

Cordless Endo Motor with Apex Locator



# **INSTRUCTIONS FOR USE**



Thinking ahead. Focused on life.

Thank you for purchasing the Tri Auto ZX2.

For optimum safety and performance, read this manual thoroughly before using the instrument and pay close attention to warnings and notes.

Keep this manual in a handy place for quick and easy reference.

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# **Overview and Features**

**Canal Shapes** 

Almost all canals can be treated with the

Description of Icons

**Normal Canals** 



#### Modes

The Tri Auto ZX2 has 5 different operating modes which can be used for depending on your intended use. (  $\wp p.10$  )

#### **Memories**

There are 8 memories with different combinations of motor operation, speed etc. that can be used at different stages of the treatment. Memory settings can be customized. (  $\bowtie p.33$ )

#### Canal shaping can be safely made by linking to the canal measurement function.

Rotation is controlled automatically at a point specified inside the canal. This ensures safety by preventing over instrumentation of the apical foramen.

- OAS (Optimum Apical Stop) File reverses slightly and then stops.
- Auto Apical Reverse File automatically reverses rotation.
- Auto Apical Stop File stops automatically.

(Apical Action (c) p. 36)

# For Canal Measurement and Linkage



# Glide path can be made with the motor.

The motor reproduces the subtle and delicate finger movements of an experienced dentist.

Penetration can be performed efficiently with a thin Ni-Ti file or stainless steel file.

(OGP Function Is p. 39)

#### Canal shaping can be made safely and efficiently without distorting the original shape.

The file alternates between forward and reverse rotation delicately in response to the load applied to it. The makes for safe and efficient treatment by reducing jamming, breakage, ledge formation, and over instrumentation.

(OTR Function p. 39)

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# **Prevent Accidents**

#### **Attention Customers**

Do not fail to receive clear instructions concerning the various ways to use this instrument as described in this accompanying Operation Instructions.

Fill out and sign the warranty and give the dealer from whom you purchased the instrument a copy.

#### Attention Dealers

Do not fail to give clear instructions concerning the various ways to use this instrument as described in this accompanying Operation Instructions.

After instructing the customer in the operation of the instrument, have him fill out and sign the warranty. Then fill in your own section of the warranty and give the customer his copy. Do not fail to send the manufacturer's copy to J. MORITA MFG. CORP.

#### **Prevent Accidents**

Most operation and maintenance 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 instrument in accordance with the manufacturer's recommendations.

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

#### Do not use this instrument for anything other than its specified dental treatment purpose.

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



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

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

This informs the user of important points concerning operation or the risk of instrument damage.

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

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

# **WARNING**

- No modification of this instrument is allowed.
- · Do not use the wireless transmission devices listed below in the examination area:
  - 1. Mobile terminals 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 LAN, cordless analogue telephones, and other electric wireless devices.
- This instrument could be adversely affect by the electromagnetic radiation produced by electric scalpels, illumination devices etc. that are being used nearby.
- Do not perform maintenance while using the instrument for treatment.

# **APROHIBITION**

· Do not use this instrument on patients who have implanted pacemakers or defibrillators.

## **Rx Only**

Caution : Federal law restricts this device to sale by or on the order of a dentist. (for U.S.A.)

#### Disclaimer

J. MORITA MFG. CORP. will not be responsible for accidents, instrument 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 or equipment made by other manufacturers, except for those procured 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 equipment in ways other than the operating procedures described in this manual or resulting from the safety precautions and warnings in this manual not being observed.
- 6. Workplace conditions and environment or installation conditions which do not conform to those stated in this manual such as improper electrical power supply.
- 7. Fires, earthquakes, floods, lightning, natural disasters, or acts of God.

The useful life of the Tri Auto ZX2 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.

#### In Case of Accident

If an accident occurs, the Tri Auto ZX2 must not be used until repairs have been completed by a qualified and trained technician authorized by the manufacturer.

#### **User Qualifications**

Intended Operator Profile

- a) Qualification : Legally qualified person such as dentists for endodontic device operation (it may differs among countries).
- b) Education and Knowledge : It is assumed that the understands the risks of root canal measuring and treatment. It is also assumed the user is thoroughly familiar with root canal measuring and treatment including the prevention of cross contamination.
- c) Language Understanding : English (Intended for professional use as described above)
- d) Experience : Experienced person with operating endodontic device.
   No special training is required except in cases where this is required by legal regulations of the relevant country or region.

#### Patient Population

Age : Child to Elderly

#### 

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

Weight : Not applicable.

Nationality : Not applicable.

Sex : Not applicable.

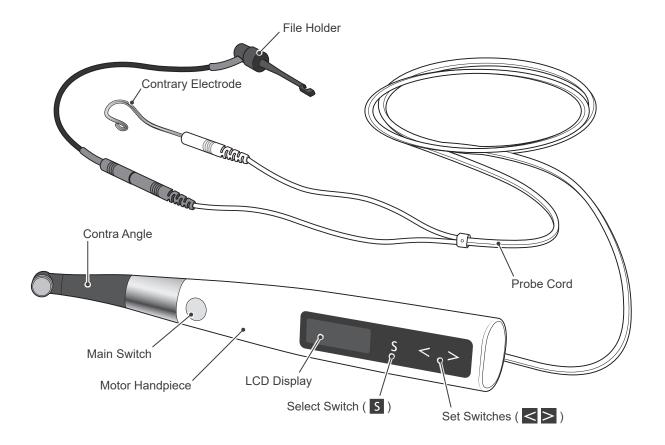
Health : It is not intended for use on patients wearing pacemakers or ICDs.

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

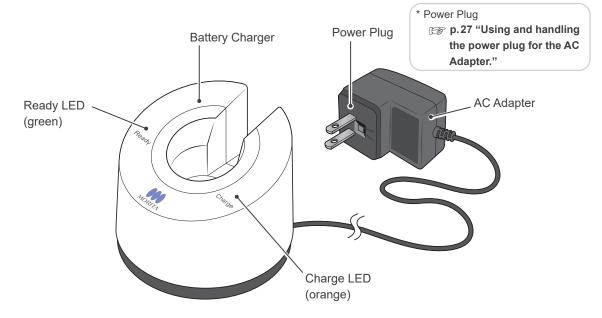
# **Parts Identification and Display Screens**

# Parts Identification

# Handpiece



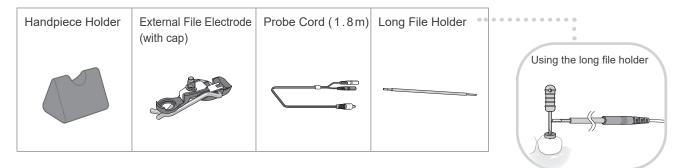
Battery Charger



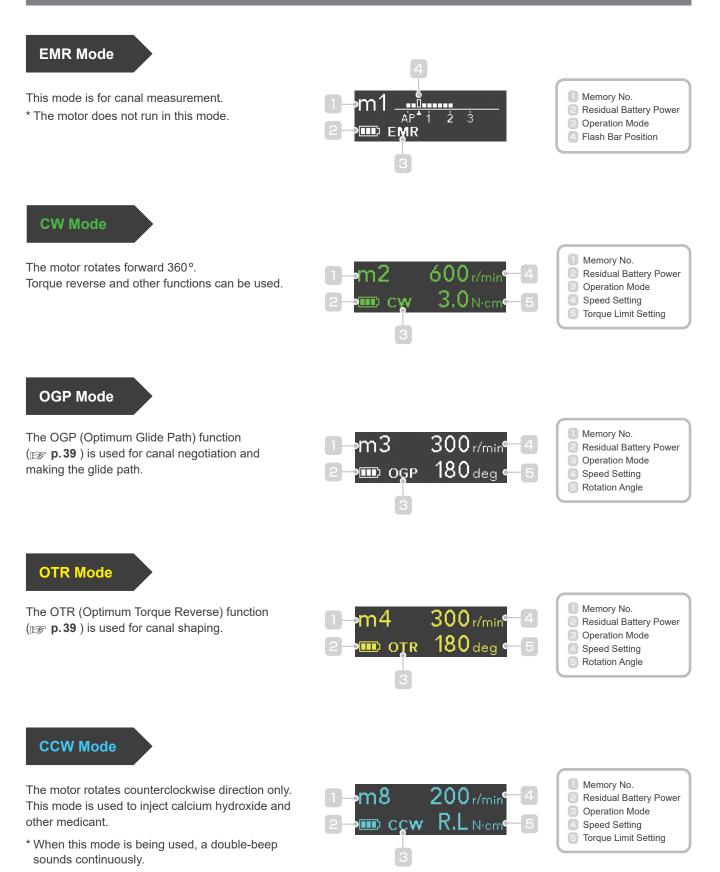
# Components

Motor Handpiece (1)	Contra Angle (1)	Built-in Electrode * Pre-installed in Contra Angle	Guide Bar (1)
		Fre-instaned in Contra Angle	* Use the guide bar when replacing the built-in electrode or external file electrode.
0 s < >			Er p.43 "Replacing Built-in Electrode"
			p.44 "External File Electrode"
Battery Charger (1)	Battery * Pre-installed in Motor Hand-	AC Adapter (1)	Power Plugs (one each of 4 types)
Probe Cord (0.75m) (1)	File Holder (1)	Contrary Electrodes (3)	Tester (1)
HP Protective Sleeve Type A (30)	LS OIL (1)		
* Replace for each patient. Never reuse.			
Contraction of			

# Options (sold separately)



# **Display Screens for 5 Operation Modes and Standby**



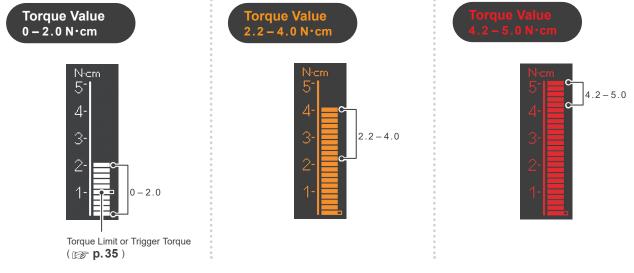
#### **Display during Operation**

#### **Torque Display** (This appears when the motor is running.)

Meter shows the torque load on the file. The color of the display changes depending on the torque load as shown below.

There is some discrepancy in the torque value depending on the condition of the motor and contra angle and this value is used only as a reference as follows: There could be some discrepancy in the torque value caused by decreased efficiency of contra angle from poor maintenance or deterioration of motor. The displayed torque should be used as a reference value.

When discrepancy between the displayed and actual torque was suspected, perform the maintenance of the contra angle, and ask for repair if failure including noise or vibration was existed. Calibration shown in P15 is also recommended.

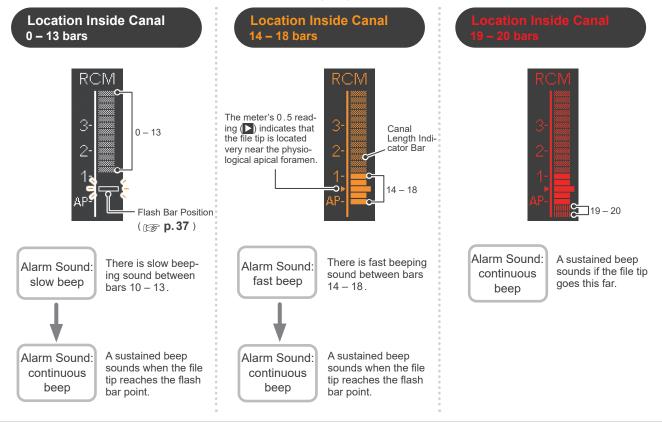


#### Canal Measurement Display

(This appears when a file is inside the canal and the contrary electrode is contacting the patient.)

Bars in meter show the location of the file tip. The color of the display changes depending on location of the file inside the canal as shown below.

\* The meter numbers 1, 2, and 3 do not represent the actual length from the apical. These numbers are used to estimate the canal's working length.



# Usage

# 1. Operating, Transport and Storage Environments

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

<u>Transport and Storage</u> 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 Tri Auto ZX2 to direct sunlight for an extended period of time.
- \* If the instrument has not been used for some time, make sure it works properly before using it again.
- \* Always remove the battery prior to storing or shipping the instrument. I p. 42

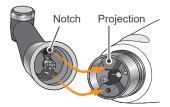
#### 2. Before Use

Check the following before using the instrument.

