



Cordless Endodontic Treatment Motorized Handpiece

Tri Auto mini

INSTRUCTIONS FOR USE





Thinking ahead. Focused on life.

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Thank you for purchasing the Tri Auto mini.

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

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Prevent Accidents

Attention Customers

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

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



Attention Dealers

Do not fail to give clear instructions concerning the various ways to use this equipment as described in this accompanying operator's manual.

Prevent Accidents

Most operation and reprocessing problems result from insufficient attention being paid to basic safety precautions and not being able to foresee the possibilities of accidents. Problems and accidents are best avoided by foreseeing the possibility of danger and operating the equipment in accordance with the manufacturer's recommendations. First thoroughly read all precautions and instructions pertaining to safety and accident prevention; then, operate the equipment with the utmost caution to prevent either damaging the equipment itself or causing bodily injury.

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

MWARNING

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

This warns the user of the possibility of mild injury or damage to the equipment.

The warning symbols (\land) and caution symbols (\land) that appear next to the main text on the right hand side of the page refer to and are explained by the Warnings and Cautions at the bottom of the page.

(Mandatory Action)

This alerts the user of important points concerning operation or the risk of equipment damage.

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

This equipment must only be used by dentists and other legally licensed professionals. Do not use this equipment for anything other than its specified dental purpose.

The Useful Life

The useful life of the Tri Auto mini is 6 years from the date of installation provided it is regularly and properly inspected and maintained.

In Case of Accident

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

Intended Operator Profile

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

Patient Population

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

ACAUTION

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

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Warnings and Prohibitions

MWARNING

- This equipment must not be connected to or used in combination with any other apparatus or system. It must not be used as an integral component of any other apparatus or system.
- J. MORITA MFG. CORP. will not be responsible for accidents, equipment damage, bodily injury or any other trouble which results from ignoring this prohibition.
- A rubber dam should be used when performing endodontic treatment.
- No modification of this equipment is allowed.
- Always wear personal protective equipment (PPE) such as safety glasses, gloves, a mask, etc. when using and reprocessing the Tri Auto mini.

PROHIBITION : This indicates when not to use the equipment.

- Electromagnetic wave interference could cause this equipment to operate in an abnormal, random and possibly dangerous manner. Cellular phone, transceivers, remote controls and all other devices which transmit electromagnetic waves located inside the building should be turned off.
- Instruments which produce considerable electrical noise such as electric scalpels can cause the Tri Auto mini to operate abnormally. Turn the Tri Auto mini off before using any instruments that produce electrical noise.
- Do not use this equipment on patients who have a pacemaker or an Implantable Cardioverter Defibrillator (ICD).
- Illumination devices such as fluorescent lights and film viewers which use an inverter can cause the Tri Auto mini to operate erratically. Do not use the Tri Auto mini near lights such as these.
- This equipment must not be connected to or used in combination with any other apparatus or system. It must not be used as an integral component of any other apparatus or system. J. MOTIRA MFG. CORP. will not be responsible for accidents, equipment damage, bodily injury or any other trouble which results from ignoring the above prohibitions.
- Blocked canals cannot be accurately measured.
- · Do not perform maintenance while using the instrument for treatment.
- * J. MORITA MFG. CORP. is not responsible for any accidents or other types of trouble that are caused by not following the prohibitions and other conditions noted above.

Features

Features and intended use:

The Tri Auto mini is a compact, cordless endodontic treatment motorized handpiece for preparation and enlargement of root canals. It may be connected to the Root ZX mini, an apex locator (sold separately).

Instructions for how to use the Tri Auto mini when it is connected to the Root ZX mini are printed on a blue background like this one.

Liquid Crystal Display (LCD) :

The LCD is easy to read and shows all settings as well as how the motor is running.

Controls:

Speed :	Eleven rotation speeds can be set from 50 to 1,000 rpm.
Torque Reverse :	The motor automatically reverses its rotation if the torque load exceeds the set value to reduce the risk of jamming.
Slow Down :	The file slows down as torque increases. The file slows down as it approaches the apex if the Tri Auto mini is connected to the Root ZX mini.
Forward & Reverse :	The file may rotate in both forward and reverse directions.
Auto Start & Stop* :	The file starts when it is inserted in the canal and stops when it is taken out.
Apical Reverse or Stop* :	The motor reverses or stops when the tip of the file reaches a preset position inside the canal.
Apical Torque Reduction* :	The automatic torque reverse value is reduced as the file tip approaches the apex.

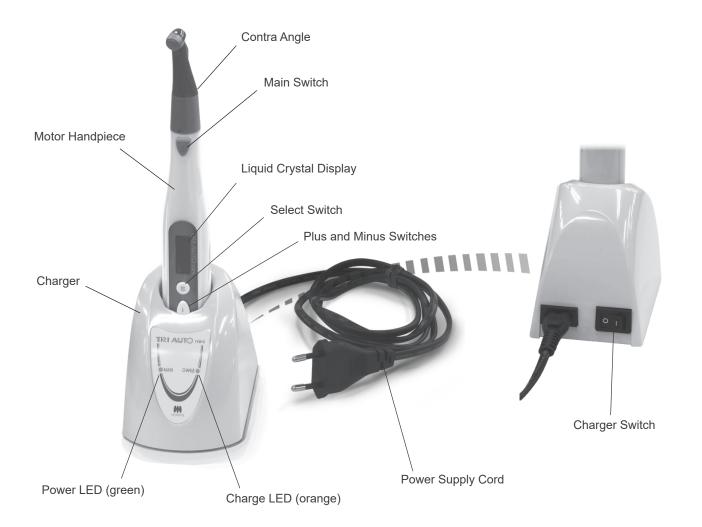
* These controls can be used if the Tri Auto mini is connected to the Root ZX mini.

Memory:

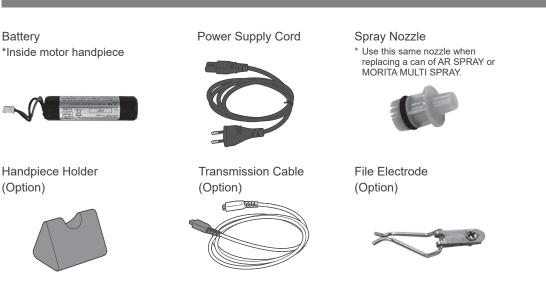
Six combinations of speed, torque etc. can be memorized.

Parts Identification and Accessories

Parts Identification



Accessories



AR SPRAY or MORITA MULTI SPRAY * Sold Separately



Usage

Operating Environments

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

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

(1) Before Use

リ Be sure to perform reprocessing on the respective parts before using them for the first time. 😥 p. 22 "Reprocessing"

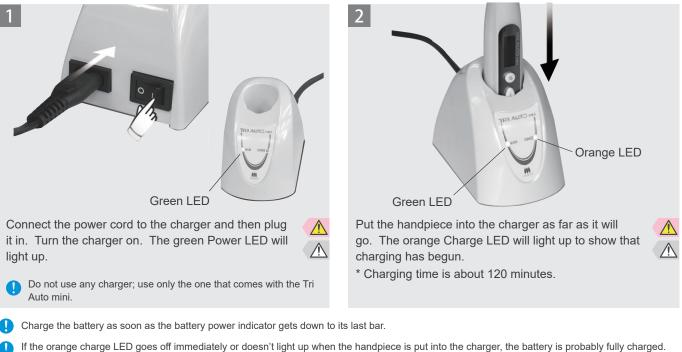
Check the following before using the instrument.

- Have the autoclavable parts been sterilized? 🔊 p. 23 "(1) Parts to be Sterilized"
- Have the disinfectable parts been disinfected? Is p. 28 "(2) Parts to be Disinfested"

Charge Battery

The battery is built into the motor handpiece.

