iOptima^{INT}
iOptima

ENG INSTRUCTIONS FOR USE

Other languages available on www.bienair.com/ifu

Set iOptima^INT REF 1700704-001

| 1x REF 1502475-001 For iPad mini® 6 | 1x REF 1600677-001 | 1x REF 1600809-001 | 1x REF 1601074-001 | 1x REF 1500666-001 | 1x REF 1502568-001 | 1x REF 1300067-001 | 1x REF 3300404-001 | 1x REF 3300403-001 |

1x REF 1308624-001

Set iOptima^INT REF 1700705-001

| 1x REF 1502475-001 For iPad mini® 6 | 2x REF 1600677-001 | 2x REF 1600809-001 | 1x REF 1601075-001 | 1x REF 1500666-001 | 1x REF 1502568-001 | 1x REF 1300067-001 | 1x REF 3300404-001 | 1x REF 3300403-001 |

1x REF 1308624-001

Set iOptima REF 1700706-001

| 1x REF 1502475-001 For iPad mini® 6 | 1x REF 1600677-001 | 1x REF 1600809-001 | 1x REF 1600755-001 | 1x REF 1600606-001 | 1x REF 1601076-001 | 1x REF 1500666-001 | 1x REF 1502568-001 | 1x REF 1300067-001 |

| 1x REF 3300404-001 | 1x REF 3300403-001 | 1x REF 1303711-001 | 1x REF 1308624-001 |

Options

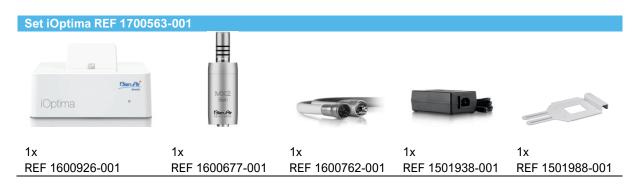| REF 1502620-001 For iPod touch® | REF 1502621-001 For iPod touch® | REF 1502622-001 For iPad mini® 6 | REF 1502623-001 For iPad mini® 6 | REF 1308624-001 USB-C | REF 1502472-001 For iPad mini® 4 & 5 | REF 1502567-001 |

| REF 1600751-001 | REF 1601096-001 |

Set iOptima REF 1700563-001

1x	1x	1x	1x	1x
REF 1600926-001	REF 1600677-001	REF 1600762-001	REF 1501938-001	REF 1501988-001

Set iOptima REF 1700544-001

1x	1x	1x	1x
REF 1600926-001	REF 1600677-001	REF 1600762-001	REF 1501938-001

Set iOptima REF 1700547-001

1x	1x	1x
REF 1600926-001	REF 1600762-001	REF 1501938-001

Options

1x
REF 1600036-006

Table of contents

iOptima^{INT} description

1. Symbols

1.1 Description of symbols for iOptimalNT

Symbol	Description	Symbol	Description
CE 0123	CE Marking with number of the notified body.	(((•)))	Non-ionizing electromagnetic radiation.
Manufacturer	Manufacturer.	∿	Alternating current.
REF	Catalogue number.	○	OFF (power).
SN	Serial number.	│	ON (power).
MD	Medical Device.	(Data Matrix)	Data Matrix code for product information including UDI (Unique Device Identification).
Rx Only	Warning: in accordance wit federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.	(Sound)	Sound alerts.
⚠	WARNING: hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.	⚠	CAUTION: hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.
(Crossed-out bin)	Separate collection of electric and electronic equipment.	(Movement arrow)	Movement to the stop in the direction indicated.
📖ⓘ	Consult instructions for use or consult electronic instructions for use (https://dental.bienair.com/fr_ch/support/download-center/).	EC REP	Authorized EC Representative in the European Community.
♻	General symbol for recovery/recyclable.	(Humidity)	Humidity limitation.
(Temperature)	Temperature limit.	(Pressure)	Atmospheric pressure limitation.
(Umbrella)	Keep away from rain.		

1.2 Description of symbols for iOptimalNT accessories

Symbol	Description	Symbol	Description
CE XXXX	CE Marking with number of the notified body.	(Crossed-out bin)	Separate collection of electric and electronic equipment.
Manufacturer	Manufacturer.	SN	Serial number.
REF	Catalogue number.	🧍	Electrical safety. Applied part type B.
MD	Medical Device.	(Data Matrix)	Data Matrix code for product information including UDI (Unique Device Identification).
EC REP	Authorized EC Representative in the European Community.	Rx Only	Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.
135°C	Sterilization up to the specified temperature.		

FIG.1

2. Identification, Intended use and Notation

2.1 Identification

iOptima^{INT}

Electronically controlled integrated unit for dentistry, oral surgery and implantology allowing operation of multiple micromotors (MX2, MCX and MX-i) with variable speed using the dental unit pedal.

iOptima^{INT} can be used as a drive unit for a piezo-ceramic oscillation system available on the market (not included in the kit), if this function has been foreseen by the installer.

iOptimaINT can be used as a drive unit for an irrigation pump available on the market (KIT STERI PUMP ACTEON F28652), if this function has been foreseen by the installer. 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 touch®/iPad mini® device as soon as it is connected. Under normal use (power supply = 32Vdc), the unit does not use any battery energy of the iPod touch®/iPad mini®.