- Have autoclavable components been sterilized? 🕼 p.28 "Autoclavable Components"

#### Assembling Components

#### Connect Contra Angle

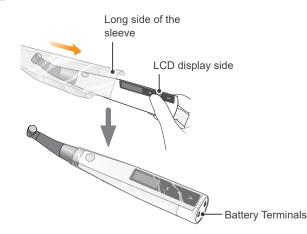


Line up the notch inside the contra angle with the projection inside the motor and slide it in until it clicks securely into place.



The contra angle rotates 290  $^\circ$  so that the LCD display can always be viewed easily.

#### 2 Put on HP Protective Sleeve



Put the protective sleeve on so that its long side is on the LCD display side.

# **MWARNING**

 Make sure the connection ends of the motor handpiece and the contra angle are not damaged. If these are damaged, the load on the contra angle could cause the motor to reverse rotation, and this might result in an injury to the oral cavity.

# 

- Push the contra angle all the way onto the motor handpiece and then give it a light tug to make sure it is securely attached.
- The contra angle does not rotate freely. Do not try to rotate it past its stopper.

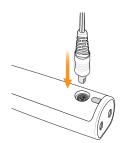
## **WARNING**

• To prevent cross contamination between patients, use a new sleeve for each patient. (Never reuse.)

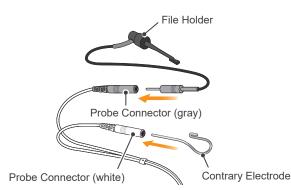
If you hold the contra angle when you put the sleeve on, the contra angle might come off. Always put in on by pushing on the battery terminal end of the motor

Make sure the sleeve is not torn.

#### **3** Connect Probe Cord



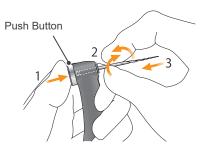
Connect the probe cord to the motor handpiece. Line up the probe jack with the notch for its mate on the back of the motor and push it all the way in.



Connect the file holder plug into the probe connector (gray) on the probe cord. Connect the contrary electrode to the

4 Install File

probe connector (white).



Hold down the push button on the contra angle and insert the file. Turn the file back and forth until it is lined up with interior latch groove and slips into place. Release the button to lock the file into the contra angle. \* This is not required if the canal measurement function will not be used.

#### 

- Do not bang or bump the plugs when they are inserted.
- Make sure the plug is all the way in. Otherwise canal measurements cannot be made.
- Do not wind the probe cord around the instrument.

#### 

• Match colors to connect the file holder and contrary electrode. Accurate measurement cannot be made if they are reversed.

\* Use only Ni-Ti or properly designed stainless steel files.

#### **MWARNING**

- Files are expendable, and they eventually wear out. Replace them before they break.
- · Never use stretched, deformed or damaged files.
- Make sure the file is all the way in. Give the file a light tug to confirm it is securely held in place. If the file is not securely placed, it could come out and injure the patient.
- Make sure the screw is tight enough.
   Otherwise, it might come out and be swallowed.
   Also, canal measurements might not be accurate.



## **▲**CAUTION

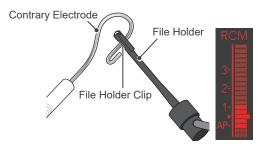
- Be careful when inserting and removing files to avoid injury to fingers.
- Inserting and removing files without holding the push button may damage the chuck.
- Take care not to touch the Main switch when putting files in. This will cause the file to rotate.
- If there is no electrical conductivity between the file and its shank, replace the cap with the one that has an external file electrode.
   p.44 "External File Electrode"
- Do not use files with shanks larger than the ISO standard. These cannot be properly installed. (ISO standard: ø2.334 to 2.350 mm)

#### **Operation Check**

#### Check Canal Measurement Function



Press the Main switch to turn on the instrument. The stand by display (m1) will appear.

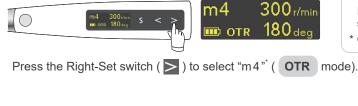


Touch the contrary electrode with the clip on the end of the file holder and check that all the indicator bars on the meter in the LCD display light up.



Touch the contrary electrode with the file in the contra angle and check that all the bars on the meter in the display light up.

## Check Motor





Press the Main switch and make sure the motor runs smoothly.

Check the following before turning on the instrument.

- Make sure the contra angle and the motor handpiece are securely connected.
- · Make sure the file is securely installed in the contra angle.
- Make sure the file holder and the contrary electrode are properly connected to the probe connector.
- Make sure the probe cord is properly plugged into its jack on the motor handpiece.



#### 🗥 WARNING

 Check the instrument's function before use with each patient. If all the indicator bars do not light up, an accurate measurement cannot be made. In this case, stop using the instrument immediately and have it repaired.

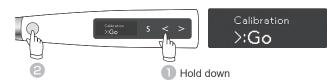
\* This is the default setting. If m4 is not set for OTR mode, select another memory that is set for OTR mode.
\* Cannot check motor rotation in EMR mode.

The torque meter appears when the motor is running.

If the motor keeps alternating between forward and reverse rotation and it does not rotate forward continuously, calibrate the instrument.

If there are abnormal vibrations or noises, stop using the instrument immediately and contact your local dealer or J. MORITA OFFICE.

#### Calibration



With the instrument turned off, hold down the Left-Set switch ( <> ) and then press the Main switch. The calibration display will appear.

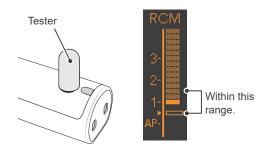


Press the Right-Set switch (  $\geq$  ). Calibration will be performed. After calibration, the instrument will automatically return to the Standby display.

#### Check with Tester



Press the Main switch to turn on the instrument. The stand by display (m1) will appear.



Connect the tester to the probe cord jack on the back of the motor handpiece.

Check that the canal length indicator bars light up to within two bars of bar number 1. $^{1}$ 

Calibrate the instrument at the following times:

- · Right after purchase.
- Whenever the contra angle has been replaced.
- When using a contra angle other than the one that has been calibrated.
- Whenever, in OTR mode, the instrument always alternates between forward and reverse rotation and never rotates forward continuously.

\* Calibration is automatically performed from 100 to 1,000 r/min.

Perform calibration with the contra head attached. If calibration is performed with a file inserted, be careful not to injure your fingers.

Check the instrument's measurement accuracy with the tester at least once a week.

- \* The canal length indicator bars may flicker up or down momentarily when the tester is plugged in. Wait for about 1 second for the indicator bar to stabilize and then check it.
- \*1 If the meter lights up to three bars more or less than bar number 1, the instrument cannot make an accurate measurement. In this case, stop using the instrument immediately and contact your local dealer or J. MORITA OFFICE.

# 3. Operation

Select the memory appropriate to the treatment to be performed. The main uses, operation modes, and apical actions for the default settings of each mode are listed below.

#### The following explanation is base on the default settings.

# **A**CAUTION

• Since the following is based on the default settings, use changed settings for your own treatment procedures.

• Always check the settings after changing the memory number.

# Default Settings

Almost all canals can be treated with the default settings of the memories from m1 to m4. However, settings can be changed to suit various stages of treatment.

We recommend using the default settings until the user has gotten used to how the instrument works.

Memory	Main Uses with Default Settings	Operation Mode transfer p. 34	Apical Action
m 1	Canal measurement	EMR	—
m 2	Shape the upper part of canal.	CW (forward)	OAS
m 3	Negotiation and making a glide path for a normal canal	OGP	OAS
m4	Canal shaping for a normal canal	OTR	OAS
m 5	Negotiation and making a glide path for a complex canal	OGP	OAS
m 6	Making a glide path for a complex canal	OGP	OAS
m 7	Canal shaping for a complex canal	OTR	OAS
m 8	Injection solutions such as calcium hydroxide, etc.	CCW (reverse)	Off

\* Refer to page ( 1000 p.33 "How to Make Various Settings" ), for how to make and change settings.

\* After changing settings, refer to page p.41 "Reset Memories to Original Default Settings", for how to restore the original settings.

#### **MWARNING**

- · Before use, run the Tri Auto ZX2 outside the oral cavity to make sure it is operating normally.
- Depending on the condition of the tooth, the type of case, and the condition of the instrument, it may not be possible to shape and measure a canal properly. Make sure to take an X-ray to check the results.
- In general Ni-Ti files can sometimes wear out rather quickly depending on the shape and the degree of curvature of the root canal. Stop using the instrument immediately if tactile feedback indicates the instrument is not working properly.
- Since files can easily break due to metal fatigue and excessive load, replace them frequently. Since stainless steel files are especially easily broken, it is best to not reuse them and replace them with new ones instead.
- Electric noise or a malfunction could make it impossible to control the motor properly. Do not depend entirely on the instrument controlling itself; always watch the display, listen to the sound and be aware of tactile feedback.
- Applying excessive force at canal shaping could cause the file to jam inside the canal or break the file.
- Do not apply excessive force. Even when using the torque reverse function, files may break depending on the torque setting.
- When changing files, always examine for stretching and other deformities or damage before using them. Deformed files tend to break.
- If the contra angle's file release button is pressed against the teeth opposite the one being treated, the file could come out and injure the patient.
- Never press the push button while the motor is running. This could cause it to heat up and burn the patient. Also the file might come out and injure the patient.
- · Always use a rubber dam to prevent accidental swallowing of files etc.

# **A**CAUTION

• Stop using the instrument immediately if tactile feedback indicates the instrument is not working properly.

- Files break more easily at high speeds; always follow the file manufacturer's recommendations. Also always check the rotation speed before using the instrument.
- Use only Ni-Ti or properly designed stainless steel files.
- Ni-Ti files break rather easily. Pay close attention to the following points:
- Never use excessive force to insert the file.
- All foreign matter, such as bits of cotton, should be removed from the root canal before using the file.
- Never use excessive force to advance the file down the root canal. Ni-Ti files break easily if too much load or force is applied.
- Take great care when working on extremely curved canals. These can break the file easily.
- Try not to trigger the auto torque reverse function as much as possible when advancing the file down the root canal.
- Use files in the order of their sizes without skipping any sizes. A sudden change to a larger file can lead to file breakage.
- If you encounter resistance or the auto torque reverse is triggered, take back the file up 3 or 4 mm and carefully advance it down the root canal again. Or replace the file with a smaller size. Never use excessive force to insert the file.
- Do not force the file down the root canal or press it against the root canal wall as it could break the file.
- Do not use the same file continuously in one position for too long as it may lead to creating "steps" etc.
- Always remove the file after use.

• Use only files that are designed for clockwise filing. Use files very carefully and follow all the recommendations of the manufacturer.



#### **Canal Measurement**

Examples using default settings

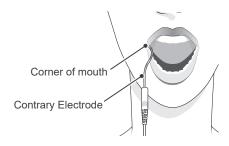
Measure a canal and determine its working length.

1 Turn Power On



Press the Main switch to turn on the instrument. The stand by display (m1) will appear.

#### **2** Apply Contrary Electrode



Hook the contrary electrode in the corner of the patient's mouth.

#### EMR mode is now selected.

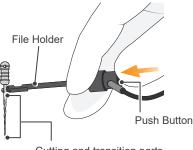
#### **WARNING**

- Never use an electric scalpel when the contrary electrode is hooked in the patient's mouth. These devices emit electrical noise that could interfere with accurate measurement or cause the instrument to malfunction.
- Make sure that the contrary electrode, file holder, and their connectors, do not come into contact with an electric power source such as a power outlet. This will result in an electric shock.
- Accurate measurement is not always possible, especially in cases of abnormal or unusual root canal morphology. Make sure to take an X-ray to check the results.
- If connections are not securely plugged in the instrument may not make an accurate measurement. If the meter does not change as the file goes down the canal, stop using the instrument immediately and make sure all the connectors are securely inserted.

# 

- 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 an adverse reaction such as inflammation.

**3** Clip the File ······



Cutting and transition parts

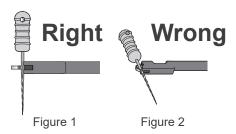
Push the button on the file holder with your thumb in the direction shown by the arrow in the illustration. Clip the holder onto the metal upper part of the file and then release the button.