* Ambient (room) temperature for charging is from +10 °C (+50 °F) to +40 °C (+104 °F).



- To make sure, take the handpiece out and put it back in again.
- Make sure the contact areas for the handpiece and charger are free of debris, especially metal fragments. Wipe with ethanol to remove any foreign debris. Do not press down too hard to wipe the charging areas; this could bend the electrical contacts.
- Do not leave the charger where it will be exposed to direct sunlight.

Unplug the battery charger when it is not being used.

WARNING

- If an electrical storm occurs while the battery is being charged, do not touch the charger or its cord as there would be a risk receiving an electric shock.
- Do not get the charger wet or use it where it might get wet.

ACAUTION

- The battery is not charged when the unit is shipped from the factory and must be charged before using the unit.
- Do not pull or yank the cord when disconnecting the AC adapter. Always grip the connectors.
- ${\boldsymbol{\cdot}}$ Use only the power cord provided and plug both ends all the way in.
- · Charger and power supply cord must be located outside the so called patient environment (2.0 m around the patient location).

Charge Battery



The number of bars shows how much battery power is left. Recharge the battery when there is only one bar left.



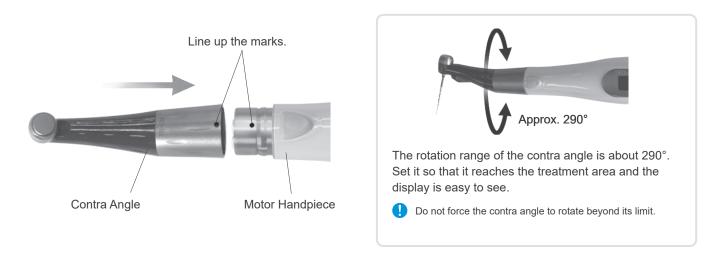
If the battery runs almost completely out, the Tri Auto mini will automatically turn itself off after about 10 seconds. Recharge the battery as soon as possible.



If the battery power is very low and a large load is applied to the file, the motor may stop or the unit may turn itself off.

This is for safety; there may not be enough power to run the motor with sufficient stability. Recharge the battery if the display shown to the left appears frequently.

Connect Contra Angle



Line up the match marks and push the contra angle onto the handpiece until there is an audible click.

* The contra angle must be lubricated with the AR SPRAY or MORITA MULTI SPRAY before using for the first time. Refer to "Autoclaving the Contra Angle".

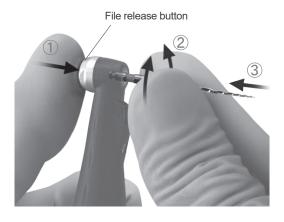
WARNING

• Make sure the connection components for both the handpiece and the contra angle are not damaged. An improper connection could cause the motor to reverse unexpectedly and result in injuring the patient.

ACAUTION

• Push the contra angle all the way onto the handpiece and then give it a light tug to make sure it is securely attached.

File Installation



Hold down the file release button Insert the file and turn it back and forth until it lines up with the latch mechanism. Push the file all the way into the latch. Release the file release button.



Use either Nickel-titanium or stainless steel files.

For use with the Root ZX mini, connect the file electrode and the transmission cable .

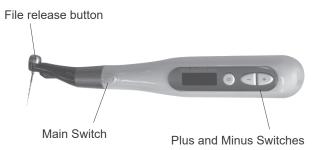
WARNING

- Never use deformed or damaged files.
- 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.

ACAUTION

- Use caution when inserting and removing files to avoid injury to fingers.
- Inserting and removing files without holding the file release button down will damage the chuck.
- Make sure the Tri Auto mini is turned off before inserting or removing files.
- Do not connect the file electrode if the handpiece is not connected to the Root ZX mini.

Check Operation





If a malfunction occurs, the Tri Auto mini will stop working. In this case, contact your local dealer or J. MORITA OFFICE.

The number that appears after Error will depend on the type of malfunction.

- Make sure the contra angle and handpiece are properly and securely connected.
- Make sure the file is securely installed; give it a light tug.
- Check switch operation.

Turn the Main switch on and use the Plus or Minus switches to select a memory. Then press the main switch again to see if the Tri Auto mini runs smoothly.

Refer to page 18 for instructions on checking the Tri Auto mini's operation when it is connected to the Root ZX mini.

MWARNING

- · Operate the Tri Auto mini outside the oral cavity to make sure it will operate properly before using it for treatment.
- Some canals may be impossible to enlarge; always take an X-ray to check.
- Nickel-titanium file may suddenly snap depending on the curvature and shape of the canal; stop using the file if you notice or feel anything amiss.
- · Files will eventually break due to metal fatigue and should be replaced before they reach this point.
- Electric noise or a malfunction could interfere with the motor control. Do not depend entirely on the unit controlling itself; always watch the display and be aware of tactile feedback.
- · Files will jam and break if too much force is applied to them.
- Files may break even when the torque reverse is turned on, depending on the setting value. Never exert excessive force on the file.
- Files designed for use with engines break easily if too much force is applied. Also do not use these files for canals with excessive curvature.
- Always examine files for stretching and other deformities or damage before using them. Any type of deformity could result in the file breaking.
- Do not let the file release button on the contra angle press against the teeth opposite to the treatment area; this could cause the file to come out and result in an injury.
- Do not press the file release button while the motor is running. It could heat up and cause a burn, or the file could come out and cause an injury.

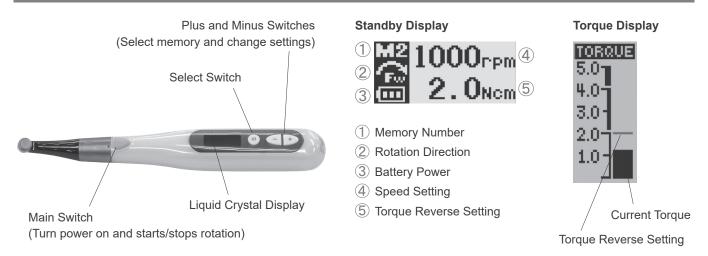
ACAUTION

- Stop using the Tri Auto mini if you feel or notice anything unusual. The Tri Auto mini cannot be used for every canal and should be used along with manual enlargement.
- File break more easily at fast speeds; always follow the file manufacturer's usage recommendations. Also always check the speed settings before use.
- Do not use any type of files except nickel-titanium and stainless steel ones.
- Nickel-Titanium files are easily broken; note the following points.
 - · Open the canal up to the apical constriction manually before using a nickel-titanium file.
 - Never use excessive force to insert the file.
 - · First remove all foreign matter, such as bits of cotton from the root canal.
 - · Never use excessive force to advance the file down the root canal.
 - Do not use for extremely curved canals.
 - Try not to trigger the auto torque reverse function when advancing the file down the canal.
 - · Do not skip file sizes; suddenly using a much larger file could break it.
 - If you encounter resistance or the auto torque reverse is triggered, 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.
 - · Do not force the file down the root canal or press it against the root canal wall.
 - Do not use the same file continuously in one position as this may create "steps" on the root canal wall.
- · Always take file out of the contra angle after use.



(2) Operation

Basic Operation



1. Turn Tri Auto mini on: Press Main switch.



The standby display will appear.

When the standby display is being shown, you can turn the Tri Auto mini off by holding down the Select Switch and pressing the Main Switch

* The Tri Auto mini turns itself off automatically if it is not used for 3 minutes (factory setting).

2. Select Memory number: Press Plus or Minus switch.

- * There are six memories for various combinations of speed, torque reverse and rotation direction settings.
- * The backlight will temporarily change color if changing the memory number changes anything other than the speed, torque reverse, and rotation direction settings.

3. Start motor: Press Main switch again.

The Torque Display will appear.

