.
- If the canal is too dry, the meter may not move until the file is near the apex. If the meter does not move, stop the operation. Moisten the canal with oxydol (hydrogen peroxide) or saline, and then try to perform apex location again.
- After apex location, make sure to take an X-ray to check the results.
- * The meter may 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.
- * When the probe cord or connector is disconnected, the apex location will stop working.



Message Indicator

Flash Bar

The message indicator shows how many apex location indicator bars there are until the flash bar.



Flash Bar 0.5 Meter Reading

Advance the file down the canal to the 0.5 meter reading point (<). Then position a rubber stopper on the surface of the tooth or other suitable point to serve as a reference.

• 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 as a reference to deter-

mine the working length.

When the apex location indicator bars exceeds the flash bar, the message indicator displays "OVER" with a blink. Also, the flash bar and "<" (0.5 meter reading) blink and continuous beep sounds.



6 Turn off the device.



Auto Power Off
 If switches are not used for 10 minutes (default setting), the device will automatically turn off.
 Example p. 37 "Auto Power Off Time"

5.2.1.1 LCD Display and Speaker Sound during Apex Location

The location of the file tip inside the canal is shown by the apex location indicator bars. The speaker sound will change according to the position of the apex location indicator bars.

This section describes the changes when the flash bar is set to FB.30 (the 30th apex location indicator bar from the top).

The apex location indicator bar in range between 0 and 19th. (Until one bar before the meter reading 2.)
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No sound. The flash bar blinks.

 The apex location indicator bar in range between 20th and 27th. (From meter reading 2 until one bar before the meter reading 1.)



A slow tempo tone sounds. The flash bar blinks.

 The apex location indicator bar in range between 28th and the bar one bar before the flash bar.



A fast tempo tone sounds. The flash bar blinks.

• The apex location indicator bars reach the flash bar.



Flash Bar (FB.30)

A continuous tone sounds. The flash bar stays on. • The apex location indicator bars exceed the flash bar.



Flash Bar (FB.30)

A continuous tone sounds. "OVER" and the flash bar blink. • The apex location indicator bars reach the Apex position.



A continuous tone sounds.

"OVER", "Apex", the flash bar, and "◀" (0.5 meter reading) blink.

- * Even if the apex location indicator bars exceed the Apex, a continuous tone sounds and "OVER", "Apex", the flash bar, and "◄" (0.5 meter reading) blink.
- The apex location indicator bars reach the 0.5 meter reading.



A continuous tone sounds. "OVER", the flash bar, and "◄" (0.5 meter reading) blink.

5.2.2 Apex Location Accuracy Manual Check

Press the function switch.



2 Accuracy check starts.



3 The result message is displayed.



If the accuracy of the apex location is within the criteria, "OK" will be displayed. Then the display returns to the apex location screen automatically.

If "ERR.0" is displayed, the apex location was not accurately confirmed. Stop using the device immediately and contact your local dealer or J. MORITA OFFICE.



5.2.3 Root Canals Not Suitable for Electric Apex Location

Root Canals not suitable for Root ZX3.

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 (①) 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 some 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 Root ZX3 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 (2) such as cement, to insulate the gingival tissue.



Fractured tooth Leakage through a branch canal

A fractured tooth (③) will cause electrical leakage and accurate apex location cannot be obtained. A branch canal (④) will also cause electrical leakage and accurate apex location cannot be obtained.



<u>Re-treatment of a root filled with</u> gutta-percha

The gutta-percha () must be completely removed to eliminate its insulating effect. After removing the gutta-percha, 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 Root ZX3 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 so that the file or reamer will not touch the metal prosthesis () before performing the apex location.



Cutting debris on tooth Pulp inside canal

The Root ZX3 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 so that the file or reamer will not touch the metal prosthesis (③) before performing the apex location.

Caries touching the gums

In this case, electrical leakage through the caries infected area to the gums (**②**) will make it impossible to obtain an accurate apex location.

Blocked canal

The meter will not move if the canal is blocked (\mathbf{I}) .

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.

4

Root ZX3 Meter Reading and Radiography

Sometimes the Root ZX3 meter reading and the X-ray image will not correspond.

This does not mean that the Root ZX3 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 to the above, the actual apex for the canal is not the same as that for 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.