## 

• When clipping the file holder onto the metal part of a file or reamer, clip the file holder onto the metal shaft near the handle. Do not clip it onto the cutting part or transition part of the file or reamer. This will cause the file holder to wear out very quickly.

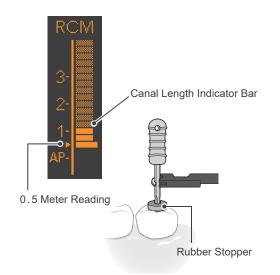
To measure a root canal, use a file or reamer with a plastic handle. If you do not wear gloves, do not use a file with a metal handle. Current leakage from a metal handle to your fingers will prevent an accurate measurement.

Do not use damaged or worn file holders, otherwise accurate measurements cannot be made.



Clip the file or reamer as shown in figure 1.

#### 4 Canal Measurement (m1) ·····



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

#### **ACAUTION**

• Do not clip them as shown in figure 2. This will prevent accurate measurement and will damage the tip of the file holder.

#### **MWARNING**

 In some cases such as a blocked root canal, a measurement cannot be made.

#### p.24 "EMR (Electric Measurement of Root canal length)"

- Accurate measurement is not always possible, especially in cases of abnormal or unusual root canal morphology. Make sure to take an X-ray to check the results.
- Stop using the instrument immediately if it does not seem to be working properly.
- If the canal length indicator bar does not appear even when the file is inserted, the instrument may be malfunctioning and must not be used.

Do not touch the gums with the file. The meter will light up all the way.

- 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 measurement. Moisten the canal with oxydol (hydrogen peroxide) or saline, and then try measuring again.
- Occasionally the meter 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.
- After measuring the root canal, make sure to take an X-ray to check the measurement results.

#### • 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 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 apical. These numbers are used to estimate the canal's working length.

# 5 Turn Power Off



While the standby display is on, you can turn off the instrument by holding down the Select switch ( $\slash$ ) and pressing the Main switch.

• Auto Power Off Function ( p.40 "Auto Power Off Time" If no switches are pressed for 10 minutes, the instrument will automatically turn off (default setting).

#### Canal Shaping (for normal canals)

Examples using default settings

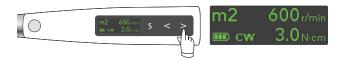
This can usually be done using memories 1 to 4. Use these four memories to shape canals until you get used to using the Tri Auto ZX2.

1 Turn Power On



Press the Main switch to turn on the instrument. The stand by display (m1) will appear.





Press the Right-Set switch (  $\geq$  ) to select "m2" ( CW mode ).

Install a suitable file and shape the upper part of the canal. Press the Main switch to start and stop the motor. The torque display appears when the motor is running. **p.11 "Torque Display"** 

## Canal Measurement (m1)



Press the Left-Set switch ( ) to select "m1" ( EMR mode ) and measure the canal. p.18 "Canal Measurement"

Corner of mouth Contrary Electrode If the contrary electrode is applied to the patient, the instrument can be linked to the canal measurement function while it is being used.

p. 36 "Settings for Canal Measurement Linkage"

\* The meter numbers 1, 2, and 3 do not represent the actual length from the apical. These numbers are used to estimate the canal's working length.

## **MWARNING**

- Never use an electric scalpel when the contrary electrode is hooked in the patient's mouth. These devices emit electrical noise that could cause the motor to run or cause the device to malfunction.
- Make sure that the contrary electrode, file holder, handpiece file electrode etc., do not come into contact with an electric power source such as a power outlet. This will result in an electric shock.

## 4 Glide Path (m3)





Press the Right-Set switch (  $\geq$  ) to select "m3" ( OGP mode ).

Install a suitable file to perform negotiation and make the glide path.

# 5 Canal Shaping (m4)



Press the Right-Set switch (  $\geq$  ) to select "m4" ( OTR mode ).

Install a suitable file and shape the canal.

The file will alternate between forward and reverse rotation when the set trigger torque is reached.



#### Linkage to Canal Measurement Function • Auto Start and Stop Functions (137) p.37

With the contrary electrode hooked in the patient's mouth, the canal measurement screen will appear when the file is inserted into the canal. ((For p.11 "Canal Measurement Display")

When the canal length indicator bar lights up more than 2 bars, the motor automatically starts rotating. The motor will stop automatically when the file is taken out of the canal and the canal length indicator bar turns off.

- \* If the canal is dry and prevents the auto start from being triggered, press the Main switch to start the motor.
- \* If the Tri Auto ZX2 is used without being linked to the canal measurement function, do not use the contrary electrode and start and stop the motor by pressing the Main switch.
- OAS Function 🔝 p. 36 "Apical Action"

The file will reverse slightly and stop when it reaches the point where the flash bar has been set.

#### 

• The file electrode, contrary electrode, and metal part at the end of the contra angle could cause an adverse reaction if the patient has an allergy to metals. Ask the patient about this before using them.

Metal part at the end

of the contra angle

- Do not touch the oral mucosa or tooth with the metal part at the end of the contra angle. The file could start up and injure the patient or the instrument might not make accurate measurements.
- Be careful when replacing files; the file will start running if the Main switch is pressed.
- Take care that medicinal solutions such as formalin cresol or sodium hypochlorite do not get on the contrary electrode or the contra angle. These could cause an adverse reaction such as inflammation.

• Note that some types of files cannot be used with the file electrode.

6 Turn Power Off



While the standby display is on, you can turn off the instrument by holding down the Select switch ( S) and pressing the Main switch. • Auto Power Off Function (For p.40 "Auto Power Off Time") If no switches are pressed for 10 minutes, the instrument will automatically turn off (default setting).

#### Canal Shaping (for complex canals)

For complex canals such as extremely curved ones or those that may produce ledge formation, use memories m5 to m7 after measuring the canal.

1 Turn Power On



Press the Main switch to turn on the instrument. The stand by display (m1) will appear.

#### 2 Shape Upper Part of Canal (m 2)



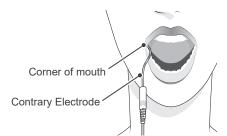
Press the Right-Set switch (  $\geq$  ) to select "m2" ( CW mode ).

Install a suitable file and shape the upper part of the canal. Press the Main switch to start and stop the motor. The torque display appears when the motor is running. **p.11 "Torque Display"** 

Examples using default settings

#### Canal Measurement (m1)





If the contrary electrode is applied to the patient, the instrument can be linked to the canal measurement function while it is being used.

p. 36 "Settings for Canal Measurement Linkage"

\* The numerals 1, 2, and 3 do not represent length in millimeters from the apical. These numbers are used to estimate the canal's working length.

#### **WARNING**

- Never use an electric scalpel when the contrary electrode is hooked in the patient's mouth. These devices emit electrical noise that could cause the motor to run or cause the device to malfunction.
- Make sure that the contrary electrode, file holder, handpiece file electrode etc., do not come into contact with an electric power source such as a power outlet. This will result in an electric shock.

#### 4 Glide Path (m 5)



Press the Left-Set switch (  $\geq$  ) to select "m5" ( OGP mode ).

Install a suitable file to perform negotiation and make the glide path.





Press the Right-Set switch ( > ) to select "m6" ( OGP mode ).

Install a file and make the glide path.

# 6 Canal Shaping (m7)



Press the Right-Set switch (  $\geq$  ) to select "m7" ( OTR mode ).

Install a suitable file and shape the canal.

The file will alternate between forward and reverse rotation when the set trigger torque is reached.



Linkage to Canal Measurement Function

#### Auto Start and Stop Functions 🔊 p.37

With the contrary electrode hooked in the patient's mouth, the canal measurement screen will appear when the file is inserted into the canal. ((E p. 11 "Canal Measurement Display")

When the canal length indicator bar lights up more than 2 bars, the motor automatically starts rotating. The motor will stop automatically when the file is taken out of the canal and the canal length indicator bar turns off.

- \* If the canal is dry and prevents the auto start from being triggered, press the Main switch to start the motor.
- \* If the Tri Auto ZX2 is used without being linked to the canal measurement function, do not use the contrary electrode and start and stop the motor by pressing the Main switch.

#### • OAS Function 🔊 p. 36 "Apical Action"

The file will reverse slightly and stop when it reaches the point where the flash bar has been set.

#### **ACAUTION**

• The file electrode, contrary electrode, and metal part at the end of the contra angle could cause an adverse reaction if the patient has an allergy to metals. Ask the patient about this before using them.

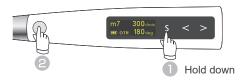
Metal part at the end

of the contra angle

- Do not touch the oral mucosa or tooth with the metal part at the end of the contra angle. The file could start up and injure the patient or the instrument might not make accurate measurements.
- Be careful when replacing files; the file will start running if the Main switch is pressed.
- Take care that medicinal solutions such as formalin cresol or sodium hypochlorite do not get on the contrary electrode or the contra angle. These could cause an adverse reaction such as inflammation.

• Note that some types of files cannot be used with the file electrode.

Turn Power Off



While the standby display is on, you can turn off the instrument by holding down the Select switch ([S]) and pressing the Main switch.

• Auto Power Off Function (For p.40 "Auto Power Off Time") If no switches are pressed for 10 minutes, the instrument will automatically turn off (default setting).

## EMR (Electric Measurement of Root canal length)

#### Root Canals not suitable for Electric Measurement

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



#### Root canal with a large apical fora-<u>men</u>

Root canal that has an exceptionally large apical foramen due to a lesion or incomplete development cannot be accurately measured. The results may show shorter measurement than the actual length.

#### Root canal with blood overflowing from the opening

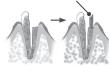


If blood overflows from the opening of the root canal and contacts the gums, this will result in electrical leakage and an accurate measurement cannot be obtained. Wait for bleeding to stop completely. Clean the inside and opening of the canal throughly to get rid of all blood, and then make a measurement.

#### Root canal with a chemical solution overflowing from the opening

An accurate measurement cannot be obtained if some chemical solution is overflowing from the canal opening. In this case, clean the canal and its opening. It is important to get rid of any solution overflowing the opening.

#### Build-up (e.g. cement)



Branch

Gutta-pe

#### Broken crown

If the crown is broken and a section of the gingival tissue intrudes into the cavity surrounding the canal opening, contact between the gingival tissue and the file will result in electrical leakage and an accurate measurement cannot be obtained. In this case, build up the tooth with a suitable material to insulate the gingival tissue.

# Fracture

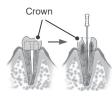
#### Fractured tooth Leakage through a branch canal

Fractured tooth will cause electrical leakage and an accurate measurement cannot be obtained A branch canal will also cause electrical

leakage.

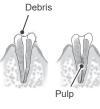
#### Re-treatment of a root filled with gutta-percha

The gutta-percha must be completely removed to eliminate its insulating effect. After removing the gutta-percha, 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

Accurate measurement cannot be obtained if the file 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 will not touch the metal prosthesis before taking a measurement.



#### Cutting debris on tooth Pulp inside canal

Thoroughly remove all cutting debris on the tooth.

Thoroughly remove all the pulp inside the canal. Otherwise an accurate measurement cannot be obtained.



Caries touches gums



Blocked



#### Caries touching the gums

In this case, electrical leakage through the caries infected area to the gums will make it impossible to obtain an accurate measurement

#### **Blocked canal**

The meter will not move if the canal is blocked. Open the canal all the way to the apical constriction to measure it.

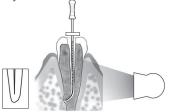
#### Extremely dry canal

If the canal is extremely dry, the meter may not move until it is quite close to the apex. In this case, try moistening the canal with oxydol or saline.

#### Too Drv

#### Tri Auto ZX2 Meter Reading and Radiography

Sometimes the Tri Auto ZX2 meter reading and the X-ray image will not correspond. This does not mean that the Tri Auto ZX2 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.

# 4. After Use

#### **1** Turn Power Off



While the standby display is on, you can turn off the instrument by holding down the Select switch ( $\s$ ) and pressing the Main switch.

2 Take Out the File



Hold down the push button on the contra angle and pull the file straight out.

• Auto Power Off Function (For p.40 "Auto Power Off Time") If no switches are pressed for 10 minutes, the instrument will automatically turn off (default setting).

