

iOptima iOptima^{INT}

ENG INSTRUCTIONS FOR USE.

other languages available on www.bienair.com/ifu iOptima Bien Air Settings Dentsply Sirona X3 300 **2.0** 300 **2.0** On Side Saver Bien Air iOptima ϵ 0120 REF 2100279-0004/2018.06

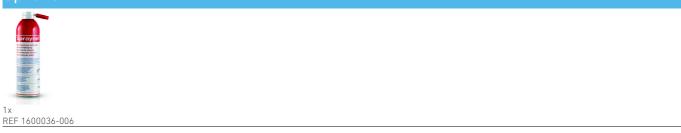
Set i0ptima REF 1700544-001



Set i0ptima REF 1700547-001



Options



Set i0ptima^{INT} REF 1700704-001



Set i0ptima^{INT} REF 1700705-001



Set iOptima^{INT} REF 1700730-001



Set i0ptima^{INT} REF 1700731-001



Options



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iOptima description





1 Symbols

1.1 Description of symbols for iOptima unit

Symbol	Description	Symbol	Description
(€ 0120	CE Marking with number of the notified body.	$\left(\left(\left(\begin{array}{c} \bullet \\ \bullet \end{array} \right) \right) \right)$	RF emitting device (Interference may occur in the vicinity of equipment marked with this symbol).
	Manufacturer.	~	Alternating current.
REF	Reference number.		Main switch - Power OFF.
SN	Serial number.		Main switch - Power ON.
Rx Only	CAUTION! In accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.		Sound alerts
X	Separate collection of electric and electronic equipment.	Qİ	Move fully to the stop, in the direction indicated.
	Refer to the accompanying documents for the correct use of the product.(www.bienair.com/ifu.)		4-hole connection and 4 electric (4VLM).
	Recyclable materials.		4-hole connection (4way).
<u></u>	CAUTION! Consult accompanying documents. Provides an instruction that should be observed for safety reasons.		

1.2 Description of symbols for iOptima accessories

Symbol	Description	Symbol	Description
C € 0120	CE Marking with number of the notified body.		Separate collection of electric and electronic equipment.
	Manufacturer.	SN	Serial number.
REF	Reference number.	★	Electrical safety. Applied part type B.



2 Identification, Intended use and Notation

2.1 Identification

i0ptima

Electronically controlled unit for dentistry allowing operation of a single MX2 micromotor with variable speed using the dental unit pedal.

It is essential to connect a compatible iPod Touch® using the lightning connector.

The unit provides power to the iPod device as soon as it is connected. Under normal use (power supply = 32Vdc), the unit does not use any battery energy of the iPod.

The iOptima unit charges the iPod battery when connected. The restorative, endodontics parameters are defined before operation using the iOptima application installed on the iPod.

The iOptima application indicates the operation steps, the ratio of the handpiece, tool speed, torque value, light intensity, footpedal mode and the micromotor rotation direction. iOptima application is compatible with Apple iOS operating system.

△ CAUTION

In endodontic mode, the predefined torque and speed values are only intended as a guide. The file values used must be adapted according to the manufacturer instructions of the files.

2.2 Intended use

Product intended for professional use only.

The iOptima equipments are only intended for use in general dentistry, restorative dentistry and endodontics procedure by dentists and dental professionals in a dental office.

FIG. 1

iOptima system connected to an iPod that controls a MX2 motor.

Any use other than that for which this product is intended is unauthorized and can be harmful.

Note 1

2.3 Notation

• A, B, C, etc.

Text preceded by a letter indicates a procedure to be carried out step-by-step.

٠ ك

Indicates a procedure result.

• (1), (2), (3), etc.

Text preceded by a number indicates text used in conjunction with an illustration.

• OK, Save, Settings, etc.

Text in bold italic font style indicates, on-screen elements such as buttons, menus, menu items, screen areas, values, fields when they are named and screen names.

Tap **Settings** to open the **Settings** screen, change parameters and tap **Done**.

• Interface device «iPod Touch®» is referred to as «iPod».

NOTES

1 The technical specifications, illustrations and dimensions contained in these instructions are given only as a guide. They may not be the subject of any claim. The manufacturer reserves the right to make technical improvements to its equipment, without amending these instructions. For all additional information, please contact Bien-Air Dental SA at the address indicated on the back cover.

3 Warnings & Precautions of Use

△ CAUTION

The iOptima unit is not designed for use in an explosive atmosphere (anesthetic gas).

△ CAUTION

To prevent any risk of electric shock, the iOptima unit must be connected only to a power supply network provided with a protective earth.

△ CAUTION

The power plug of the iOptima is the device used for disconnection in case of problems, it must be easily accessible at all times.

△ WARNING

Never connect a handpiece on a running micromotor.

△ CAUTION

Ensure that the micromotor hose is not bent.

⚠ WARNING

The iPod must never be disconnected from the iOptima dental unit during operation!

△ WARNING

The parameters contained in the dental procedures are indicative only.

Bien-Air Dental SA cannot be held liable for them.

Note 1

NOTES

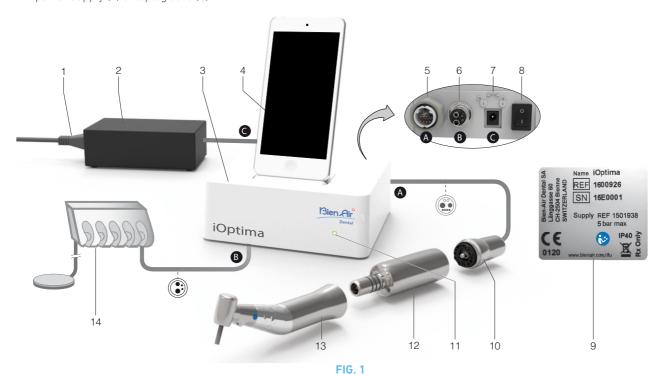
1 The predefined parameters may be subject to modification without notice.

4 Description

4.1 iOptima system overview

The iOptima system consists of:

- iOptima unit (3) with docking station for iPod (4);
- A MX2 micromotor (12) and MX2 hose (10, A);
- A pneumatic 4-way connection input (6, **B**);
- A power supply (2) and plug cord (C).



- (1) Power supply cord
- (2) Power Supply (C)
- (3) iOptima unit
- (4) iPod [not provided in set]
- (5) MX2 micromotor hose output (A)
- (6) 4-way connector input, air and water inlet from your pneumatic unit (B)
- (7) Power input connector (with lock) (C)

- (8) Main power switch
- (9) Label (under the unit)
- (10) MX2 micromotor hose* (A)
- (11) iOptima status light (green power on)
- (12) MX2 micromotor*
- (13) Handpiece* [not provided in set]
- (14) Dental unit with pedal (B) [not provided in set] *Applied parts (per IEC 60601-1)

4.2 iOptima system table

Summary of the iOptima functions and technological features.

Product	Device	Technology	Motor	Restorative	Endodontics	CA ENDO option	Surgery
iOptima	iPod	DMX2	MX2	X	X	-	-

4.3 Set supplied

4.3.1 iOptima system

iOptima set REF 1700544-001

Designation	REF number
iOptima unit (1x)	1600926-001
MX2 Micromotor (1x)	1600677-001
MX2 Micromotor hose (1x)	1600762-001
Power supply (1x)	1501938-001
3P cable system, Switzerland, length 2.00 m (1x)	1300065-001
3P cable system, Europe, length 2.50 m (1x)	1300066-001
3P cable system, US/Asia, length 2.00 m (1x)	1300067-001

iOptima set REF 1700547-001

Designation	REF number
iOptima unit (1x)	1600926-001
MX2 Micromotor hose (1x)	1600762-001
Power supply (1x)	1501938-001
3P cable system, Switzerland, length 2.00 m (1x)	1300065-001
3P cable system, Europe, length 2.50 m (1x)	1300066-001
3P cable system, US/Asia, length 2.00 m (1x)	1300067-001

4.4 Options

Designation	REF number
Spraynet, cleaning spray 500 ml, box of 6 cans	1600036-006

4.5 Technical data

Dimensions L x W x H

iOptima unit	125 x 145 x 75 mm
iOptima unit (with iPod)	125 x 145 x 160 mm
MX2 hose	L 1.7 m
MX2 micromotor	Ø 21 x L 73.5 mm
Power Supply	130 x 75 x 45 mm

Weight

iOptima unit	0.4 kg
Power Supply	650 g
MX2 micromotor	94 q

Electrical and pressure data

Voltage	100-240 VAC
Frequency	47-63 Hz
Nominal power	90 W
Max. input power	160 W
Max. input pneumatic pressure	5 bar / 72.5 psi
Min. input pneumatic pressure	3 bar / 43.5 psi

Environmental conditions

Environmental conditions	Operating	Transport and storage (max. 15 weeks)
Temperature	+10°C (50°F) to +25°C (77°F)	-25°C (-13°F) to +70°C (158°F)
Relative humidity	30% to 80%	30% to 80%
Atmospheric pressure	700 hPa to 1060 hPa	500 hPa to 1060 hPa
Altitude	0 to 3'048 m (0 to 10'000 ft)	-

△ CAUTION

Do not use iOptima outside the range of operating temperature.