5.3 After Use

1 Turn off the device.

p. 20 "6 Turn off the device."

2 Unclip the file.

ACAUTION

• Be careful when clipping and unclipping files to avoid injury to fingers.



3 Disconnect the probe cord.

Do not wind the probe cord around the device.



Correct



Incorrect



5.4 Reprocessing

Even items designed to be reusable may need to be treated as single patient use or single use and disposed of. Use in accordance with the laws and local regulations of the country or region in which it is used.

Hygiene Plan Guidebook

A reference guidebook of hygiene information about our products is available. Scan the following QR code and visit our website.



In order to view PDF documents, you will need the free Adobe Acrobat Reader distributed by Adobe Inc. Download the latest version via the Adobe website. PDF documents may not be displayed correctly using previous versions.

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



WARNING

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

ACAUTION

- 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



5.4.1 Parts to be Sterilized

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



necessary depending on degree of scratches and wear.



Recommended Conditions for Washer-Disinfectors

Unit Name	Miele G7881
Mode	Vario TD (cleaning time: 5 minutes)
Detergent	neodisher MediClean
(concentration)	(0.3% to 0.5%)
Rinse	neodisher MediKlar
(concentration)	(0.03% to 0.05%)

* 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 table above 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.

Packing

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. Use only FDA-cleared pouches. (Only for U.S.A.)

4 Sterilization

MWARNING

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

ACAUTION

- 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 or stain on the parts.
- Do not autoclave any parts other than the file holder and contrary electrode.
- 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

Country: U.S.A.

Sterilizer Type	Tempera- ture	Time	Drying Time after Sterilization
Crowity	+132°C (+269.6°F)	15 minutes	1E minutos
Gravity	+121°C (+249.8°F)	30 minutes	15 minutes

Country: Other than U.S.A.

Sterilizer Type	Tempera- ture	Time	Drying Time after Sterilization	
Dynamic Air	+134°C (+273.2°F)	3 minutes	10 minutes	
Removal	+134°C (+273.2°F)	5 minutes		
Crovity	+134°C (+273.2°F)	Min. 6 minutes	Min. 10 minutes	
Gravity	+121°C (+249.8°F)	Min. 60 minutes		

Autoclave the autoclavable parts.

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

5.4.2 Parts to be Disinfected

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



Opti-Cide3 (wipes)

FD333 forte (wipes)

Other than

U.S.A.



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

6 How to Modify Various Settings

6.1 Memory Contents

6.1.1 Editable Items and Default Settings

ACAUTION

• Always check the settings after changing the memory contents.

The flash bar position and speaker volume can be changed for each memory.

Editable Items

Item (displayed name)	Description
Flash Bar Position (FB.)	Indicates the position inside the root canal that provides a reference for the apex location.
Speaker Volume (VOL.)	Sound volume for switch operation and the indication of the file tip position inside the root canal.

Default Settings

The default memory settings are listed below. These settings can be changed as needed.

Item (displayed name)	M1	M2	M3
Flash Bar Position (FB.)		32 (0.5 meter reading)	
Speaker Volume (VOL.)		2	

6.1.2 Procedures

Turn on the device.





ACAUTION

• Always check the settings of the selected memory before use.



3 Select an editable item.



Hold down S more than 1 second to switch the display into flash bar position configuration screen.

Press S to switch the items.

FB. ∶Flash Bar Position ↓ VOL. ∶Speaker Volume

4 Change the settings.

• Flash Bar Position



The flash bar position can be set between meter gauge 2 (FB.20) and the Apex (FB.36).



Meter Gauge Display and Flash Bar Display

Meter Gauge Display	Flash Bar Display Value
2	FB.20
1	FB.28
0.5	FB.32
Арех	FB.36

• Speaker Volume



5 Complete configuration.



One of the following actions completes the change and the memory settings will be saved.

- Press Fn .
- Press 🕐 to turn off the device.
- * If any switches are not used for a defined period of time (standby screen return time), the device will save the changes.

6.2 Other Functions

Speaker tone, auto power off time, screen return time, and LCD brightness can be configured. These settings are common for all memories.