## **ACAUTION**

- Be careful when inserting and removing files to avoid injury to fingers.
- Inserting and removing files without holding the push button may damage the chuck.
- Take care not to touch the Main switch when removing the file. This will cause the file to rotate.

**3** Remove HP Protective Sleeve



Remove the protective sleeve and throw it away.

\* A new protective sleeve must be used for each patient. (Never reuse.)

# **MWARNING**

To prevent cross contamination between patients, use a new sleeve for each patient. (Never reuse.)

# 4 Battery Charging



Plug the DC end of the adapter cable all the way into the bottom of the charger, and plug the other end into a power outlet. The Ready LED (green) will light up.



Put the handpiece all the way into the battery charger. The Ready LED (green) will go out and the Charge LED (orange) will light up and start charging the handpiece.



When the battery is fully charged, the Charge LED (orange) goes out and the Ready LED (green) will light up.

\* The battery is inside the motor handpiece.

#### **▲**WARNING

- Always use the adapter that comes with the Tri Auto ZX2. Using another adapter can result in electric shocks, malfunctions, fires, etc.
- The charger and its adapter must be located at least 2 meters away from the patient.
- Do not use the battery charger for any device except the Tri Auto ZX2.

\* It takes about 100 minutes to fully charge the battery.

#### **MWARNING**

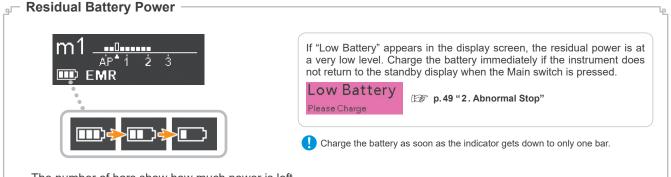
- Do not touch the battery charger or AC adapter if there is lightening while the battery is being charged. This will result in an electric shock.
- Do not use the battery charger in a place where it might get wet.

#### 

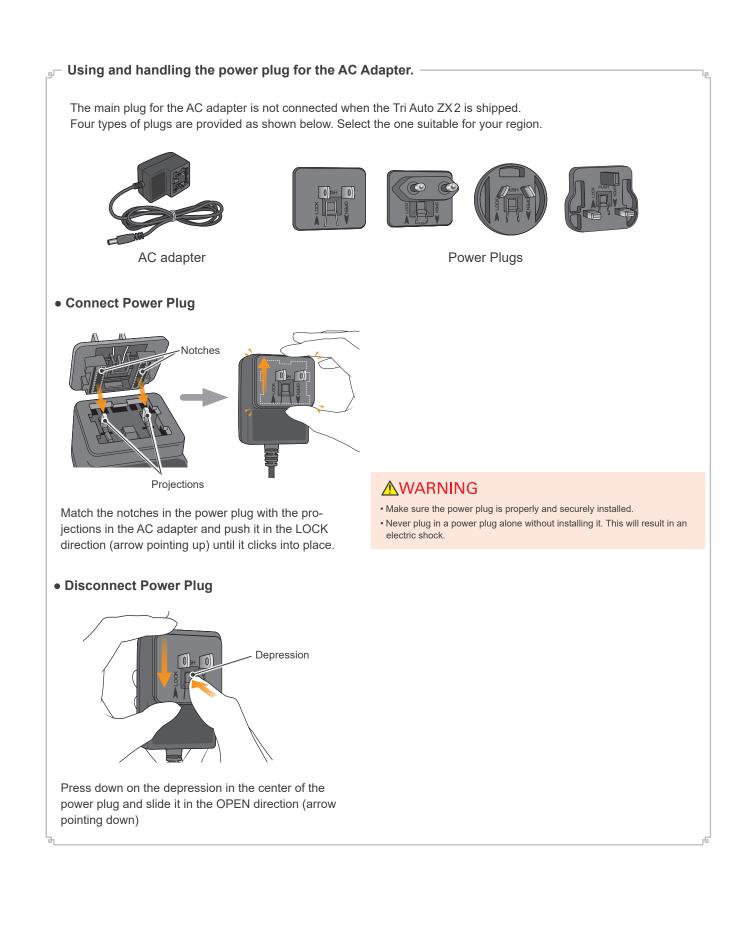
- Do not charge the handpiece with the probe cord connected or wrapped around the handpiece. This could break a wire inside the cord or damage the jack.
- There is a magnet inside the charger and this could attract metal clips etc. If this happens simply remove the metal clip etc.
- If the Charge LED (orange) goes off immediately or doesn't light up when the handpiece is put into the charger, the battery is already fully charged. To make sure, take the handpiece out and put it back in again.
- Make sure there is no dirt, metal fragments etc. on the connection contacts for both the handpiece end and the battery charger. If the contacts are dirty, wipe them with a piece of gauze dampened with ethanol (70 vol% to 80 vol%) after thoroughly wringing it out first. Pay attention to avoid bending or deforming the connection contacts.

Do not leave the battery charger where it will be exposed to direct sunlight.

Unplug the battery charger when it is not being used.

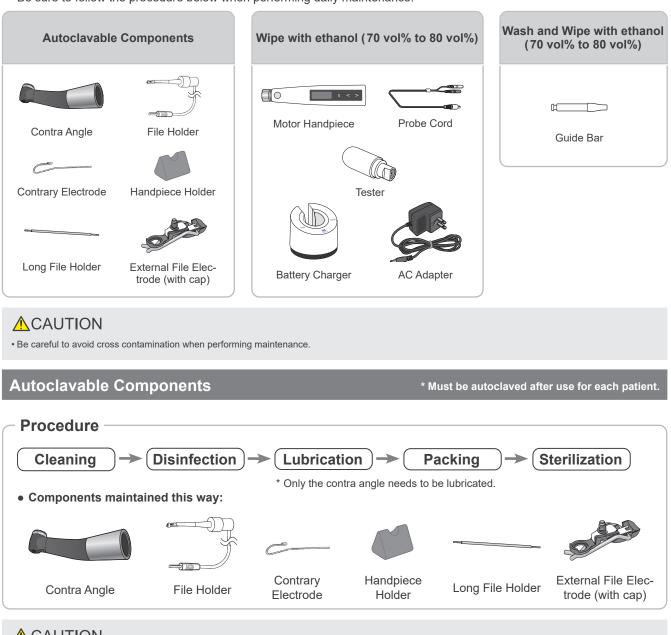


The number of bars show how much power is left.



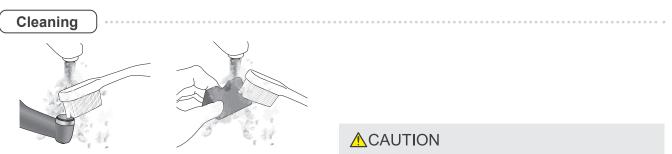
# 5. Maintenance

There are 3 ways to clean and disinfect components depending on the component. Be sure to follow the procedure below when performing daily maintenance.



**ACAUTION** 

• Before cleaning the contra angle, do not fail to take out the file.



(1) Disconnect the contra angle from the motor handpiece. Clean off the cutting debris with running water and a soft brush and then wipe off the water. • If a medical agent being used for the treatment has adhered to the components, wash it off in running water.

• Do not clean the components with an ultra sonic cleaning device.



(2)Use a threeway syringe etc. to blow out any moisture remaining inside the contra angle.

#### Disinfection



Wipe the components with a piece of gauze that has been dampened with ethanol (70 vol% to 80 vol%) and wrung out thoroughly.



- Check to see if the contra angle including its inside, is completely dry. If any water remains inside the component, expel it with an air gun or another such tool. Failure to do so could result in the remaining water coming out during use and cause malfunction, or poor lubrication and sterilization.
- If dust or other impurities enter the contra angle, they may cause poor rotation.

# 

- Do not use anything except ethanol (70 vol% to 80 vol%). Do not use too much ethanol as it could seep inside and damage the contra angle.
- Do not immerse the components in or wipe it with any of the following: functional water (acidic electrolyzed water, strong alkaline solution, or ozone water), medical agents (glutaral, etc.), or any other special types of water or commercial cleaning liquids. Such liquids may result in metal corrosion and adhesion of the residual medical agent to the components.
- Never clean the components with chemicals such as formalin cresol (FC) and sodium hypochlorite. These will damage the plastic parts of the components. If any of these liquids being applied to the components, wash it off in running water.
- Use only ethanol (70 vol% to 80 vol%) and OPTI-CIDE-3 ™ Surface Wipes for cleaning. Any other cleaning chemical or products should not be used including but not limited to the following cleaning products and similar cleaning products listed below because of the potential damage to the plastic components of the Tri Auto ZX2.
   • CaviWipes™ • CaviCide™ • SANI-CLOTH™



#### Operating conditions for high-temperature washer-disinfectors

\* When using a high-temperature washer-disinfector to clean the contra angle, strictly adhere to the conditions specified below.

Unit Name	Mode	Detergent (concentration)	Neutralizer∗ (concentration)	Rinse (concentration)
Miele G7881	Vario TD	neodisher MediClean (0.3% to 0.5%)	neodisher Z (0.1% to 0.2%)	neodisher Mieclear (0.02% to 0.04%)

#### High-temperature cleaning conditions

\* After cleaning there may be streaks or white spots on the contra angle. Use a neutralizer only if there are streaks or white spots.

#### **Operating Precautions**

- Always use a handpiece holder when washing the contra angle, making sure to rinse the inside of the contra angle thoroughly.
- If any medical agent remains inside the contra angle, it may corrode, resulting in a malfunction of the contra angle.
- For details on handling medical agents or adjusting their concentration, refer to the user manual for the washing device.
- Check to see if the contra angle including its inside, is completely dry. If any water remains inside the contra angle, expel it with an air gun etc. Failure to do so could result in the remaining water coming out during use and cause poor lubrication or sterilization.
- · Always lubricate the contra angle after washing.

Inappropriate cleaning methods and solutions will damage the contra angle.

Do not clean the contra angle using strong acidic or alkaline solutions that could cause the metal to corrode.

Do not leave the contra angle in the high-temperature washer-disinfector.

#### Lubrication

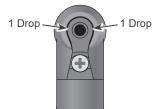
\* Only the contra angle needs to be lubricated.



(1)Place the contra angle in a paper cup with the connection end facing up.



(2)Put 5 drops of the LS OIL on the gear and wait for 10 minutes.



(3)Put a drop of the LS OIL in each of the two points between the built-in electrode and the head as indicated by the arrows in the illustration.



(4) Take the contra angle out of the paper cup and wipe off any excess oil which may have seeped out.Dampen a piece of gauze with ethanol, wring it out and then wipe the contra angle with it.

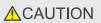
Packing

Put components in individual sterilization pouches. Use only FDA-cleared pouches. (for U.S.A) Before autoclaving, the contra angle must be lubricated with the LS OIL.

#### 

• Do not use any type of spray other than the LS OIL.

· Failure to lubricate the contra angle will result in a malfunction.



- Put the cap on after use. Oil could seep out if the container is tipped over or the nozzle points down.
- After lubricating, wipe oil from the outside of the nozzle. Otherwise oil may seep out from under the cap.
- Leave the contra angle in the paper cup for at least 10 minutes so that the oil is thoroughly absorbed by the contra angle mechanism.

Do not use anything except ethanol (70 vol% to 80 vol%) for cleaning. Never wipe the contra angle with solutions containing formalin cresol (FC) or sodium hypochlorite, which damage plastic; wipe them off immediately if they accidentally get on the contra angle.

Do not immerse in any fluid.

Do not connect the contra angle to the motor handpiece immediately after lubrication for use or charging. Otherwise the oil seep inside the motor handpiece and it might malfunction.

## **ACAUTION**

• Do not put stress on the cable when you place the file holder in a sterilization pouch.

#### Sterilization



Autoclave the components.

#### Recommended Temperature and Time

			,	
Sterilizer type	Temperature	Time	Drying time after sterilization	Country
Gravity	+132°C (+269.6°F)	15 minutes	15 minutes	U.S.A.
Gravity	+121°C (+249.8°F)	30 minutes	15 minutes	0.3.A.
Gravity	+134°C (+273.2°F)	min. 6 minutes	min. 10 minutes	
Gravity	+121°C (+249.8°F)	min. 60 minutes	min. 10 minutes	Other countries
Dynamic Air Removal*	+134°C (+273.2°F)	3 minutes	10 minutes	

\*This condition is not applicable in Korea.