- * If you hold the Main Switch down when you start the motor, it will run only while the switch is held down and stop when the switch is released.
- * You can temporarily change the torque reverse setting while the motor is running by pressing the Plus or Minus switch.
- * The color of the backlight changes depending on the load applied to the file.
- * The backlight starts blinking when the load approaches the torque reverse setting.

4. Stop motor: Press Main switch again.

The standby display will reappear.

When connected to the Root ZX mini, refer to page 19 for meter readings and operation.

MWARNING

• Do not fail to check the new settings whenever you change the Memory Number.

≜CAUTION

• The temperature of the motor handpiece rises up to +47.5°C (+117.5°F) when the ambient temperature is +40 °C (+104 °F).

Memory Settings

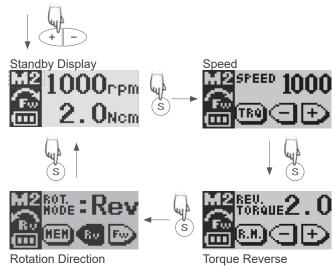
The factory settings are shown below. These settings can be changed.

Catting	Memory			
Setting	M1, M4	M2, M5	M3, M6	
Speed (rpm)	400	400	250	
Torque Reverse (Ncm)	1.0	0.8	0.6	
Rotation Direction	Forward			
Torque Slow Down	OFF			
Canal Measurement Linkage**	ON			
Apical Reverse or Stop**	Reverse			
Auto Start or Stop**	ON			
Apical Slow Down**	OFF			
Apical Torque Reduction**	OFF			

** These functions are available only when connected to the Root ZX mini.

Memory Settings: Primary Functions

Primary Functions: Rotation Speed, Torque Reverse, Rotation Direction



Rotation Direction

- 1. Select a memory number for the standby display by pressing the Plus or Minus switch.
- 2. Press the Select Switch to choose one of the primary functions.
- 3. Press the Plus or Minus switch to change the setting.
- * The display will go back to the standby display if 5 seconds (factory setting) elapses without a switch being pressed.

Speed Settings:

50, 100, 150, 200, 250, 300, 400, 500, 600, 800 and 1000 rpm

Torque Reverse Settings:

0.2, 0.4, 0.6, 0.8, 1.0, 1.5, 2.0, 2.5 and 3.0 Ncm This function can also be turned off: TRL (torque reverse-less).

Rotation Direction:

Fwd: Forward, Rev: Reverse

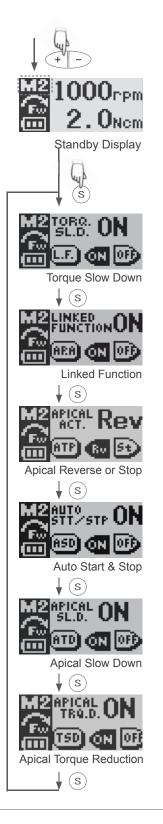
ACAUTION

• If the torque reverse function is turned off, the file could jam inside the canal and break.

- Torque reverse should be set depending on the canal and the file.
- · If the torque reverse seems to be activated too frequently increase its value.

Memory Settings: Additional Operation Settings

Additional Functions: Torque Slow Down (TORQ.SL.D.), Linked to canal measurement (LINKED FUNCTION**), Apical Reverse or Stop (APICAL ACT.**), Auto Start and Stop (AUTO STT/STP**), Apical Slow Down (APICAL SL.D.**), Apical Torque Reduction (APICAL TRQ.D.**)



- 1. Select a memory number for the standby display; press the Plus or Minus switch.
- 2. Hold down the Select switch for at least 1 second to show the displays for additional operation settings.
- 3. Press the Select switch to go from one display to the next.
- 4. Change the setting; press the Plus or Minus switch.
 - * The display will go back to the standby display if 5 seconds (factory setting) elapses without a switch being pressed.

Torque Slow Down:

When this is turned on, the motor will slow down as the torque load increases.

Linked Function**:

When this is turned on, the functions below will be activated.

Apical Reverse or Stop**:

The file will reverse or stop when the file tip reaches the Flash Bar.

Auto Start & Stop**:

When this is turned on, the file starts rotating when it is inserted and stops when it is taken out of the canal.

Apical Slow Down**:

When this is turned on, the file slows down as it approaches the apex.

Apical Torque Reduction**:

When this is turned on, the torque setting that triggers reverse rotation is reduced as the file tip approaches the apex.

** These functions are available only when connected to the Root ZX mini.

Memory Settings: Other Settings

Other Settings: The factory settings are shown below.

Beeper (BEEP VOLUME)	Big	Right or Left Handed (DOMI. HAND)	Right
Auto Power Off (AUTO PWR)	3 min.	Backlight (B.L.COLOR CHANGE)	ON
Positive/Negative Display (DISP. TYPE)	Posi	Return to Standby Time (S.S.R TIME)	5 sec.

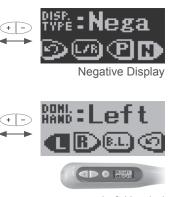
- 1. With unit turned off, hold down Select Switch and then press the Main Switch.
- 2. Press the Select Switch to select one of the settings.
- 3. Press the Plus or Minus switches to change the setting.
- 4. Press the Main Switch to return to the standby display.

Beeper Volume:

Press Plus or Minus switch to set beep volume used for switch operation and alarms at Off, Low or Big.

Auto Power Off Time:

The time lapse for automatic shut off when the unit is not used can be set from 1 to 15 minutes. Press Plus or Minus switch to set the time.



Positive / Negative Display:

Set display for black on white background or vice versa.

Left Handed

Right or Left Handed:

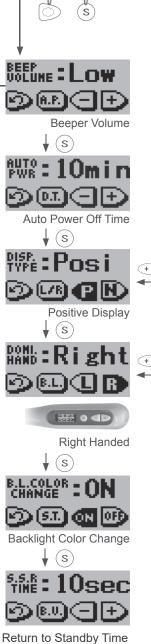
Set display for right- or left-handed user. Display turns upside down for left-handed users.

Backlight Color Change:

When this is turned on, the backlight will change color depending on torque and file tip location. It also changes color for setting displays. Does not change color when turned off.

Return to Standby Time:

Set the time that elapses before display returns to standby from settings displays. Set from 1 to 15 seconds by pressing Plus or Minus switches.



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Restore Default Memories

Restore the original factory settings for the memories in the following way.

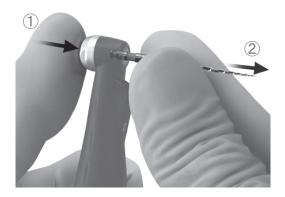
* This will restore the original memory settings. You cannot restore settings for just one memory.



- 1. Hold down the Select Switch, the Plus Switch and the Minus Switch and then turn the unit on with the Main Switch.
- 2. The "MemClear" display will appear. Press the Select Switch to restore the default memories or press the Main switch to cancel the operation.
- 3. Wait unit the "Finished" display appears and then press the Main switch to go to the standby display.

(3) After Use

Take Out File



- 1. Hold down the Select switch and press the Main switch to turn the power off.
 - * The power will go off automatically if the unit is not used and no switches are pressed for 3 minutes.
- 2. Hold down the file release button and pull the file straight out.

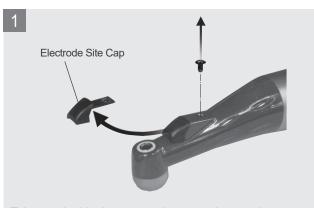
ACAUTION

- · Take care not to injure your fingers when inserting and removing files.
- · Never insert or remove files without holding down the button; this will damage the chuck.
- Make sure the unit is turned off before inserting or removing files.

