

**Dental Handpiece Maintenance Unit** 

# LUBRICARE

## **Operation Instructions**

Thank you for purchasing LUBRICARE, a handpiece maintenance unit of Bien-Air Dental SA. LUBRICARE 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 Bien-Air Dental SA regional 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:

<b>MWARNING</b>	This warns the user of danger of death, serious bodily injury or total equipment damage and failure or fire.
	This identifies methods which must not be used or purposes which the instrument is not suited for.
<b>≜</b> 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.

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

#### ATTENTION

Bien-Air Dental SA will not be responsible for accidents, instrument damage, or bodily injury resulting from:

- 1. Repairs made by personnel not authorized by Bien-Air Dental SA.
- 2. Any changes, modifications, or alterations of its products.
- 3. The use of products or instruments made by other manufacturers, except for those procured by Bien-Air Dental SA.
- 4. Maintenance or repairs using parts or components other than those specified by Bien-Air Dental SA. 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.

Bien-Air Dental SA 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. Warnings and Prohibitions

## **WARNING**

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

## **A**PROHIBITION

- LUBRICARE cannot be used for air bearing handpieces (Astron series).
- Electromagnetic wave interferences 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	LUBRICARE
Model	HIM-1
Туре	ВА
Rating	AC 100 to 240 V 50/60 Hz
Power Consumption	25 VA
Fuse	250 V 2 A Slow Blow and High breaking Type $\emptyset$ 5 × 20 mm
Input Air Pressure	1.0 MPa max.
Air Pressure	0.3 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 to 60 NL/min
Weight	Approx. 10 kg
Size (including regulator)	Width $300 \times \text{Height } 370 \times \text{Depth } 300 \text{ mm}$

#### **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 - 0.5 MPa Air Flow Rate: 40 - 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 Humidity: 30% to 75 % (without condensation) Atmospheric Pressure: 70 kPa to 106 kPa