The Optima^{INT} unit charges the iPod touch®/iPad mini iPad mini® battery when connected.

The restorative, endodontics and surgery parameters are defined before operation using the iOptima application installed on the iPod touch®/iPad mini®.

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 operating systems (iOS & iPadOS).

2.2 Intended use

Product intended for professional use only. The iOptima^{INT} systems fitted with MX2 micromotors are intended for use in restorative dentistry, endodontics, dental prophylaxis and orthodontics. The iOptima^{INT} systems fitted with a MX-i micromotors are intended for use in oral surgery and implantology. The iOptima^{INT} system is intended to be used by dentists and dental professionals in a dental office. The iOptima^{INT} systems fitted with MCX micromotors are intended for use in restorative dentistry, dental prophylaxis and orthodontics.

FIG.1

According to the most complete installation scheme, iOptimaINT system connected to an iPod touch®/iPad mini® controls a MX2 micromotor (endodontics + restorative), a MX-i micromotor which grants access to the surgery (SR) mode and a piezo scaler allowing access to the piezo scaling (PZ) mode: in this case, the irrigation cannot be regulated by the iOptima^{INT} system in combination with the piezo scaler, but only with a MX-I micromotor in the surgery (SR) mode. Any use other than that for which this product is intended is unauthorized and can be harmful. ***Note 1***

2.3 Intended patient population

The intended patient population of the iOptimaINT consoles includes any person visiting a dental practitioners' office or a dental hospital to receive treatment in line with the intended medical condition. There is no restriction concerning subject age, race, or culture. The intended user is responsible to select the adequate device for the patient according to the specific clinical application.

2.4 Intended User

The iOptimaINT is meant to be used only by dentists and dental surgeons in dental offices and hospitals.

2.5 Intended medical conditions

- General dentistry which includes restorative dentistry, endodontics, dental prophylaxis, orthodontics and addresses the maintenance or reestablishment of dental health.

- Dental implantology is the elective treatment to replace one or more missing teeth. Teeth can be missing for various reasons, such as traumas, partial or total edentulism, and advanced decay that leads to tooth sacrifice because restorative treatments are no longer possible.
  Dental implantology requires to prepare jawbone to accommodate a dental implant, which is typically a titanium screw fitted with an abutment and a prosthetic crown made of ceramic material mimicking the natural missed tooth.

  Multi-teeth prosthetic solutions are also available, usually supported by more than one single implant.

- The main Endodontics treatments include:
  - Root canal treatment: this is used to treat irreversibly damaged infected tooth pulp, which would be otherwise extracted. This is usually caused when bacteria enter the pulp through a deep cavity or failed filling. Sometimes endodontic treatment is followed by re-implantation to preserve the aesthetics and function of the tooth. Root canal treatment involves multiple steps: removing the infected pulp, shaping, cleaning and disinfecting the entire root canal system, and finally placing a restoration such as a composite filling or a crown.
  - Apicoectomy: removal of a root end

- Root resection: removal of an entire root
- Repair of an injured root due to perforation or resorption
- Removal of broken fragments of the tooth or a filling material
- Exploratory surgery to look for root fractures.
- Hemisection, where a root and its overlying portion of the crown are separated from the rest of the tooth and optionally removed.

- The main oral surgery treatments include:
  - impacted teeth extraction: when a tooth partially or totally hidden in the jawbone needs to be removed;
  - wisdom teeth extraction: when a third molar, either impacted or not, needs to be removed;
  - non salvageable decayed teeth extraction: when a tooth with a decay at an advanced status must be sacrificed because it cannot be restored anymore;
  - guided and not-guided bone regeneration: when bone grafting, either with artificial or biological grafts, is needed to build a more solid platform where being able to place a dental implant;
  - apicoectomy: when a tooth's root tip is removed, and a root end cavity is prepared and filled with a biocompatible material. An apicoectomy is necessary when conventional endodontic root canal therapy has failed. The only alternative may be extraction followed by prosthetic replacement for instance with a dental implant;
  - osteotomy: when a jawbone must be cut, for instance during a ridge split treatment aiming at increasing crestal bone width to have enough room to accommodate an implant;
  - sequestrectomy: when a portion of necrotic bone must be removed;
  - hemisection: when a tooth with two roots is cut in half. This procedure may be needed when there is bone loss, or dental decay between the roots, due to periodontal disease. The tooth is cut in half to remove the damaged bone and any damaged root or crown.
  - Periodontology concerns the treatment of periodontium that is the supporting tissue of the tooth.

2.6 Patient contra-indications and side effects

No specific patient contra-indication, side effect nor warnings exist for the iOptimaINT device family when the device is used as intended.

2.7 In case of accidents

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

If any serious incident occurs in relation to the device, report it to a competent authority of your country, as well as the manufacturer through your regional distributor. Observe relevant national regulations for detailed procedures.

2.8 Notation

- **A**, **B**, **C**, etc.

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

- ✏️

    Indicates a procedure result.

- **(1)**, **(2)**, **(3)**, etc.

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

- *OK*, *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*.

⚠️CAUTION

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

⚠️CAUTION

The "portrait" format is used throughout the manual and the information remain the same whether your device is set on "landscape" or "portrait".

