

**Dental Handpiece Maintenance Unit** 



# **Operation Instructions**

Thank you for purchasing the Lubrina, a dental handpiece maintenance unit.

The Lubrina lubricates and internally cleans dental handpieces easily and effectively.

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

Keep this manual in a handy place for ready reference.

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### ATTENTION CUSTOMERS

Do not fail to receive clear instructions concerning the various ways to use this equipment as described in this accompanying Operator's Manual.

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

### 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.

After instructing the customer in the operation of the equipment, have the customer fill out and sign the warranty. Then fill in your own section of the warranty and give a copy to the customer. Do not fail to send the manufacturer's copy to your local J. MORITA OFFICE.

#### PREVENT ACCIDENTS

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

Note the meaning of the following symbols and expressions:

**↑**WARNING Thi

This warns the user of danger of death, serious bodily injury or total

equipment damage and failure or fire.

**⚠**PROHIBITION

This identifies methods which must not be used or purposes which the

instrument is not suited for.

**△** CAUTION

This alerts the user to the risk of light to medium injury or equipment

damage.

Usage Note

This alerts the user of important points concerning operation.

The user (e.g., healthcare facility, clinic, hospital etc.) is responsible for the management, maintenance and use of medical devices. Also this equipment must not be used by anyone except legally qualified dentist, doctor, or other legally qualified professional.

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

Rx Only

Prescription Device

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

#### **ATTENTION**

- J. MORITA MFG. CORP.will not be responsible for accidents, instrument damage, or bodily injury resulting from:
  - 1. Repairs made by personnel not authorized by J. MORITA MFG. CORP.
  - 2. Any changes, modifications, or alterations of its products.
  - 3. The use of products or instrument made by other manufacturers, except for those procured by J. MORITA MFG. CORP.
  - 4. Maintenance or repairs using parts or components other than those specified by J. MORITA MFG. CORP. and other than in their original condition.
  - 5. Operating the instrument in ways other than the operating procedures described in this manual or resulting from the safety precautions and warnings in this manual not being observed.
  - 6. Workplace conditions and environment or installation conditions which do not conform to those stated in this manual such as improper electrical power supply.
  - 7. Fires, earthquakes, floods, lightning, natural disasters, or acts of God.
- The useful life of the Lubrina is 5 years (based on self-cerfification) from the date of installation provided it is regularly and properly inspected and maintained.
- J. MORITA MFG. CORP. will supply replacement parts and be able to repair the product for a period of 10 years after the manufacture of the product has been discontinued.

### 1. Warning and Prohibitions

### **MARNING**

• No modification of this equipment is allowed. The customer is not allowed to repair this equipment themselves.

### **⚠**PROHIBITION

- The Lubrina cannot be used for air bearing handpieces (Astron series).
- Electromagnetic wave interference caused by cellular phones, transceivers, remote controls and similar transmission devices could cause the equipment to operate randomly. All devices which transmit electromagnetic waves located near the work area should be turned off.

### 2. Technical Specifications

### **Specifications**

| Name                            | Lubrina   |
|---------------------------------|---|
| Model                           | HIM-1   |
| Туре                            | US  |
| Rating                          | AC 100 V to 240 V 50/60 Hz                            |
| Power Consumption               | 25 VA   |
| Fuse                            | 250 V 2 A Slow Blow and High breaking Type Ø5 × 20 mm |
| Input Air Pressure              | 1.0 MPa max.  |
| Air Pressure                    | 0.3 MPa to 0.5 MPa                                    |
| Class                           | Class I   |
| Isolation from the Supply Mains | Unplug the power cord from supply mains               |
| Recommended Air Pressure        | 0.35 MPa  |
| Air Flow Rate                   | 40 NL/min to 60 NL/ min                               |
| Weight                          | Approx. 10 kg   |
| Size (including regulator)      | Width 300 mm × Height 370 mm × Depth 300 mm           |

#### **Product Description**

Used to maintain optimum performance and prolong working life of dental handpieces.

Delivers oil and air automatically to handpiece.

Used after dental treatment and before autoclaving.

### **Operating Principle**

Physical methods used to accomplish its intended use:

Air Pressure: 0.3 MPa to 0.5 MPa

Air Flow Rate: 40 NL/min to 60 NL/min

Maintenance oil spray can

Mechanisms by which it works:

Maintenance spray can is operated by pressurized air. Sprayed air delivers oil and lubricates the inside of the handpieces. Also, excess oil is removed from the handpieces.