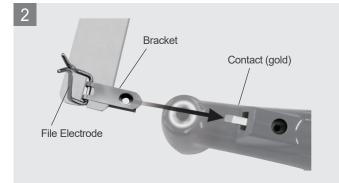
A

Usage; Operation with the Root ZX mini

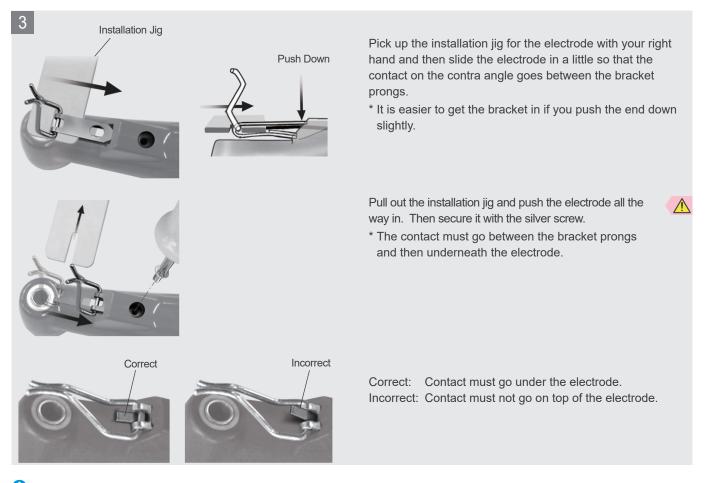
Install File Electrode



Take out the black screw and remove the cap that covers the elctrode installation area.



Take out the silver screw used to secure the file electrode.

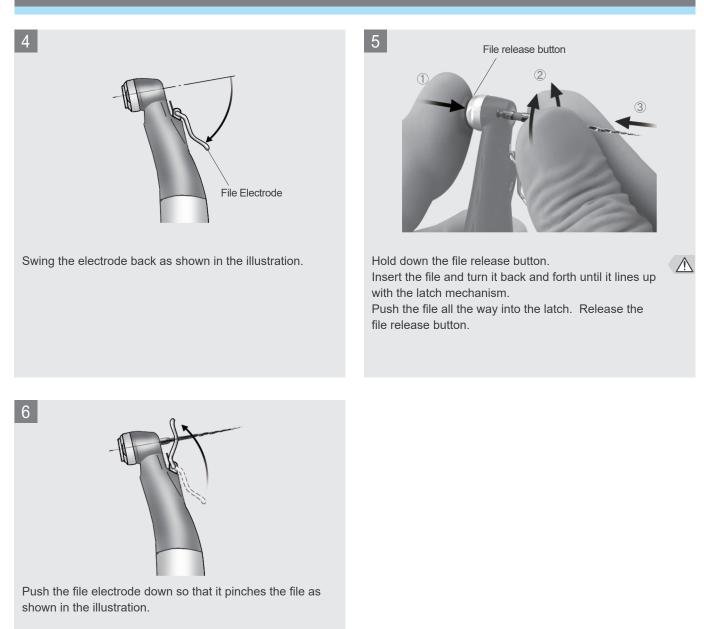


Do not mix up the black screw used for the cap and the silver screw used for the electrode.

WARNING

Make sure the screw is properly tightened up; otherwise it might come out and be swallowed.

Install File Electrode



Inserting and removing files without holding the file release button down will damage the chuck.

Do not let the electrode pinch the cutting part of the file.

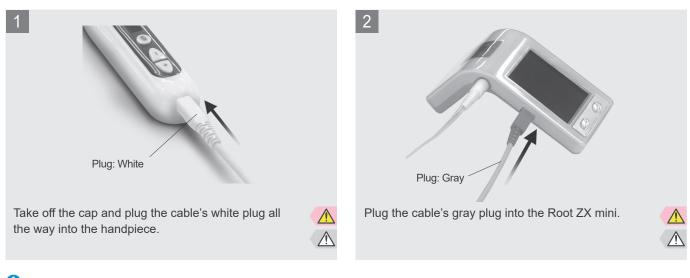
- The file electrode may not fit on some types of files.
- P The file electrode cannot be used for files with a shank diameter greater than 1.2 mm, files with large cutting heads such as largo burrs, files with shanks that are not round and Gates Glidden drills. Do not mix up the black screw used for the cap and the silver screw used for the electrode.

ACAUTION

- Use caution when inserting and removing files to avoid injury to fingers.
- Make sure the file goes all the way in. Give the file a light tug to make sure it is properly installed.

Connect the Transmission Cable

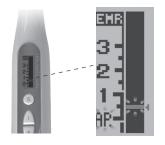
* Refer to the user manual for the Root ZX mini.



Do not mix up the cable plugs.

Check Operation





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Make sure file electrode is making good contact with the file.

Touch the file with the contrary electrode and make sure the meter goes all the way to its end and there are no segments that do not light up.

Watch out because the motor might start up when you do this.

WARNING

- Use only the special cable provided. Other cable could be electrically risky and result in damage or injury. Make sure the file goes all the way in. Give the file a light tug to make sure it is properly installed.
- Check the meter activity before each patient and do not use the instrument if all the segments of the display do not light up. This suggests that the meter cannot make an accurate reading.

ACAUTION

• Make sure the plugs go straight in.

- After insertion give plugs a light tug to make sure they are securely connected. Otherwise, data may not be transmitted acurately.
- Do not bump the plugs or drop anything on them when they are plugged in.

Meter Display

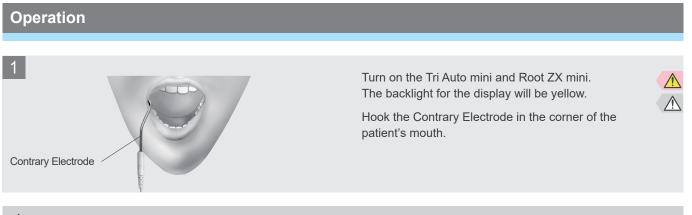
* Refer to the user manual for the Root ZX mini for information about canal measurement and for warnings and notes about use.



i. The Measurement Bar shows the location of the file tip. The Flash Bar blinks on and off when the file is inside the canal.



- ii. The meter's 0.5 reading indicates that the file tip is located very near the physiological apical foramen. Use this position as a reference to determine the working length depending on the individual case. The exact working length depends on the shape and condition of the canal, and a clinical judgment must be made by the dentist.
 - * The numerals 1, 2, and 3 do not represent length in millimeters from the apex. These numbers are used to as a reference to determine the working length.
- iii. If the file tip goes past the Flash Bar, an alarm will sound and the backlight will blink on and off.



MWARNING

- In some cases such as a blocked root canal, a measurement can not be made. (For details refer to the section of the Root ZX mini manual that covers canals not suitable for measurement.)
- Accurate measurement is not always possible, especially in cases of abnormal or unusual root canal morphology; always take an X-ray to check the measurement results.
- If the meter does not move when the file is inserted, the unit may be malfunctioning and must not be used.
- Do not use an ultra sonic scaler while the contrary electrode is hooked in the patient's mouth; noise from the scaler could cause the motor to start running resulting in an accident or injury.
- Absolutely never allow the contrary electrode, the handpiece file electrode or the connections for these to contact an ordinary AC power source such as a socket; this could result in a very serious and angerous shock.

- 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.
- The contrary electrode, file electrode and metal parts of the contra angle could cause an adverse reaction if the patient has an allergy to metals. Ask the patient about this before using the Tri Auto mini.
- Take care that medicinal solutions such as formalin cresol (FC) or sodium hypochlorite do not get on the contrary electrode or the contra angle. These could cause an adverse reaction such as inflammation.
- The file electrode cannot be used with the following types of files including nickel-titanium ones. Use these files without attaching the file electrode. Files with a shank diameter greater than 1.2 mm, Files with shanks that do not have a circular cross section, Gates Glidden Drills, Tools with large cutting heads such as largo burrs.