⚠️CAUTION

For the iPad mini® and only for the iPad mini®, the app is able to detect whether the device is used in "landscape" or "portrait" format and will display the application according to the orientation used.

> **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. User and Patient Safety: Warnings & Precautions for use

To prevent any risk of explosion, the warning below must be observed:

⚠️WARNING

According to IEC 60601-1:2005+A12012/AnnexG, electrified devices (motors, control units, couplers and attachments), can be safely used in a medical environment in which potentially explosive or flammable mixtures of anaesthetic substances are delivered to the patient only if:
1. The distance between the motor and the anaesthetic breathing circuit exceeds 25 cm.
2. The motor is not used simultaneously to the administration of the anaesthetic substances to the patient.

To prevent any risk of electric shock, the warning below must be observed:

⚠️ WARNING

The iOptimalNT unit must be connected only to a power supply network provided with a protective earth.

To prevent any risk of infection, the warnings below must be observed:

⚠️ WARNING

If the irrigation pump is used, the sterile irrigation line recommended by the pump manufacturer must be used.

The cleaning procedure defined in §13.2 must be followed. The use of sterile protective sheet for the iPod touch®/iPad mini® is recommended for surgical applications. If the practitioner comes into contact with the sterile protective sheet, it should be replaced at once.

Always refer to the accessories IFU for dedicated maintenance procedure.

To prevent any risk of bone overheating, the caution below must be observed:

⚠️ CAUTION

If the irrigation pump is used and regulated by the iOptimalNT system, verify that the pump is working properly before starting the treatment as well as during the treatment. The iOptimalNT system has neither been conceived for controlling the working status of the pump nor for detecting possible failures of the pump.

To prevent any risk of motor overheating, the cautions below must be observed:

⚠️ CAUTION

Always refer to the micromotor IFU to set the required motor cooling air flow.

Always ensure that both the cable and the motor are in good condition.

Ensure that the micromotor hose is not bent.

Do not use iOptimalNT outside the range of operating temperature.

The symbol is used to indicate overheating, please refer to chapter 12 for additional information.

To prevent any risk of injury (damage to bone, teeth, tissue) the cautions below must be observed:

⚠ CAUTION

The iPod touch®/iPad mini® must never be disconnected from the iOptimaINT dental unit during operation.

Before starting any medical operation, make sure all iPod/iPad applications are closed and notifications popup are disabled in order to avoid any disruption of the practitioner work. Be aware that any notification alert may stop the micromotor and active peripherals.

The predefined settings contained in the iOptima app dental procedures are indicative only. Bien-Air Dental SA cannot be held liable for them.

The predefined torque and speed values are only intended as a guide. The file values used must be adapted according to the files manufacturer instructions. Always refer to the Endodontic file manufacturer specifications to set up the console settings.

The predefined torque and speed values are only intended as a guide. The drill values used must be adapted according to the implant manufacturer instructions. Always refer to the implant manufacturer specifications to set up the console settings.

Always verify that the configured parameters correspond to your medical application. The predefined parameters may be subject to modification without notice.

To prevent any risk of adverse tissue reaction, the caution below must be observed:

⚠ CAUTION

If the irrigation pump is used, only use biocompatible irrigation line recommended by the manufacturer and refer to the recommendation of the pump manufacturer.

To prevent any risk of injury and/or material damage the cautions below must be observed:

⚠ CAUTION

Never connect a handpiece on a running micromotor.

Note 1
Note 2

NOTES	
1	The predefined factory parameters may be subject to modification following application update
2	Refer to chapter 12 for operating errors and trouble shooting.

4. Description

4.1 iOptima^{INT} system overview

The iOptimaINT system mainly consists of:
- A unit as a docking station (2) for iPod touch®/iPad mini® device.
- The iPod touch®/iPad mini® provide the user interface to the iOptimaINT system, except speed reference input.
- The electronic board (1), integrated in the dental unit system, is in charge to drive the micromotor (MX2, MCX and/or MX-i), a piezo scaler (or an irrigation pump) and communicate with the interface through the Lightning connector.
- A dental micromotor and the related hose (MX2, MCX MX-i).
- A power supply 100-240 VAC.
- Instrument holders which are connected to the iOptimaINT system. Up to three holders may be connected, allowing up to three instruments to perform treatments.

FIG.1

4.2 iOptima^{INT} system table

Summary of the iOptimaINT functions and technological features.

Product	Device	Technology	Motor	Restorative	Endodontics	Oral surgery	Implantology	Prophylaxis
iOptima INT	iPod touch/ iPad mini	DMX3	MX2	X	X	-	-	X
iOptima INT	iPod touch/ iPad mini	DMX3	MCX	X	-	-	-	X
iOptima INT	iPod touch/ iPad mini	DMX3	MX-i	-	-	X	X	-

4.3 Technical data

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

Torque

Implant torque with MX-i LED and CA 20:1 .... > 50Ncm

Environmental conditions

Operating conditions	
Temperature range:	+ 10°C / + 35°C
Relative humidity range:	30% - 80%
Air pressure range:	700 hPa – 1060 hPa

Storage	
Temperature range:	0°C / + 40°C
Relative humidity range:	10% - 80%
Air pressure range:	650 hPa – 1060 hPa

Transport	
Temperature range:	-20°C / + 50°C
Relative humidity range:	5% - 80%
Air pressure range:	650 hPa – 1060 hPa

⚠️ CAUTION

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

Classification

Class IIa in accordance with European Regulation 2017/745 concerning medical devices.