#### **Transport and Storage Environments**

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

#### <u>Disposal</u>

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**

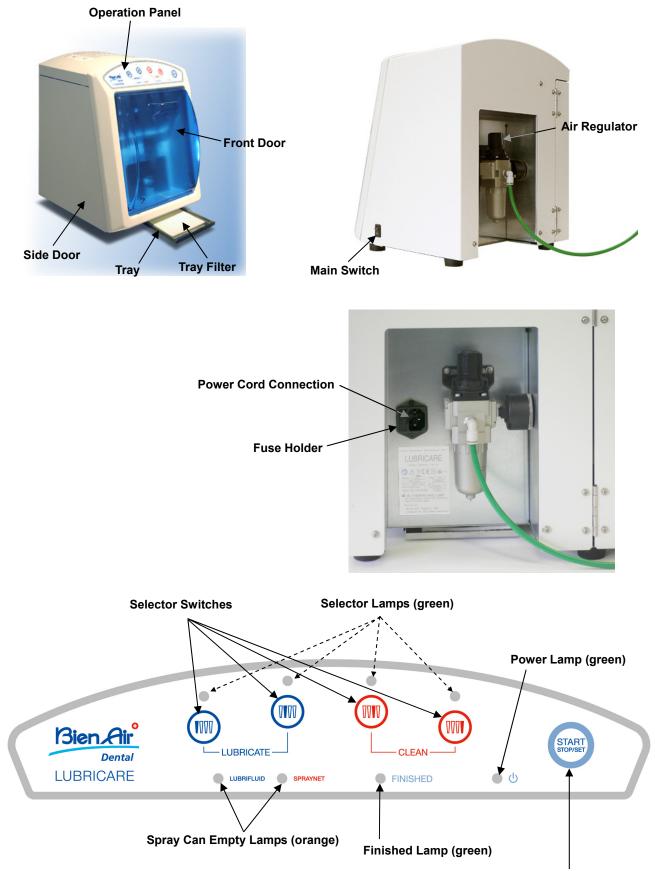
#### **Rating Label**



## <u>Symbols</u>

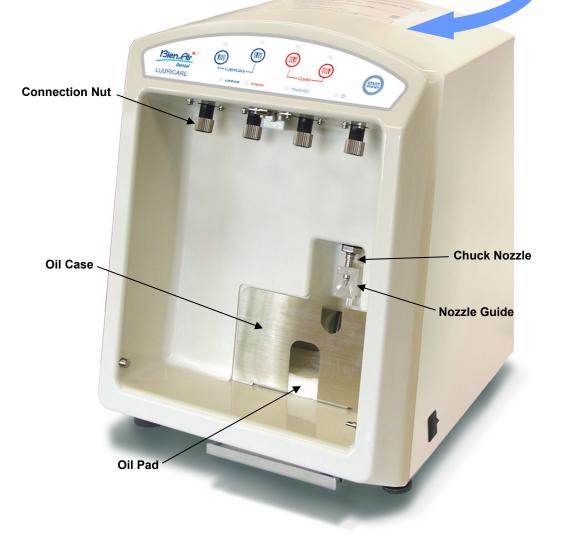
CE	CE marking Conforms with the European Directive, 93/42/EEC. and 2011/65/EU	Â	Attention, consult accompany documents
SN	Serial number E.g., $G \xrightarrow{A} XXXX$ (1) (2) (3) (1) Year of Manufacture E.g., F: 2017, G: 2018, H: 2019 (2) Month of Manufacture E.g., A: Jan., B: Feb., C: March (3) Lot No. 0001, 0002, 0003	U	Rated supply voltage
INPUT	Rated input amperes	f	Supply frequency
$\sim$	Alternating current	N13700	C-tick Supplier Code Number
	Manufacturer		Indicating separate collection waste of electronic equipment
C	C-tick Mark	C US	cTUVus certification mark for the U.S. and Canadian
	Note Firing (ISO 3864-B3.2)	<u>\</u>	General warning sign
Carlo	Refer to instructions for use		No open flame; Fire, open ignition source and smoking prohibited
$(\mathbf{b})$	Stand-by (If the main switch is on, green power lamp next this mark lights up)	10	Main switch on off

#### 3. Parts Identification



Start, Stop and Set Switch

WARNING DANGER
<ul> <li>Spray cans will explode if they get too hot.</li> <li>Do not use this device near an open flame or in a spot where it might heat up.</li> <li>Use only the sprays approved by Bien-Air Dental SA. PREVENT EXPLOSION AND IGNITION OF SPRAY CANS!</li> <li>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 Bien-Air Dental SA. EVITER EXPLOSION ET ECHAUFFEMENT DES BOMBES AEROSOLS</li> </ul>
<ul> <li>Ventilate the room while using the Lubricare.</li> <li>BREATHING CONTAMINATED AIR IS HARMFUL.</li> <li>Aérer les locaux durant l'utilisation du Lubricare.</li> <li>RESPIRER L'AIR CONTAMINE EST NOCIF.</li> </ul>
<ul> <li>Read the user's manual and follow the instructions carefully.</li> <li>Lire le mode d'emploi et suivre rigoureusement les instructions.</li> </ul>



## Components

#### Main Unit



## Accessories

Oil Absorption Pads (5)	Oil Absorption Case (1)	Power Cord (1)
		(CE · 230 V) (US · 120 V)
Tray Filter (1)	Tray (1)	Spray Can Stand (2)
TR Coupling (2)	Air Tube (1)	

\* Direct inquires concerning types of couplings, sprays, and spray can stands to your local dealer or Bien-Air Dental SA.

## **MWARNING**

- Explosion Hazard: Do not use near open flames or other ignition sources.
- Use only spray provided by Bien-Air Dental SA.
- Health Hazard: The area must be well ventilated. Breathing fumes could damage your health.
- The equipment must be properly grounded.

## **≜**CAUTION

Set the unit on a level and stable surface.

#### Usage Note

• Leave at least 5 cm of free, open space around the unit.

#### (1) Air Connection

 Connect the green air tube provided to the air regulator and the main air supply.
 Open the valve for the main air supply.

#### Usage Note

- The main air supply must be clean and oil-free.
- Make sure the tube is securely connected.

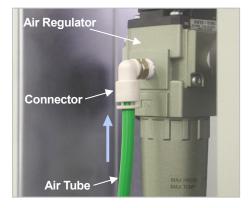
- Air Regulator Dial
- 2. Set the air regulator dial between 0.3 and 0.5 MPa. Pull the dial up to unlock it. Push it back down after setting the pressure.
- \* Recommended Air Pressure is 0.35 MPa.

#### Usage Note

- Less than 0.3 MPa will result in poor performance.
- More than 0.5 MPa could result in damage.

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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.



#### (2) Power Cord



Connect one end of the power cord to the main unit and plug the other end into a standard receptacle.