Classification

Class IIa in accordance with European Directive 93/42/EEC concerning medical devices.

Electric insulation class

Class I per IEC 60601-1 (apparatus protected against electric shocks).

Degree of protection

IP 40 (protection against insertion of objects larger than 1 mm)

Memory

Restorative

Storage of 20 user-defined Operations

Endodontics

Storage of 10 user-defined Brands Storage of 10 user-defined Systems Storage of 8 Files per System including adjustment of speed and torque values for each file

List of errors & Troubleshooting

See chapter "16 List of errors & Troubleshooting" on page 59.

Important: Consult the Instructions for Use of the following devices:

Product	Micromotor	IFU	Hose	IFU
i0ptima	MX2 LED	2100199	MX2	2100223

4.6 Environmental protection and information for disposal



The disposal and/or recycling of materials must be performed in accordance with the legislation in force.



This unit and its accessories must be recycled.

Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards. The user must return the unit to its dealer or establish direct contact with an approved body for treatment and recovery of this type of equipment (European Directive 2002/96/EC).

4.7 Limitation of liability

Bien-Air Dental SA shall not be held liable for any non-compliant use of the iPod.

The conditions for and restrictions on use set by Apple must be respected (jailbreak, hardware modification, etc.).

To ensure optimum operation of iOptima the application, iOS updates must be according to version used during validation of the application.

4.8 Electromagnetic compatibility (technical description) for iOptima

Precautions regarding Electromagnetic Compatibility (EMC)

Electro-medical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document.

△ CAUTION

Dental professionals need to be aware of potential electromagnetic interference between electronic dental devices and active implantable medical devices, and should always inquire about any devices implanted in the patient.

△ CAUTION

iOptima complies with the EMC requirements according to IEC 60601-1-2. Radio transmitting equipment, cellular phones, etc. shall not be used in close proximity to the unit since they could influence the performance of the unit. Special precautions must be taken when using strong emission sources such as High Frequency surgical equipment and similar equipment so that the HF cables are not routed on or near the unit. If in doubt, please contact a qualified technician or Bien-Air Dental SA.

iOptima should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, iOptima should be monitored to verify normal operation in the configuration in which it will be used.

△ CAUTION

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Bien-Air Dental SA as replacements parts for internal components, may result in increased emissions or decreased immunity of iOptima.

Guidance and manufacturer's declaration - electromagnetic emissions

iOptima is intended for use in the electromagnetic environment specified below.

The customer or the user of iOptima should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance	
RF emissions CISPR 11	Group 1	iOptima uses RF energy only for its internal function. CISPR 11 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		
Harmonic emissions IEC 61000-3-2	Compliant	iOptima is suitable for use in all establishments including domestic establishments and the directly connected to the public low-voltage power supply network that supplies buildings	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	for domestic purposes.	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD)	±6 kV contact	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the
IEC 61000-4-2	±8 kV air	±8 kV air	relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for lines no input/output	±2 kV for power supply lines ±1 kV for lines no input/output	Mains power quality should be that of a typical commercial or hospital environment.
Shock waves IEC 61000-4-5	±0.5 kV line to line ±1 kV line to line ±0.5 kV line to earth ±1 kV line to earth ±2 kV line to earth	±0.5 kV line to line ±1 kV line to line ±0.5 kV line to earth ±1 kV line to earth ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and outages	<5% U _T (>95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T	Mains power quality should be that of a typical commercial or hospital environment. If the user of iOptima requires continued operation during
IEC 61000-4-11	$(30\% \ \text{dip in U}_{\text{T}})$ for 25 cycles <5% U _T (>95% \ \text{dip in U}_{\text{T}}) for 5 sec	$(30\% \ \text{dip in U}_{\text{T}})$ for 25 cycles $<5\% \ \text{U}_{\text{T}}$ $(>95\% \ \text{dip in U}_{\text{T}})$ for 5 sec	power mains interruptions, it is recommended that iOptima be powered from an uninterruptible power supply or a battery.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note : U_T is the a.c. mains voltage prior to application of the test level.

Essential performance: The essential performance is the maintaining of the visual lighting intensity of the LED and the maintaining of motor speed. Maximum allowed speed deviation is \pm 5%.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of iOptima, including cables, than the
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=1.2\sqrt{P}$ 800 MHz to 2.5 GHz $d=2.3\sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: (((•)))

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted 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 iOptima is used exceeds the applicable RF compliance level above, the iOptima should be observed to verify normal operation.

Note 1 - 2

If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the iOptima.

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

Recommended separation distances between portable and mobile RF communications equipment and the iOptima

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

2.1.	Separation distance according to frequency of transmitter [m]				
Rated maximum output power of transmitter [W]	150 kHz to 80 MHz 80 MHz to 800 MHz		800 MHz to 2.5 GHz		
polici el dicilionistimos (117	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$		
0.01	0.12	0.12	0.23		
0.1	0.38	0.38	0.73		
1	1.2	1.2	2.3		
10	3.8	3.8	7.3		
100	12	12	23		

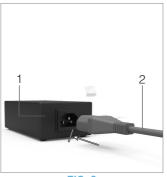
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter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

Note 1 - 2

NOTES

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





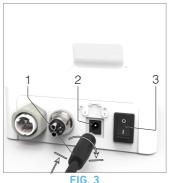




FIG. 1

FIG. 2

FIG

5 Installation

5.1 Install the iOptima app

- A. Open the "App Store".
- B. Search the iOptima application.
- C. Install the iOptima application designed by Bien-Air Dental.

Note 1

5.2 Install the iOptima system

△ CAUTION

Before installing, please read carefully this product instruction.

Note 2

FIG. 1

A. Place the iOptima on a flat surface capable of bearing its weight.

△ CAUTION

It may be positioned on a table, on a trolley or any another surface but in no circumstances on the floor. It is not designed to be placed on wet surfaces or to come in contact with liquids.

FIG. 2

B. Connect the power cord (2) to the power supply (1) and plug to the mains.

Note 3

△ CAUTION

The power plug is the device used for disconnection in case of problems, it must be easily accessible at all times.

FIG. 3

C. Connect the power supply cable (1) to the input connector (2) and turn right to lock.

⚠ CAUTION

Ensure that the power switch (3) is off «0».

△ CAUTION

Before connecting the MX2 cable ensure that all o-rings are correctly fitted and connectors are clean of dust.

FIG. 4

- **D.** Connect the MX2 cable plug (2) to the output connector (1):
 - First sleeve up and carefully and firmly insert the cable plug, by guiding the connector and plug with the index pin on the connector;
 - Sleeve down and tighten (CW).



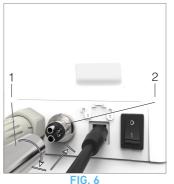




FIG. 7

FIG. 5

FIG. 5

E. Connect the MX2 cable (2) to the MX2 micromotor (1), by guiding the connector and plug with the index pin on the connector and tighten (CW).

△ CAUTION

Never connect a handpiece on a running micromotor.

FIG. 6

- **F.** Connect the 4-way hose (1) to the 4-way connector of the iOptima unit (2):
 - First guide the sleeve and carefully and firmly insert the hose sleeve, by matching the connector and the coupling;
 - · Tighten (CW).

FIG. 7

- **G.** Switch on the water and power supply of the dental unit (refer to vour dental unit instructions).
- **H.** Switch on the iOptima (1) ($\langle I \rangle = ON$).
- **I.** Once it has been switched on, connect the interface device «iPod» (2) to the iOptima carefully sliding it along the lightning adapter (3).
- $\$ The iOptima is ready for use.

See chapter "6 Interface overview" on page 19.

NOTES

- 1 The iPod must be correctly connected to a Wi-Fi network before the App Store is opened; refer to Apple's user guide for appropriate use of the iPod.
- 2 In order to conform to the IEC 60601-1-2 standards, take into account the different routes of the wires through the system (bend, fold, section etc) (see chapter "4.1 iOptima system overview" on page 10 and only use the power supply provided with the iOptima. In order to maintain warranty, this unit must be installed with the greatest care. Follow all the necessary instructions. Protect the unit from direct sunlight and dust. Keep the original packaging for storage and shipment.
- ${f 3}$ The equipment is powered by your mains power supply (100-240 VAC).



FIG. 1 (iPod Touch®)

6 Interface overview

6.1 iOptima application

The iOptima application allows to carry out endodontics and restorative dentistry operations.

6.1.1 Compatibility

The iOptima application is compatible with iPod from 6th generation.

6.1.2 Notation

In order to simplify the notation, in this manual:

- iOptima application is referred to as «iOptima app»;
- Restorative and Endodontics modes are referred to as «RESTO» and «ENDO».