# **MWARNING**

 To prevent the spread of infections, the components (contra angle, file holder, contrary electrode, handpiece holder, long file holder, external file electrode) must be autoclaved after each patient's treatment has been completed.

# **ACAUTION**

Do not sterilize the components by any method other than autoclaving.
Components are extremely hot right after autoclaving. Wait for them to cool off before touching.

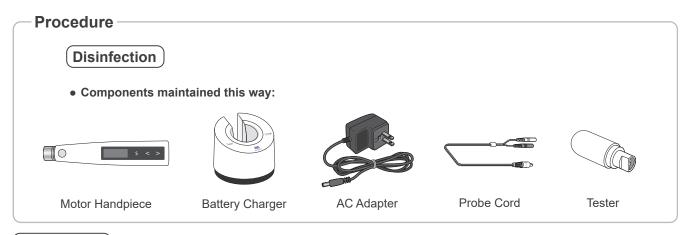
• Do not leave the components in the autoclave.

- Thoroughly clean and wash the components before autoclaving. If chemical solutions or foreign debris are not removed, autoclaving could damage or deform the components.
- The sterilization and drying temperatures must not exceed +135°C (+275°F).

No components can be autoclaved other than the contra angle, file holder, contrary electrode, handpiece holder, long file holder, and external file electrode.

- Take the file out of the contra angle or file holder before autoclaving.
- Do not fail to lubricate the contra angle with the LS OIL before autoclaving it.
- Follow file manufacturer's recommendations for autoclaving files.

#### Wipe with Ethanol (70 vol% to 80 vol%)



Disinfection



Wipe the components with a piece of gauze that has been dampened with ethanol (70 vol% to 80 vol%) and wrung out thoroughly.

# 

- Do not use anything except ethanol (70 vol% to 80 vol%). Do not use too much ethanol as it could seep inside and damage the components. Do not apply or spray with any fluid.
- Do not immerse the components in or wipe it with any of the following: functional water (acidic electrolyzed water, strong alkaline solution, or ozone water), medical agents (glutaral, etc.), or any other special types of water or commercial cleaning liquids. Such liquids may result in metal corrosion and adhesion of the residual medical agent to the components.
- Never clean the components with chemicals such as formalin cresol (FC) and sodium hypochlorite. These will damage the plastic parts of the components. If any of these liquids being applied to the components, use dry gauze etc. to wipe it off.
- Use only ethanol (70 vol% to 80 vol%) and OPTI-CIDE-3 ™ Surface Wipes for cleaning. Any other cleaning chemical or products should not be used including but not limited to the following cleaning products and similar cleaning products listed below because of the potential damage to the plastic components of the Tri Auto ZX2.
   • CaviWipes™ • CaviCide™ • SANI-CLOTH™

# Wash and Wipe with Ethanol (70 vol% to 80 vol%)

Procedure	
Cleaning	
Components maintained this way:	
Guide Bar	
Cleaning	

Clean off the cutting debris in running water with a soft brush and then wipe off the water.

# **A**CAUTION

• Do not clean the components with an ultra sonic cleaning device.

#### Disinfection



Wipe the components with a piece of gauze that has been dampened with ethanol (70 vol% to 80 vol%) and wrung out thoroughly.

# 

- Do not use anything except ethanol (70 vol% to 80 vol%).
- Do not immerse the components in or wipe it with any of the following: functional water (acidic electrolyzed water, strong alkaline solution, or ozone water), medical agents (glutaral, etc.), or any other special types of water or commercial cleaning liquids. Such liquids may result in metal corrosion and adhesion of the residual medical agent to the components.
- Never clean the component with chemicals such as formalin cresol (FC) and sodium hypochlorite. These will damage the plastic parts of the components. If any of these liquids being applied to the components, wash it off in running water.
- wash it off in running water.
  Use only ethanol (70 vol% to 80 vol%) and OPTI-CIDE-3 ™ Surface Wipes for cleaning. Any other cleaning chemical or products should not be used including but not limited to the following cleaning products and similar cleaning products listed below because of the potential damage to the plastic components of the Tri Auto ZX2.
- CaviWipes™ · CaviCide™ · SANI-CLOTH™

# **Rotation Controls**

The Tri Auto ZX2 has the rotation controls listed below. These controls can be assigned to each memory.

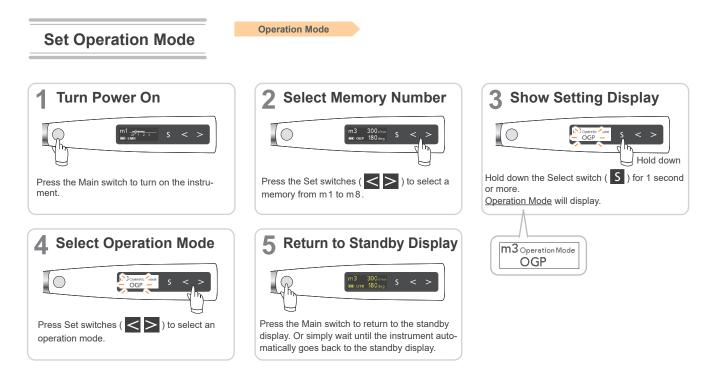
I Some functions cannot always be used or set depending on the operation mode and other settings for various functions.

Function	Description	Setting Method
Operation Mode	5 operation modes for canal shaping and measurement.	p.34
Speed	File rotation speed.	
Torque (Torque Limit / Trigger Torque)	For CW and CCW modes, the torque value (Torque Limit) that triggers reverse rotation. For OTR mode, the torque value (Trigger Torque) that triggers OTR action. For CW and CCW modes, also R.L (torque reverse less) can be set.	p.35
Apical Action	The file action when file tip reaches the flash bar point.	p.36
Auto Start	The file rotation starts automatically when the file is inserted in the canal.	
Auto Stop	The file rotation stops automatically when the file is taken out of the canal.	p.37
Flash Bar Position	Shows the point inside the canal where specified apical action is triggered.	
Apical Slow Down (Apical Slow Dwn.)	The file slows down automatically as it approaches the apex.	- <u>2</u> 9
Torque Slow Down (Torq. Slow Dwn.)	The file slows down automatically as the torque loads increases.	p.38
Apical Torque Down (Apical Torq. Dwn.)	Torque limit automatically decreases as the file approaches the apex.	
Rotation Angle	For OTR and OGP modes, this shows the arcs for forward and reverse rotation.	p.39
Beeper Volume	Volume of beeping for indicating the position inside the canal, torque reverse etc.	

#### Default Memory Settings

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

Cotting Itom			Normal Canals	;	Co	omplex Canals	;		
Setting Item	m 1	m2	m 3	m4	m5	m6	m7	m8	Setting Meth-
Function	Canal Measurement	Upper Part Shaping	Glide Path	Canal Shaping	Glide Path	Glide Path	Canal Shaping	Inject Medicinal Solutions	od
Operation Mode	EMR	cw	OGP	OTR	OGP	OGP	OTR	ccw	p.34
Speed (r/min)	N/A	600	300	300	100	300	300	200	
Torque Limit (N∙cm)	N/A	3.0	N/A	N/A	N/A	N/A	N/A	R.L	p.35
Trigger Torque (N•cm)	N/A	N/A	N/A	0.2	N/A	N/A	0.2	N/A	
Apical Action	N/A	OAS	OAS	OAS	OAS	OAS	OAS	Off	p.36
Auto Start	N/A	Off	On	On	On	On	On	Off	
Auto Stop	N/A	Off	On	On	Off	Off	Off	Off	p.37
Flash Bar Position		1		1			1		
Apical Slow Down	N/A	Off	N/A	N/A	N/A	N/A	N/A	Off	p.38
Torque Slow Down	N/A	Off	N/A	N/A	N/A	N/A	N/A	Off	p. 30
Apical Torque Down	N/A	Off	N/A	N/A	N/A	N/A	N/A	Off	
Rotation Angle (OGP mode)	N/A	N/A	180	N/A	90	90	N/A	N/A	
Rotation Angle (OTR mode)	N/A	N/A	N/A	180	N/A	N/A	180	N/A	p.39
Beeper Volume	Vol. 3	Vol. 3	Vol. 3	Vol. 3	Vol. 3	Vol. 3	Vol. 3	Vol. 3	



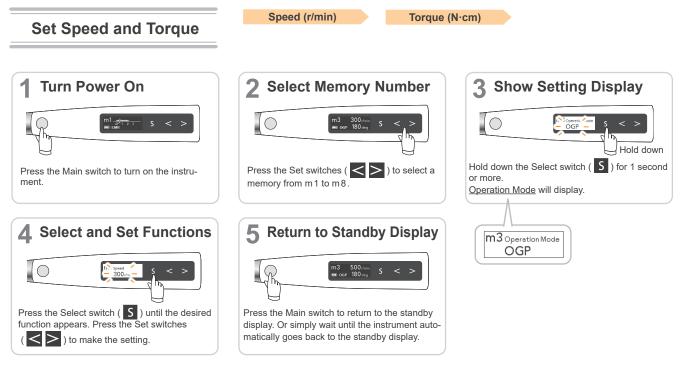
## Operation Mode Settings



There are 5 modes for canal shaping and measurement.

EMR	Canal	measurement
-----	-------	-------------

- ccw : Reverse rotation only. Used to inject calcium hydroxide and other solutions.
   \* When this mode is being used, a double-beep sounds continuously.
- cw : Normal 360° forward rotation. Torque reverse and other functions can be used.
- **OTR** : Used for canal shaping.
- **OGP** : Used for negotiation and making glide paths.



#### Speed and Torque Settings

Speed (r/min)

This is the file rotation speed.

· Possible speed settings for various modes.

m3 Speed

300 r/mir

EMR	CW (forward)	CCW (reverse)	OTR	OGP
N/A	100 150 200 250 300	400 500 600 800 1000	100 30	500

Torque (N·cm)

m2 Torque Limit 3.0 N·cm

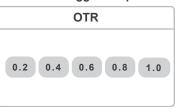
For CW and CCW modes, the torque value (Torque Limit) that triggers reverse rotation. For OTR mode, the torque value (Trigger Torque) that triggers OTR action. For CW and CCW modes, also **R.L** (torque reverse less) can be set. For EMR and OGP modes, Torque Limit and Trigger Torque value cannot be set.

\* In CCW mode, the motor only runs in reverse and does not change rotation direction even when it reaches the set torque limit. The beeping sound changes to alert the user when Torque Limit has been reached.

Possible Torque Limit Values

•	Possible	Trigger	Torque	Values
	1 0331010	Ingger	loique	values

CW (forward)	CCW (reverse)		
0.2 0.4 0.6 0.8 1.0	1.5 2.0 2.5 3.0 4.0 5.0 R.L		
If Torque Slow Down or Apical Torq reverse less) cannot be selected.	ue Down is turned on, 0.2 N · cm and R.L (torqu		

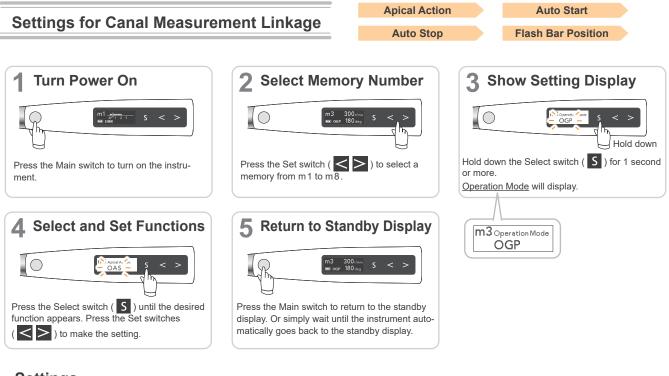


# **A**CAUTION

• If the instrument is set for R.L (torque reverse less), the motor will not reverse rotation no matter how large the torque load is.

• Match the torque setting to the canal and file.

] There is some discrepancy in the torque value depending on condition of the motor and contra angle and this value is used only as a reference.