#### **Intended User**

- a) Engaged person (peoples) in dental clinic
- b) Language Understanding: English or languages offered in the instruction for use. Understanding of attention and warning marks.
- c) Experience: Not relevant

#### **Operating Envionments**

Dental clinic, hospital

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 +50°C (+14°F to +122°F) Humidity: 30% to 75 % (without condensation) Atmospheric Pressure: 50 kPa to 106 kPa

#### **Disposal**

The package 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.

#### **Meaning of Symbols**

\* Some symbols may not be used.

|       | Manufacturer                |               | Date of manufacture  |
|-------|-----------------------------|---------------|--|
| SN    | Serial number               | $\triangle$   | Attention, consult accompany documents   |
|       | Refer to instruction manual | $\sim$        | Alternating current  |
| INPUT | Rated input amperes         | U             | Rated supply voltage   |
| f     | Supply frequency            | $((\bullet))$ | Non-ionizing electromagnetic radiation   |
|       | Main switch<br>Off On       |               | Stand-by  If the main switch is on, green power lamp next this mark lights up. |



General warning sign



Warning; Flammable material



No open flame; Fire, open ignition source and smoking prohibited



**GS1** DataMatrix



This way up



Fragile; handle with care



Keep away from rain



Temperature limitation



**Humidity limitation** 



Atmospheric pressure limitation



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



cTUVus certification mark (U.S.A. and Canada)



CE marking

Conforms with the European Directive, 93/42/EEC and 2011/65/EU.



Authorized representative in the European Community



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



C-Tick mark

Conforms with applicable electromagnetic compatibility (EMC) requirements (Australia and New Zealand)

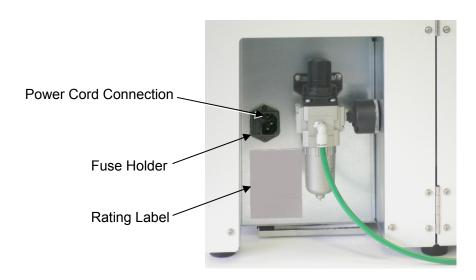
N13700

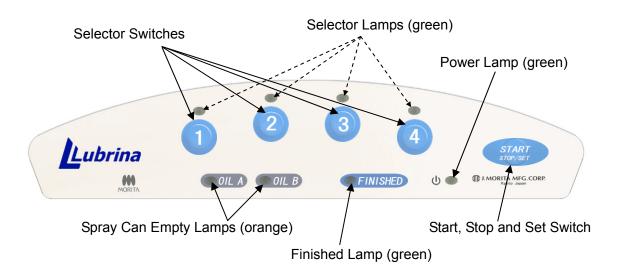
C-Tick supplier code number

# 3. Parts Identification











### **WARNING**

### DANGER



- Spray cans will explode if they get too hot.
- Do not use this device near an open flame or in a spot where it might heat up.
- Use only the sprays approved by J. MORITA MFG. CORP. PREVENT EXPLOSION AND IGNITION OF SPRAY CANS!



Les bombes aérosols peuvent exploser si elles sont exposées à une source de chaleur. Ne pas utiliser ce dispositif à proximité directe d'une flamme ou d'une source de chaleur. Utiliser uniquement les bombes aérosol de J. MORITA MFG. CORP. EVITER EXPLOSION ET ECHAUFFEMENT DES BOMBES AEROSOLS



- Ventilate the room while using the Lubrina.
BREATHING CONTAMINATED AIR IS HARMFUL.



Aérer les locaux durant l'utilisation du Lubrina. RESPIRER L'AIR CONTAMINE EST NOCIF.

- Read the user's manual and follow the instructions carefully.

Lire le mode d'emploi et suivre rigoureusement les instructions.





### (7) Spray Can Removal

1. Pull the lock lever straight up to lower the stand.



2. Take the spray can out.

If the can's nozzle is stuck in place, simply pull the can down slightly and take it out.

### 5. Operation

### **Handpiece Autoclave Sterilization**

### **MWARNING**

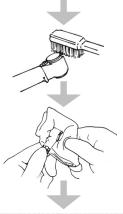
To prevent the spread of grave, life-threatening diseases like HIV and hepatitis B, autoclave handpieces after performing regular maintenance using the Lubrina.

<Take Off>



Take the handpiece off its tube. (Remove the bur as well.)

<Clean>



Clean the head with a brush and running water.

Wipe the handpiece with gauze dampened with Ethanol for Disinfection (Ethanol 70 vol% to80 vol%).