6.2 Sound alerts



Sound alert	Description
One long beep	Entering in endodontics or restorative mode
	ENDO mode when selecting the first File
Alternate short beeps	Warning notifications
Alternate medium	Micromotor REVERSE running indicator
beeps	ENDO mode when the micromotor is running in reverse
Alternate long beeps	System failure notification

6.3 iPod and iOptima connection / disconnection conditions

6.3.1 Disconnection

If the iPod is disconnected, the iOptima system is in standby mode (micromotor stopped).

⚠ WARNING

The iPod must never be disconnected from the iOptima dental unit during operation! If the iPod is disconnected during an operation, the micromotor stops immediately.

6.3.2 Connection

The micromotor can start only when the iPod is connected and the application is in operative mode.

⚠ CAUTION

If the footpedal is pressed before entering in operative mode, a warning message «Please release the pedal...» will be displayed. The micromotor will not start to run until the footpedal is released and pressed again.

6.3.3 iOptima unit switched ON

If the iOptima app is running and the iPod plugged to the iOptima (switch ON):

- The iPod will charge up (even if the app is not running);
- The sleep mode is deactivated;
- The micromotor can be operated with the pedal (iOptima app in operative mode).



iOptima^{INT} description



7 Symbols

7.1 Description of symbols for $iOptima^{INT}$

Symbol	Description	Symbol	Description
(€ 0120	CE Marking with number of the notified body.	$\left(\left(\begin{pmatrix} \bullet \\ \bullet \end{pmatrix} \right) \right)$	RF emitting device (Interference may occur in the vicinity of equipment marked with this symbol).
	Manufacturer.	~	Alternating current.
REF	Reference number.		Main switch - Power OFF.
SN	Serial number.		Main switch - Power ON.
<u></u>	CAUTION! Consult accompanying documents. Provides an instruction that should be observed for safety reasons.		Sound alerts
X	Separate collection of electric and electronic equipment.	Qİ	Move fully to the stop, in the direction indicated.
	Refer to the accompanying documents for the correct use of the product.(www.bienair.com/ifu.)		4-hole connection and 4 electric (4VLM).
0	Recyclable materials.		4-hole connection (4way).

7.2 Description of symbols for iOptima^{INT} accessories

Symbol	Description	Symbol	Description
C € 0120	CE Marking with number of the notified body.		Separate collection of electric and electronic equipment.
***	Manufacturer.	SN	Serial number.
REF	Reference number.	†	Electrical safety. Applied part type B.



8 Identification, Intended use and Notation

8.1 Identification

$iOptima^{INT}$

Electronically controlled integrated unit for dentistry allowing operation of multiple micromotors (MX2) with variable speed using the dental unit pedal.

It is essential to connect a compatible iPod Touch® or iPad Mini® using the lighting connector with the provided docking station.

The unit provides power to the iPod/iPad device as soon as it is connected. Under normal use (power supply = 32Vdc), the unit does not use any battery energy of the iPod/iPad.

The $iOptima/iOptima^{INT}$ unit charges the iPod/iPad battery when connected.

The restorative and endodontics parameters are defined before operation using the iOptima application installed on the iPod/iPad.

The iOptima application indicates the operation steps, the ratio of the handpiece, tool speed, torque value, light intensity, footpedal mode and the micromotor rotation direction. iOptima application is compatible with Apple iOS operating system.

△ CAUTION

The predefined torque and speed values are only intended as a guide. The file values used must be adapted according to the manufacturer instructions of the files.

8.2 Intended use

Product intended for professional use only.

The iOptima^{INT} systems are only intended for use in general dentistry, restorative dentistry and endodontics procedure by dentists and dental professionals in a dental office.

FIG. 1

iOptima^{INT} system connected to an iPod/iPad that controls a MX2 micromotor in holder 1 (endodontics + restorative).

Any use other than that for which this product is intended is unauthorized and can be harmful.

Note 1

8.3 Notation

• A, B, C, etc.

Text preceded by a letter indicates a procedure to be carried out step-by-step.

· 4

Indicates a procedure result.

• (1), (2), (3), etc.

Text preceded by a number indicates text used in conjunction with an illustration.

• OK, Save, Settings, etc.

Text in bold italic font style indicates, on-screen elements such as buttons, menus, menu items, screen areas, values, fields when they are named and screen names.

Tap **Settings** to open the **Settings** screen, change parameters and tap **Done**.

 Interface device «iPod Touch®/iPad Mini®» is referred to as «iPod/iPad».

△ CAUTION

All illustrations and screenshots shown in this manual refer to the iPod and may differ from what is displayed on the iPad.

NOTES

1 The technical specifications, illustrations and dimensions contained in these instructions are given only as a guide. They may not be the subject of any claim. The manufacturer reserves the right to make technical improvements to its equipment, without amending these instructions. For all additional information, please contact Bien-Air Dental SA at the address indicated on the back cover.

9 Warnings & Precautions of Use

△ CAUTION

The iOptima^{INT} unit is not designed for use in an explosive atmosphere (anesthetic gas).

△ CAUTION

To prevent any risk of electric shock, the iOptima^{INT} unit must be connected only to a power supply network provided with a protective earth.

⚠ WARNING

Never connect a handpiece on a running micromotor.

△ CAUTION

Ensure that the micromotor hose is not bent.

△ WARNING

The iPod/iPad must never be disconnected from the iOptima^{INT} dental unit during operation!

△ WARNING

Never touch simultaneously the iPod/iPad and the patient.

△ WARNING

The parameters contained in the dental procedures are indicative only.

Bien-Air Dental SA cannot be held liable for them.

Note 1

NOTES

1 The predefined parameters may be subject to modification without notice.

10 Description

10.1 iOptima^{INT} system overview

The iOptima^{INT} system mainly consists of:

- A unit as a docking station (2) for iPod/iPad device.
- The iPod/iPad provide the user interface to the iOptima^{INT} system, except speed reference input.
- The electronic board (1), integrated in the dental unit system, is in charge to drive the micromotor (MX2) and communicate with the interface through the Lightning connector.
- A dental micromotor and the related hose (MX2).
- A power supply 100-240 VAC.



FIG 1

10.2 iOptima^{INT} system table

Summary of the iOptima^{INT} functions and technological features.

Product	Device	Technology	Motor	Restorative	Endodontics	CA ENDO option	Surgery
i0ptima ^{INT}	iPod/iPad	DMX3	MX2	X	Χ	X	-

10.3 Set supplied

10.3.1 iOptima^{INT} system

iOptima^{INT} set REF 1700704-001

Designation	REF number
iOptima ^{INT} iDevice fixation (1x)	1502475-001
MX2 Micromotor (1x)	1600677-001
MX2 Micromotor hose (1x)	1600809-001
Power supply reset switchs	1502568-001
Power supply PMP90 (1x)	1500666-001
3P cable system, US/Asia, length 2.00 m (1x)	1300067-001
1 Motor Control Boards	1601074-001

iOptima^{INT} set REF 1700705-001

Designation	REF number
iOptima ^{INT} iDevice fixation (1x)	1502475-001
MX2 Micromotor (2x)	1600677-001
MX2 Micromotor hose (2x)	1600809-001
Power supply reset switch	1502568-001
Power supply PMP90 (1x)	1500666-001
3P cable system, US/Asia, length 2.00 m (1x)	1300067-001
Dual Motor Control Boards	1601075-001

iOptima^{INT} set REF 1700730-001

Designation	REF number
MX2 Micromotor hose (1x)	1600809-001
Power supply reset switch	1502568-001
Power supply PMP90 (1x)	1500666-001
3P cable system, US/Asia, length 2.00 m (1x)	1300067-001
1 Motor Control Boards	1601074-001

iOptima^{INT} set REF 1700731-001

Designation	REF number
MX2 Micromotor hose (2x)	1600809-001
Power supply reset switch	1502568-001
Power supply PMP90 (1x)	1500666-001
3P cable system, US/Asia, length 2.00 m (1x)	1300067-001
Dual Motor Control Boards	1601075-001

10.4 Options

Designation	REF number
Mechanical interface iPod right mount	1502620-001
Mechanical interface iPod left mount	1502621-001
Mechanical interface iPad right mount	1502622-001
Mechanical interface iPad left mount	1502623-001
Mounting tools	1502567-001

10.5 Technical data

Dimensions L x W x H

MX2	hoseL	1.7	m		
MX2	micromotorØ	21	хL	73.5	mm

Weight

Electrical and pressure data

Voltage	.100-240 VAC
Frequency	.47-63 Hz
Nominal power	.90 W
Max. input power	.160 W
Max. input pneumatic pressure	.5 bar / 72.5 psi
Min. input pneumatic pressure	.3 bar / 43.5 psi

Environmental conditions

Environmental conditions	Operating	Transport and storage (max. 15 weeks)	
Temperature	+10°C (50°F) to +35°C (77°F)	-25°C (-13°F) to +70°C (158°F)	
Relative humidity	30% to 80%	30% to 80%	
Atmospheric pressure	700 hPa to 1060 hPa	500 hPa to 1060 hPa	
Altitude	0 to 3'000 m (0 to 9842 ft)	-	

△ CAUTION

Do not use iOptima^{INT} outside the range of operating temperature.

