Instructions for Use 1/4 2022-09-21 Pub. No.: K190-62001-504 (EN)

## INSTRUCTIONS FOR USE

**TRA-200** 

**AIR TORX** 



Thank you for purchasing the AIR TORX

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

#### Intended Use

This device transduces compressed air supplied from a dental treatment unit into rotational power, and transmits it to cutting or grinding tools such as straight or geared-angle handpieces through gears to cut or grind teeth, artificial dentures, etc. with the same or transformed rotation speed.

The user (e.g., healthcare facility, clinic, hospital, etc.) is responsible for the management, maintenance, and use of medical devices. This device must not be used by anyone other than dentists, doctors, or other legally licensed professional

#### Do not use the AIR TORX for purposes other than its specified intended use in dental treatment.

\* Handpieces (e.g., straight handpiece, contra-angle handpiece, etc.) have separate user manuals. Be sure to read these manuals before using the instruments and follow all instructions and precautions.

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



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

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

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

#### **Disclaimer**

- J. MORITA MFG. CORP. will not be responsible for accidents, product damage, or bodily injury resulting from:
- 1. Repairs made by personnel not authorized by J. MORITA MFG. CORP.
- 2. Any changes, modifications, or alterations of its products
- 3. The use of products made by other manufacturers, except for those produced by J. MORITA MFG. CORP
- 4. Maintenance or repairs using parts or components other than those specified by J. MORITA MFG. CORP. and other than in their original condition.
- 5. Operating the device in a manner other than described in the operating procedures in this user manual or in a manner inconsistent with the safety precautions and warnings in this user manual.
- 6. Workplace, environmental, or installation conditions that do not conform to those stated in this user manual, such as an improper electrical power supply.
- 7. Fires, earthquakes, floods, lightning, natural disasters, or forces majeure.
- The useful life of the AIR TORX is 7 years from the date of installation provided it is regularly and properly inspected and maintained.

#### In Case of Accident

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

#### Trademarks and Registered Trademarks:

Parts of the names of companies, products, services, etc. used in this manual may contain either trademarks or registered trademarks owned by each company.

#### **TERMS AND CONDITIONS**

#### J. MORITA MFG. CORP. warrants the Product as follows

- 1. Warranty Term. J. MORITA MFG. CORP. warrants that the Product will be free from defects in materials and workmanship for 12 months.
- 2. Items Not Covered by Warranty. This Warranty will not cover parts of the Product or consumables which normally need to be replaced such as glass or rubber compo-nents, lamps, cartridge, ball bearings and the like. Further, this warranty will not cover defects or damage caused by:
- a. Failure to operate or use the Product in accordance with the Operation Instructions or warning/cautionary labels. b. Modifications of the Product, connecting the Product to other products, or using components or replacement parts not specified or approved by J. MORITA MFG. CORP.
- approved by a MORT mired. CORP:
   c. Repairs performed by parties not designated by J. MORITA MFG. CORP.
   d. Accidents or forces outside of J. MORITA MFG. CORP's control, such as dropping the Product or collision of the Product with other
- obiects, fire, flood, natural disaster, etc. Use or operation of the Product in settings or under conditions not specified by J. MORITA MFG. CORP. or set forth in the Opera-tion Instructions including, without limitation, unauthorized changes in equipment settings, connection to unauthorized devices.
- 3. Remedies of Customer. Customer must present this Warranty when claiming coverage or application thereof, and either ship or deliver the Product to an authorized location of J. MORITA MFG. CORP. or its subsidiaries or authorized dealers. Upon receipt and verification of this Warranty, inspection of the Product, and determination of coverage by this Warranty, J. MORITA MFG. CORP. will, at its sole option, supply the parts or components either replaced or repaired free of charge to the Customer. Delivery and shipping charges are the responsibility of

#### LIMITATIONS AND EXCLUSIONS FROM WARRANTY

LIMITATIONS AND EXCLUSIONS FROM WARRANTY. The remedy set forth in paragraph 3 is the sole and exclusive remedy of Customer. J. MORITA MFG. CORP. MAKES NO OTHER EX-PRESS OR IMPLIED WARRANTIES AND SPECIFICALLY EXCLUDES ALL OTHER WARRANTIES INCLUDING, WITHOUT LIMITA-TION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL J. MORITA MFG. CORP. BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL, DIRECT OR INDIRECT, OR SPECIAL DAMAGES OF ANY KIND INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF REVENUE, LOSS OF BUSINESS OR BUSINESS OPPORTUNITY, OR OTHER SIMILAR FINANCIAL LOSS ARISING OUT OF THE PERFORMANCE, USE OR INTERRUPTED USE OF ETHE PRODUCT OF THE PRODUCT.