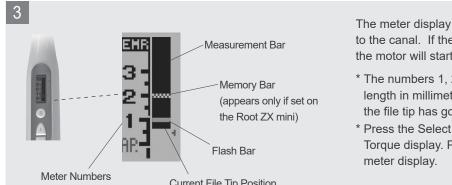
Operation





Select a memory number (M1 to M6) with the Plus or Minus switch.

- * Before using motor handpiece, use a small hand file, such as #10 or #15, to penetrate the root canal manually down to the apical constriction.
- * The file electrode must be clipped onto the file for accurate measurement and instrument control. (In some cases, a root canal cannot be measured because of an overflow of blood, saliva or chemicals or because the root canal is blocked.)



The meter display appears when the file is iinserted in to the canal. If the Auto Start and Stop is turned on, the motor will start running too.



- * The numbers 1, 2, and 3 on the meter do not indicate length in millimeters but are used to estimate how far the file tip has gone down the canal.
- * Press the Select switch to change the display to the Torque display. Press it again to go back to the canal

Current File Tip Position

The motor will stop when the file tip reaches the point specified by the Flash Bar.

A single sustained beep will sound when this happens. If the unit is set for Apical Reverse, the motor will run backwards after it stops.*

If the load on the file exceeds the setting for torque reverse, the motor will stop and then reverse its rotation.* A rapid, repeated three-toned beep will sound when this happens.

The motor will stop when the file is taken out of the canal.* Gradually increase the size of the file until the root canal preparation is completed.

If necessary, prepare the apical seat.

(*: Depends on setting.)

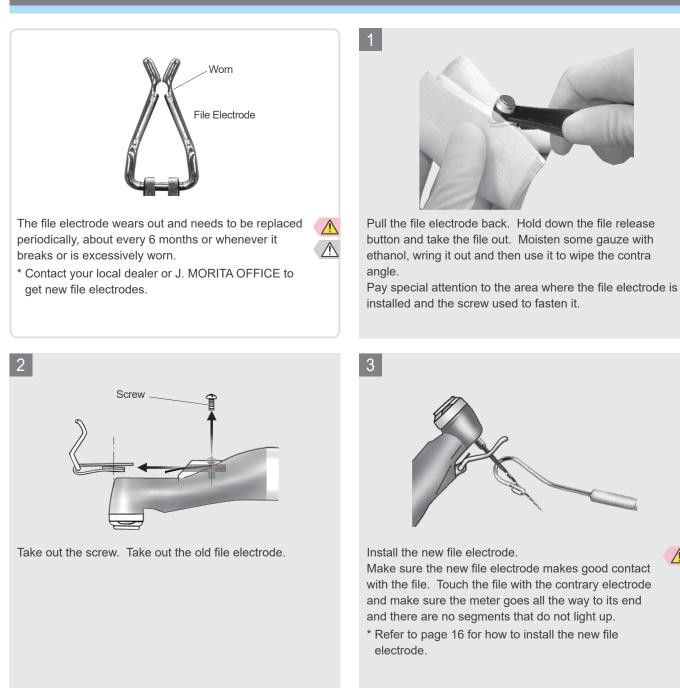
! If the canal is very dry, the Auto Start may not be triggered; in this case, press the Main switch to start the motor.

WARNING

- · Accurate measurements cannot be made in some cases because of shape or other conditions. Always check the measurement with an X-ray.
- Do not let the file or metal parts of the contra angle touch the oral mucosa. This could cause the motor to start running and result in injuring the patient.
- An accurate measurement cannot be made if all the connectors are not properly plugged in. If the meter does not move along with the file, stop using the instrument and check all the connections.

• The meter may not appear if the canal is infected or extremely dry. In this case, put a little hydrogen peroxide or saline solution in the canal but do not let it overflow

File Electrode Replacement



Watch out because the motor might start up when you do this.

WARNING

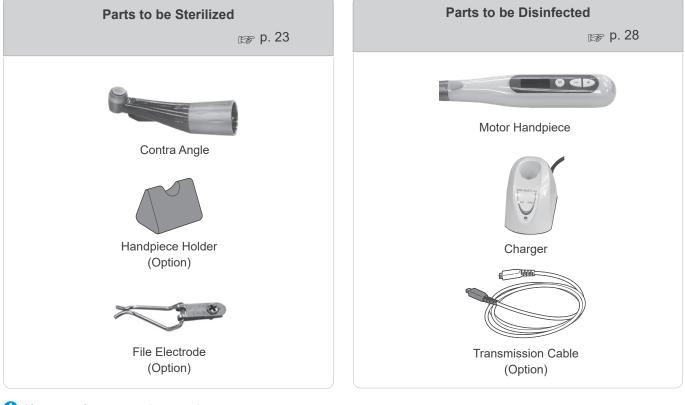
- Replace the file electrode if it is worn out. Otherwise accurate measurements cannot be made. Also it could break and be swallowed by the patient.
- Make sure the screw is properly tightened up; otherwise it might come out and be swallowed.
- Accurate measurements cannot be made if the file electrode is not properly installed.

· Handle the file electrode carefully.

Reprocessing

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





After use, perform reprocessing promptly.

Before reprocessing, make sure that all the parts (e.g., file, etc.) are separated individually.

Preparation

Turn off the power. Disconnect all parts.

WARNING

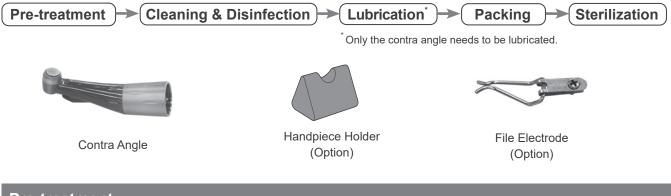
- To prevent the spread of infections, be sure to perform the reprocessing procedures after use with each patient.
- Be careful to avoid cross infection when performing reprocessing.
- Always wear personal protective equipment (PPE) such as safety glasses, gloves, a mask, etc. when performing the reprocessing procedures.

ACAUTION

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

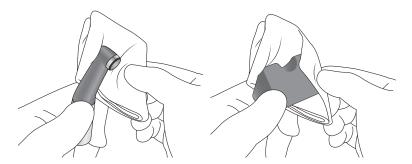
(1) Parts to be Sterilized

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

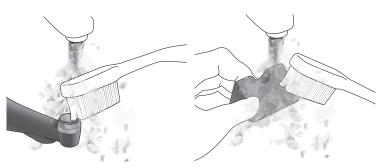


Pre-treatment

This must be performed after use with each patient.



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



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

- After use, perform reprocessing promptly. If the parts are left contaminated with blood, it will be difficult to remove.
- Do not use any chemicals that may coagulate proteins before cleaning.
- If a medical agent being used for the treatment has adhered to the part, wash it off under tap water.
- Do not clean the parts with an ultra sonic cleaning device.
- If dust or other impurities enter the contra angle, they may cause poor rotation.

ACAUTION

· Before reprocessing the contra angle, do not fail to take out the file.

 \wedge

Cleaning & Disinfection

Put parts in the parts washing basket.

 \sim .

(For the contra angle, set it in a handpiece holder.)