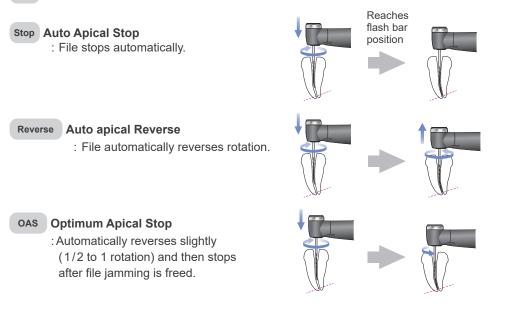


## Settings



Actions that happen automatically when the file tip reaches the point inside the canal determined by the Flash Bar setting. **p.37 "Flash Bar Position"** 

off : Rotation continues as before without stopping or reversing.



#### • Possible apical action settings for various modes.

EMR	CW (forward)	CCW (reverse)	OTR	OGP
N/A	Off Stop	Off Stop	Off Stop	Off Stop
	Reverse OAS	OAS	Reverse OAS	Reverse OAS

Auto Start	M3 Auto Start On	
------------	---------------------	--

Rotation starts automatically when the file is inserted into the canal and the canal length indicator bar lights up more than 2 bars.

- On : Motor starts automatically. More than RCM 2 bars : Motor does not start when file is inserted into the canal. Off The Main switch is used to start and stop the motor. 3. 2 · Possible Auto Start on/off settings for various modes. EMR CW (forward) CCW (reverse) OTR OGP Flash Bar Position On Off N/A If Auto Stop is turned on, this cannot be turned off.
- Auto Stop 0n

Rotation stops automatically when the file is taken out of the canal and the canal length indicator bar turns off.

On : Motor stops automatically.

**off** : Motor does not stop when file is taken out. The Main switch is used to start and stop the motor.

### • Possible Auto Stop on/off settings for various modes.

EMR	CW (forward)	CCW (reverse)	OTR	OGP
N/A		On	Off	
IN/A	If Auto Start	is turned off, this ca	annot be turned on.	

The auto stop function works only if the motor was started with the auto start function. It will not work if the motor was started with the Main switch even if it is turned on.

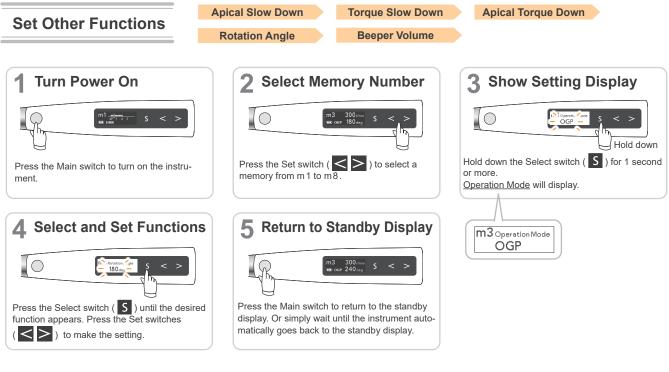


This is the point where various apical actions are triggered.

▲ The meter's 0.5 reading indicates that the file tip is located very near the physiological apical foramen.

The flash bar can be set from 2 to AP (Apex) on the meter.

EMR	CW (forward)	CCW (reverse)	OTR	OGP
	Settin	g Range: AP (Ape	x) – 2	



# Settings



Rotation automatically slows down as the file tip approaches the apex.

On : Automatically slows down.

off : Does not slow down.

· Possible apical slow down settings for various modes.

EMR	CW (forward)	CCW (reverse)	OTR	OGP
N/A	On If Apical Torque Down is turr	Off ned on, this cannot be turned on.	N/A	N/A

**Torque Slow Down** 

m2 Torq. Slow Dwn. Off

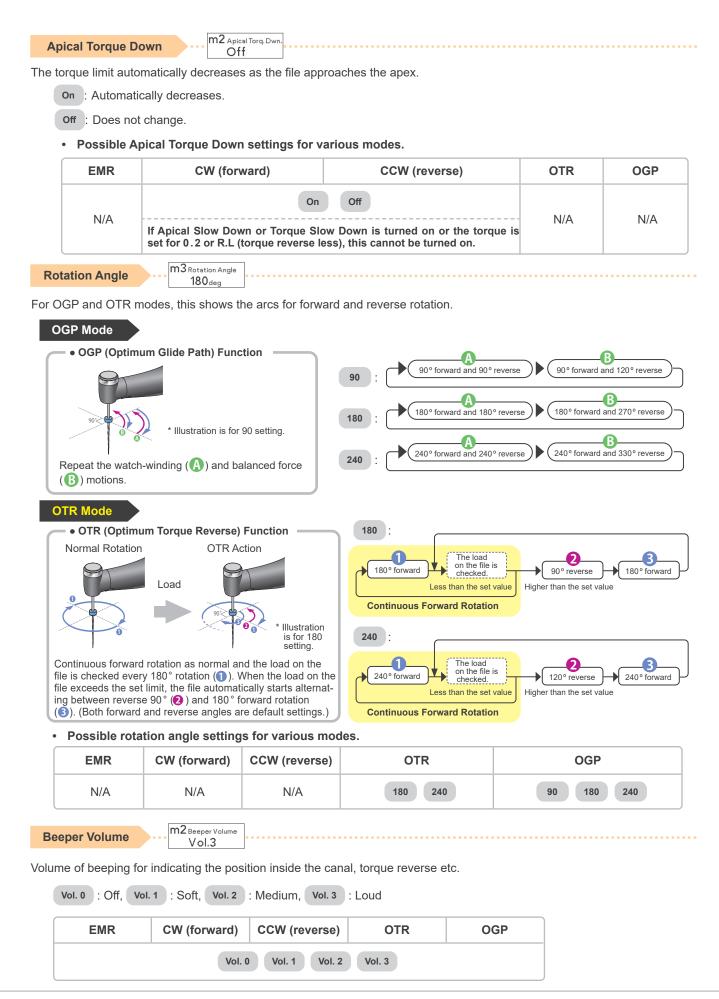
Rotation automatically slows down as the torque load on the file increases.

On : Automatically slows down.

off : Does not slow down.

Possible torque slow down settings for various modes.

EMR	CW (forward)	CCW (reverse)	OTR	OGP
N/A	On If Apical Torque Down is turned on (torque reverse less), this cannot b		N/A	N/A



## **Other Handpiece Functions**

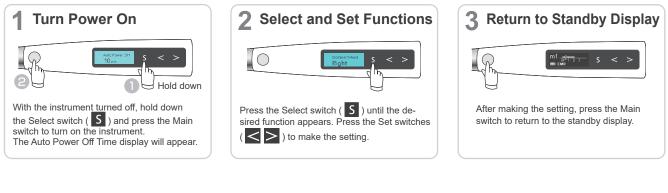
In addition to the rotation control functions, the Tri Auto ZX2 has the following functions as well. These settings are common for all memories.

### Default Handpiece Settings

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

Auto Power OffAuto Standby Scr.(Auto Power Off Time)(Auto Return to Standby Display)		Dominant Hand	Startup Memory (Startup Memory Number)
10 min	10 sec	Right	m 1

## **Set Handpiece Functions**



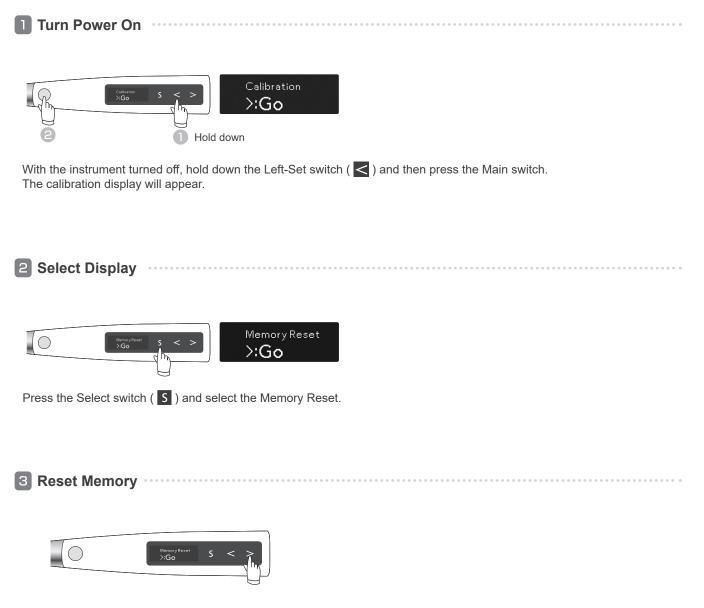
## Settings

Auto Power Off Auto Power Off Time 10 ... This shows how long it takes for the instrument to shut itself off if no switches are pressed. It can be set from 1 to 30 minutes in 1 minute increments. 1 min 30 min Auto Standby Sc Auto Return to Standby Display 105 This shows how long it takes for the instrument to go back to the standby display if no switches are pressed. 3 sec 15 sec It can be set from 1 to 15 seconds in 1 second increments. **Dominant Hand** Right This will rotate the display direction 180°. Set this for right or left depending on the user's dominant hand. Right or Left Startup Memor **Startup Memory Number** m1 This sets the memory number that appears right after the instrument is turned on. m1 : Memory m1 will appear when the instrument is turned on. **Previous** : The memory being used when the instrument was turned off will appear.

# **Reset Memories to Original Default Settings**

All memories and handpiece settings will revert to their original default settings.

\* All memories (m1 to m8) and handpiece functions will be initialized. It is not possible to initialize just one of them.



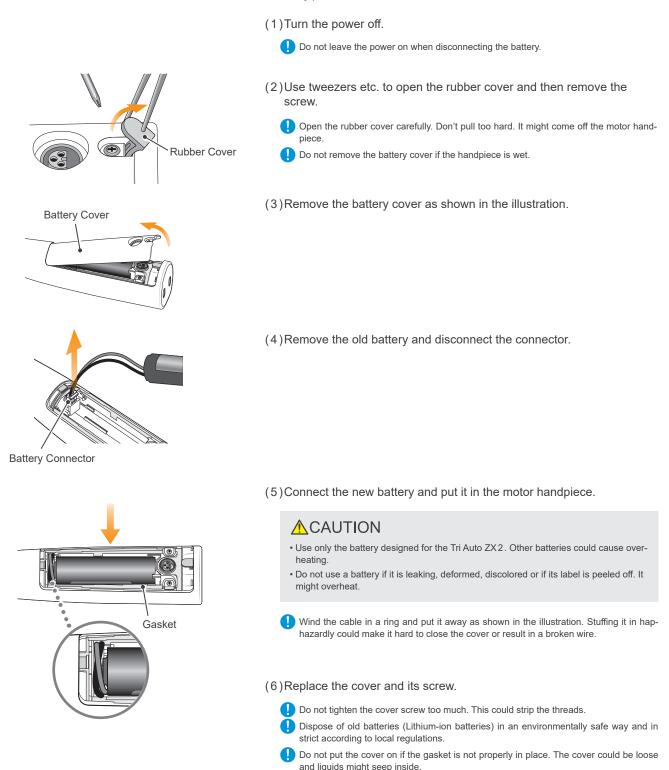
Press the Right-Set switch ( $\geq$ ) to reset the memories to their default settings. After the memories are reset, the instrument will automatically return to the standby display.

# **Replacement Parts**

- \* Replacement parts and consumable parts are described in the Regular Inspection List. Replace the parts as necessary depending on degree of wear and length of use.
- \* Order parts from your local dealer or J. MORITA OFFICE.