# **Lubrina Procedure** <Clean and Lubricate>



Perform chuck lubrication for MORITA ball bearing handpieces. Those are as follows:

PAR 4H (K042408)

PAR-4H (K043498) PAR-DI (K043498) PAR-4HX (K061701) PAR-4HEX (K061701)

Perform the lubrication procedure.





Remove excess oil by wiping with Ethanol for Disinfection (Ethanol 70 vol% to 80 vol%).

<Autoclave>

Autoclave in a sterilization pouch.

### Usage Note

♦ Some oil may remain inside the handpiece even after autoclaving. Refer to the user instructions for each handpiece for proper storage. (Storing the handpiece in an upright position is recommended.)

\* If the Lubrina hasn't been used for a while, make sure it operates properly and safely before using it.

### **MARNING**

- Avoid the risks of electrical shock, equipment damage and fire during an electrical storm: Turn the Lubrina off and do not touch it or its cord.
- Wear surgical gloves, mask and protective eyewear to operate and clean the Lubrina.

#### <Setup>

- Carefully clean off the outside of the handpiece before performing maintenance.
- Remove the bur.

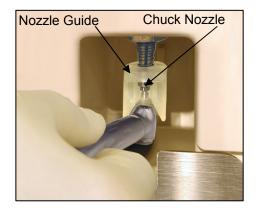
### Chuck Cleaning and Lubrication



Turn the main switch on. (Green power lamp lights up.)



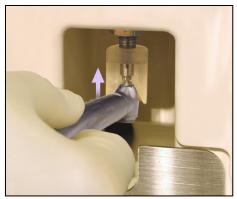
Open the front door.



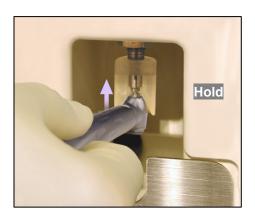
Line up the front end of the head with the nozzle guide and set the chuck in place.

# **∆**CAUTION

Make sure the head is flat against the nozzle guide. If it is tilted, the nozzle might be bent or oil might spray out.



Lift the handpiece up slightly to begin cleaning and lubricating the chuck.

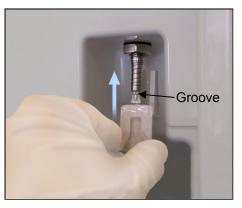


Hold it in place for about 5 seconds. A beep sounds when the procedure is finished.

\* A series of beeps signals an error. In this case, try again.

# **∆**CAUTION

Oil will spray out of the nozzle if the handpiece is removed too soon (before the beep).



### Usage Note

- ♦ Chuck cleaning and lubrication is only for MORITA handpieces.
- ♦ If the nozzle guide comes off, line up the tab on it with the groove and slide it back on.



#### Handpiece Maintenance

Turn on the main switch.

(Green power lamp lights up.)

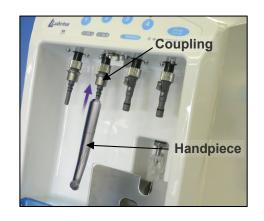


Open the front door.

\* For micromotor attachments (straight, contra etc.), some should have a bur inserted and some should not. Refer to the user instructions for the micromotor attachments.

### **≜**CAUTION

- For some handpieces, an oil mist may be released if a bur is not inserted.
- Depending on the type of handpiece and coupling, there could be a release of oil mist. In this case, lower the pressure to 0.3 MPa.



Attach a handpiece to its coupling with the chuck facing back. (See photo.)

Spray can A is for nozzles 1 and 2. Spray can B is for 3 and 4.

### **ACAUTION**

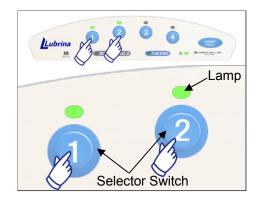
Do not damage the o-ring on the coupling when attaching a handpiece.

This could result in oil spraying out or poor performance.

### Usage Note

- ♦ Put the handpiece all the way on until it clicks into place.

  A handpiece could come off during the maintenance if it is not properly connected.
- ♦ If the chuck is facing the front door, the inside of the unit will tend to get dirtier.



Press the selector switch corresponding to the handpieces which are connected.

Selector lamps light up.

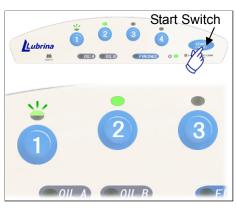
(If you press the wrong one, just press it again to turn it off.)



Close the front door.

### Usage Note

♦ The Lubrina will not start if the front door is not closed.



Press the Start Switch.

The handpiece lamps blink while maintenance is performed.