6. Repairs Not Covered by Warranty. With respect to repairs not within the period of this Warranty or otherwise not covered by this Warranty, J. MORITA MFG. CORP. will perform the same, timely, efficiently, and for an appropriate cost.

# **Operating, Transport and Storage Environments**

### Operating Environments

MORITA

Temperature: +10 °C to +40 °C (+50 °F to +104 °F) Humidity: 30% to 75% (without condensation) Atmospheric Pressure: 70 kPa to 106 kPa

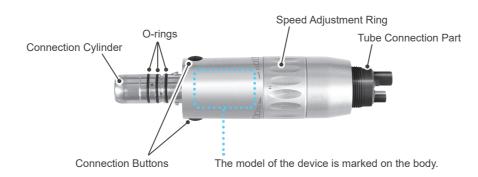
#### Transport and Storage Environments

Temperature: -10°C to +70°C (+50°F to +158°F) Humidity: 10% to 85% (without condensation) Atmospheric Pressure: 70 kPa to 106 kPa

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

\* If the device will not be used for an extended period of time, store it in a clean, dry place after autoclaving it.

# **Parts Identification**



# **Accompanying Items**

Spray Nozzle (Qty: 1) Code No.: 5071200



(Alcohol Disinfectable)

# Sold Separately

MORITA MULTI SPRAY (Qty: 1) Code No.: 5010201 or 7914113



(Alcohol Disinfectable)

# **Technical Specifications** Generic Name Essential Performance Operable Drive Air Pressu Recommended Drive Air F Water Pressure [MPa] Chip Air Pressure [MPa]

## Recommended Exhaust Pr (at 0.25 MPa drive air pres Maximum Rotation Speed (at recommended drive air Usage Speed Range [rpm] Stop Torque [N•cm] Air Consumption [NL/min] Water Consumption [mL/m (for 0.2 MPa water pressur Weight [g] Motor Length [mm] Outer Diameter [mm] Connector Type Connectable Handpiece **Tube Connector Shape**

Mode

# **Symbols**

\* Some symbols may not be used







Rx Only Prescription Device

12-3-4-5-6789012

USA EU



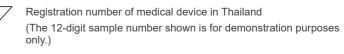


\* Use this device with dental treatment units that conform to IEC 60601-1.

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

	Air Motors
	TRA-200
	None (There is no unacceptable risk.)
ıre [MPa]	0.2 to 0.3
Pressure [MPa]	0.25
	0.05 to 0.2 (with handpiece)
	0.2 to 0.3 (with handpiece)
Pressure [MPa] ssure)	0.07 or less
l [rpm] r pressure 0.25 MPa)	20,000 ±2,000
1]	5,000 to 20,000
	3.5
	40 to 55
nin] ıre at handpiece end)	70 or more
	Approx. 75
	Approx. 70
	Approx. 20
	Short (ISO 3964)
	Conform to ISO 14457
	Conform to ISO 9168 Type C

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



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

# Usade

## **Precautions**

### **WARNING**

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

#### Reprocessing

- · Always wear personal protective equipment (PPE), such as safety glasses, gloves, a mask, etc. when using this device.
- Before use, run the device outside the patient's oral cavity to make sure of the following points: • Bur does not wobble
- No abnormal vibration or sound
- No looseness
- · No heat is generated
- · Rotation speed and direction are correct
- Stop using the device immediately if it is hot, the rotation speed reduces, or it makes abnormal vibration or noise. Ball bearings inside the device are consumable parts.
- Do not use the device if there is no or not enough cooling air. Operation without cooling air can cause the device to overheat and result in burns to the user or patient.
- · Be careful not to press the connection buttons while the motor is running. There is a risk of disconnecting the handpiece and causing a hazardous situation.