### **WARNING**

- Use the right cord!! Since power supply ratings differ depending on the country, two power supply cords are provided. Use the one suited for your local power supply; using the wrong cord could cause a fire.
- Make sure the ground is properly connected.
- Do not place objects around the power input plug at any time so that the equipment can be cut off from the supply mains when necessary.
- Do not place this equipment where the main switch cannot be operated.



#### (3) Coupling

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

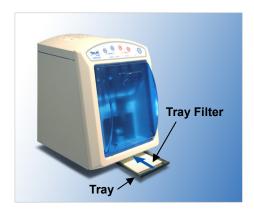
#### Usage Note

 Make sure the nut is properly tightened. Otherwise oil and air will escape and the maintenance will not be properly performed.



#### (4) Oil Pad

Put an oil pad in its case and install the case.



## (5) Tray

Put a filter in the tray and slide it into place.

#### Usage Note

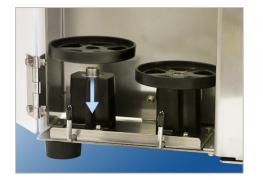
 Slide the tray all the way in; otherwise, a film of oil will be deposited on the unit.

#### (6) Spray Cans

1. Open the side door. Press the spot indicated in the photo to open the door.



Side Door



2. Set the stands for the cans in place as shown in the photo.



4. Push the lock levers down to a horizontal position to secure the cans.

## **≜**CAUTION

Oil will leak or spray out if the cans are not properly installed.

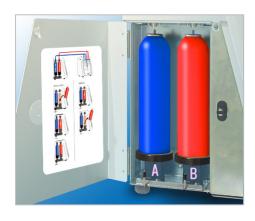
#### Usage Note

- Make sure the lock levers are all the way down.
   Otherwise, the oil will not come out. (The empty lamp will start blinking.)
- Pull and push the cans to make sure they are secure and do not wobble.
- 5. Close the side door.

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3. Can A is for the chuck maintenance and handpiece nozzles 1 and 2. Can B is for nozzles 3 and 4.





#### (7) Spray Can Removal

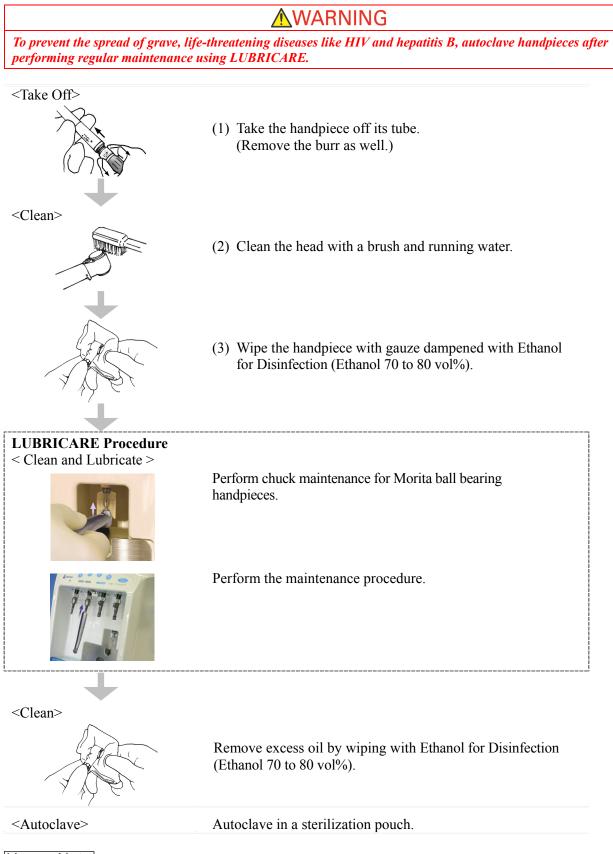
1. Pull the lock lever straight up to lower the stand.

2. Take the can out.

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

#### 5. **Operation**

#### Handpiece Autoclave Sterilization



#### 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 LUBRICARE hasn't been used for a while, make sure it operates properly and safely before using it.

## **WARNING**

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

#### <Set Up>

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

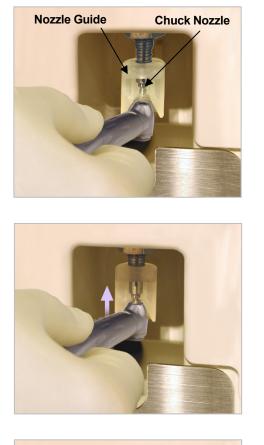
#### Chuck Cleaning and Lubrication

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



Front door

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 into your eyes.

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.