\* Press the Start Switch again if the procedure was stopped before finishing.

### **ACAUTION**

Do not select a coupling that does not have a handpiece attached to it. This would result in oil spraying out when the Start Switch is pressed.

### **MARNING**

- Do not select a coupling that does not have a handpiece attached to it. Otherwise, you may inhale sprayed oil mist, or it may splash into your eyes.
- Select the most appropriate lubrication mode for each handpiece. Otherwise, too much oil will remain inside the handpiece and it will spray out when using the handpiece.
- Use this equipment with proper air pressure (0.3 MPa to 0.5 MPa). Otherwise, too much oil will remain inside the handpiece and it will spray out when using the handpiece.

### Usage Note

- **♦** Never remove the spray can during maintenance.
- **♦** Opening the front door will immediately stop the maintenance procedure.
- \* If a can runs out during maintenance, the empty lamp will start flashing, and the procedure will stop. Replace the can and press the Start Switch to repeat the procedure from the beginning.

When the maintenance for all the handpieces is completed, their lamps will go out, a beep will sound and the Finished Lamp will light up.



Finished Lamp

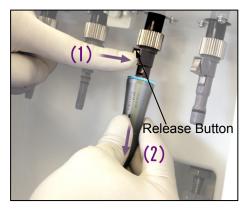
FINISHED

Open the front door and remove the handpieces.

Hold the handpiece with one hand and push up the release ring with the other.
(for MORITA couplings)

#### Usage Note

♦ Use Ethanol for Disinfection (Ethanol 70 vol% to 80 vol%) to wipe off excess oil from the handpiece.



For micromotor attachments, hold the attachment with one hand and press the release button with the other.



Take out the handpieces and close the door.

### **△** CAUTION

Take care not to cut your fingers on the front door or other parts.



Turn the main switch off after use. The power lamp will go out.

### **MCAUTION**

- Do not fail to turn off the main switch after use.
- If the unit will not be used for a while, unplug it and close the main air valve.

#### Change Lubrication Mode (time)

There are three lubrication modes: the short mode (with less oil), the long mode (with more oil), and the long blow-out mode (to remove excess oil more thoroughly).

#### Short Mode (Oil supply time 0.3 sec)

\* With less oil

The selector switch lamp blinks at 0.3 second intervals.

Lubrication time for one handpiece is about 25 seconds.

#### Long Mode (Oil supply time 1.0 sec)

\* With more oil

The selector switch lamp blinks at 1.0 second intervals.

Lubrication time for one handpiece is about 25 seconds.

#### Long Blow-out Mode (Oil supply time 0.3 sec)

\* To remove excess oil more thoroughly

The selector switch lamp blinks at 2.0 second intervals.

Lubrication time for one handpiece is about 120 seconds.

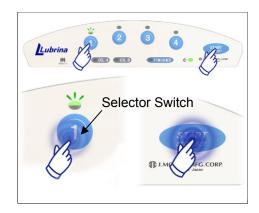
This mode blows out excess oil for a longer time after the short mode completes the oiling procedure.

#### **Usage Note**

♦ For some types of spray cans, the long setting will supply too much oil and it will spray out of the head.



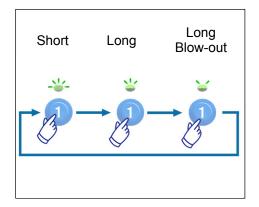
1. Turn the main switch on.



2. Hold down the Start Switch (Start / Stop / Set Switch) and then hold down a Selector Switch for 2 seconds.

Release it when a beep sounds.

The Selector Lamp will blink to show that you can now change its setting.



3. Now press the Selector Switch to change modes.

Each press of the Selector Switch will change the modes in sequence.

\* The lamp's blinking rate will change.



4. Check the time setting by how fast the lamp blinks, and then press the Start Switch for 2 seconds.

A double beep signals that the change has been made. After this the lamp goes out.

### Usage Note

**♦** Each Selector Switch must be set separately using the above procedure.





#### **Coupling Replacement**

Loosen the coupling's nut and take the coupling off.

Fit the replacement coupling onto the nozzle and tighten up its nut.

### Usage Note

- ♦ Make sure the nut is securely finger tight. Otherwise oil and air will escape and the maintenance will not be properly performed.
- ♦ Do not tighten the nut with pliers or other tools. This will damage the coupling.

# **∆**CAUTION

For handpieces not made by J. MORITA, do not fail to use the correct Lubrina coupling or the coupling for the main tube.