6.2.1 Editable Items and Default Settings

Item (displayed name)	Description	Default Setting
Speaker Tone (SPK.)	Select the tone for apex location. If there are multiple Root ZX3 units, you can set different tone for each unit.	SPK.1
Auto Power Off Time (AP.)	This sets the time it takes for the auto power off function to be triggered when no switches have been pressed.	AP.10
Screen Return Time (SR.)	This shows how long it takes for the device to exit the con- figuration screen if no switches have been pressed.	SR.10
LCD Brightness (LCD.)	The LCD display brightness can be changed.	LCD.2

6.2.2 Procedures





2 Select an editable item.



Press S to switch the items.



3 Change the settings.

• Speaker Tone



Select the tone for apex location.

SPK.1: A three-toned beep will sound. SPK.2: A continuous short beep will sound.

Auto Power Off Time



• Screen Return Time



• LCD Brightness







One of the following actions completes the change and the settings will be saved.

- Press Fn .
- Press 🕐 to turn off the device.
- * If any switches are not used for a defined period of time (auto power off time), the device will automatically turn it off and save the changes.

6.3 Resetting the Default Settings

All memories and other function settings will revert to their original default settings.

* This operation will affect all memories (M1, M2, M3) and other function settings. It is not possible to initialize just one of them.



While the device power is off, hold down \leq and press @.

"RST" is displayed.

1

2 Reset the memory settings.



 $\overset{\mathbb{V}}{\scriptscriptstyle{\rm A}}$ blinks and the initialization starts.



After approximately 2 seconds, the memory settings will reset and "FIN" will be displayed.

7 Troubleshooting

7.1 Troubleshooting

If the Root ZX3 does not seem to be working properly, the user should first try to inspect and adjust it themselves.

* If you cannot inspect the device yourself or if the device fails to work properly after being adjusted or after parts are replaced, contact your local dealer or J. MORITA OFFICE.

Symptoms	Check Points	Possible Cause / Remedies	Ref. Page
Cannot turn on the	Are the dry batteries installed properly?	Check the dry batteries' installation.	p. 14
device.	Is the battery power level low?	Replace all the dry batteries with new ones.	p. 14
The device turns off by itself.	Have you left the device unop- erated for a long time?	The auto power off function was triggered. Press the power switch to turn on the de- vice again.	p. 37
Display does not appear.	Is there a sound when the unit is turned on and off?	If there is no sound, replace all the dry bat- teries with new ones. If there is a sound but still no display after replacing the dry batteries, the LCD display may be broken.	N/A
No sound from the speaker.	Is the speaker volume set for "VOL.0"?	Set it for "VOL.1", "VOL.2", or "VOL.3".	p. 34
Cannot switch the memory number.	Is apex location being performed?	You cannot operate anything other than the power switch during apex location.	N/A
Cannot change the memory settings.	Does any switch work?	If it does not, it may be broken. Have the device professionally repaired.	p. 48
	Is the contrary electrode prop- erly hooked in the corner of the patient's mouth?	Hook it in the corner of the patient's mouth.	p. 18
Cannot perform	Are all cords properly connected?	Make sure all connectors are plugged in all the way.	p. 16
	Is a wire in the probe cord broken?	Touch the contrary electrode with the clip on the end of the file holder and check that all the apex location indicator bars on the meter in the LCD display light up.	p. 17
The display of the apex location indicator bars is	Does the contrary electrode properly touch the patient's mouth?	Adjust the contrary electrode position to touch the patient's oral mucosa properly so that the display stabilizes.	p. 18
uristadie.	Is the file holder dirty?	Wipe the file holder and clean it off.	p. 28