Classification

Class IIa in accordance with European Directive 93/42/EEC concerning medical devices.

Electric insulation class

Class I per IEC 60601-1 (apparatus protected against electric shocks).

Memory

Restorative

Storage of 20 user-defined Operations

Endodontics

Storage of 10 user-defined Brands Storage of 10 user-defined Systems Storage of 8 Files per System including adjustment of speed and torque values for each file

List of errors & Troubleshooting

See chapter "16 List of errors & Troubleshooting" on page 59.

Important: Consult the Instructions for Use of the following devices:

Product	Micromotor	IFU	Hose	IFU
i0ptima ^{INT}	MX2 LED	2100199	MX2	2100223

10.6 Environmental protection and information for disposal



The disposal and/or recycling of materials must be performed in accordance with the legislation in force.



This unit and its accessories must be recycled.

Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards. The user must return the unit to its dealer or establish direct contact with an approved body for treatment and recovery of this type of equipment (European Directive 2002/96/EC).

10.7 Limitation of liability

Bien-Air Dental SA shall not be held liable for any non-compliant use of the iPod/iPad.

The conditions for and restrictions on use set by Apple must be respected (jailbreak, hardware modification, etc.).

To ensure optimum operation of iOptima INT the application, iOS updates must be according to version used during validation of the application.

10.8 Electromagnetic compatibility (technical description) for iOptima™

10.8.1 Electromagnetic compatibility warnings

The intended EM environment (per IEC 60601-1-2 ed. 4.0) is Professional healthcare facility environment.

△ CAUTION

The iOptima^{INT} complies with the EMC requirements according to IEC 60601-1-2. Radio transmitting equipment, cellular phones, etc., should not be used in the immediate vicinity of the device, since this could affect its operation. The device is not suitable for being used close to high-frequency surgical equipment, magnetic resonance imaging (MRI) and other similar devices where the intensity of electromagnetic disturbances is high. In any case, ensure that no high frequency cables are routed above or near the device. If in doubt, contact a qualified technician or Bien-Air Dental SA. Special precautions should be taken when using strong emission sources such as high-frequency surgical equipment and other similar devices, to ensure that HF cables are not routed above or near the device. If in doubt, please contact a qualified technician or Bien-Air.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the iOptima^{INT}, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

△ CAUTION

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Bien-Air as spare parts for internal components, may result in increased emissions or decreased immunity.

△ CAUTION

Since this device is intended to be used adjacent to or stacked with other equipment, the responsibility of verifying normal operation in the configuration in which it will be used falls onto the dental unit manufacturer.

10.8.2 Electromagnetic compatibility – emissions & immunity

Guidance and manufacturer's declaration - electromagnetic emissions

iOptima^{INT} is intended for use in the electromagnetic environment specified below.

The customer or the user of iOptima^{INT} should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The iOptima INT uses RF energy for its internal operation only. 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	
Harmonic emissions IEC 61000-3-2	Class A	The iOptima INT is suitable for use in any building, including residential buildings and those directly connected to the public low-voltage power supply network that supplies buildings used for residential purposes.
Emissions due to voltage fluctuations IEC 61000-3-3	Conforming	

Guidance and manufacturer's declaration – Electromagnetic immunity

The iOptima INT is intended for use in the electromagnetic environment specified below. The customer or the user of the iOptima INT must ensure that it is actually used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±8 kV contact ±2 kV air ±2 kV air ±4 kV air ±4 kV air ±8 kV air ±8 kV air ±15 kV air ±15 kV air		Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for other lines	±2 kV for power supply lines ±1 kV for lines no input/output	Mains power quality should be that of a commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV line to line ±1 kV line to line ±0.5 kV line to earth ±1 kV line to earth ±2 kV line to earth	±0.5 kV line to line ±1 kV line to line ±0.5 kV line to earth ±1 kV line to earth ±2 kV line to earth	Mains power quality should be that of a commercial or hospital environment.

Immunity test	IEC 60601 test lev	el	Complia	nce level	Electromagnetic environment - guidance
Voltage dips, short inter- ruptions and voltage variations on power sup-	0% U _T for 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°		0% U _T for 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°		Mains power quality should be that of a commercial or hospital environment. If the user of the iOptima INT requires continued operation during mains power interruptions, it is recom-
ply input lines IEC 61000-4-11	0% U _T for 1 cycle a 70% U _T for 25/30 cyc			or 1 cycle and or 25/30 cycles at 0°	mended that the iOptima INT be powered from an uninterruptible power supply or a battery.
Magnetic field due to mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m		30 A/m		Magnetic fields generated by the mains frequency should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V _{RMS} 0,15 MHz – 80 MH: 6 V _{RMS} in ISM band 0,15 MHz – 80 MH: 80% AM at 1 kHz	ISM bands – 80 MHz		z – 80 MHz n ISM and ama- ds z – 80 MHz at 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz			– 2,7 GHz 1 at 1 kHz	
	Test freq. [MHz]	Max. po	wer [W]	Immunity test level [V/m]	
	385	1.8		27	
Proximity fields from RF	450	2		28	
wireless communications equipment	710, 745, 780	0.2		9	Distance: 0.3 m
IEC 61000-4-3	810, 870, 930	2		28	
	1720, 1845, 1970	2		28	
	2450	2		28	
	5240, 5500, 5785	0.2		9	

NOTE: U_T is the AC mains voltage prior to application of the test level.

Essential performance per IEC 60601-1: The essential performance is to maintain the visual luminous intensity of the LED and the motor speed. The maximum speed deviation is $\pm 5\%$.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and mobile field radios, amateur radios, AM and FM radio broadcasts and TV broadcasts cannot be predicted 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 iOptima INT is used exceeds the RF compliance level mentioned above, the iOptima INT should be observed to verify that it is operating normally. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the iOptima INT.

11 Installation

11.1 Install the iOptima app

- A. Open the "App Store".
- B. Search the iOptima application.
- **C.** Install the iOptima application designed by Bien-Air Dental.

Note 1

11.2 Install the iOptima™ system

Refer to the iOptima $^{\rm INT}$ installation manual. Note 2

- 1 The iPod/iPad must be correctly connected to a Wi-Fi network before the App Store is opened; refer to Apple's user guide for appropriate use of the iPod/iPad.
- **2** The iOptima^{INT} system must be installed by a service engineer certified by Bien-Air Dental SA.



FIG. 1 (iPod Touch®)

12 Interface overview

12.1 iOptima application

The iOptima application allows to carry out endodontics and restorative dentistry operations.

12.1.1 Compatibility

The iOptima application is compatible with iPod from 6th generation and iPad from 4th generation.

12.1.2 Notation

In order to simplify the notation, in this manual:

- iOptima application is referred to as «iOptima app»;
- Restorative and Endodontics modes are referred to as «RESTO» and «ENDO».

12.2 Sound alerts



Sound alert	Description	
One long beep	Entering in endodontics or restorative mode	
	ENDO mode when selecting the first File	
Alternate short beeps	Warning notifications	
Alternate medium	Micromotor REVERSE running indicator	
beeps	ENDO mode when the micromotor is running in reverse	
Alternate long beeps	System failure notification	

12.3 iPod/iPad and iOptima^{INT} connection / disconnection conditions

12.3.1 Disconnection

If the iPod/iPad is disconnected, the iOptima^{INT} system is in standby mode (micromotor stopped).

⚠ WARNING

The iPod/iPad must never be disconnected from the iOptima^{INT} dental unit during operation! If the iPod/iPad is disconnected during an operation, the micromotor stops immediately.

12.3.2 Connection

The micromotor can start only when the iPod/iPad is connected and the application is in operative mode.

△ CAUTION

If the footpedal is pressed before entering in operative mode, a warning message «Please release the pedal...» will be displayed. The micromotor will not start to run until the footpedal is released and pressed again.

12.3.3 iOptima^{INT} unit switched ON

If the iOptima app is running and the iPod/iPad plugged to the iOptima^{INT} (switch ON):

- The iPod/iPad will charge up (even if the app is not running);
- · The sleep mode is deactivated;
- The micromotor can be operated with the pedal (iOptima app in operative mode).