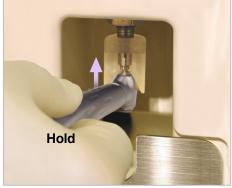
\* A series of beeps signals an error. In this case, try again.

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

#### Usage Note

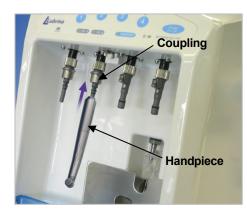
- Chuck cleaning and lubrication is only for Bien-Air handpieces.
- If the nozzle guide comes off, line up the tab on it with the groove and slide it back on.











Handpiece Maintenance

\* It takes about 25 seconds to clean and lubricate one handpiece.

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

Open the front door.

\* For micromotor attachments (straight, contra etc.), some should have a burr 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 burr 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.

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

This could result in oil spraying out or poor performance.

## **WARNING**

- 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

- 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

• LUBRICARE will not start if the front door is not closed.

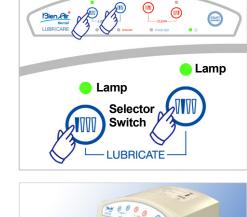
Press the Start Switch.

The handpiece lamps blink while maintenance is performed.

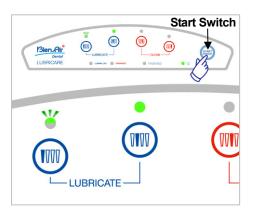
Press the Start Switch again if the procedure was stopped before finishing.

## **ACAUTION**

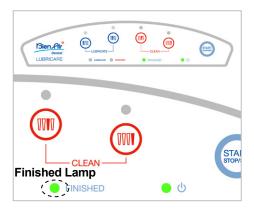
Do not select a coupling that does not have a handpiece attached to it. This would result in oil spraying out when the Start Switch is pressed.



Close



\*





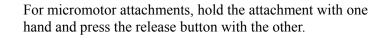
- Never remove the spray can during maintenance.
- Opening the front door will immediately stop the maintenance procedure.
- \* If a can runs out during maintenance, the empty lamp was start flashing, and the procedure will stop. Replace the can and press the Start Switch to repeat the procedure from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

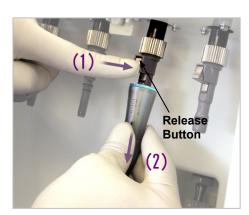
When the maintenance for all the handpieces is completed, their lamps will go out, a beep will sound and the Finished Lamp will light up.

(1) Release Ring (2) Open the front door and remove the handpieces. Hold the handpiece with one hand remove it from coupling.

#### Usage Note

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





Take out the handpieces and close the door.



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.

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- 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)

\* LUBRICARE can be used with sprays other than those made by Bien-Air Dental SA. To do this the stand for the spray can and the coupling must be replaced.

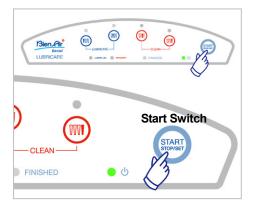
Change the lubrication time for other sprays in the following way.

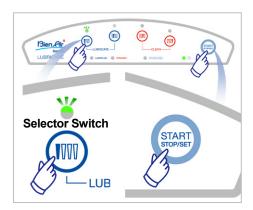
There are three lubrication modes: the short mode (with less oil), the long mode (with more oil), and the long blow-out mode (to remove excess oil more thoroughly).

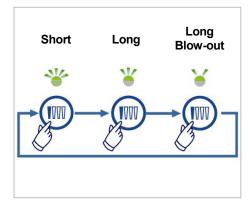
Short Mode * For less oil The selector switch lamp blinks at 0.3 second intervals. Lubrication time for one handpiece is about 25 seconds. Long Mode * For more oil The selector switch lamp blinks at 1.0 second intervals. Lubrication time for one handpiece is about 25 seconds. Long Blow-out Mode * To 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.	
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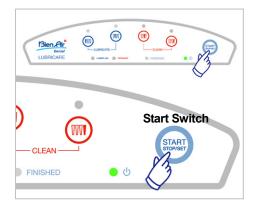
#### Usage Note

• 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.

 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 Select Switch must be set separately using the above procedure.

#### Coupling Replacement

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





2. 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 Bien-Air Dental SA, do not fail to use the correct LUBRICARE coupling or the coupling for the main tube.

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





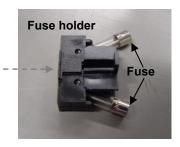
#### **Replacing Fuses**

The power supply code is detached from the main body.