Symptoms Check Points		Possible Cause / Remedies	Ref. Page
	Does blood or chemical solu- tion overflow from the opening of the root canal, or does blood or chemical solution contact the gums?	If blood or chemical solution has overflowed from the root canal, or if it has adhered to a crown or cervical area, the meter will sud- denly light up all the way due to electrical shorting from the gums. In this case, clean the canal, crown, and cervical area.	p. 24
	Is the root canal filled with blood or chemical solution?	The meter suddenly will light up all the way when the file contacts with blood or chemi- cal solution. In this case, advancing the file down the root canal will resume the meter display in the correct position and the apex location can be obtained properly.	p. 24
	Does cutting debris or chemical solution remain on the tooth?	Throughly remove all cutting debris and chemical solutions from the tooth.	p. 24
The display of the apex location indi- cator bars makes	Is the file touching the gums?	This will result in electrical leakage and the apex location indicator bars light up all the way. Do not touch the gums with the file.	р. 19
ments as follows.	Does pulp remain inside the canal?	If significant pulp remains inside the ca- nal, an accurate apex location may not be obtained.	p. 24
Too shortInaccurateToo sensitive	Is the file touching a metal prosthesis?	This will result in electrical leakage and the apex location indicator bars light up all the way. Do not touch the metal prosthesis with the file.	p. 24
	Is there a caries?	Electrical leakage through the caries infect- ed area to the gums will make it impossible to obtain an accurate apex location.	p. 24
	Is there a branch or root fracture?	Branch's opening or root fracture could re- sult in electrical leakage to the periodontal membrane and displays the apex.	p. 24
	Is a large part of the crown bro- ken resulting in electrical leak- age to the gums? Is there a periapical lesion?	If there is a periapical lesion, physiological tissue is absorbed and accurate apex loca- tion may not be obtained. Build up the tooth with a suitable material to avoid electrical leakage to the gums.	p. 24
	Is the file holder broken?	Replace it with a new one.	p. 19
	Is the file holder dirty?	Clean it thoroughly.	ud- cal eanp. 24way eni- apexp. 24way eni- eni- apexp. 24dp. 24dp. 24dp. 19e.p. 24fect- siblep. 24fect- siblep. 24fre- ntalp. 24ical oca- tooth calp. 24ical oca- toothp. 24
The meter of the apex location indi-	Is it a blocked canal?	Open the canal all the way (patency) to the apical constriction.	p. 24
cator bars does not move.	Is the apical foramen open?	If the apical foramen is open or a tooth's apex is immature, the meter may make a sudden and large movement near the apex.	p. 24 p. 24 p. 19 p. 24 p. 24 p. 24 p. 24 p. 24 p. 24 p. 24 p. 24 p. 28 p. 24 p. 24 p. 24 p. 24 p. 24
(It moves only near the apex.)	Is the canal extremely dry?	Moisturize the inside of the canal with oxy- dol or saline.	p. 19

7.2 Error Numbers

If an error or problem is detected, the Root ZX3 will stop working, an error number will appear in the LCD display, and an alarm will sound.

Turn the device off and then back on again. If the error message appears again, stop using the device immediately and contact your local dealer or J. MORITA OFFICE.

Make a note of the error number as well as the device serial number and report it when requesting support.

Error No.	Problems	E
ERR.0	Apex location error	ſ
ERR.1	Apex locator module's memory error	
ERR.2	Speaker malfunction	
ERR.3	Communication error between the modules	
ERR.5	Battery power error	



8 Replacement Parts

8.1 Parts Replacement

* Replace the parts as necessary depending on degree of wear and length of use.

* Order parts from your local dealer or J. MORITA OFFICE.

* For instructions on how to replace the dry batteries; 1 p. 14 "5.1.1 Install the Dry Batteries."

Replacement Parts



Consumables



9 Electromagnetic Disturbances (EMD)

The Root ZX3 (Model: RZX3, hereafter "this device") conforms to IEC 60601-1-2 Edition 4.0, the relevant international standard for electromagnetic disturbances (EMD).

Use Environment

The use environment of this device is the PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT.

WARNING

- Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by us could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the RZX3, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.

Cable List

No.	Name	Cable Length, Shielding	SIP/SOP & In/Out Port Type
1	Probe Cord	1.9 m, Un-shielded	PATIENT-Coupled Cable

Compliance for Each EMISSIONS and IMMUNITY Standards

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1 Class B	This device uses RF energy only for its internal func- tion. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group 1 Class B	This device is suitable for use in all establishments, including domestic establishments and those direct- ly connected to the public low-voltage power supply
Harmonic emissions IEC 61000-3-2* ¹	N/A	network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3* ¹	N/A	