Electric insulation class

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

List of errors & Troubleshooting

See chapter "12 List of errors & Troubleshooting".

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

Product	Micromotor	IFU	Hose	IFU
iOptima^{INT}	MX2 LED	2100199	MX2	2100223
iOptima^{INT}	MCX	2100231	MCX	2100230
iOptima^{INT}	MX-i	2100245	MX-i	2100163

4.4 Performances

Performances	
Speed accuracy	5%
Memory	Restorative, Surgery, Piezoscaling Storage of 20 user-defined Operations for each mode Endodontics Storage of 10 user-defined Brands Storage of 10 user-defined Systems per Brand Storage of 8 Files per System including adjustment of speed and torque values for each file
LED adjustment	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

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.

5.2 Install the iOptima^{INT} system

The iOptima^{INT} system must be installed by a service engineer certified by Bien-Air Dental SA.

NOTES

1 The iPod touch®/iPad mini® must be correctly connected to a Wi-Fi network before the App Store is opened; refer to Apple's user guide or appropriate use of the iPod touch® / iPad mini®.

6. Interface overview

6.1 iOptima application

The iOptima application with iOptima^{INT} allows to carry out restorative, endodontics, surgery and piezo scaling dentistry operations.

⚠ CAUTION

Always verify that the latest version of the software is used. It is recommended to connect the unit to the Internet periodically to detect if an app update is available.

6.1.1 Compatibility

Refer to Bien-Air Website
iOptima INT webpage => Technical Data => COMPATIBLE DEVICES WITH IOPTIMA INT

6.1.2 Notation

In order to simplify the notation, in this manual:
- iOptima application is referred to as «iOptima app»;
  Restorative, Endodontics, Surgery and Piezo scaling modes are referred to as «RESTO», «ENDO», «SURG» and «PIEZO»

6.2 Sound alerts

Sound alert	Description
One short beep	Enterring ENDO or RESTORATIVE with micromotor REVERS
	Selecting micromotor REVERS
Alternate short beeps	Alert message notifications (see chapter 12)
Alternate medium beeps	Micromotor REVERSE running indicator
	ENDO mode when the micromotor is running in reverse
Alternate long beeps	System failure notification (see chapiter 12)

6.3 iPod touch®/iPad mini® and iOptima^{INT} connection / disconnection conditions

6.3.1 Disconnection

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

⚠ CAUTION

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

6.3.2 Connection

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

⚠️CAUTION

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

6.3.3 iOptimaINT unit switched ON

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

- The iPod touch®/iPad mini® 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).

6.3.4 iOptimaINT 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).

6.3.5 System malfunction

FIG 1

If the iOptima^{INT} system freezes or malfunctions in any way, it is possible to reboot the entire system by pushing on the reset switch button. The reset switch button is located near the Apple device and is easily accessible at all times. For a picture of the reset switch button, please refer to FIG 1.

iOptima / iOptima^{INT} Operation

FIG.1	FIG.2	FIG.3	FIG.4	FIG.5
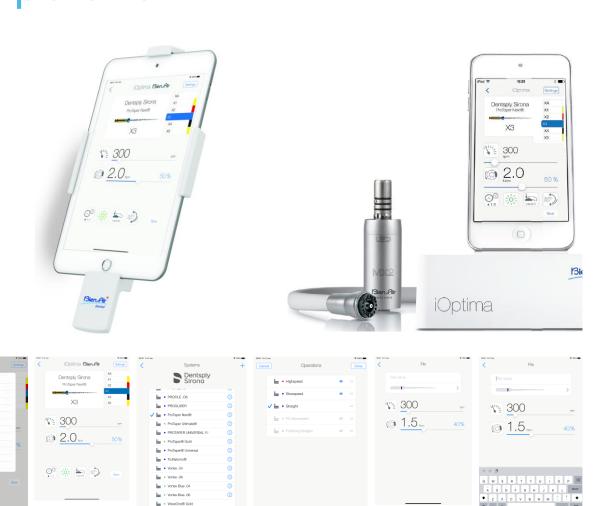
7. Getting started

7.1 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 and the hide and show functions;

- **Drag** ≡ **and drop** to sort files/operations;

- **Tap** to hide 👁 or show 👁 files/operations.

7.2 Display onscreen keyboard

FIG.5

- Tap a text field to display the onscreen keyboard;
- Type characters with the onscreen keyboard (tap ⊗ to delete all characters).

FIG.6

FIG.8

7.3 Launch iOptima app

FIG.6

A. Make sure that the sound volume on your iPod touch®/iPad mini® 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 touch®/iPad mini®.

D. Ensure that the latest application updates have been installed (see chapter "7.9 iOptima app update").

E. Tap the app icon (5) to launch the iOptima application.

Note 1

⚠ CAUTION

When used on an iPad mini®, before starting the app, always check that the screen's rotation lock (1) is off by using the screen's rotation key (2) 🔄 from the control panel. If the screen's orientation is not correct when you start the app, you will need to:

- Follow steps described in chapter "7.4 Quit iOptima app".
- Disable the screen's rotation lock (2).
- Check that the ipad is positioned according to the desired screen orientation.
- Restart the app.