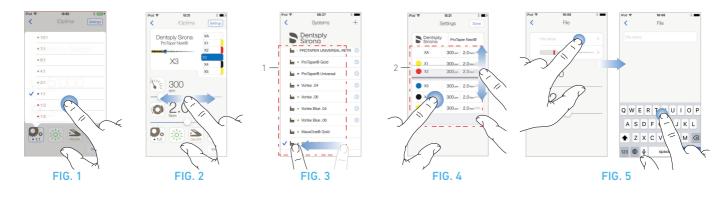
12.3.4 iOptima^{INT} last set operation memory

For iOptima^{INT}, the operation displayed by default is associated to the active motor. Memory of each operation set at last usage for each motor is kept (e.g. a user who has two motors can leave a blue CA on «motor 1» and a red CA on «motor 2» and, depending on which motor is activated, the corresponding modes are automatically activated).



iOptima/iOptima^{INT} operation





13 Getting started

13.1 Back up data

Use iTunes or iCloud to automatically back up your iOptima application user-defined settings.

Refer to Apple's user guide for appropriate use of the iPod/iPad, iTunes or iCloud.

13.2 Use of the Touch screen

The iOptima application is operated with the iPod Touch®/iPad Mini® screen with a few simple gestures:

FIG. 1

• Tap to click.

FIG. 2

• Slide to scroll and adjust parameters.

FIG. 3

• Swipe to restore or remove parameters.

Note 1

FIG. 4

- Long tap to access the drag and drop function;
- **Drag and drop** to sort files/operations.

13.2.1 Display onscreen keyboard

FIG. 5

- Tap a text field to display the onscreen keyboard;

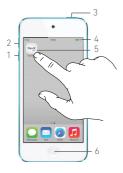


FIG. 6

13.3 Launch iOptima app

FIG. 6

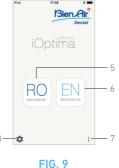
- **A.** Make sure that the sound volume on your iPod/iPad is ON and set to an appropriate level according to the ambient noise of the room:
 - Volume down (1) and up (2).
- **B.** Close all other applications in order not to disrupt the operation:
 - Double-click the home button (6) to show the multitasking display and drag the app up to close.
 - Click the home button again to return to the main screen.
- **C.** Deactivate all alerts. Refer to Apple's user guide for appropriate use of the iPod/iPad.
- **D.** Ensure that the latest application updates have been installed (see chapter "13.7 iOptima app update" on page 43).
- **E.** Tap the app icon (5) to launch the iOptima application.

Note 2

- 1 The swipe gesture is only active in the delimited area (1).
- 2 If not using your iPod/iPad, press the Sleep/Wake button (3) to lock it







13.4 Welcome screen and disclaimer

A. To ensure the appropriate working of the iOptima Dental unit, make sure to only use your iOptima application with the iOS version validated by Bien-Air Dental.

FIG. 7

Refer to the current version of your device (1).

See also chapter "16.3 iOS compatibility errors (disclaimer screen)," on page 61.

For more information go to the App Store @ under «what's new» of the selected application.

B. Tap OK (2) to acknowledge disclaimer message and access the **DISCLAIMER** message second screen (3).

FIG. 8

C. Make sure to have set all steps of disclaimer (3) and tap OK (4), see chapter "13.3 Launch iOptima app" on page 40 for details.

☼ The Welcome screen is displayed.

FIG. 9

The Welcome screen differs whether using the iOptima or iOptima^{INT} system and depends on which type of micromotor is connected.

See chapter "4.2 iOptima system table" on page 11 for more information

D. Tap **RO** (5) to enter the restorative mode. See chapter "14.1 Enter Restorative mode" on page 45.



E. Tap **EN** (6) to enter the endodontics mode. See chapter "15.1 Enter Endodontics mode" on page 51 for details.



F. Tap *i* (7) to open the *Information* screen. See chapter "13.5 Information" on page 42 for details.



G. Tap Settings (8) to open the Settings screen. See chapter "13.5 Information" on page 42 for details.











FIG. 12

FIG. 13

13.5 Information

FIG. 10

A. Tap (1) to access Bien-Air (catalogue, new products, etc.) and iOptima (User Manual and About) information screen.

FIG. 11

- The information screen allows to navigate to the following pages:
 - Latest news (2) (opens Bien-Air website latest news page);
 - User manual (3) (application detects the language of the iPod/iPad and downloads the User Manual in the same language);

Note 3

- Catalogue (4) (opens online catalogue (pdf file));
- Web TV (5) (opens Bien-Air web TV);
- About (6) (displays About screen (FIG. 12, 8) with iOptima system and Bien-Air factory information);
- Contact us (opens email application with predefined email address iOptima@bienair.com).

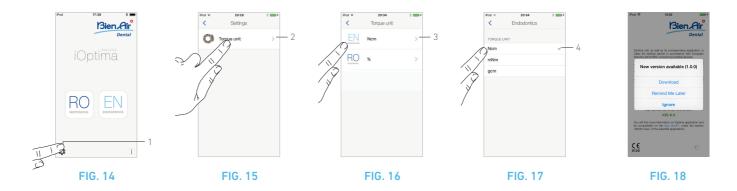
Note 4

FIG. 13

• Chapter links and the table of contents

By clicking on a chapter section in the table of contents or in
the manual, the user can directly access it. The dedicated
button (9) links the user directly to the table.

- **3** If the User Manual is not available in the correct language, the English manual is downloaded.
- 4 Latest News, Catalogue, Web TV and Contact us functions are available only if the iPod/iPad is connected to a Wi-Fi network.



13.6 Settings

FIG. 14

A. Tap (1) to access iOptima/iOptima^{INT} system **Settings** screen.

The **Settings** screen allows to set the torque unit for each available mode.

FIG. 15

B. Tap Torque unit to access its screen.

FIG. 16

C. Tap ENDO (3) to access the endodontics screen.

FIG. 17

D. Tap your preferred torque unit.

E. Select between; *Ncm*; *mNm*; *qcm* and % (RESTO mode only).

13.6.1 Service engineer settings

With service engineer access (password protected), the settings screen also allows access to the micromotor holder configuration (iOptima^{INT}) and lock settings.

Important: if *Lock settings* is set, it is not possible to save any user-defined data!

Note 5

13.7 iOptima app update

FIG. 18

When the application is launched, it will check whether a new version is available on the App Store.

If a new update is available, a message box will be displayed on Disclaimer screen to notify the user should download the application.

Note 6

- Download: user can automatically access App Store application page.
- Remind Me Later: user can delay the update and continue to work with currently installed app version (the message appears once a day).
- *Ignore:* User can ignore the update and continue to work with currently installed app version (the message reappears only if a new version is available).

- 5 To modify service engineer settings, please contact a service engineer certified by Bien-Air Dental SA.
- **6** This function is active only when the iPod/iPad is connected to a Wi-Fi network.

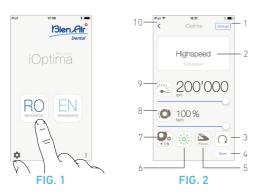








FIG. 5

14 Operation - Restorative mode

14.1 Enter Restorative mode

FIG. 1

Tap RO to enter the restorative mode.

Predefined restorative operations are available by default, it is possible to modify and restore them.

It is possible to create and delete User-defined operations.

Note 1 - 2

14.2 Operative screen description

FIG. 2

The operative screen displays the selected operation type and settings:

- (1) Settings (access to operation types and settings)
- (2) Selected operation type
- (3) Micromotor rotation mode: FORWARD and REVERSE
- (4) Save (customize settings)
- **(5)** Footpedal mode: PROGRESSIVE or ON/OFF mode
- (6) Light intensity
- (7) Handpiece ratio
- (8) Maximum micromotor torque in % (or according to settings, see chapter "13.6 Settings" on page 43)
- (9) Maximum micromotor speed in rpm
- (10) Back to the previous screen

Note 3

See chapter "14.3 Standard Use - Operating mode (Start)" on page 47.

14.2.1 Micromotor Speed & Torque

FIG. 3

Slide to adjust the maximum speed and torque values.

Or tap the icons (to activate the wheel scroller.

FIG. 4

Slide to precisely adjust the motor speed and torque values and tap *Cancel* or *Done* to validate.

FIG. 5

When the power demand of the micromotor is excessive, the

operative screen displays the overheating symbol . In this case the iOptima unit automatically lowers the torque in order to avoid overheating of the micromotor.

To restore 100% torque, allow the motor to idle or stop for a few seconds.

14.2.2 Handpiece ratio

FIG. 6

Tap and select the handpiece ratio.









 ⚠ CAUTION

Verify that the handpiece corresponds to your selection.

Note 4 - 5

14.2.3 Light intensity

FIG. 7

Slide or tap the appropriate dot to set up the light intensity of the micromotor.

11 levels of adjustment are possible:

 light OFF, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90% and 100% of the max light intensity value.

Note 6 - 7

14.2.4 Footpedal mode

FIG. 8

Tap and select the footpedal mode:

- ON/OFF (1): The speed consign is equal to the maximum speed once the footpedal is pressed; whatever the pressure on it.
- **Progressive** (2): The speed consign value is (linear) function to the pressure on it.

Note 8

14.2.5 Micromotor rotation direction

FIG. 9

Tap and select the rotation mode of the micromotor:

- Forward (clockwise)
- Reverse (counterclockwise).