The fuse holder is pulled out.

The fuse is exchanged for the new article. Fuse: 250 V 2 A Slow-Blow and High breaking Type

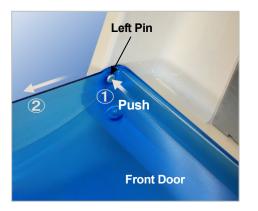
The fuse holder is inserted.

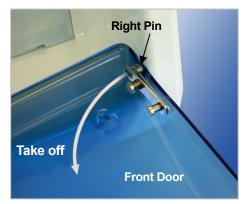


#### 6. Maintenance and Replacement Parts

#### **WARNING**

Wear surgical gloves to operate and clean LUBRICARE.







#### 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.

## 

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 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 to 80 vol%).

## **≜**CAUTION

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

#### Usage Note

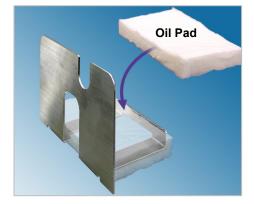
 Do not use disinfectants that contain chlorine-based cleaners or benzalkonium chloride or chlorinated aromatics. These solutions could discolor or damage plastic and corrode metal.

#### Oil Pad Replacement

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

Remove the oil pad case.





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

## **≜**CAUTION

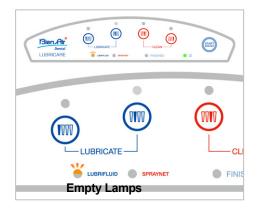
Dispose of used oil pads according to regulations for medical waste.

#### Usage Note

- An oily film will form on LUBRICARE 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 pages 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.

## 

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.

## 

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





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 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, an oily film will collect on the outside of LUBRICARE.

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 to 80 vol%).

#### Usage Note

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



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

#### 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, he may rely on a qualified medical device serviceman. Contact your local dealer or Bien-Air Dental SA 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 Bien-Air Dental SA, if the apparatus does not work normally even after inspection, adjustment or parts replacement, or if the dentist cannot perform maintenance procedures himself.
- \* Before inspection and adjustment, make sure the power is on.

Problem	Cause	Solution	
Main power lamp does not	Power supply cord not properly plugged into supply socket.	Plug in properly.	
light up.	Power supply cord not properly plugged into LUBRICARE.		
Does not start when Start	Front door may be open.	Close front door.	
Switch is pressed.	Empty can	Replace can.	
(1) Double beep sounds.	Can is not properly installed.	Fix can installation.	
(2) Spray can Empty Lamp is	Compressor air not connected.	Connect air.	
blinking.	Air regulator not set right.	Set regulator properly.	
	Use without connecting handpiece.	Select only couplings that have a handpiece connected.	
Unusual odor.	Oil pad is saturated.	Clean LUBRICARE and replace oil pad.	
Surfaces are unusually dirty.	Tray filter is saturated.	Clean LUBRICARE and replace filter.	
	Spray can not set right.	Install can properly.	
	Air regulator not set right.	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 by maker other than Bien-Air Dental SA.	Use a Bien-Air Dental SA spray can.	
	Handpiece type	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.	
Oil mist is released.	Air pressure is too high.	Reduce air pressure, but not less than 0.3 MPa.	
Equipment surfaces get oily.	No burr incortod in straight	Refer to the user instructions for the handpiece.	
	No burr inserted in straight attachment.	* For some handpieces, an oil mist may be released if a burr is not inserted.	

#### 9. Service Contacts

- \* For repair or other types of service contact your local dealer or Bien-Air Dental SA.
- \* Working-Life

The working-life of this equipment is 5 years from the date of shipment, provided it is regularly and properly inspected and maintained.

\* 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.

#### J. MORITA MFG. CORP.

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#### **10.** Appendix – Electromagnetic Declaration

This device conforms to IEC 60601-1-2: 2007, the relevant international standard for electromagnetic compatibility (EMC).

The following is the "Guidance and Manufacturer's Declaration" which is required by IEC 60601-1-2: 2007, the relevant international standard for electromagnetic compatibility.