7.4 Quit iOptima app

- Refer to iPod touch®/iPad mini® user manual

NOTES

1 If not using your iPod touch®/iPad mini®, press the Sleep/Wake button (3) to lock it.
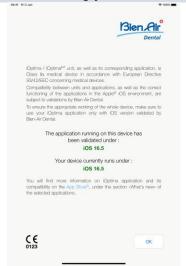
FIG.9	FIG.10	FIG.11

7.5 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.9

👆 Refer to the current version of your device (1). This screen appears in case of any notification to the user (new app version available, instructions for use update, etc.).

See also chapter "12.3 iOS compatibility errors (disclaimer screen)".

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.10

↳ This screen appears only in case of any notification to the user (new app version available, instructions for use update, etc.).

C. Make sure to have set all steps of disclaimer (3) and tap *OK* (4), see chapter "7.3 Launch iOptima app" .

↳ The Welcome screen is displayed.

FIG.11
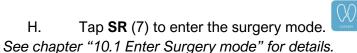
The Welcome screen differs whether using the iOptima or iOptima^{INT} system and depends on which type of micromotor is connected (e.g. Surgery mode is available only if the micromotor MX-i is connected using the iOptima^{INT} system).
See chapter "4.2 iOptimaINT system table" for more information.
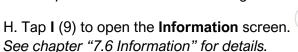
D. Tap **RO** (5) to enter the restorative mode.
See chapter "8.1 Enter Restorative mode".

    H.   Tap **EN** (6) to enter the endodontics mode.
See chapter "9.1 Enter Endodontics mode" for details.

    H.   Tap **SR** (7) to enter the surgery mode.
See chapter "10.1 Enter Surgery mode" for details.
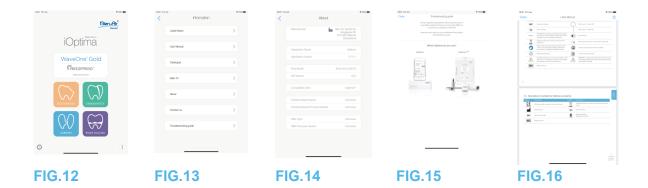
    H.   Tap **PZ** (8) to enter the piezo scaling mode.
See chapter "11.1 Enter Piezo scaling mode" for details.

H. Tap **I** (9) to open the **Information** screen.
See chapter "7.6 Information" for details.

I. Tap **Settings** (10) to open the **Settings** screen.
See chapter "7.6 Information" for details.

J. Tap **WaveOne** (11) to enter the CA ENDO mode.
See chapter "9.8 CA ENDO / Reciproc option" for details.

FIG.12 **FIG.13** **FIG.14** **FIG.15** **FIG.16**

7.6 Information

FIG.12

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

FIG.13

👆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 touch®/iPad mini® 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. 14, 9) with iOptima system and Bien-Air factory information);
- **Contact us** (7) (opens email application with predefined email address iOptima@bienair.com);
- **Troubleshooting** (8) (opens troubleshooting guide (FIG. 15), follow the guide in case of performance issue).

Note 4
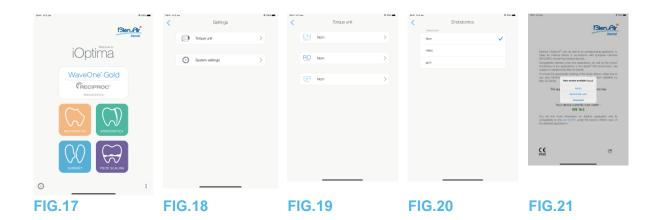
FIG.16

- **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 (10) links the user directly to the table.

NOTES

3 If the User Manual is not available in the selected language, the English manual is downloaded.

4 Latest News, Catalogue, Web TV and Contact us functions are available only if the iPod touch®/iPad mini® is connected to a WiFi network.

FIG.17 **FIG.18** **FIG.19** **FIG.20** **FIG.21**

7.7 Settings

FIG.17

A. Tap ⚙ (1) to access iOptima/iOptimaINT system Settings screen.

👆 The **Settings** screen allows to set the torque unit for each available mode and to define the system settings.

FIG.18

B. Tap **Torque unit** to access its screen.

FIG.19

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

FIG.20

D. Tap your preferred torque unit.

E. Select between; **Ncm; mNm; gcm**.

7.8 Service engineer settings

With service engineer access (password protected), the settings screen also allows access to the micromotor holder configuration (iOptimaINT) and lock settings.

Important: if **Lock settings** is set, it is not possible to save any user-defined data!
Note 5
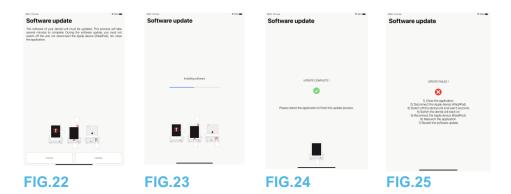
7.9 iOptima app update

FIG.21

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 dosettimgwnload 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).