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

不	<u>Recon</u>	<u>nmended Conditi</u>	ons for Washer-Disinfe	<u>ctors</u>
Unit Na	ame	Mode	Detergent (concentration)	(1

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

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

Rinse

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



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

- Be sure to remove visible contaminants before this step.
- Be sure to use washer-disinfectors that conform to ISO 15883-1 (must be capable of achieving disinfection values of not less than $A_0 = 3000$). 63
- If your region is susceptible to hard water scale buildup, use deionized water (ion-exchanged water).
- For details on handling detergents and neutralizers, concentration, water quality as well as parts washing baskets, refer to the accompanying user manual for the washer-disinfector.
- Inappropriate cleaning methods and solutions may damage the parts.
- 0 Do not use strong acidic or alkaline chemicals that could cause the metal to corrode.
- Do not start drying when the interior of the part is filled with water. Otherwise, this could result in corrosion of the part due to condensation of the rins-0 ing solution.
- Ω After completing the cleaning process, expel remaining moisture inside the parts with compressed air.
- Do not leave the parts in the washer-disinfector. This may cause corrosion or malfunction of the parts.
- Ω Parts' surface may get scratched and wear out during the cleaning process due to contact with the parts washing basket or other parts. Replace the parts as necessary depending on degree of scratches and wear.
- Always use a handpiece holder when washing the contra angle, making sure to rinse the inside of the contra angle thoroughly.
- Always lubricate the contra angle after washing.

WARNING

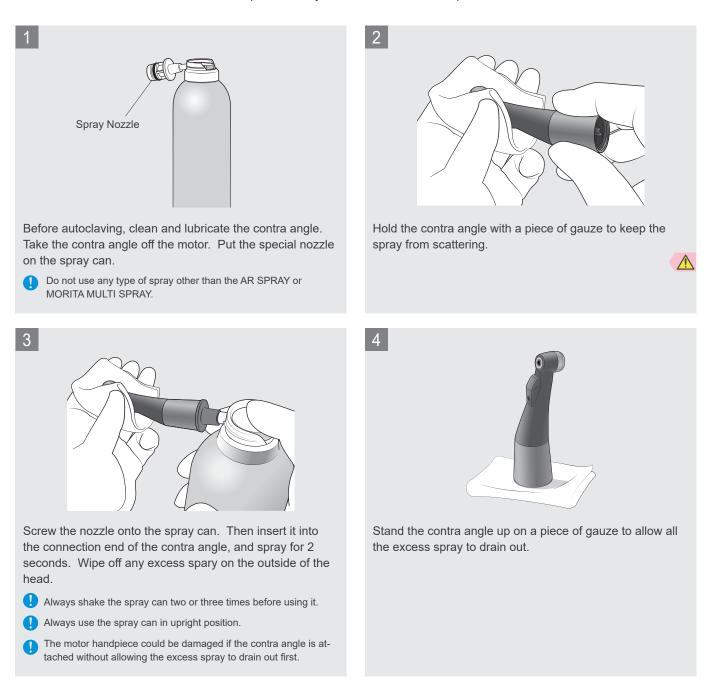
• If any moisture is left inside the parts after cleaning, it could cause corrosion or poor sterilization. Also, the remaining water may come out during use. After cleaning, use a syringe or compressed air to expel remaining moisture.

• Dust and other impurities adhering to the parts' electrical contacts can cause the device to malfunction.

Lubrication

Before autoclaving, make sure that you lubricate and clean the contra angle with the AR SPRAY or MORITA MULTI SPRAY.

* Lubrication and excess oil removal can be performed by J. MORITA's dental handpiece maintenance device.

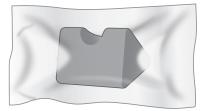


MWARNING

• Prevent spray from splashing into your eyes etc. by always covering the contra angle with gauze etc.

Packing





Place the parts individually in a sterilization pouch. Use only FDA-cleared pouches. (for U.S.A.)

Use sterilization pouches that conform to ISO 11607.

Do not use any sterilization pouches that contain hydrosoluble adhesive ingredients such as PVA (polyvinyl alcohol). Otherwise, its adhesive ingredient may elute, seep into the contra angle during the sterilization, resulting in a solid residue and a failure to rotate properly. Note that even ISO 11607 conformable sterilization pouches may contain PVA.

When placing a part in a sterilization pouch, be sure not to put stress on the part.

Sterilization

Autoclave the autoclavable parts.

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



Recommended Autoclave Settings

Country : U.S.A.

Country . 0.0.	л.			0	oundy. Our					
Sterilizer type	Temperature	Time	Drying time after sterilization		Sterilizer type	Temperature	Time	Drying time after sterilization		
Gravity	+132°C (+269.6°F)	15 minutes	15 minutes		15 minutes		Dynamic	+134°C (+273.2°F)	3 minutes	
Clavity	+121 °C (+249.8 °F)	30 minutes			Air Removal	+134°C (+273.2°F)	5 minutes	10 minutes		
					Crovity	+134°C (+273.2°F)	min. 6 minutes	min.		
					Gravity	+121°C (+249.8°F)	min. 60 minutes	10 minutes		

Country · Other than U.S.A

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

MWARNING

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

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

(2) Parts to be Disinfested

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



Pre-treatment

This must be performed after use with each patient.

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

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

Cleaning & Disinfection

Wipe the part's surface with disinfectants approved by J. MORITA MFG. CORP.

Disinfectants Approved by J. MORITA MFG. CORP.

Disifectant	Country	
Ethanol (70 vol% to 80 vol%)		
Opti-Cide 3 (wipes)	U.S.A.	
FD 333 forte (wipes)	Other than U.S.A.	

Make sure that there is no visible moisture and contamination when wiping the parts.

Be sure not to tug on the cable when you clean the parts. This could cause the wire to break.

Do not use disinfectants other than those designated by J. MORITA MFG. CORP.

For details on handling disinfectants, refer to the accompanying user manual for each disinfectant.

🌗 If too much disinfectant is applied to the piece of gauze or microfiber cloth, it will seep into the part and cause a malfunction.

Do not immerse the parts in or wipe them with any of the following: functional water (acidic electrolyzed water, strong alkaline solution, and ozone water), medical agents (glutaral, etc.), or any other special types of water or commercial cleaning liquids. Such liquids may result in metal corrosion or adhesion of the residual medical agent to the parts.

Do not clean or immerse the parts with chemicals such as formalin cresol (FC) and sodium hypochlorite. These will damage the metal and plastic parts. Immediately wipe away any chemicals that are accidentally spilled on the parts.

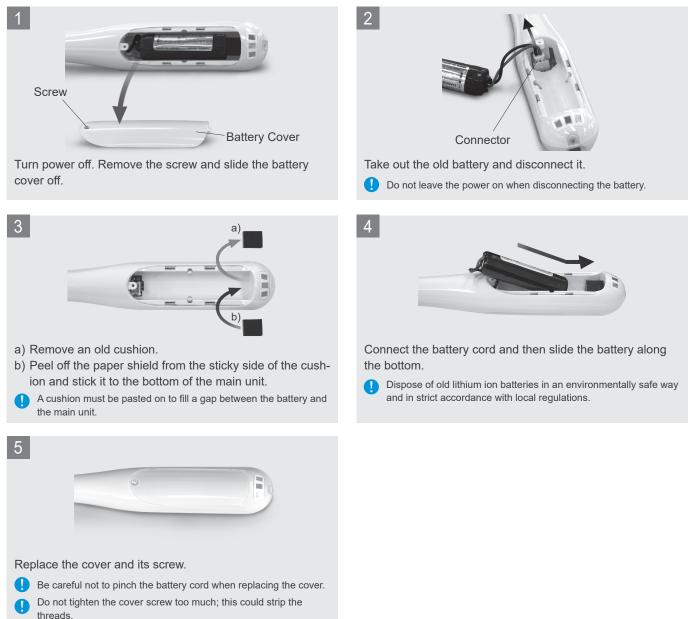
Replacement Parts, Transport and Storage Environments

Replacement Parts

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

Battery Replacement

Replace the battery when it starts to loose power relatively quickly after being fully charged. The battery will last for approximately 1 year under normal circumstances and use.