Do not use couplings made for maintenance equipment other than the Lubrina. This could result in release of oil mist or poor handpiece maintenance.

#### **Replacing Fuses**

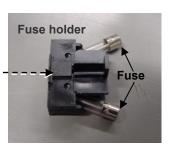
- 1. The power supply code is detached from the main body.
- 2. The fuse holder is pulled out.
- 3. The fuse is exchanged for the new article. Fuse: 250 V 2 A Slow-Blow and High breaking type
- 4. The fuse holder is inserted.

### **MARNING**

For fuse repair, contact your local dealer or J. MORITA OFFICE.





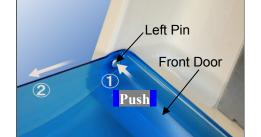


### 6. Maintenance and Replacement Parts

### **MARNING**

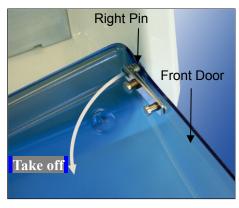
Wear surgical gloves, mask and protective eyewear to operate and clean the Lubrina.

### Remove and Clean Front Door



1. Push the pin on the left side in the direction of the arrow in the photo.

Push the pin all the way in and then pull the door forward.



2. Take the door off the pin on the right side.

# **∆**CAUTION

Take care not to cut your finger on the hardware.

### Usage Note

- ♦ Hold the door securely and pull it off carefully. Excessive force could damage it.
- \* Fit the door back onto the pin on the right side to replace it.
- 3. After removing the door wash it with water and a neutral detergent or wipe it with Ethanol for Disinfection (Ethanol 70 vol% to 80 vol%).

### Usage Note

- ♦ Do not use hot water; this could damage the plastic.
- **♦** Use only soft gauze to wipe the door.





4. Clean the main body with a neutral detergent or Ethanol for Disinfection (Ethanol 70 vol% to 80 vol%).

### **∆**CAUTION

Take care not to cut your finger on the couplings or other parts.

### Usage Note

 Do not use disinfectants that contain chlorine-based cleaners or benzalkonium chloride or chlorinated aromatics.

These solutions could discolor or damage plastic and corrode metal.

### Oil Pad Replacement

- \* Inspect the oil pad once a week and replace it before oil reaches the top.
- 1. Remove the oil pad case.



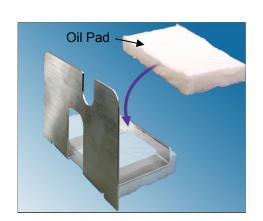
2. Take the pad out of the case and replace it with a new one.

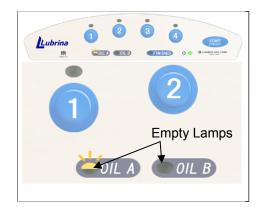


Dispose of used oil pads according to regulations for medical waste.

### Usage Note

- ♦ An oily film will form on the Lubrina if the pad is not replaced.
- ♦ A single oil pad can absorb the oil from about 2 spray cans. However, the absorbed oil could start leaking from the pad if it is not replaced soon enough.





### Spray Can Replacement

Replace a can if its empty lamp starts to blink. (See page 13 "(6) Spray Cans".)



### Empty Drainage from Air Regulator

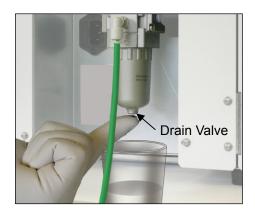
Empty the drainage from the air regulator about once a month.



1. Pull up the dial on the air regulator and turn it until the pressure drops to 0 MPa.

# **∆**CAUTION

If the drain valve is opened without releasing the pressure inside the regulator, the water in the drain could spray out into your eyes.



2. Put a container under the regulator and then press the drain valve.

The dirty water in the regulator will drain out.

### **MCAUTION**

If water is inadvertently mixed with the air, handpieces could be severely damaged.

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3. After draining the regulator, turn the dial back to adjust the pressure and push it back down.



### Cleaning the Tray

Pull out the tray and clean it with a neutral detergent or Ethanol for Disinfection (Ethanol 70 vol% to 80 vol%) about once a month.

### Usage Note

- ♦ The tray cannot be autoclaved. Autoclaving will cause it to rust.
- ♦ Do not use disinfectants that contain chlorine-based cleaners or benzalkonium chloride or chlorinated aromatics.
  - These solutions will corrode the tray.
- ♦ If this tray is not cleaned, oil will overflow from the tray.



Throw away the old filter and replace it with a new one.