## **▲**CAUTION

 Always perform pre-use inspection before using the handpiece. 
 Before Use · Handle the device carefully; do not drop it or let is swing and bang against the dental treatment unit. etc.

# **Before Use**

\* The device is not sterilized before shipping. It must be autoclaved before it is used for the first time.

# Before using the device, always check the following points outside the

- . There are no gaps or looseness at the connection cylinder and the tube connection part.
- There are no scratches, deformation, rust, or dirt on the device.
- . The O-rings are properly installed and not degraded.
- . Connect the device to its tube, and give it a light tug to check that the device is securely connected.
- Without connecting a handpiece, rotate the speed adjustment ring to the F (forward) direction all the way. Run the motor and check that the cooling air is properly emitted from the tip of the connection cylinder, and that there is no rotation speed reduction, abnormal vibration, or noise. \* Turn the sprav water off.
- · Connect a handpiece to the device, and give it a light tug to check that the handpiece is securely connected
- Run the motor for approximately 10 seconds and check that there is no rotation speed reduction, abnormal vibration, or noise.
- . Immediately after the above test, touch the device with your hand and check that there is no heat. . The handpiece spray has a fine, misty quality.
- · Check the handpiece connection; ensure it is not loose and there is no air or water leakage from the connection.

If any abnormality is found, do not use the device and have it professionally repaired.

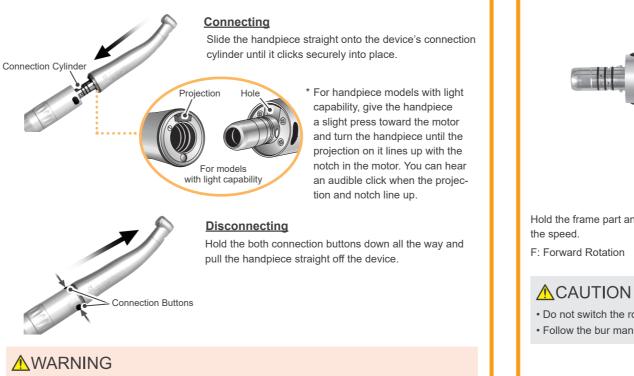
() Use compressed dry air that does not contain debris or oil. Failure to do so could cause a malfunction.

() Check the dental treatment unit's technical specifications for the air and water pressure, and set them within the recommended range.

Technical Specifications

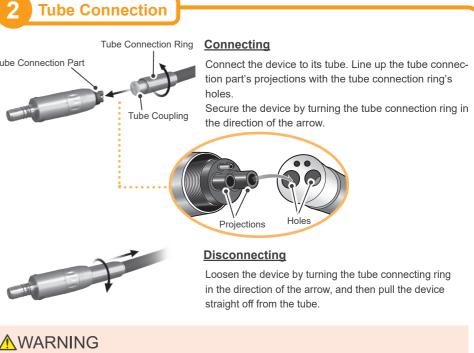
## Handpiece Connection

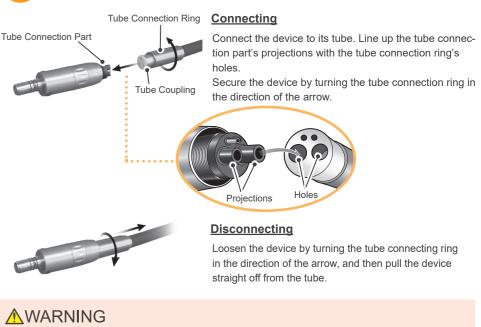
\* Check that the connection cylinder's O-rings are properly installed.



• Before use, give the tube a light tug to check if the handpiece is securely connected and run the handpiece outside the patient's oral cavity. If the connection is loose, the handpiece could be dismounted and cause a hazardous situation.

- · Wait for the handpiece to stop rotating before connecting or dismounting the handpiece.
- Be sure that both connection sides are free of dust such as cotton fibers or debris from of an O-ring, etc. This may damage the device.