*¹ The test is not applicable since the EUT does not have AC power input ports.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic dis- charge (ESD) IEC 61000-4-2	<u>Contact</u> ±8 kV <u>Air</u> ±2 kV, ±4 kV, ±8 kV, ±15 kV	<u>Contact</u> ±8 kV <u>Air</u> ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidi- ty should be at least 30%.
Electrical fast transients/bursts IEC 61000-4-4	Power Supply Lines ±2 kV Input/Output Lines ±1 kV	Power Supply Lines ^{*1} ±2 kV Input/Output Lines ^{*2} ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	$\frac{\text{Input Power Ports}}{\pm 0.5 \text{ kV}, \pm 1 \text{ kV}}$ $\text{line(s) to line(s)}$ $\pm 0.5 \text{ kV}, \pm 1 \text{ kV}, \pm 2 \text{ kV}$ line(s) to earth $\frac{\text{Signal Input/Output}}{\pm 2 \text{ kV line(s) to earth}}$	$\frac{\text{Input Power Ports}^{*1}}{\pm 0.5 \text{ kV}, \pm 1 \text{ kV}}$ $\text{line(s) to line(s)}$ $\pm 0.5 \text{ kV}, \pm 1 \text{ kV}, \pm 2 \text{ kV}$ line(s) to earth $\frac{\text{Signal Input/Output}^{*3}}{\pm 2 \text{ kV line(s) to earth}}$	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* ¹	$\frac{\text{Dips}}{0\% U_{T}: 0.5 \text{ cycles (at}} \\ 0, 45, 90, 135, 180, 225, 270, 315°) \\ 0\% U_{T}: 1 \text{ cycle (at 0°)} \\ 70\% U_{T}: 25/30 \text{ cycle} \\ (at 0°) \\ 25 (50 \text{ Hz})/30 (60 \text{ Hz}) \\ \frac{\text{Short Interruptions}}{0\% U_{T}: 250/300 \text{ cycle}} \\ 250 (50 \text{ Hz})/300 (60 \text{ Hz}) \\ \end{array}$	$\frac{\text{Dips}}{0\% U_{T}: 0.5 \text{ cycles (at}} \\ 0, 45, 90, 135, 180, 225, 270, 315°) \\ 0\% U_{T}: 1 \text{ cycle (at 0°)} \\ 70\% U_{T}: 25/30 \text{ cycle} \\ (at 0°) \\ 25 (50 \text{ Hz})/30 (60 \text{ Hz}) \\ \frac{\text{Short Interruptions}}{0\% U_{T}: 250/300 \text{ cycle}} \\ 250 (50 \text{ Hz})/300 (60 \text{ Hz}) \\ \end{array}$	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires con- tinued operation during power mains interruptions, it is recommended that this device be powered from an unin- terruptible power supply or a battery.
Power frequency (50/60 Hz) mag- netic field IEC 61000-4-8	30 A/m (r.m.s) Select from 50 Hz, 60 Hz as required	30 A/m (r.m.s) 50 Hz and 60 Hz	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE 1: $U_{\rm T}$ 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 does not have power input pots.

*² This test is not applicable since the EUT signal cable is less than 3 m.

*³ Not applicable because it does not connect directly to outdoor cable.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance	
Conducted RF IEC 61000-4-6* ¹	3 V 0.15 MHz to 80 MHz 6 V ISM ^(c) bands between 0.15 MHz to 80 MHz	3 V 0.15 MHz to 80 MHz 6V ISM ^(c) bands between 0.15 MHz to 80 MHz	Portable and mobile RF communica- tions equipment should be used no closer to any part of this device, in- cluding cables, than the recommend- ed separation distance calculated from the equation applicable to the frequency of the transmitter.	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	Recommended Separation Distance: d = $\frac{6}{E} \sqrt{P}$	
	27 V/m 385 MHz	27 V/m 385 MHz	Where <i>P</i> is the maximum output pow-	
	28 V/m 450 MHz	28 V/m 450 MHz	er rating of the transmitter in watts (V according to the transmitter manufac	
	9 V/m 710, 745, 780 MHz	9 V/m 710, 745, 780 MHz	and d is the recommended separation distance in meters (m).	
	28 V/m 810, 870, 930 MHz	28 V/m 810, 870, 930 MHz	Field strengths from field RF transmitters, as determined by an electromagnetic site survey ^(a) , should be less that the compliance level in each frequency range ^(b) . Interference may occur in the vicinity of equipment marked with the following symbol:	
	28 V/m 1720, 1845, 1970	28 V/m 1720, 1845, 1970		
	28 V/m 2450 MHz	28 V/m 2450 MHz		
	9 V/m 5240, 5500, 5785 MHz	9 V/m 5240, 5500, 5785 MHz		

NOTE: 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 0.15 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.