# **∆**CAUTION

- Dispose of used filters according to regulations for medical waste.
- Do not fail to push the tray all the way in.
   Otherwise, oil could leak out or oil mist might be released.

### **Cleaning Couplings**

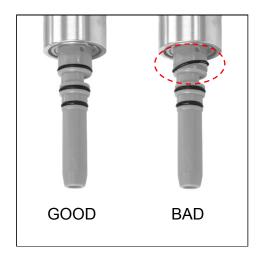
Loosen its nut and take the coupling off. Clean it with Ethanol for Disinfection (Ethanol 70 vol% to 80 vol%).

### Usage Note

- **♦** Take care not to damage the o-ring.
- **♦** Couplings cannot be autoclaved. Autoclaving could crack the plastic parts.



\* See page 24 "Coupling Replacement" for how to attach couplings.



\* An o-ring could slip out of its groove.

Make sure all o-rings are properly seated in their grooves before attaching a handpiece.

### Usage Note

♦ Attaching a handpiece when an o-ring is not properly in its groove could cut the o-ring, and, if it gets stuck in the coupling, this will make it hard to put on and take off handpieces.

### 7. Maintenance and Inspection

#### **Regular Inspection**

- \* Maintenance and inspection are generally considered to be the duty and obligation of the user, but if, for some reason, the user is unable to carry out these duties, they may rely on a qualified medical device serviceman. Contact your local dealer or J. MORITA OFFICE for details.
- 1. Power Supply Cord Inspect visually for wear and broken wires.
- 2. Main and Operation Switches
  Turn main switch on and check that main lamp lights up. Check that the unit operates correctly.
- 3. Oil Absorption Pad
  Open case and replace oil pad if oil has seeped all the way to its top. (Replace after using 2 cans of spray.)
- 4. Drain Air Regulator
  Check and drain air regulator. (once a month)
- 5. Tray Filter
  Replace tray filter. (once a month)

#### Regularly Required Replacement Parts

Fuse

Other Replacement Parts

Oil Absorption Pad Tray Filter

# 8. Troubleshooting

Use the check list below if the apparatus does not seem to be working properly.

- \* Contact your local dealer or J. MORITA OFFICE if the apparatus does not work normally even after inspection, adjustment or parts replacement, or if the dentist cannot perform maintenance procedures themselves.
- \* Before inspection and adjustment, make sure the power is on.

| Problem   | Cause  | Solution  |
|---|--|---|
| Main power lamp does not light  | Power supply cord not properly plugged into supply socket. | N   |
| up.   | Power supply cord not properly plugged into Lubrina.       | Plug in properly.   |
|   | Front door may be open.                                    | Close front door.   |
| Does not start when Start Switch is pressed.                            | Empty can.   | Replace can.  |
| (1) Double beep sounds.   | Can is not properly installed.                             | Properly install the can.   |
| (2) Spray can Empty Lamp is blinking.                                   | Compressor air is not connected.                           | Connect air.  |
|   | Air regulator is not set properly.                         | Set regulator properly.   |
|   | Use without connecting handpiece.                          | Select only couplings that have a handpiece connected.  |
|   | Oil pad is saturated.                                      | Clean Lubrina and replace oil pad.  |
| <ul><li> Unusual odor.</li><li> Surfaces are unusually dirty.</li></ul> | Tray filter is saturated.                                  | Clean Lubrina and replace filter.   |
|   | Spray can is not properly installed.                       | Install can properly.   |
|   | Air regulator is not set properly.                         | Set regulator properly.   |
|   | Bent spray can nozzle pin.                                 | Replace can.  |
| Cannot install spray can.   | Wrong stand for spray can.                                 | Use proper stand for can.   |
| Oil leaks from spray can.   | Spray can not specified by J. MORITA.                      | Only use sprays specified by J. MORITA.   |
| Oil mist is released.   | Type of handpiece or coupling.                             | Depending on the type of handpiece and coupling, there could be a release of oil mist. In this case, lower the pressure to 0.3 MPa. |
| • Equipment surfaces get oily.  | Air pressure too high.                                     | Reduce air pressure, but not less than 0.3 MPa.   |
|   | No bur inserted in straight attachment.                    | Refer to the user instructions for the handpiece.  *For some handpieces, an oil mist may be released if a bur is not inserted.      |

# 9. Service Contacts

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

#### **10. Electromagnetic Disturbances (EMD)**

The Lubrina (Model:HIM-1, Type:US, 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.

| <b>Emissions Test</b>                          | Compliance         | Electromagnetic Environment – Guidance   |
|--|--------------------|--|
| Conducted disturbance<br>CISPR 11              | Group 1<br>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<br>CISPR 11               | Group 1<br>Class B | This device is suitable for use in all establishments, including domestic establishments and those directly  |
| Harmonic current*1<br>IEC 61000-3-2            | Class A            | connected to the public low-voltage power supply network that supplies buildings used for domestic   |
| Voltage fluctuations and flicker IEC 61000-3-3 | Clause 5           | purposes.  |

<sup>\*1:</sup> 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.