ACAUTION

- Use only the battery designed for the Tri Auto mini. Other types could cause overheating.
- Do not use a battery if it is leaky, deformed, discolored or if its label is peeled off. It might overheat.

File Electrode Replacement

When connected to the Root ZX mini, refer to page 21 for how to replace the file electrode.

Transport and Storage Environments

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

- Do not expose to direct sunlight frequently or for long times.
- If the unit has not been used for a long time, make sure it works properly before using.
- Always remove the battery prior to storing or shipping the unit.

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, he may rely on a qualified medical device serviceman. Contact your local dealer or J. MORITA OFFICE for details.
- Replace the parts listed in the Parts Lists as necessary depending on degree of wear and length of use.
- This apparatus should be inspected every 6 months in accordance with the following maintenance and inspection items.
- 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.

Inspection Items

- 1. Check that the battery does not seem to be losing its charge too quickly.
- 2. Check that pressing the Main Switch turns the unit on. After the unit is on, check that pressing the Main switch turns the motor on and off. Check that the unit turns off when the Main Switch is pressed while the Select switch is being held down.
- 3. Check that pressing the Plus and Minus switches changes the memory number from M1 through M6.
- 4. Check that the settings for each memory can be changed.
- 5. Make sure the connection end of the motor handpiece is not damaged or dirty.
- 6. Make sure that the connection end of the contra angle is not damaged or dirty and that it can be securely connected to the motor handpiece. Make sure that the file release button operates properly and that files can be securely installed. When used with the Root ZX mini, make sure that the file electrode clips securely onto the file and that it is not damaged or worn out.
- 7. When used with the Root ZX mini, touch the file with the contrary electrode and make sure that all the segments for the meter light up properly.
- * For repairs contact your local dealer or J. MORITA OFFICE.

Parts List



Disposal of Medical Devices

Any medical devices which could possibly be contaminated must be first decontaminated by the responsible doctor or medical institution and then be disposed by an agent licensed and qualified to handle medical and industrial waste.

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.

Service

The Tri Auto mini may be repaired and serviced by:

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

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	Response
Does not turn on.	Check battery power.	Charge battery
	Check battery installation.	Install battery properly.
No beeping sound.	Check if sound is turned off.	Set beep volume for Low or Big
Beep sounds even when unit is not being used.	• Unit may be set for reverse rotation.	 A beep sounds periodically whenever the unit is set for reverse rotation. Turn the beeper off if it is annoying. (This will stop all beeping except when the unit is turned on.)
Backlight color does not change.	• See if this function has been turned off.	• Turn this function on, if necessary.
Motor does not start when file is inside	 Is Root ZX mini properly connected and turned on? 	 Check transmission cable connections. Turn on Root ZX mini
canal.	 Is the contrary electrode for the Root ZX mini hooked in the patient's mouth? 	 Hook the contrary electrode in the corner of the patient's mouth.
	Is "Linked Function" setting turned off?	Turn "Linked Function" setting on.
	Is Auto Start & Stop turned off?	• Turn "Auto Start & Stop" setting on.
	• Has the meter gone past the Flash Bar?	Set the Apical Stop or Reverse for Reverse (REV)
Motor starts but then stops right away.	• Did you hold down the Main switch for more than 1 second?	• If you hold the Main switch down for more than 1 second, the motor runs only while the switch is held down and stops when it is released. The motor will run without stopping if you release the switch in less than 1 second.
	 Does "Abn.Stop LowBat" appear in the display? 	Very low battery power. Charge battery.
Motor reverses rotation on its own.	Check Torque Reverse setting.	 The torque reverse can be turned off (TRL setting).
	Check Apical Reverse setting.	 You can change the Apical Reverse setting to Apical Stop.
Motor reverses rotation	Check Torque Reverse setting	• Increase the torque reverse setting.
too quickly.	 Is the Apical Torque Reduction setting turned on? 	 The torque reverse value goes down as the file approaches the apex if the Apical Torque Reduction is turned on. Turn this function off to keep the torque reverse value constant.
Motor handpiece will	Is Torque Reverse setting turned on?	Set torque reverse value
not go in reverse rotation.	Is Torque Reverse setting too high?	Reduce torque reverse value
i otationi	 Is "Linked Function" setting turned off? 	Turn "Linked Function" setting on.
	Is Root ZX mini set for Apical Stop?	Change Apical Stop to Apical Reverse.

Problem	Check Points	Response
Canal measurement display does not	 Is the contrary electrode for the Root ZX mini hooked in the patient's mouth? 	 Hook the contrary electrode in the corner of the patient's mouth.
appear.	 Did you press the Select switch while the motor was running? 	 Press the Select switch again to display the measurement meter.
	• Did a beep sound when you connected the transmission cable? Except for when the beeper is turned off	 If a beep does not sound when you connect the transmission cable, the cable may be defective. Replace it. If this does not solve the problem the connectors or the control board may be defective.
Micromotor changes speed on its own.	 Is Apical Slow Down setting tuned on? 	• When this is turned on, the motor slows down as the file approaches the apex. Refer to page 13 for how to turn this setting on and off.
	Is Torque Slow Down setting tuned on?	• When this is turned on, the motor slows down as the torque increases. Refer to page 13 for how to turn this setting on and off.
Unit turns off on its own.	• Was the unit no used for a long time?	• Auto power off was probably activated. Press the Main switch to turn the unit back on.
	 Does "Please Charge" appear in the display? 	Battery must be charged right away.
	 This can happen if the battery is very low and a large load is applied to the file. 	Battery must be charged right away.
Error 01	Transmission cable is probably not properly connected.	Check cable and connect is properly.

Technical Specifications

Specifications

* Specifications may be changed without notice due to improvements.

Name	Tri Auto mini
Model	TR-CM
Degree of Protection against Ingress of Water	IPX0
Intended Use	The Tri Auto mini is a compact and cordless endodontic treatment mo- torized handpiece for preparation and enlargement of root canals. It can be connected to the Root ZX mini, an apex locator (sold separately). It can be used to enlarge and prepare root canals, remove gutta-percha and softened dentin, and perform professional mechanical tooth clean- ing (PMTC).
Operating Principle	By electric drive, the Tri Auto mini transmits motion, such as rotation and vibration, to treatment instruments (dental files, reamers, etc.).
Essential Performance	None (There is no unacceptable risk.)
Expected Service Life	6 years

Handpiece	
Free Running Operation Speed	50 ±5 – 1,000 ±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
Battery	Lithium ion battery (DC 3.7 V)
Dimensions	Approx. Dia. 28 × Length 196 mm (including contra angle and motor handpiece)
Weight	Approx. 100 g (including contra angle and motor handpiece)
Coupling Identification	Tri Auto mini coupling
Applied Part	Contra angle, Motor handpiece

Battery Charger		
Rated Input voltage	A.C. 100 – 240 V	
Frequency	50/60 Hz	
Power Consumption	19 VA	
Protection against Electric Shock	Class II / No applied part	
Dimensions	Approx. Height 85 × Width 68 × Length 108 mm	
Weight	Approx. 330 g	

Symbols

* Some symbols may not be used.



CE(0197) marking Conforms with the European Directive, 93/42/EEC. CE marking Conforms with the European Directive, 2011/65/EU.