Note 9 - 10

- 1 In restorative mode, the air spray is always switched ON by the help of the electro-valve integrated in the iOptima unit.
- 2 Save and create () buttons are disabled if a lock is set (see chapter "13.6 Settings" on page 43).
- 3 All parameters can be changed and saved directly in the operative screen (except if a lock is set).
- 4 The handpiece ratio is red-colored for multiplication gears, blue-colored for direct-drive, and green-colored for reduction gears.
- 5 The operative screen always displays the selected handpiece ratio.
- 6 The light intensity value is set for each operation. The default value of the light intensity is 100%.
- 7 The operative screen always displays the selected light intensity value.
- 8 The operative screen always displays the selected footpedal mode
- 9 In reverse mode (CCW), the symbol flashes and there is a sound alert (alternate medium beeps).
- 10 The operative screen always displays the selected rotation direction.







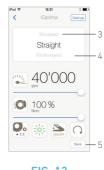




FIG. 13

FIG. 14

14.3 Standard Use - Operating mode (Start)

FIG. 10

A. Tap RO to enter the RESTO mode, the operative screen opens.

Note 11

FIG. 11

B. Tap **Settings** to open the **Operations** screen.

Note 12

FIG. 12

C. Tap to select an operation type.

\$\textstyle \text{The app navigates back to the operative screen.}

D. Press the dental unit pedal to switch on the micromotor.

⚠ CAUTION

If the footpedal is pressed before entering in operative mode, a warning message «Please release the pedal...» will be displayed. The micromotor will not start to run until the footpedal is released and pressed again.

FIG. 13

Note 13 - 14

- · Slide to adjust the micromotor speed and torque values of the selected operation.
- · Adjust the handpiece ratio, light intensity, footpedal mode or rotation direction of the selected operation.
- Tap Save (5) to validate the new settings.

Note 15

E. Tap the operation type above (3) or below (4) the selected operation type to navigate to the operation respectively preceding or following the current one in the predefined operation list.

See chapter "14.4.3 Sort operations" on page 48 to sort operations in the list

14.4 Customize default operations

FIG. 14

A. From the operative screen, tap Settings to open the Operations screen.

FIG. 15

B. Tap \bigcirc to customize an operation type.

The *Operation* screen opens.

FIG. 16

C. Customize the operation settings.

D. Tap *Cancel* (2) or *Save* (3) to validate custom settings and tap back (1).

♦ If saved, the symbol

(factory predefined settings) changes to **L** (custom settings).

E. Select an operation.

♦ The app navigates back to operative screen.



FIG. 15









14.4.1 Restore (default) and delete (user-

defined) operations

FIG. 17

Swipe left to restore or delete.

Note 16 - 17

14.4.2 Default Operations

FIG. 18

△ CAUTION

The parameters contained in the dental procedures are indicative only.

Bien-Air Dental cannot be held liable for them.

Note 18

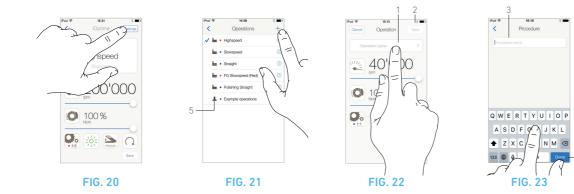
14.4.3 Sort operations

FIG. 19

- **A.** Do a long tap on an operation to activate the drag and drop function and display the icons $\equiv (2)$.
- **B.** Tap the icon to drag and drop the operations.
- C. Tap *Done* (1) to validate.

- 11 If using iOptima INT system, each time you pull a motor from a holder, the operative mode previously used with that motor is displayed by default (only from Home page).
- 12 Each operation in the list is tagged with a colored dot to indicate which type of gear ratio it is associated to: red for multiplication gears, blue for direct-drive, green for reduction gears.
- 13 When the micromotor is switched ON, the speed and torque values displayed in the operative screen FIG. 13, toggle from predefined values to real time values. Once the motor stops running, the speed and torque values displayed toggle back to maximum predefined values.
- 14 All parameters can be directly modified in the operative screen (only when the footpedal is released).
- 15 Modifications are discarded when leaving the operative screen without saving.
- 16 Predefined RESTO operations can not be deleted. But it is possible to restore the default values if modified. Only user-defined operations can be deleted.
- 17 Custom and user-defined operations are represented by ...

 Default operations are represented by ...
- **18** The predefined parameters may be subject to modification without notice



14.5 Create new operations (user-defined)

FIG. 20

 $\mathbf{A}.$ From the operative screen, tap $\pmb{Settings}$ to open the $\pmb{Operations}$ screen.

FIG. 21

B. Tap + to create a new operation type.

The *Operations* screen opens.

Note 19

FIG. 22

C. Tap in the *Operation name* text field (1) to display the onscreen keyboard.

FIG. 23

D. Type the new *Operation name* (3) and tap *Done* (4).

 $\boldsymbol{\mathsf{E}}.$ Set handpiece ratio and operation settings.

F. Tap *Cancel* or *Save* (2) to validate user-defined operation and tap back, FIG. 22.

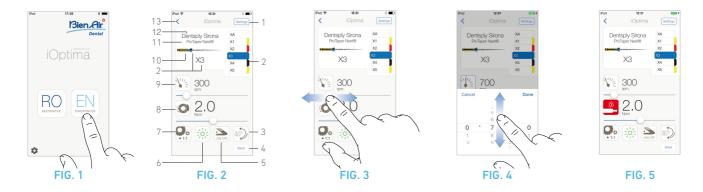
If saved, the new operation is displayed in the *Operations* screen (5) with the symbol **(**user-defined) beside it, FIG. 21.

G. Select an operation.

 $\$ The app navigates back to operative screen.

NOTES

19 Maximum storage of 20 user-defined operations, if reached the $\stackrel{\bot}{-}$ icon disappears.



15 Operation - Endodontics Mode

15.1 Enter Endodontics mode

FIG. 1

Tap | EN | to enter the endodontics mode.

Predefined endodontics systems are available by default, it is possible to modify and restore them.

It is possible to create and delete User-defined endodontics brands, systems and files.

Note 1 - 2

15.2 Operative screen description

FIG. 2

The operative screen displays the selected operation brand, system type and file settings:

- (1) Access to brands, systems and file settings
- (2) File name and color designation of file according to ISO 3630-1 standard
- (3) Micromotor rotation mode: FORWARD, AUTO-REVERSE, AUTO-FORWARD
- (4) Save (to customize settings)
- (5) Footpedal mode: PROGRESSIVE or ON/OFF mode
- (6) Light intensity
- (7) Handpiece ratio
- (8) Maximum micromotor torque in Ncm (or according to settings, see chapter "13.6 Settings" on page 43)

- (9) Maximum micromotor speed in rpm
- (10) Figure of the file
- (11) File system name
- (12) File brand
- (13) Back to the previous screen

Note 3

15.2.1 Micromotor Speed & Torque

FIG. 3

Slide to adjust the maximum speed and torque values.

Or tap the icons to activate the wheel scroller.

FIG. 4

Slide to precisely adjust the motor speed and torque values and tap *Cancel* or *Done* to validate.

FIG. 5

When the power demand of the micromotor is excessive, the

operative screen displays the overheating symbol . In this case the iOptima unit lowers the torque automatically in order to avoid overheating of the micromotor.

To restore 100% torque, allow the motor to idle or stop for a few seconds.







15.2.2 Handpiece ratio

FIG. 6

Tap and select to modify the handpiece ratio.

△ CAUTION

Verify that the handpiece corresponds to your selection.

Note 4 - 5 - 6

15.2.3 Light intensity

FIG. 7

Slide or tap the appropriate dot to set up the light intensity of the micromotor.

11 levels of adjustment are possible:

 light OFF, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90% and 100% of the max light intensity value.

Note 7 - 8

15.2.4 Footpedal mode

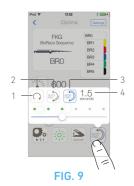
FIG. 8

Tap and select the footpedal mode:

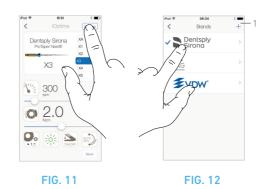
- ON/OFF (1): the speed consign is equal to the maximum speed once the footpedal is pressed; whatever the pressure on it.
- **Progressive** (2): The speed consign value is (linear) function to the pressure on it.