### **MARNING**

- The use environment of this device is the Professional healthcare facility environment.
- This device needs special precautions regarding EMD and needs to be installed and put into service according to the EMD information provided in the ACCOMPANYING DOCUMENTS.
- Use of parts other than those accompanied or specified by J. MORITA MFG. CORP. could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- Do not use this device as adjacent or stacked as possible with other.

  When adjoining or stacking is necessary, use it after observing whether this equipment and other equipment work properly.
- Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the HIM-1, including cables specified by the manufacturer.

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#### 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<br>Environment – Guidance   |
|---|--|--|---|
| Electrostatic discharge (ESD) IEC 61000-4-2   | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV, ±15 kV<br>air  | ±2 kV, ±4 kV, ±6 kV, ±8 kV<br>contact<br>±2 kV, ±4 kV, ±8 kV, ±15 kV<br>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<br>transients/bursts<br>IEC 61000-4-4   | ±2 kV for power supply lines<br>±1 kV for input/output lines   | ±2 kV for power supply lines<br>±1 kV for input/output line  | Mains power quality should<br>be that of a typical<br>commercial or hospital<br>environment.  |
| Surge<br>IEC 61000-4-5  | AC/DC power<br>±0.5 kV, ±1 kV line(s) to<br>line(s)<br>±0.5 kV, ±1 kV, ±2 kV line(s)<br>to earth<br>Signal input/output<br>±2 kV line(s) to earth  | AC/DC power<br>±0.5 kV, ±1 kV line(s) to<br>line(s)<br>±0.5 kV, ±1 kV, ±2 kV line(s)<br>to earth<br>Signal input/output*1<br>±2 kV line(s) to earth  | Mains power quality should<br>be that of a typical<br>commercial or hospital<br>environment.  |
| Voltage dips, short<br>interruptions and voltage<br>variations on power supply<br>lines<br>IEC 61000-4-11 | dips<br>0% $U_T$ : 0.5 cycle (at 0, 45, 90,<br>135, 180, 225, 270, 315°)<br>0% $U_T$ : 1 cycle (at 0°)<br>70% $U_T$ : 25/30 cycles (at 0°)<br>25 (50 Hz)/30 (60 Hz)<br>short interruptions<br>0% $U_T$ : 250/300 cycles<br>250 (50 Hz)/300 (60 Hz) | $\begin{array}{c} \underline{\text{dips}} \\ 0\% \ U_{\text{T}} : 0.5 \ \text{cycle} \ (\text{at} \ 0, 45, 90, \\ 135, 180, 225, 270, 315^\circ) \\ 0\% \ U_{\text{T}} : 1 \ \text{cycle} \ (\text{at} \ 0^\circ) \\ 70\% \ U_{\text{T}} : 25/30 \ \text{cycles} \ (\text{at} \ 0^\circ) \\ 25 \ (50 \ \text{Hz})/30 \ (60 \ \text{Hz}) \\ \underline{\text{short interruptions}} \\ 0\% \ U_{\text{T}} : 250/300 \ \text{cycles} \\ 250 \ (50 \ \text{Hz})/300 \ (60 \ \text{Hz}) \\ \end{array}$ | Mains power quality should be that of a typical commercial or hospital environment.  If user of this device requires continued operation during power mains interruptions, it is recommended that this device be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz)<br>magnetic field<br>IEC 61000-4-8   | 30 A/m (r.m.s.)<br>50 Hz or 60 Hz  | 30 A/m (r.m.s.)<br>50 Hz or 60 Hz  | Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.  |

NOTE 1:  $U_T$  is the a.c. mains voltage prior to application of the test level.