FIG.22   **FIG.23**   **FIG.24**   **FIG.25**

7.10   Software update

FIG.22

When the application is launched and the iOptima/iOptimaINT connected, it will check whether a new software of the dental unit is available. If a new software is available, a message box will be displayed on the screen to notify the user should update the software. Tap **Update** to install it.

FIG.23

☝ The screen shows the installation progress.

⚠CAUTION
- The iPod touch®/iPad mini® must not be disconnected from the iOptima/iOptimaINT dental unit during installation.
- The iOptima application must not be closed during installation.
- The iOptima/iOptimaINT power supply must not be disconnected during installation.

When the installation is completed, there are two possibilities:

FIG.24
- Update complete: restart the application to finish the update process.
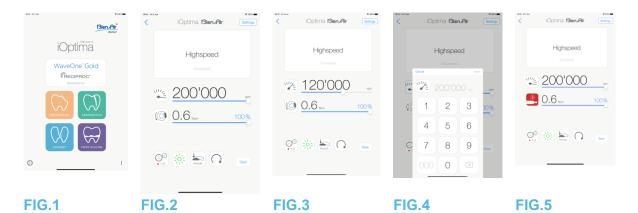
FIG.25
- Update failed: follow the instructions on the screen.

> **NOTES**
> **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 touch®/iPad mini® is connected to a Wi-Fi network..

FIG.1 FIG.2 FIG.3 FIG.4 FIG.5

8. Operation – Restorative mode

8.1 Enter Restorative mode

FIG. 1

Tap [icon] 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

8.2 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 Ncm, indicative percentage of maximum torque that can be delivered is also displayed (or according to settings, see chapter "7.6 Settings")
(9) Maximum micromotor speed in rpm
(10) Back to the previous screen

Note 3
See chapter "8.3 Standard Use - Operating mode (Start)".

8.2.1 Micromotor Speed & Torque

FIG.3

Slide to adjust the maximum speed and torque values.

Or tap the icons [icon] [icon] to enter a precise value.

FIG.4
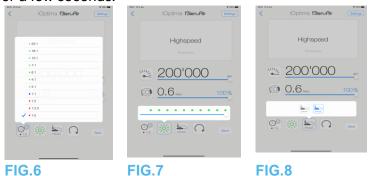
Tap the motor speed or torque values and tap Cancel or Done to validate.

Note 4

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.

FIG.6   **FIG.7**   **FIG.8**

8.2.2   Handpiece ratio

FIG.6

Tap and select the handpiece ratio.

⚠ CAUTION

Verify that the handpiece corresponds to your selection.

Note 5 - 6

8.2.3   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

8.2.4   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

8.2.5   Micromotor rotation direction

Tap to change the rotation mode of the micromotor:

- **Forward** (clockwise)
- **Reverse** (counterclockwise)

Note 10 – 11

NOTES

1 In restorative mode, the motor cooling air 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 "7.7 Settings").

3 All parameters can be changed and saved directly in the operative screen (except if a lock is set).

4 If the entered value is out of range, the maximal or minimal value will be indicated.

5 The handpiece ratio is red-colored for multiplication gears, blue-colored for direct-drive, and green-colored for reduction gears.

6 The operative screen always displays the selected handpiece ratio.

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.

10 In reverse mode (CCW), the symbol flashes and there is a sound alert (alternate medium beeps).

11 The operative screen always displays the selected rotation direction.
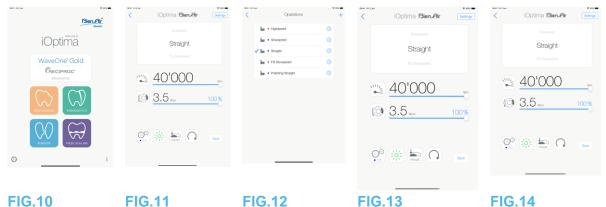
FIG.10   FIG.11   FIG.12   FIG.13   FIG.14

8.3 Standard Use - Operating mode (Start)

FIG.10

A. Tap [icon] to enter the RESTO mode, the operative screen opens.

Note 12

FIG.11

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

Note 13

FIG.12

C. Tap to select an operation type.

[icon] 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, an alert message «Please release pedal…» will be displayed. The micromotor will not start to run until the footpedal is released and pressed again.

FIG.13

Note 14 - 15

- 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** (3) to validate the new settings.

Note 16

E. Tap the operation type above (1) or below (2) the selected operation type to navigate to the operation respectively preceding or following the current one in the predefined operation list.

See chapter "8.4.3 Sort operations" in the list.

8.4 Customize default operations

FIG.14

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

FIG.15

B. Tap [icon] to customize an operation type.

[icon] 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] (factory predefined settings) changes to ![person] (custom settings).

E. Select an operation.

The app navigates back to operative screen.