Note 9

- 1 $\,$ In endodontics mode, the air spray is always switched OFF by the help of the electro-valve integrated in the iOptima/iOptima $^{\rm INT}$ unit.
- 2 Save and create (+) buttons are disabled if a lock is set (see chapter "13.6 Settings" on page 43).
- 3 All parameters can be changed and saved directly in the operative screen (except if a lock is set).
- 4 The operative screen always displays the selected handpiece ratio.
- 5 If a different ratio than 8:1 Bien-Air or 1:1 Bien-Air is chosen, a disclaimer is displayed on the handpiece ratio popup:
- «IMPORTANT WARNING: If instruments other than the 8:1 Bien-Air or the 1:1 Bien-Air Dental are used with the iOptima, please note that the displayed torque values cannot be guaranteed any longer (they represent a purely indicative information). In such case, Bien-Air Dental declines all responsabilities in case of any injury or any damage resulting of the inappropriate use of the equipment.».
- 6 The handpiece ratio is red-colored for multiplication gears, blue-colored for direct-drive, and green-colored for reduction gears.
- 7 The light intensity value is set for each operation. The default value of the light intensity is 100%.
- 8 The operative screen always displays the selected light intensity value.
- 9 The operative screen always displays the selected footpedal mode.









15.2.5 Micromotor rotation direction

FIG. 9

Tap to select the rotation mode of the micromotor:

- Forward (clockwise) (1)
- Auto-reverse (2): the direction of rotation reverses automatically once the maximum torque set is reached (clockwise to counterclockwise).
- Auto-forward (3): the direction of rotation reverses automatically once the maximum torque set is reached (clockwise to counterclockwise).

In Auto-forward mode (reverse), the motor stops and reverses automatically after the time set (4): 0.5 to 3.0 seconds counterclockwise to clockwise).

Note 10 - 11

15.3 Standard Use - Operating mode (Start)

FIG. 10

A. Tap to enter the ENDO mode, the operative screen opens.

Note 12

FIG. 11

B. Tap Settings to open the Brands screen,

FIG. 12

C. Tap to choose a brand, the **Systems** screen opens.

FIG. 13

D. Tap to select a file system.

Note 13

- \$\textstyle \text{The app navigates back to the operative screen, FIG. 14.}
- **E.** Press the dental unit pedal to switch on the micromotor.

△ CAUTION

If the footpedal is pressed before entering in operative mode, a warning message «Please release the pedal...» will be displayed. The micromotor will not start to run until the footpedal is released and pressed again.

FIG. 14

F. Tap the file figure area to jump to the next file, parameters of the file system previously selected are automatically loaded (or directly tap the required file (3)).

Note 14 - 15

15.4 Customize settings

15.4.1 Customize default settings (operative screen)

FIG. 15

Note 15

- **A.** Slide to adjust the micromotor speed and torque values of the selected file.
- **B.** Adjust the handpiece ratio, light intensity, footpedal mode or rotation direction to customize settings for the selected file system.
- C. Tap Save to validate the new settings.

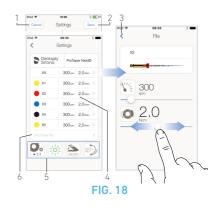
Note 16











15.4.2 Customize system settings

FIG. 16

FIG. 14

A. Tap **Settings** to open the **Brands** screen.

FIG. 17

- B. Tap a Brand to open the Systems screen.
- **C.** Tap \bigcirc to customize a file system, the **Settings** screen opens.

FIG. 18

- **D.** Customize the file system settings:
 - tap any file (4) to open the *File* screen and modify motor speed and torque values (tap (3) to go back);
 - tap the icons (5) to modify the handpiece ratio, etc...;
 - tap in the **Add new file** field (6) to create a new file, make a long tap to sort the files, or swipe left to remove existing files. See chapter "15.5 Add, sort or remove files" on page 55, for details.
- E. Tap Cancel (1) or Save (2) to validate custom settings.
- 🖔 If saved, the symbol 🏧 (factory predefined settings) changes to **L** (custom settings).

Note 17

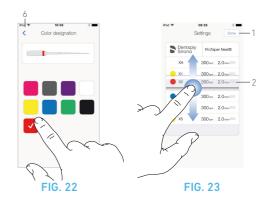
See chapter "15.7 Create new Brands and Systems" on page 57, for details

- 10 The operative screen always displays the selected rotation direction
- 11 In reverse mode (CCW), the symbol flashes and there is a sound alert (alternate medium beeps).
- 12 If using iOptima $^{\rm INT}$ system, each time you pull a motor from a holder, the operative mode previously used with that motor is displayed by default (only from Home page).
- 13 If an ENDO file systems foreseeing the reciprocating movement is selected, speed, torque, motor direction, light, pedal mode disappear and the gear ratio is fixed. See chapter "15.8 CA ENDO / Reciproq option" on page 58.
- 14 When the micromotor is switched ON, the speed and torque values displayed toggle from predefined values to real time values. Once the motor stops running, the speed and torque values displayed toggle back to maximum predefined values.
- 15 All parameters can be directly modified in the operative screen (only when the footpedal is released). See chapter "15.4.1 Customize default settings (operative screen)" on page 53.
- 16 Modifications are discarded when leaving the operative screen without saving.
- 17 From the Systems screen it is also possible to chose a different brand and create a new system or a new brand with the + symbol.









15.5 Add, sort or remove files

Note 18

15.5.1 Add new files

FIG. 19

A. Tap in the *Add new file* field to open the *File* screen.

FIG. 20 - FIG. 21

B. Tap in the *File name* field (3) to display the onscreen keyboard, type the new *File name* (5) and tap *Done* (onscreen keyboard).

FIG. 22

C. Tap the file figure (4) to display the *Color designation* screen, select a color for the new file and tap back (6) (color designation of file is according to ISO 3630-1 standard).

D. Adjust the micromotor speed and torque values (7), FIG. 20. See "15.2 Operative screen description" on page 51, for details.

E. Tap back (2) and *Save* (1), FIG. 19.

15.5.2 Sort files

FIG. 23

A. Do a long tap on a file to activate the drag and drop function and display the icons \equiv (2).

B. Tap the icon to drag and drop the files.

C. Tap *Done* (1) to validate.











FIG. 26

FIG. 28

15.5.3 Remove files

FIG. 24

A. Swipe left to remove existing files and tap Save or Cancel.

15.6 Restore (default) and delete (userdefined) systems

FIG. 25

Swipe left to restore or delete.

Note 19 - 20

15.6.1 Default Systems

FIG. 26

Dentsply Sirona

Note 21

FIG. 27

FKG swiss endo

FIG. 28

VDW

△ CAUTION

The parameters contained in the dental procedures are indicative only.

Bien-Air Dental cannot be held liable for them.

Note 22

NOTES

- 18 New files can be added, sorted or removed in default and user-defined files
- 19 Predefined ENDO systems can not be deleted. But it is possible to restore the default values if modified. Only user-defined systems can be deleted.
- 20 Custom and user-defined systems are represented with the symbol ...

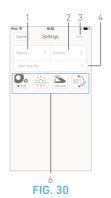
Default manufacturer files are represented by the symbol

21 Predefined endo file systems foreseeing the reciprocating movement need activation on the iOptima^{INT} system. In case the movement wasn't previosuly activated, taping it leads to the activation page.

See chapter "15.8 CA ENDO / Reciproq option" on page 58.

22 The predefined parameters may be subject to modification without notice.











15.7 Create new Brands and Systems

FIG. 29

A. Tap + to add a new brand or a new system, the **Settings** screen opens.

Note 23 - 24

FIG. 30

B. Tap in the *Brand* text field (1) to display the onscreen keyboard.

FIG. 31

C. Type the new **Brand name** (5) or select an existing brand from the drop-down list box and tap **Done** (onscreen keyboard).

FIG. 30

D. Tap in **System** field (2), type the **System name** and tap **Done** (onscreen keyboard).

E. Tap *Add new file* (4), refer to chapter "15.5.1 Add new files" on page 55.

F. Tap the icons (6) to set the iOptima unit parameters:

- · Handpiece ratio
- Light intensity
- · Footpedal mode: PROGRESSIVE or ON/OFF mode
- Micromotor rotation mode: FORWARD, AUTO-REVERSE, AUTO-FORWARD

See chapter "15.2 Operative screen description" on page 51, for details.

G. Tap *Save* (3).

15.7.1 Restore (custom) and delete (userdefined) brand

Note 25 - 26

Restore default brands (factory settings)

FIG. 32

A. Swipe left on a default brand.

A message box opens: *Restore factory brand*.



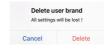
B. Tap Cancel or Restore to acknowledge.

Delete user-defined brands

FIG. 33

A. Swipe left on a user-defined brand.

A message box opens: **Delete user brand**.



B. Tap Cancel or Delete to acknowledge.







FIG. 36

FIG. 34

FIG. 35

15.8 CA ENDO / Reciproq option

Predefined endo file systems foreseeing the reciprocating movement need activation on the iOptima^{INT} system. In case the movement wasn't previously activated, tapping it leads to the activation page.

15.8.1 Activation page

FIG. 34

A. Tap *More information* and follow the instructions displayed.

FIG. 35

- B. Input the code obtained and tap Activate (2)
- A message box displays either:

License not Activated.	License Activated.
LICENSE ACTIVATION FAILED!	LICENSE ACTIVATED!
8	•

FIG. 36

C. If activated the app navigates back to the operative screen.

Note 27 - 29

D. Press the dental unit pedal to switch on the micromotor.

△ CAUTION

- · Valid only with Bien-Air CA ENDO.
- CA ENDO must be used only with specific tools.