## **WARNING**

- LUBRICARE (hereafter referred to as the HIM-1-BA) needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.
- Portable and mobile RF communications equipment can affect the HIM-1-BA.
- Use of parts other than those accompanied or specified by manufacturer or distributor may result in increased EMC emissions or decreased EMC immunity of the HIM-1-BA.
- The HIM-1-BA should not be used adjacent to with other equipment. If adjacent use is necessary, the HIM-1-BA should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufact	Guidance and Manufacturer's Declaration – Electromagnetic Emissions				
The <b>HIM-1-BA</b> is intended for use in the electromagnetic environment specified below. The customer or the user of the <b>HIM-1-BA</b> should assure that it is used in such an environment.					
Emissions Test	Compliance	Electromagnetic Environment – Guidance			
RF emissions CISPR 11	Group 1	The <b>HIM-1-BA</b> 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.			
RF emissions CISPR 11	Class B	The <b>HIM-1-BA</b> is suitable for use in all establishments, includ domestic establishments and those directly connected to the public low-voltage power supply network that supplies building			
*Harmonic emissions IEC61000-3-2	Class A	used for domestic purposes.			
*Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies				

#### Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The **HIM-1-BA** is intended for use in the electromagnetic environment specified below. The customer or the user of the **HIM-1-BA** should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance	
Electrostatic discharge (ESD)	$\pm 2, 4, 6 \text{ kV contact}$	±2, 4, 6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.	
IEC 61000-4-2	±2, 4, 8 kV air	±2, 4, 8 kV air	numenty should be at least 50 70.	
*Electrical fast transients/bursts IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.	
*Surge	±0.5, 1 kV line(s) to line(s)	±0.5, 1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.	
IEC 61000-4-5	±0.5, 1,2 kV line(s) to earth	±0.5, 1,2 kV line(s) to earth		
	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle	$0\% U_{\rm T}$ (>95% dip in $U_{\rm T}$ ) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If user of the <b>HIM-1-BA</b> requires continued operation during power mains	
*Voltage dips, short interruptions and voltage	40% $U_{\rm T}$ (60% dip in $U_{\rm T}$ ) for 5 cycles	$\begin{array}{l} 40\% \ U_{\rm T} \\ (60\% \ {\rm dip \ in \ } U_{\rm T} \ ) \\ {\rm for \ 5 \ cycles} \end{array}$	interruptions, it is recommended that the <b>HIM-1-BA</b> be powered from an uninterruptible power supply or a battery.	
variations on power supply lines IEC 61000-4-11	70% $U_{\rm T}$ (30% dip in $U_{\rm T}$ ) for 25 cycles	70% $U_{\rm T}$ (30% dip in $U_{\rm T}$ ) for 25 cycles		
	<5% $U_{\rm T}$ (>95% dip in $U_{\rm T}$ ) for 250 cycles	0% $U_{\rm T}$ (>95% dip in $U_{\rm T}$ ) for 250 cycles		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3.15 A/m	3.15 A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.	
Note $U_{\rm T}$ is the a.c. m	ains voltage prior to appl	ication of the test level.	1	

#### Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the <b>HIM-1-BA</b> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3.15 Vrms 150 kHz – 80 MHz	3.15 Vrms	$d = \frac{3.5}{3.15} \sqrt{p}$
Radiated RF IEC 61000-4-3	3.7 V/m 80 MHz – 2.5 GHz	3.7 V/m	$d = \frac{3.5}{3.7} \sqrt{p}  80 \text{ MHz} - 800 \text{ MHz}$ $d = \frac{7}{3.7} \sqrt{p}  800 \text{ MHz} - 2.5 \text{ GHz}$ Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol:

The HIM-1-BA is intended for use in the electromagnetic environment specified below. The customer or the

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 be absorption and reflection from structures, objects and people.

а 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 the HIM-1-BA is used exceeds the applicable RF compliance level above, the HIM-1-BA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting of relocating the HIM-1-BA.

Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3.7 V/m.

## Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the HIM-1-BA.

The **HIM-1-BA** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **HIM-1-BA** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **HIM-1-BA** as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter	Separation Distance According to Frequency of Transmitter (m)			
(W)	$150 \text{ kHz} - 80 \text{ MHz}$ $d = 1.11 \sqrt{p}$	$80 \text{ MHz} - 800 \text{ MHz}$ $d = 0.95 \sqrt{p}$	<b>800 MHz</b> – <b>2.5 GHz</b> $d = 1.89 \sqrt{p}$	
0.01	0.11	0.10	0.19	
0.1	0.35	0.30	0.60	
1	1.11	0.95	1.89	
10	3.51	3.00	5.98	
100	11.11	9.50	18.9	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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.

#### \*Basic Performance (Criteria):

• Noise does not cause the HIM-1-BA to malfunction.

#### \*Cable Length:

• AC Cable: 2.5 m (2-Wire), 3.0 m (3-Wire)

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