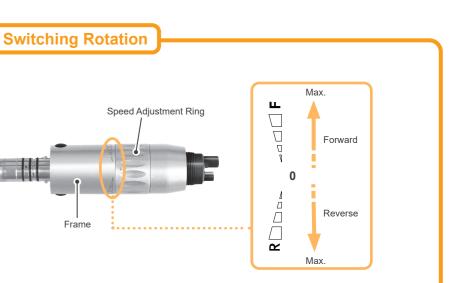




wise, it could damage the instrument.

. Connect the device to the tube, and then give the tube a light tug to check if the device and tube are securely connected. If the connection is loose, it may result in the tube becoming detached by air pressure, which could cause physical injury.

Be sure that the connection parts are free of dust such as cotton fibers or debris of O-ring, etc. Other-



Hold the frame part and rotate the speed adjustment ring to switch the rotation direction and change

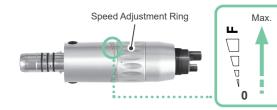
#### F. Forward Rotation R. Reverse Rotation

· Do not switch the rotation direction while the device is running. • Follow the bur manufacturer's recommendations for rotation speed and direction.

#### **Cleaning & Disinfection** Reprocessing **ACAUTION WARNING** · Reprocessing of the motor is not completed with disinfection. Be sure to sterilize it. · Always wear personal protective equipment (PPE) such as safety glasses, gloves, a mask, etc. when performing the reprocessing procedures. () This device is not capable of being cleaned and disinfected with a washer-disinfector. \* Be sure to perform the reprocessing procedures in the following procedures (1) through (6)Clean the device in running water with a tooth-After Use brush. Remove the bur from the handpiece, turn on the water supply switch on the Be sure to remove contaminants promptly after use with each patient. If a component dental treatment unit, then run the motor (idle running) for 20 seconds. is left contaminated with blood, it will be difficult to remove Do not use any chemicals that may coagulate After cleaning, use the syringe or an air blow Wipe the whole instrument from the tube connection part to the handpiece proteins before cleaning gun to blow out any moisture remaining inside head with a piece of gauze that has been dampened with tap water or If a medical or adhesive agent being used the motor to dry it out. protein anticoagulant agent to remove visible contaminants. for treatment has adhered to a component, immediately wash it off under tap water. Do not immerse the motor in any protein anticoagulant agent. Disconnect the handpiece from the motor. Disconnect the motor from the tube Wipe the motor with a piece of gauze or mi-Be sure to clean the disconnected handpiece and crofiber cloth (e.g., Toraysee for CE - Medical motor promptly. Equipment and Instruments Maintenance Cloth) that has been dampened with mikrozid AF liquid, \* If you cannot clean the components immediately, spray protein anticoagulant agent over them and FD322, or rubbing alcohol to remove visible clean them within 2 hours contaminants Usable Protein Anticoagulant Agent: Neutral and foamless agent applicable to aluminum and brass materials. Lubricant Removal Packaging

3 Lubrication

\* Be sure to lubricate the device with the MORITA MULTI SPRAY after use with each patient. Be sure to lubricate the handpiece after the cleaning and disinfection steps or before autoclaving.



Turn the speed adjustment ring to F side all the way.



Insert the spray nozzle into the drive air port.



Cover the air exhaust port with a piece of gauze, hold the device firmly, and then spray for 2 seconds.

### **WARNING**

· Never direct the spray towards a person

• Do not use the spray in a closed space without proper ventilation. Open windows or turn on exhaust fans to make sure the room is well ventilated

• Be careful not to get the spray in your eyes. If you accidentally get it in your eyes, wash your eyes with plenty of water and consult a doctor. • Be careful not to get the spray on your skin. If it gets on your skin, wash it off with soap and water. • If used in a sink or other enclosed space, a flammable propellant could permeate the air; keep the area free of open flames or other ignition sources.

Do not use any type of maintenance spray other than the MORITA MULTI SPRAY.

Make sure to use the accompanying spray nozzle designed for the AIR TORX.