- 23 New systems and brands can also be created directly from the system screen.
- 24 Maximum storage of 10 user-defined brands and 10 systems per brand, if reached the + icon disappears.
- 25 Restore ALL default system settings from the Brands screen.
- 26 It is only possible to delete user-defined brands
- 27 If an ENDO file systems foreseeing the reciprocating movement is selected, speed, torque, motor direction, light, pedal mode disappear and the gear ratio is fixed.
- When the power demand of the MX2 micromotor is excessive, the operative screen displays the overheating symbol (3). In this case the iOptima/iOptima^{INT} unit lowers the torque automatically in order to avoid overheating of the MX2 micromotor. To restore 100% torque, allow the motor to idle or stop for a few seconds.
- 29 If stress is excessive on the file, the file stress warning displays (4).

16 List of errors & Troubleshooting

16.1 Safety warning (operating)

Warning description	Message	Cause of warning	Action
Footpedal to be released Please release pedal		Pedal is pressed when accessing operative page. Pedal remains pressed when acknowledging any system notification. Motor is jammed for more than 2 seconds.	Release footpedal and press it again.
Motor torque limitation active	<u> </u>	Motor drive limits delivered torque to prevent motor overheating.	Avoid extended use. Let system cool down.
iPod/iPad speaker OFF	Please switch ON sound vol- ume on your iPod/iPad and set it to an appropriate level according to the ambient noise level in your practice room.	iPod/iPad speaker was switched OFF, or sound volume was disabled by user. It is necessary to have iPod/iPad speaker turned ON so that system sound notifications and alarms may be heard distinctly.	Turn iPod/iPad speaker ON and set sound volume to an appropriate level.
Non-verified iOS version in use	Durstay Malade Durstay Malade Pl	iOS version installed on the iPod/iPad has not been verified according to Bien-Air validation protocols. Therefore it is NOT recommended to use the system with this configuration.	Do NOT update iPod/iPad with new iOS versions unless Bien-Air recommends to do so. If the iPod/iPad has been updated with a new iOS version despite everything, do not use the system until Bien-Air has verified and approved the new iOS version.
User Manual has been updated	User Manual has been updated, and may be consulted in the Information page.	As an update of the User Manual was available on Bien-Air website, it has been automatically downloaded and updated on the iPod/iPad.	It is highly recommended to consult the updated User Manual before using the system.
Motor torque threshold limit reached, file stress condition encountered	FILE	System detects that motor torque threshold limit is reached.	Release file pressure. Slow down treatment.

16.2 Device operating error

Error description	Message	Cause of error	Action		
ERROR 4					
Motor connection missing	Motor is not connected! Please check motor connection.	Motor phase missing failure. Motor is not properly connected.	Check motor connection. If problem persists, contact Bien-Air Dental SA.		
ERROR 5					
Motor cable failure	Motor cable fault! Please replace motor cable.	Motor drive power protection failure. Motor cable may be defect.	Replace motor cable. If problem persists, contact Bien-Air Dental SA.		
ERROR 6					
Motor drive over temperature	Overall system overheating ! Please wait until cool.	Motor drive over temperature failure.	Wait for system cooling. If problem persists, contact Bien-Air Dental SA.		
GEN ERROR [FailCode]					
System electrical failure.	Electrical system fault ! Please contact Bien-Air Dental SA.	[FailCode] = EC100 : Motor drive communication failure [FailCode] = EC101 : Motor drive under voltage failure [FailCode] = EC102 : Motor drive over voltage failure [FailCode] = EC120 : Motor drive other failure	1. Switch OFF unit 2. Disconnect iPod/iPad device from unit 3. Close iOptima application 4. Switch unit back ON 5. Reconnect iPod/iPad device to unit 6. Restart iOptima application 7. If problem persists, contact Bien-Air Dental SA.		

16.3 iOS compatibility errors (disclaimer screen),

Color	iOS version (identifier digit change)	Text version	Restriction (recommendations)
Green	None. Currently installed iOS is identical to iOS verified during app validation.	Currently installed iOS x.y.z text section is displayed in green color.	No restrictions
Orange	Last digit is different: iOS x.y.Z. Currently installed iOS was updated for a minor change compared to iOS verified during app validation.	Currently installed iOS x.y.z text section is displayed in orange color. User must be aware that the configuration he is using is slightly different from the recommended configuration.	Configuration in use is slightly different from recommended configuration. No restrictions
Red	 First and/or second digit are/is different: iOS X.y.z, or iOS X.Y.z. Currently installed iOS was updated for major or at least significant changes compared to iOS verified during app validation 	Currently installed iOS x.y.z text section is displayed in red color.	Configuration in use is significantly different from recommended configuration. CAUTION The current configuration should NOT be used!

Note 1

NOTES

1 It is imperative to read and understand this IFU before carrying out any troubleshooting on the iOptima.

In case of unclear information or for any error message that is not listed in the following tables contact Bien-Air Dental SA.



FIG. 1

17 Maintenance

△ CAUTION

Only use original Bien-Air Dental maintenance products and parts or those recommended by Bien-Air Dental. Using other products or parts may cause operational failure and/or void the guarantee.

17.1 Servicing

Never disassemble the device. For any modification and repair, we recommend to contact your regular supplier or Bien-Air Dental SA directly at the address indicated on the back cover.

Note 1

17.2 Cleaning-disinfection

- Disinfect the surfaces of the iOptima unit / iOptima^{INT} dockin and footpedal by gently rubbing for about 15 seconds with a clean cloth soaked in a suitable product (i.e. Bien-Air Dental Spraynet or isopropyl alcohol) or with an appropriate disinfectant wipe.
- Do not immerse in disinfectant solution.
- Do not immerse in an ultrasonic bath.

17.3 Important

For maintenance of micromotors and hoses: See IFU

Product	Micromotor	IFU	Hose	IFU
i0ptima	MX2 LED	2100199	MX2	2100223
i0ptima ^{INT}	MX2 LED	2100199	MX2	2100223

17.4 Replace 4VL seal

FIG. 1

△ CAUTION

Immediately replace any damaged or leaking O-rings and seals. Never use sharp tools!

- **A.** Switch off the water and the dental unit power supply.
- B. Switch OFF the iOptima unit «O».
- C. Unscrew and unplug the 4VL hose (1).
- **D.** Remove the damaged 4VL seal (2).
- E. Replace with a new 4VL seal (REF 1302403-010).

Refit hose, switch ON units and water.

See chapter "5.1 Install the iOptima app" on page 17 for details.

17.5 iOptima^{INT}

Refer to the iOptima^{INT} installation manual

△ CAUTION

Only a qualified Bien-Air Dental service engineer is permitted to open the dental unit and repair the iOptima $^{\rm INT}$ system.

NOTES

1 Bien-Air Dental SA recommends the user to have its dynamic instruments regularly checked or inspected (at least once a year).

18 General information and guarantee

18.1 General information

The device must be used by qualified professionals in compliance with the current legal provisions concerning occupational safety, health and accident prevention measures, and these instructions for use. In accordance with such requirements, the operators:

- must only use devices that are in perfect working order; in the event of irregular functioning, excessive vibration, abnormal heating or other signs that may indicate malfunction of the device, the work must be stopped immediately; in this case, contact a repair center that is approved by Bien-Air Dental SA;
- must ensure that the device is used only for the purpose for which it is intended, must protect themselves, their patients and third parties from any danger, and must avoid contamination through the use of the product.

18.2 Terms of guarantee

Bien-Air Dental SA grants the user a guarantee covering all functional defects, material or production faults.

The device is covered by this guarantee for:

- 12 months for the hose
- 12 months for the power supply
- 12months for integrable electronic boards
- 24 months for the iOptima/iOptima^{INT} unit
- 36 months for series MX2 LED electric micromotors

from the date of invoicing.

In case of justified claim, Bien-Air Dental SA or its authorized representative will fulfill the company's obligations under this guarantee by repairing or replacing the product free of charge. Any other claims, of whatever nature, in particular in the form of a claim for damages and interest, are excluded.

Bien-Air Dental SA shall not be held responsible for damage or injury and the consequences thereof, resulting from:

- · excessive wear and tear
- · improper use
- non-observance of the instructions for installation, operation and maintenance
- unusual chemical, electrical or electrolytic influences
- poor connections, whether of the air, water or electricity supply.

The guarantee does not cover flexible "fiber optic" type light conductors, or any parts made of synthetic materials.

The guarantee shall become null and void if the damage and its consequences are due to improper manipulation of the product, or modifications to the product carried out by persons not authorized by Bien-Air Dental SA.

Claims under the terms of the guarantee will be considered only on presentation, together with the product, of the invoice or the consignment note, on which the date of purchase, the product reference and the serial no. should be clearly indicated.



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