FIG.15   **FIG.16**   **FIG.17**   **FIG.18**   **FIG.19**
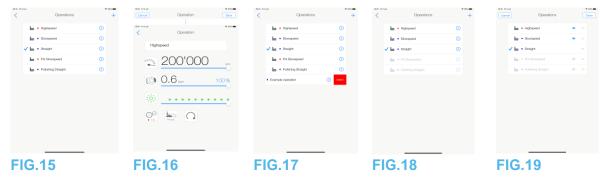
8.4.1 Restore (default) and delete (user defined) operations

FIG.17

Swipe left to restore or delete. *Note 17 – 18*

8.4.2 Default Operations

FIG.18

⚠ CAUTION

The parameters contained in the dental procedures are indicative only. Bien-Air Dental SA cannot be held liable for them. *Note 19*

8.4.3 Sort operations
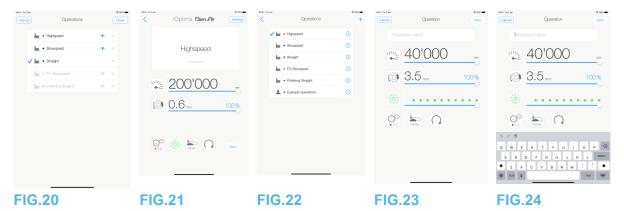
FIG.19

A. Do a long tap on an operation to activate the drag and drop function and display the icons ☰ (2).

B. Tap the icon ☰ to drag and drop the operations.

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

NOTES

12 If using iOptimalNT 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 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.

14 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.

15 All parameters can be directly modified in the operative screen (only when the footpedal is released).

16 Modifications are discarded when leaving the operative screen without saving.

17 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.

18 Custom and user-defined operations are represented by . Default operations are represented by .

19 The predefined factory parameters may be subject to modification following application update.

FIG.20   **FIG.21**   **FIG.22**   **FIG.23**   **FIG.24**

8.4.4 Hide / show operations

FIG.20

A. Do a long tap on an operation which is not hidden to activate the hide function and display the icons 👁 (2) and 👁 (3).

B. To hide an operation, tap it in the list, the icon 👁 (2) will pass to 👁 (3).

C. To show an operation, tap it in the list, the icon 👁 (3) will pass to 👁 (2).

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

Note 20

8.5 Create new operations (user-defined)

FIG.21

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

FIG.22

B. Tap ➕ to create a new operation type.

↪ The Operations screen opens.

Note 21

FIG.23

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

FIG.24

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

E. Set handpiece ratio and operation settings.

F. Tap Cancel or Save (2) to validate user-defined operation and tap back, FIG. 23.

↪ If saved, the new operation is displayed in the Operations screen (5) with the symbol 👤 (user-defined) beside it, FIG. 22.

G. Select an operation.
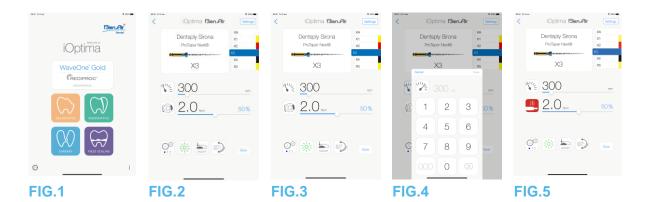
↪ The app navigates back to operative screen.

NOTES

20 When an operation is hidden, it doesn't show anymore in the operative screen, so the user can show only the operation that he wants to use.

21 Maximum storage of 20 user-defined operations, if reached the ➕ icon disappears

| **FIG.1** | **FIG.2** | **FIG.3** | **FIG.4** | **FIG.5** |

9. Operation – Endodontics mode

9.1 Enter Endodontics mode

Tap [icon] 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

9.2 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, indicative percentage of maximum torque that can be delivered is also displayed (or according to settings, see chapter "7.6 Settings")
(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

9.2.1 Micromotor Speed & Torque

FIG.3

Slide to adjust the maximum speed and torque values.

Or tap the icons [icon] [icon] to enter a precise value.
FIG.4

Enter the motor speed or torque values and tap **Cancel** or **Done** to validate.
Note 4

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.

FIG.6

FIG.7

FIG.8

9.2.2 Handpiece ratio

FIG.6

Tap and select to modify the handpiece ratio.

⚠ CAUTION

Verify that the handpiece corresponds to your selection.

Note 5 – 6 – 7

9.2.3 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 8 – 9

9.2.4 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 10

> NOTES
>
> **1** In endodontics mode, the motor cooling air is always switched OFF by the help of the electro-valve integrated in the iOptima/iOptimaINT unit.
>
> **2** Save and create ✚ buttons are disabled if a lock is set (see chapter "7.7 Settings").
>
> **3** All parameters can be changed and saved directly in the operative screen (except if a lock is set).
>
> **4** If the entered value is out of range, the maximal or minimal value will be indicated.
>
> **5** The operative screen always displays the selected handpiece ratio.
>
> **6** If a different ratio than 8:1 Bien-Air or 1:1 Bien-Air is chosen, please note that the displayed torque values cannot be guaranteed any longer (they represent a purely indicative information).
>
> **7** The handpiece ratio is red-colored for multiplication gears, blue-colored for direct-drive, and green-colored for reduction gears.
>
> **8** The light intensity value is set for each operation. The default value of the light intensity is 100%.
>
> **9** The operative screen always displays the selected light intensity value.
>
> **10** The operative screen always displays the selected footpedal mode.

FIG.9   **FIG.10**   **FIG.11**   **FIG.12**   **FIG.13**

9.2.5   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 11 – 12

9.3 Standard Use – Operating mode (Start)

FIG.10

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

Note 13

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 14

The app navigates back to the operative screen, FIG. 14.