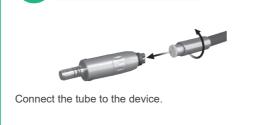


Spray Nozzle (Designed for the AIR TORX)

I The device cannot be lubricated if the speed adjustment ring is set on 0.

Always keep the maintenance spray can in an upright position when using and storina

Failure to lubricate the device will result in a malfunction





Run the device for at least 15 seconds to expel excess oil from it.



Disconnect the tube



Wipe the device off with a piece of gauze.

position) to 0.

Turn the speed adjustment ring and set it from F (maximum

Speed Adjustment Ring

. . . . . . . . . . . . . . .

Max.

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0



Make sure that the motor is not wet, and then put it in an individual sterilization pouch.

Do not use any sterilization pouches that contain hydrosoluble adhesive ingredients such as PVA (polyvinyl alcohol). Otherwise, its adhesive ingredient may seep into this device during sterilization, resulting in a solid residue that may cause a failure to rotate properly or poor water delivery. Note that even ISO 11607 conformable sterilization pouches may contain PVA.

### **WARNING**

- If any moisture is left inside the motor after cleaning, it could cause corrosion or poor lubrication and sterilization.
- I Do not clean the motor with ultra sonic cleaning or immersion cleanina devices
- If dust or other impurities enter the motor, they may cause poor rotation or poor spray delivery.
- Do not use disinfectants other than those designated by J. MORITA MFG. CORP.

Do not immerse the motor in or wipe it 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.

#### 6 **Sterilization**



Autoclave the parts. After autoclaving, store the device in a dry environment.

#### **Recommended Autoclave Settings**

Pre-vacuum Type (class B) Temperature: +134°C (+273.2°F) Time: 3 minutes or more

Gravity Type (except class B) Temperature: +134°C (+273.2°F) Time: 5 minutes or more

### **WARNING**

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

### **▲**CAUTION

- Parts are extremely hot after autoclaving; wait for them to cool off before touching.
- Do not sterilize the device by any method other than autoclav-
- Do not autoclave the device with the handpiece connected.
- I Failure to clean and lubricate the handpiece before autoclaving will result in a malfunction
- The sterilization and drving temperatures must not exceed +135°C (+275°F). If they exceeded +137°C (+278.6°F), it will result in discoloration of the device or a malfunction.
- Do not let this device come into contact with the heat source or chamber wall inside of the autoclave to avoid damage of the O-rings or other parts due to the high temperature.
- I After completion of the autoclaving process, do not leave the device in the autoclave

# Troubleshooting

If the device does not seem to be working properly, first inspect the items described below. Before inspection and adjustment, check to see if the main switch of the device, such as a dental treatment unit that the device is connected to, is turned on and if the main air and water valves are open. For repair or other types of service, contact your local dealer or J. MORITA OFFICE.

Symptoms	Check Points	Remedies
Cutting tool does not rotate.	Is the speed adjustment ring set to 0?	Turn the speed adjustment ring and set it to a position other than 0.
	Is the tube properly connected with the device?	Check the connection.
	Disconnect the handpiece and operate the foot control. Does the motor rotate?	If the motor rotates, have the handpiece profes- sionally repaired.
		If the motor does not rotate, see (1).
	(1) Disconnect the device from its tube and operate the foot control. Is air	If air is coming out of the tube, have the device professionally repaired.
	coming out of the tube?	If air is not coming out of the tube, have the tube and dental treatment unit professionally repaired.
No spray is emitted.	Is the dental treatment unit's spray func- tion turned on? Is the dental treatment unit's spray adjustment knob open?	Check that the spray function is turned on and the spray adjustment knob is open.
	Disconnect the handpiece from the mo- tor and operate the foot control. Is water coming out of the motor?	If water is coming out from the motor, see (2) and (3). If this does not solve the problem, have the handpiece professionally repaired.
		If water does not come out from the motor, see (4).
	(2) Check all O-rings on the connection cylinder.	If you find any damaged or worn-out O-rings, replace them with new ones. (Coring Replacement)
	(3) Is the handpiece's spray hole(s) clogged?	Clean the spray hole(s) and spray filter on the handpiece.
	(4) Disconnect the device from its tube and operate the foot control. Is water coming out of the tube?	If water is coming out of the tube, have the device professionally repaired.
	coming out of the tube?	If water does not come out from the tube, have the tube and dental treatment unit professional- ly repaired.