*¹ This test is not applicable since the EUT does not have applicable ports or calbes.

10 Technical Specifications

10.1 Specifications

* Specifications may be changed without notice due to improvements.

Name	Root ZX3	
Model	RZX3	
Туре	RCM	
Operating Principle	The Apex Locator module has the apex locating function achieved by measuring the electrical impedance between the active electrode and the neutral electrode, which makes it pos- sible to measure the root canal length. Apex position is detected and the root canal length and working length can be determined with reference to this apex position.	
Essential Performance	None (There is no unacceptable risk.)	
Protection Against Ingress of Water	IPX0	
Degree of Protection against Electric Shock	Internal power supply device / Type BF applied part	
Applied Parts	File holder, Contrary electrode	
Rated Input Voltage	Solo operation: DC 6 V (alkaline dry batteries [AA size], Qty: 4) Connected with HF Module: DC 9.6 V (Ni-MH battery)	
Outer Dimensions	Approx. 100 mm (Height) × 95 mm (Width) × 85 mm (Length)	
Weight	Approx. 390 g (with dry batteries)	

10.2 Symbols





Serial number



Medical device



GS1 DataMatrix



Type BF applied part



Supports washer-disinfectors



Fragile



Temperature limitation



Atmospheric pressure limitation



CE (0197) marking Conforms with the European Regulation, EU 2017/745 CE marking Conforms with the European Directive,



EU Authorized Representative under the European Regulation, EU 2017/745



Prescription Device CAUTION: Federal law restricts this device to sale by or on the order of a dentist. (Valid only for U.S.A.)



Importer

EU 2011/65



* Some symbols may not be used.





Refer to instructions for use

Keep away from rain

This way up

Humidity limitation



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





Packaging unit



Distributor



Model number

11 Regular Inspection

11.1 Regular Inspection

- * Regular inspection is generally consider to be the duty and obligation of the user, but, if, for some reason, the user is unable to carry out this duty, this may be performed by the accredited service personnel. Contact your local dealer or J. MORITA OFFICE for details.
- * The Root ZX3 should be inspected every 6 months in accordance with the following regular inspection items.
- * For repair or other types of service, contact your local dealer or J. MORITA OFFICE.
- * J. MORITA MFG. CORP. will offer replacement parts and service for the product for a period of 10 years after the manufacturing of the product has been discontinued. Replacement parts and service will continue to be available during that period.

11.1.1 Regular Inspection Items

Inspection Item		Check Point
1	Switches	Check that the device turns on when the power switch is pressed, and that the unit turns off when the power switch is pressed again.
		Check that the memory number (M1, M2, M3) is changed when the forward or reverse switch is pressed.
		Check the settings for each of the memories can be changed when the select or function switch is pressed.
2	Probe Cord (plug and connectors)	Visually inspect the probe cord and its plug and connectors carefully and make sure that they are not damaged or dirty.
		Check that the plug of the probe cord goes into the apex locator module's con- nection port properly.
	File Holder Contrary Electrode	Visually inspect the file holder and contrary electrode carefully and make sure that they are not damaged or dirty.
3		Check that the file holder plug fits properly into its probe connector (gray).
		Check that the file holder holds a file properly.
		Check that the contrary electrode fits properly into its probe connector (white).
4	Apex Location Indica- tor Bar	Touch the contrary electrode with the file holder contact and check the following points. All of the apex location indicator bars light up. "OVER", "Apex", and "◀" (0.5 meter reading) blink. A continuous beep sounds.

12 Service and Disposal

12.1 Service

For repair or other types of service, contact your local dealer or J. MORITA OFFICE.

The Root ZX3 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.

12.2 Standards and Procedures for Disposal of Medical Devices

The dentist or doctor responsible for the patient's treatment must confirm that a medical device is uncontaminated, and must then have it disposed of by a healthcare facility or an agent licensed and qualified to handle standard industrial waste and industrial waste requiring special treatment.

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





Treatment Units

Handpieces and Instruments

Endodontic Systems

Laser Equipment

Laboratory Devices

Educational and Training Systems

Auxiliaries



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