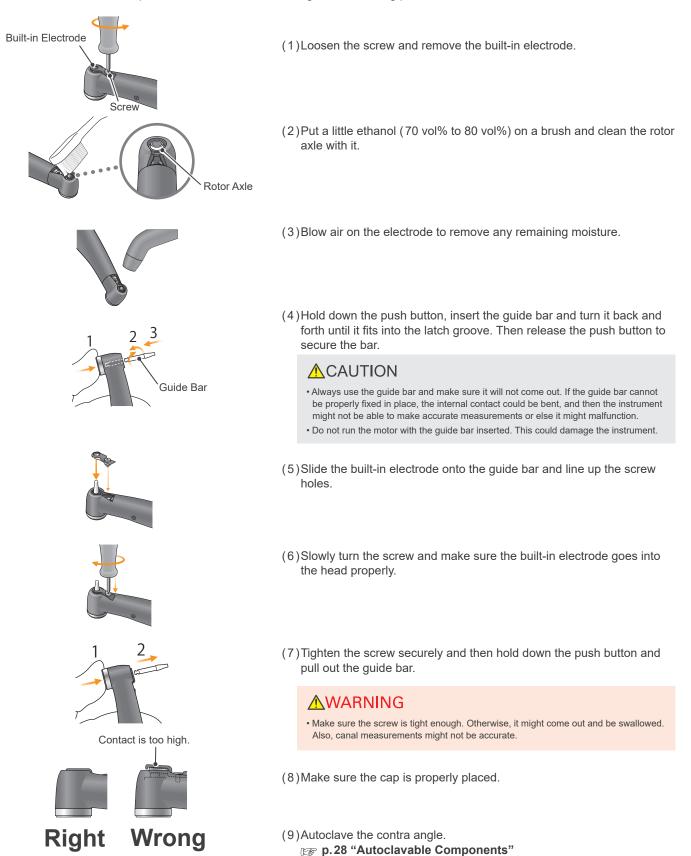
## **Replacing Battery**

Replace the battery if it seems to be running out of power sooner than it should. The battery will last for approximately 1 year under normal circumstances and use. (This depends somewhat on how the instrument is used and ambient conditions such as humidity.)



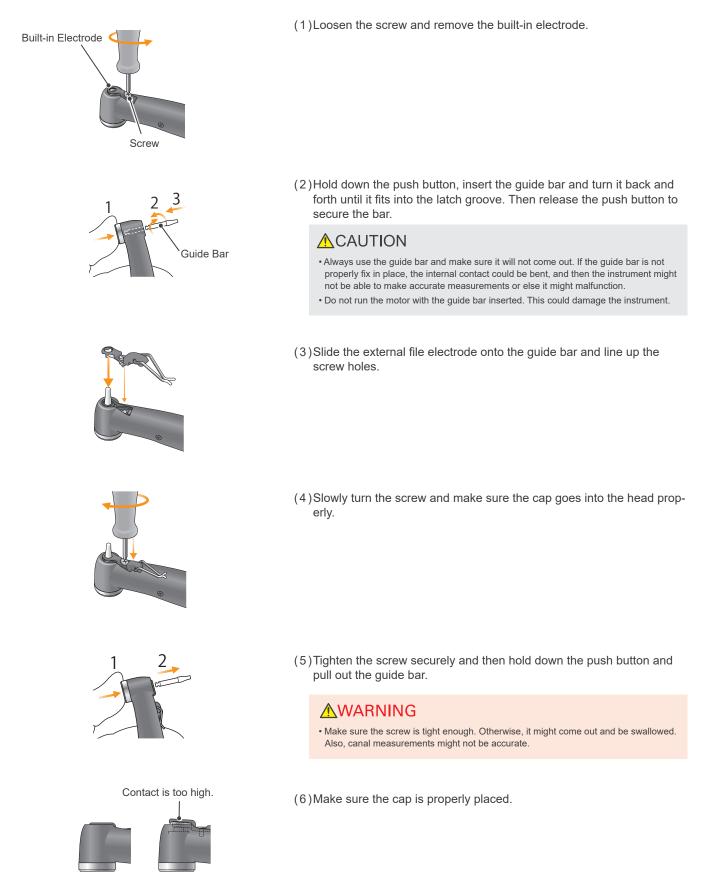
## Replacing Built-in Electrode

If the canal length indicator bars flicker during use, or if all the bars in the meter do not light up when the file touches the contrary electrode, and cleaning the rotor axle and built-in electrode does not solve the problem, then the built-in electrode is worn out and must be replaced with a new one according to the following procedure.



# **External File Electrode**

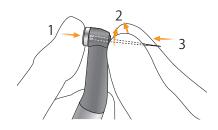
If you use a file that cannot make a measurement with the built-in electrode, replace it with external file electrode (sold separately).



(7) Autoclave the contra angle. [SF] p.28 "Autoclavable Components"

Right

Wrong



(8) Hold down the push button on the contra angle and insert the file. Turn the file back and forth until it is lined up with interior latch groove and slips into place. Release the button to lock the file into the contra angle.

\* Use only Ni-Ti or properly designed stainless steel files.

# **WARNING**

- Make sure the file is all the way in. Give it a light tug to make sure it is held securely.
- Never use stretched, deformed or damaged files.

# 

- · Be careful when inserting and removing files to avoid injury to fingers.
- Never put file in or take it out without pressing the button down. This could damage the chuck. Always hold the button down to put a file in or take it out.
- Do not use files with shanks larger than the ISO standard. ISO Standard: 02.334 to 2.350 mm

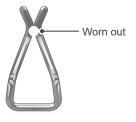
(9)Lift the electrode up and clip it onto the file.

# **WARNING**

 Always clip the electrode on the file when using it. Otherwise, measurements may not be accurate or rotation may not be properly controlled. (It may not be possible to measure a canal if blood or some other liquid overflows the canal or if the canal is completely blocked.)

# **ACAUTION**

- Do not let the cutting part of the file touch the electrode. Otherwise the file electrode will wear out very quickly.
- Some files cannot be used with this electrode.
- Also the Ni-Ti files noted below cannot be used. To use these types of files, do not clip on the electrode and use the motor in manual mode.
- Those with a file diameter of more than 1.2 mm.
- Those with chuck shanks that are nor perfectly round.
- Gates-Glidden Drills
- Those that have cutting sections with large diameters such as largo burs.



# **WARNING**

• Replace the external file electrode if it is worn out as shown in the photo to the left.



# **Maintenance and Inspection**

## Regular Inspection

- \* Maintenance and inspection are generally consider to be the duty and obligation of the user, but if, for some reason, the user is unable to carry out these duties, they may be performed by the accredited service personnel. Contact your local dealer or J. MORITA OFFICE for details.
- \* Consumable and replacement parts are described in page 51.
- \* This instrument should be inspected every 6 months in accordance with the following maintenance and inspection items.
  - Connect the AC adapter to the battery charger, plug it in and check that the Ready LED (green) lights up.
  - Make sure there is no dirt, metal fragments etc. on the connection contacts for both the motor handpiece end and the battery charger.
  - Put the motor handpiece into the battery charger and check that the Charge LED (orange) lights up. Check that the battery does not seem to be losing its charge too quickly.
  - · Check that the connection end of the motor handpiece is not damaged of dirty.
  - Check that the connection end of the contra angle is clean and not damaged and that it can be properly connected to the motor handpiece.
  - · Check that the push button works and a file can be properly installed.
  - · Check that the external file electrode (option) clips onto the file properly and that it is not worn or damaged.
  - Check that the instrument turns on when the Main switch is pressed, and that the instrument turns off when the Select switch is held down and the Main switch is pressed.
  - Press the Set switch ( <>) to select a memory from m1 to m8.
  - Check that the settings for each of the memories can be changed.
  - · Visually inspect the probe cord and its plugs and connectors carefully and make sure that they are not damaged or dirty.
  - · Make sure the probe cord connector goes into its motor jack properly.
  - Visually inspect the file holder and contrary electrode to make sure that are not damaged or dirty.
  - Make sure the file holder plug fits properly into its probe connector (gray).
  - · Make sure the file holder holds a file properly.
  - · Make sure the contrary electrode fits properly into its probe connector (white).
  - · Contact the file with the contrary electrode and check that all the root canal length indicator bars on the display are lit.
  - Connect the tester and make sure the meter reads within 2 bars above or below bar 1 on the meter.
  - Press the Main switch and make sure that this starts and stops the motor.
  - Run the motor in OGP mode, and check that it changes rotation direction.
  - Run the motor in CW mode and make sure the torque meter changes according to the load on the file.

\* For repairs contact your local dealer or J. MORITA OFFICE.

## Standards and Procedures for the 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 rechargeable battery should be recycled. Metal parts of the equipment 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 city/community administrations concerning local disposal companies.

# Troubleshooting

# 1. Troubleshooting

If the instrument 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	Remedies	Ref.
	Check the battery power.	Charge the battery.	p. 26
No power.	Check the battery installation.	Install the battery properly.	p.42
	Degraded battery.	Replace the battery.	
Display does not appear.	Is there a sound when the instrument is turned on and off?	Charge battery if there is no sound. Broken display if there is a sound.	p.26
Motor handpiece does not run.	Is it set for EMR mode?	Select a mode other than EMR mode.	p. 34
No sound.	Beep volume set to 0?	Set beep volume to 1, 2, or 3.	
Beep sound an alarm even though the instrument is not being used.	Is the instrument set to CCW (reverse rota- tion) mode?	When set to CCW mode, the beeper sounds an alarm after a set time period elapses. If this is annoying, set the beeper sound for 0.	p.39
	Is contrary electrode properly hooked in the corner of the patient's mouth?	Hook the contrary electrode in the corner of the patient's mouth.	p. 18
	Is the instrument set to EMR mode?	Select a mode other than EMR mode.	p.34
Motor does not run when	Is auto start turned off?	Turn the auto start function on.	
the file is inserted in the canal.	Does the canal length indicator bar light up only 1 bar or it does not light up?	Advance the file down the root canal, or add some moisture such as saline solution to the canal to light up 2 bars or more.	
	Does the fixing screw for the built-in elec- trode or external file electrode loose?	Tighten the screw securely.	
	Is the external file electrode worn out?	Replace the external file electrode with a new one.	p.44
	Does the canal length indicator bar light up?	Advance the file down the root canal, or add some moisture such as saline solution to the canal to light up 1 bar or more.	p.37
Motor stops too easily.	Does the fixing screw for the built-in elec- trode or external file electrode loose?	Tighten the screw securely.	p. 13
	Is the external file electrode worn out?	Replace the external file electrode with a new one.	p.44
	Torque limit may be set.	Set the Torque Reverse function for R.L (torque reverse less) if this is not desired.	p.35
Motor spontaneously starts running in reverse.	Is the apical action setting on reverse?	Change the Apical Action setting to Off or Stop.	p.36
5	Is the instrument set to CCW (reverse rota- tion) mode?	Change rotation mode to something other than CCW (reverse rotation) mode.	p.34
	Torque limit value might be set too low.	Increase the torque limit value.	p.35
Motor reverse its rotation	The Apical Torque Down function might be turned on.	The torque limit automatically decreases as the file ap- proaches the apex. To use a fixed reverse torque value, turn the Apical Torque Down function off.	p.39
too easily.	Does the canal retain some blood or chemi- cal solution?	In that case, the canal measurement meter could indi- cate a large movement and reach the flash bar. Advance the file down the root canal so that the meter display will resume in the appropriate position and the file rotation will return to the forward direction.	p. 19

Problem	Check Points	Remedies	Ref.	
	Set for R.L (torque reverse less)?	Change this to something other than R.L (torque reverse less).	p.35	
Motor does not reverse its	Torque reverse setting might be too high.	Lower the torque reverse setting.		
rotation.	Apical Action might be turned off.	Set Apical Action to Reverse.		
	Is Apical Action setting "Stop" or "OAS"?	Set Apical Action to Reverse.	p.36	
Motor changes speed	Apical Slow Down might be turned on.	Rotation slows down as file approaches the apex. For a steady rotation speed, turn it off.		
spontaneously.	Torque Slow Down might be turned on.	Rotation slows down as file torque increases. For a steady rotation speed, turn it off.		
Instrument turns off by	Instrument might not have been used for a while.	Auto Power Off was triggered. Press the Main switch to turn on the instrument again.	p.40	
itself.	Momentary large load when battery is low?	If pressing the Main switch returns to standby display but the battery is low, charge the battery.	p.49	
	Does the built-in electrode need replace- ment? Has it been replaced recently?	<ul><li>Clean and lubricate the contra angle.</li><li>Remove the internal electrode and clean it and the rotor axle with a brush.</li></ul>	p.43	
Canal measurement meter is unstable.		Replace the built-in electrode.		
	Does the fixing screw for the built-in elec- trode or external file electrode loose?	Tighten the screw securely.		
	Is the external file electrode worn out?	Replace the external file electrode with a new one.		
	Is it set to OTR mode?	In OTR mode, rotation alternates between forward and reverse if the torque is greater than the specified value.		
Motor alternates between forward and reverse rota- tion.	Is it set to OGP mode?	In OGP mode, the motor always alternates between forward and reverse.	p.39	
	Does alternating rotation happen even after calibration?	Raise the trigger torque 1 level.	p.35	
	Is the contrary electrode properly hooked in the corner of the patient's mouth?	Hook the contrary electrode in the corner of the patient's mouth.	p.18	
Cannot make a canal measurement.	Does the file or reamer lack electrical con- ductivity between the shank and the file?	Use a file or reamer that has conductivity or use the external file electrode.		
	A wire in the probe cord might be broken.	Touch the white connector on the probe cord with the gray one and see if all the bars on the meter light up.		
		Check the AC adapter is connected correctly.		
	Does the Ready LED (green) light up?	Make sure the AC adapter that comes with the Tri Auto ZX2 is used. If any other AC adapter that is not dedicated to the Tri Auto ZX2 is connected, the battery charger could be damaged.	-	
Battery cannot be charged.	Does the Charge LED (orange) light up when putting the motor handpiece into the battery charger?	If the motor handpiece is nearly fully charged, LED indi- cators will change as below. 1. The Ready LED (green) turns off. ↓ 2. The Charge LED (orange) lights up for a brief sec- ond, then goes out. ↓ 3. The Ready LED (green) lights up.	p.26	
		If the motor handpiece is not fully charged, put it back into the charger again. If the Charge LED (orange) still does not light up, contact your local dealer or J. MORITA OFFICE.		