# **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.

### Consumables

O-rings Set (Qty: 1)	Water Check Valve (Qty: 1)	Gasket (Qty: 1)
Code No.: 5811575	Code No.: 5811837	Code No.: 5811831
00		

# **O-ring Replacement**

\* The O-rings on the connection cylinder wear out after a while, and this leads to air or water leakage. Replace all three O-rings at the same time.

Connection Cylinde



Remove the O-rings with tweezers or another such tool and install the replacements

After replacement, apply a small amount of the MORITA MULTI SPRAY to the new O-rings.

## M WARNING

• Be sure to remove the old O-rings. Be sure to replace all three O-rings at the same time and make sure that there is no debris or broken pieces of the old O-rings. If something remains, the tube could detach suddenly due to air pressure and cause physical injury.

### 

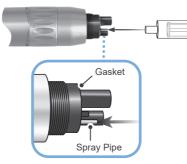
• If any lubricant other than the MORITA MULTI SPRAY is used, the O-rings will swell, making connection and disconnection of the handpiece difficult.

Use only the specified O-rings.

## Water Check Valve Inspection & Replacement

#### **Inspection**

\* If the water check valve is defective, it results in sucking cutting debris or other dirt into the tube. Inspect the part more than once a month in the following order.



Use a disposable plastic syringe with no needle. Slide the end of the syringe over the spray pipe and press it flush up against the gasket.

Pull the plunger out slightly and see if it goes back towards the device by itself because of the partial vacuum created. If it does not move back at all, replace the water check valve with a new one.

() If there is a gap between the syringe and gasket, a vacuum will not be created inside the syringe, and the plunger will not be pulled back even if the water check valve is in good condition and working properly

#### Replacement



Use a needle or a similar tool to take the gasket off.

Then take the water check valve out and replace it with a new one

Put the gasket back in its original position.

## 

. The raised rims of the holes have a critical role in making a good seal; do not scratch or damage them.

· Failure to install a gasket properly will result in a malfunction.

# **Regular Inspection**

- inspection items.

### Regular inspection items

Inspection Item 1 Handpiece Connect 2 Rotation and Spray 3 Overheating

# Service and Disposal

The AIR TORX may be repaired and serviced by:

waste requiring special treatment.

lopment and Manufacturing MORITA MFG. CORP.
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\* Regular inspection is generally considered to be the duty and obligation of the user, but if, for some reason, the user is unable to carry out this duty, the user may rely on gualified medical device service personnel. Contact your local dealer or J. MORITA OFFICE for details.

\* The device should be inspected every 3 months in accordance with the following regular

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

\* J. MORITA MFG. CORP. will offer replacement parts and service for the product for a period of 10 years after the manufacturing of the product has been discontinued. Replacement parts and service will continue to be available during that period.

	Check Point
tion	Check the following points three times.
	<ol> <li>Connect and disconnect a handpiece to check that the operation can be made properly.</li> </ol>
	2. Connect a handpiece and run the device, and then pull the handpiece with a force similar to that applied during treatment to see that the handpiece does not come off.
	<ul> <li>Run the device at maximum speed without a handpiece at- tached and check the following points.</li> </ul>
	1. The rotation is smooth with no abnormal noise.
	2. The cooling air is coming out from the connection cylinder.
	<ul> <li>Connect a handpiece and run the device at maximum speed to check the following points.</li> </ul>
	<ol> <li>The handpiece rotates smoothly with no abnormal noise, and the spray has a fine, misty consistency.</li> </ol>
	<ol><li>There is no air or water leakage at the tube connection parts.</li></ol>
	• Run the device without connecting a handpiece at maximum speed for 3 minutes and check if it feels abnormally warm.
	• Connect a handpiece to the device and check the same as above.

- 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.

#### Standards and Procedures for the Disposal of Medical Devices

- When disposing of this device, it should be categorized as infectious waste.
- The dentist or doctor must confirm that the 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

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