NOTE 2: r.m.s.: root mean square

<sup>\*1:</sup> 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<br>Test Level  | Compliance Level   | Electromagnetic Environment – Guidance   |  |
|-------------------------------|--|--|--|--|
| Conducted RF<br>IEC 61000-4-6 | 3 V<br>ISM <sup>(c)</sup> frequency band: 6 V<br>150 kHz to 80 MHz | 3 V<br>ISM <sup>(c)</sup> frequency band: 6 V<br>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.  Recommended separation distances |  |
| Radiated RF<br>IEC 61000-4-3  | 3 V/m<br>80 MHz to 2.7 GHz   | 3 V/m<br>80 MHz to 2.7 GHz   |  |  |
|                               | 27 V/m<br>385 MHz  | 27 V/m<br>385 MHz  | $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz<br>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz  |  |
|                               | 28 V/m<br>450 MHz  | 28 V/m<br>450 MHz  | $d = \frac{6}{E} \sqrt{P}$ Portable wireless RF communication equipment  |  |
|                               | 9 V/m<br>710, 745, 780 MHz   | 9 V/m<br>710, 745, 780 MHz   | Where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, $E$ is the compliance level in V/m and $d$ is the recommended  |  |
|                               | 28 V/m<br>810, 870, 930, MHz<br>28 V/m                             | 28 V/m<br>810, 870, 930, MHz<br>28 V/m                             | separation distance in meters (m).  Field strengths from field RF transmitters, as determined by an electromagnetic site survey <sup>(a)</sup> , should be less than the compliance level in each  |  |
|                               | 1720, 1845, 1970 MHz   | 1720, 1845, 1970 MHz   | frequency range <sup>(b)</sup> .  Interference may occur in the vicinity of  |  |
|                               | 28 V/m<br>2450 MHz   | 28 V/m<br>2450 MHz   | equipment marked with the following symbol:  |  |
|                               | 9 V/m<br>5240, 5500, 5785 MHz                                      | 9 V/m<br>5240, 5500, 5785 MHz                                      |  |  |

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- (a) Field strengths from fixed transmitters, such as base stations for ratio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicated theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this device is used exceeds the applicable RF compliance level above, this device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting of relocating this device.
- (b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
- (c) The ISM (Industrial, Scientific and Medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

#### **Essential Performance**

None

#### Cable List

| No. |    | Interface(s):  | Max. Cable Length, Shielding | Cable Classification |  |
|-----|----|----------------|------------------------------|----------------------|--|
|     | 1. | AC Power Cable | 3 m, Un-shielded             | AC Power Line        |  |

**Development and Manufacturing** 

### J. MORITA MFG. CORP.

680 Higashihama Minami-cho, Fushimi-ku, Kyoto 612-8533, Japan T +81. (0)75. 611 2141, F +81. (0)75. 622 4595

#### Morita Global Website www.morita.com

#### Distribution

#### J. MORITA CORP.

3-33-18 Tarumi-cho, Suita-shi, Osaka 564-8650, Japan T +81. (0)6. 6380 1521, F +81. (0)6. 6380 0585

#### J. MORITA USA, INC.

9 Mason, Irvine CA 92618, USA T +1. 949. 581 9600, F +1. 949. 581 8811

#### J. MORITA EUROPE GMBH

Justus-von-Liebig-Strasse 27a, 63128 Dietzenbach, Germany T +49. (0)6074. 836 0, F +49. (0)6074. 836 299

#### MORITA DENTAL ASIA PTE. LTD.

150 Kampong Ampat #06-01A KA Centre, Singapore 368324 T +65. 6779. 4795, F +65. 6777. 2279

#### J. MORITA CORP. AUSTRALIA & NEW ZEALAND

Suite 2.05, 247 Coward Street, Mascot NSW 2020, Australia T +61. (0)2. 9667 3555, F +61. (0)2. 9667 3577

#### J. MORITA CORP. MIDDLE EAST

4 Tag Al Roasaa, Apartment 902, Saba Pacha 21311 Alexandria, Egypt T +20. (0)3. 58 222 94, F +20. (0)3. 58 222 96

#### J. MORITA CORP. INDIA

Filix Office No.908, L.B.S. Marg, Opp. Asian Paints, Bhandup (West), Mumbai 400078, India T +91-22-2595-3482

#### J. MORITA MFG. CORP. INDONESIA

28F, DBS Bank Tower, Jl. Prof. Dr. Satrio Kav. 3-5, Jakarta 12940, Indonesia T +62-21-2988-8332, F + 62-21-2988-8201

#### SIAMDENT CO., LTD.

71/10 Mu 5, Thakham, Bangpakong, Chachuengsao 24130, Thailand T +66. 38. 573042. F +66. 38. 573043 www.siamdent.com

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



#### MEDICAL TECHNOLOGY PROMEDT CONSULTING GmbH

Altenhofstraβe 80, 66386 St. Ingbert, Germany T +49. 6894 581020, F +49. 6894 581021

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