# 2. Abnormal Stop

The motor handpiece may stop working in the 4 cases listed below.

Display	Cause	Remedies
Error 01 See Operation menual	Control circuits may have malfunctioned.	Turn the instrument off and then back on again. If the error message appears again, stop using the instrument immediately and contact your local dealer or J. MORITA OFFICE. The number that appears after "Error" depends on the malfunction. <b>p.49 "3. Error Numbers</b> "
Low Battery Please Charge	Battery power is very low or the motor was subjected to a very large load mo- mentarily.	Normally, press the Main switch to return to the Standby display. If the instrument does not return to the Standby display when the Main switch is pressed or if the message reappears after returning to the Standby display, the battery is very low and must be recharged. (For p.26 "Battery Charging" However, if the Standby display does not appear while a file is in the canal, take the file out and then press the Main switch.
Overload Motor Stop	This appears if the motor is subjected to a large load constantly such as when the file is locked in the canal and the motor cannot rotate.	<ul> <li>Normally, press the Main switch to return to the Standby display. If the instrument does not return to the Standby display when the Main switch is pressed the battery is very low and must be recharged.</li> <li>P.26 "Battery Charging"</li> <li>However, if the Standby display does not appear while a file is in the canal, take the file out and then press the Main switch.</li> </ul>
Overload Sudden Power Off	If the motor was subjected to a very large load momentarily and the battery does not have enough power, the instrument will turn off automatically. When the instrument is turned back on, the message shown to the left appears in the screen.	If pressing the Main switch returns to the Standby display but the battery is low, charge the battery. (FF) p.26 "Battery Charging"

# 3. Error Numbers

If an error or problem is detected, the instrument will stop and an error number will appear in the display. If the instrument stops, turn it off and then back on again. If the error message appears again, stop using the instrument and contact your local dealer or J. MORITA OFFICE.

Make a note of the error number and report it when requesting assistance.

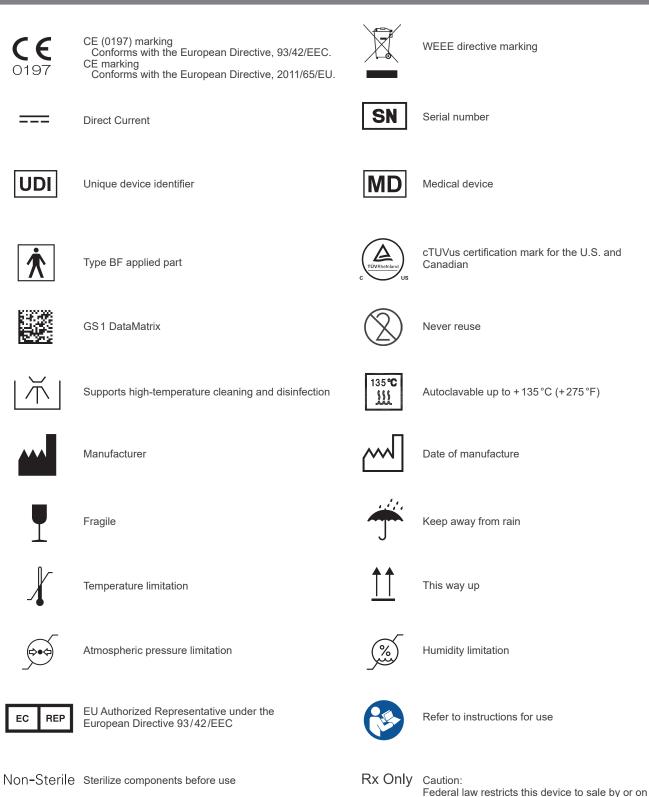
Error No.	Problem	Error No.	Problem
01	Battery power detection fault	65	EEPROM fault
04	Motor fault	66	Canal measurement fault
08	Torque settings fault	96	Watch dog fault
16	Internal buffer fault		

# **Technical Specifications**

\* Specifications may be changed without notice due to improvements.

Name	Tri Auto ZX 2
Model	TR-ZX2
Degree of Protection against Ingress of Water	IPX0
Indications for use	The Tri Auto ZX2 device is a cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge the canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device for measuring canal length.
Operating principle	By electric drive, it transmits motion, such as rotation and vibration, to treatment instruments (dental files, reamers, etc.). The impedance in the root canal is measured by measuring at two frequencies and the position of the treatment instruments in the root canal is detected.
Essential Performance	None (There is no unacceptable risk.)
Handpiece	
Free Running Operation Speed	100 ±20 – 1000 ±100 r/min
Gear Ratio	1.9:1
Usable Burs	Type 1 (CA)
Rated Torque	min. 4 N·cm
Chuck Type	Push button latch type
Protection against Electric Shock	Internal powered ME equipment / Type BF applied part
Battery	Lithium ion battery (DC 3.7 V)
Dimensions	Approx. Dia.31 × Length 202 mm (including contra angle and motor handpiece)
Weight	Approx. 140 g (including contra angle and motor handpiece)
Applied Part	Contra angle, Motor handpiece, File holder, Contrary electrode
Battery Charger	
Rated Input Voltage	DC 5 V
Rated Input Current	2.4 A
Dimensions	Approx. Dia. 86 × Height 72 mm
Weight	Approx. 280 g
AC Adapter	
Rated Input Voltage	AC 100 – 240 V
Rated Input Frequency	47 – 63 Hz
Rated Input Current	0.4 A
Classification of Protection against Electric Shock	Class II
0	

# Symbols



the order of a dentist.(for U.S.A.)

# **Service Contacts**

The Tri Auto ZX2 may be repaired and serviced by

- The technicians of J. MORITA's subsidiaries worldwide.
- Technicians employed by authorized J. MORITA dealers and specially trained by J. MORITA.
- Independent technicians specially trained and authorized by J. MORITA.

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

# **Consumable and Replacement Parts**

Battery	(1)	AC Adapter	(1)	Built-in Electrode (with guide bar)	(1)	Guide bar	(1)
Code No. 7505628		Code No. 8456097		Code No. 8491887		Code No. 8491763	
Probe Cord (0.75m)	(1)	File Holder	(5)	Contrary Electrode	(5)	Tester	(1)
Code No. 8456062		Code No. 7503670		Code No. 7503680		Code No. 8456089	
	<b>D</b>			0	-		
HP Protective Sleeve Type A (box of )	100)	LS OIL	(1)				
Code No. 8456070		Code No. 8491720					
Constraint of							

Handpiece Holder (	1)	External File Electrode (with cap and guide bar) (1)	Probe Cord (1.8m) (1)	Long File Holder (5)
Code No. 9181504		Code No. 8491879	Code No. 8449422	Code No. 8447055
		0		

# **Electromagnetic Disturbances (EMD)**

The Tri Auto ZX2 (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.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions			
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.			
Emissions Test	Emissions Test Compliance Electromagnetic Environment – Guidance		
Conducted disturbance CISPR 11	Group 1 Class B	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.	
Radiated disturbance CISPR 11	Group 1 Class B	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	
Harmonic current <sup>*1</sup> IEC 61000-3-2	Class A	buildings used for domestic purposes.	
Voltage fluctuations and flicker IEC 61000-3-3	Clause 5		

\*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.

# **MWARNING**

• 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 equipment and other equipment 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 TR-ZX2, 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 environ

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 <sup>1</sup> ±1 kV for input/output lines <sup>1</sup>	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	$\begin{array}{l} \underline{AC/DC \ power} \\ \pm 0.5 \ kV, \pm 1 \ kV \ line(s) \ to \ line(s) \\ \pm 0.5 \ kV, \pm 1 \ kV, \pm 2 \ kV \ line(s) \ to \ earth \\ \underline{Signal \ input/output}^2 \\ \pm 2 \ kV \ line(s) \ to \ earth \end{array}$	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	$\begin{array}{l} \underline{\text{dips}}\\ 0\%U_{\tau}:0.5\text{cycle}(\text{at}0,45,90,135,\\ 180,225,270,315^\circ)\\ 0\%U_{\tau}:1\text{cycle}(\text{at}0^\circ)\\ 70\%U_{\tau}:25/30\text{cycles}(\text{at}0^\circ)\\ 25(50\text{Hz})/30(60\text{Hz})\\ \underline{\text{short interruptions}}\\ 0\%U_{\tau}:250/300\text{cycles}\\ 250(50\text{Hz})/300(60\text{Hz})\\ \end{array}$	$\begin{array}{l} \displaystyle \frac{dips}{0\%U_{T}\colon 0.5 \text{ cycle (at } 0,45,90,135,\\ 180,225,270,315^{\circ})\\ 0\%U_{T}\colon 1 \text{ cycle (at } 0^{\circ})\\ 70\%U_{T}\colon 25/30 \text{ cycles (at } 0^{\circ})\\ 25(50Hz)/30(60Hz)\\ \displaystyle \frac{shortinterruptions}{0\%U_{T}\colon 250/300 \text{ cycles}}\\ 250(50Hz)/300(60Hz) \end{array}$	Mains power quality should be that of a typi- cal 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:  $O_T$  is the a.c. mains voltage prior to application of the test lev 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.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance	
Conducted RF IEC 61000-4-6	3 V ISM <sup>(c)</sup> / amateur radio frequency band: 6 V 150 kHz to 80 MHz	3 V ISM <sup>(c)</sup> / amateur radio frequency band: 6 V 150 kHz to 80 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.	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	Recommended separation distances	
	27 V/m	27 V/m 385 MHz	d = $1.2\sqrt{P}$ 150 kHz to 80 MHz	
	385 MHz		d = 0.4 $\sqrt{P}$ 80 MHz to 800 MHz	
	28 V/m 28 V/m 450 MHz 450 MHz		d = $0.7\sqrt{P}$ 800 MHz to 2.7 GHz	
		d = $\frac{6}{F}\sqrt{P}$ Portable wireless RF communication equipment		
	9 V/m 710, 745, 780 MHz	9 V/m 710, 745, 780 MHz	Where P is the maximum output power rating of the transmitter in	
	28 V/m 810, 870, 930, MHz	28 V/m 810, 870, 930, MHz	watts (W) according to the transmitter manufacturer, E is the com- pliance level in V/m and d is the recommended separation distance in meters (m).	
	28 V/m 1720, 1845, 1970 MHz	28 V/m 1720, 1845, 1970 MHz	Field strengths from field RF transmitters, as determined by an electromagnetic site survey <sup>(a)</sup> , should be less than the compliance	
	28 V/m	28 V/m	level in each frequency range <sup>(b)</sup> .	
	2450 MHz	2450 MHz	Interference may occur in the vicinity of equipment marked with the following symbol:	
	9 V/m 5240, 5500, 5785 MHz	9 V/m 5240, 5500, 5785 MHz		

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

N	۱o.	Interface(s):	Max. Cable Length, Shielding	Cable Classification
	1.	DC Power Cable	1.8 m, Un-shielded	DC Power Line
2	2.	Probe Cord	1.8 m, Un-shielded	Signal Line (Patient-Coupled Cable)

**Diagnostic and Imaging Equipment** 

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Development and Manufacturing

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