Serial number



GS1 DataMatrix



Type BF applied part



Class II equipment



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



Manufacturer



Date of manufacture



Supports high-temperature cleaning and disinfection



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



Keep away from rain



This way up



Atmospheric pressure limitation



Sterilize components before use



Autoclavable up to +135°C (+275°F)



Consult Instructions for use



Fragile



Temperature limitation



Humidity limitation

Rx Only

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



Authorized representative in Switzerland

Electromagnetic Disturbances (EMD)

The Tri Auto mini (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	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 ^{*1} 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 AC-COMPANYING 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-CM, including cables specified by the manufacturer.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Immunity Test IEC 60601 Test Level		Compliance Level	Electromagnetic Environment – Guidance	
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.	
Electrical fast transients/ bursts IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ^{*1} ±1 kV for input/output lines ^{*1}	Mains power quality should be that of a typi- cal 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 <u>Signal input/output</u> ±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 typi- cal commercial or hospital environment.	
Voltage dips, short inter- ruptions and voltage varia- tions on power supply lines IEC 61000-4-11	$\begin{array}{l} \underline{\text{dips}} \\ 0\%U_{\text{T}}\colon 0.5 \;\text{cycle}\;(\text{at}\;0,45,90,135,\\ 180,225,270,315^\circ) \\ 0\%U_{\text{T}}\colon 1\;\text{cycle}\;(\text{at}\;0^\circ) \\ 70\%U_{\text{T}}\colon 25/30\;\text{cycles}\;(\text{at}\;0^\circ) \\ 25\;(50\;\text{Hz})/30\;(60\;\text{Hz}) \\ \underline{\text{short}\;\text{interruptions}} \\ 0\%U_{\text{T}}\colon 250/300\;\text{cycles} \\ 250\;(50\;\text{Hz})/300\;(60\;\text{Hz}) \end{array}$	$\begin{array}{c} \underline{\text{dips}} \\ 0\% \ U_{T} : \ 0.5 \ \text{cycle} \ (\text{at } 0 \ , 45 \ , 90 \ , 135 \ , \\ 180 \ , 225 \ , 270 \ , 315 \ ^{\circ}) \\ 0\% \ U_{T} : \ 1 \ \text{cycle} \ (\text{at } 0 \ ^{\circ}) \\ 70\% \ U_{T} : \ 25/30 \ \text{cycles} \ (\text{at } 0 \ ^{\circ}) \\ 25 \ (50 \ \text{Hz})/30 \ (60 \ \text{Hz}) \\ \underline{\text{short interruptions}} \\ 0\% \ U_{T} : \ 250/300 \ \text{cycles} \\ 250 \ (50 \ \text{Hz})/300 \ (60 \ \text{Hz}) \end{array}$	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 2: r.m.s.: root mean square

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

^{*2}: Not applicable because it does not connect directly to outdoor cable.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

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

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

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

(c) The ISM (Industrial, Scientific and Medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27. 283 MHz; and 40. 66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1

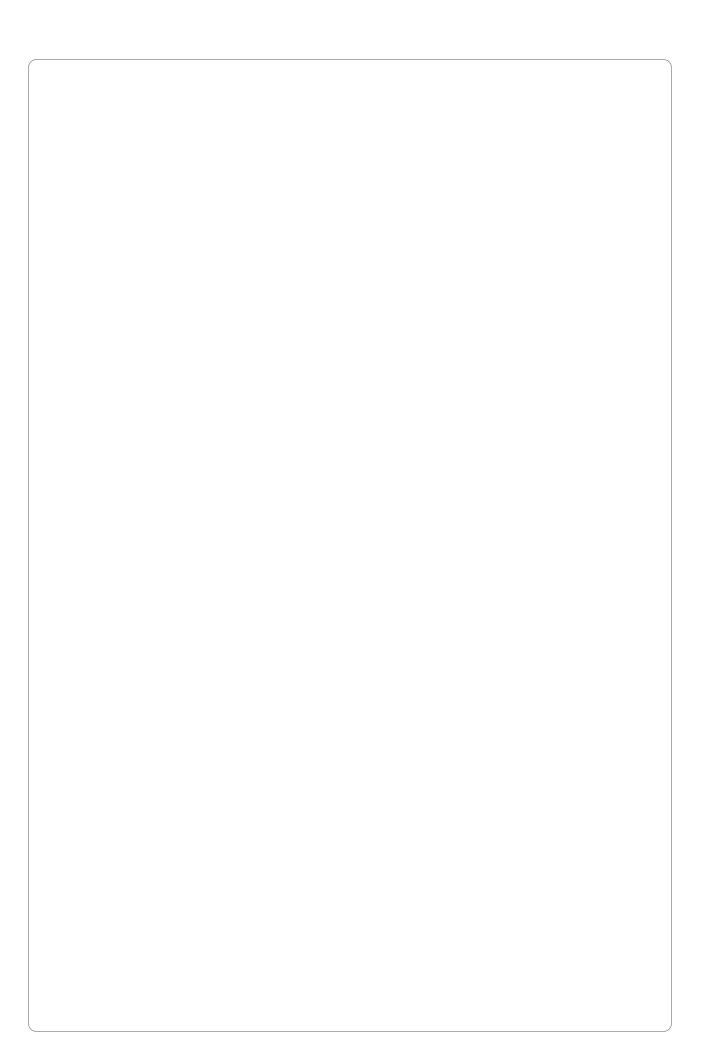
MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

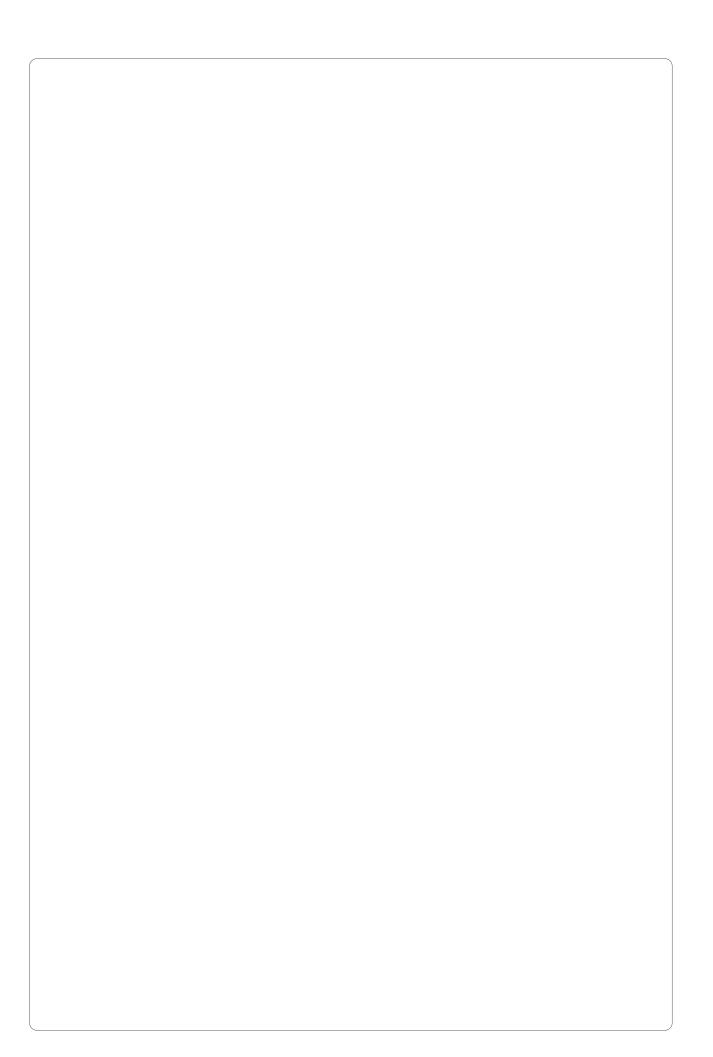
Essential Performance

None

Cable List

No.	Interface(s):	Max. Cable Length, Shielding	Cable Classification
1.	AC Power Cable	1.5 m, Un-shielded	AC Power Line
2.	Probe Cord	1.7 m, Un-shielded	Signal Line (Patient-Coupled Cable)
3.	Communication Cable	1.6 m, Un-shielded	Signal Line





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