   Press the dental unit pedal to switch ON the micromotor.

⚠ CAUTION

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

FIG.14

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 (1)).

Note 15 – 16

9.4 Customize settings

9.4.1 Customize default settings (operative screen)

FIG.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 17

FIG.14　　FIG.15　　FIG.16　　FIG.17　　FIG.18

9.4.2 Customize system settings

FIG.16

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

FIG.17

B. Tap a **Brand** to open the **Systems** screen.

C. Tap ⊘ 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 "9.5 Add, sort or remove files for details.

Tap **Cancel** (1) or **Save** (2) to validate custom settings.

☞ If saved, the symbol 🏭 (factory predefined settings) changes to 👤 (custom settings).

Note 18
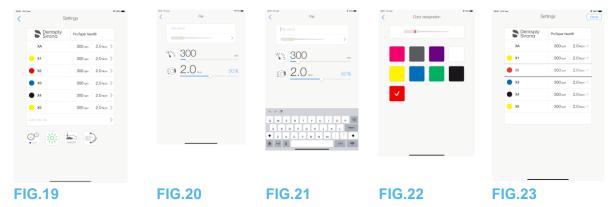
See chapter "9.7 Create new Brands and Systems", for details.

NOTES

11 The operative screen always displays the selected rotation direction.

12 In reverse mode (CCW), the symbol flashes and there is a sound alert (alternate medium beeps).

13 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).

14 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 "9.8 CA ENDO / Reciproc option".

15 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.

16 All parameters can be directly modified in the operative screen (only when the footpedal is released). See chapter "9.4.1
Customize default settings (operative screen)".

17 Modifications are discarded when leaving the operative screen without saving.

18 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.

FIG.19 FIG.20 FIG.21 FIG.22 FIG.23

9.5 Add, sort or remove files

Note 19

9.5.1 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 "9.2 Operative screen description" for details.
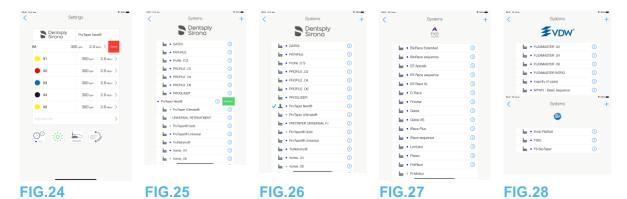
Tap back (2) and **Save** (1), FIG. 19.

9.5.2 Sort files

FIG.23

A. Do a long tap on a file to activate the drag and drop function

and display the icons ≡ (2).

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

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

FIG.24   **FIG.25**   **FIG.26**   **FIG.27**   **FIG.28**

9.5.3   Remove files

FIG.24

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

9.6 Restore (default) and delete (userdefined) systems

FIG.25

Swipe left to restore or delete.

Note 20 – 21

9.6.1   Default Systems

FIG.26

Dentsply Sirona

Note 22

FIG.27

FKG swiss endo

FIG.28

Komet

VDW

⚠️CAUTION

The parameters contained in the dental procedures are indicative only. Bien-Air Dental cannot be held liable for them.
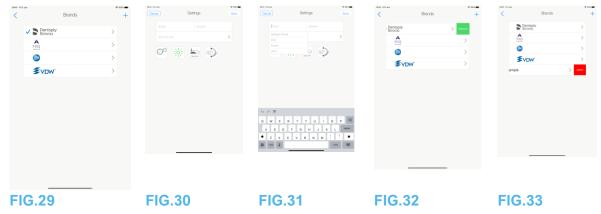
Note 23

<div style="background:#d9e0e6;">

NOTES

19 New files can be added, sorted or removed in default and user-defined files.

20 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.

21 Custom and user-defined operations are represented by 👤 . Default operations are represented by 🏭.

22 Predefined endo file systems foreseeing the reciprocating movement need activation on the iOptimalNT system. In case the movement wasn't previously activated, taping it leads to the activation page.

See chapter "9.8 CA ENDO / Reciproc option".

23 The predefined factory parameters may be subject to modification following application update.

</div>

| FIG.29 | FIG.30 | FIG.31 | FIG.32 | FIG.33 |

9.7 Create new Brands and Systems

FIG.29

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

Note 24 - 25

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 "9.5.1 Add new files".

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 "9.2 Operative screen description" for details.

G. Tap Save (3).
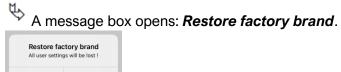
9.7.1   Restore (custom) and delete (userdefined) brand

Note 26 - 27

Restore default brands (factory settings)

A. Swipe left on a default brand.

☝ A message box opens: ***Restore factory brand***.

Restore factory brand
All user settings will be lost !

Cancel   Restore
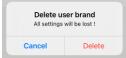
B. Tap **Cancel** or **Restore** to acknowledge.

Delete user-defined brands

A. Swipe left on a user-defined brand.

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

Delete user brand
All settings will be lost !

Cancel   Delete

B. Tap Cancel or Delete to acknowledge.

| **FIG.34** | **FIG.35** | **FIG.36** | **FIG.37** | **FIG.38** |

9.8 CA ENDO / Reciproc option

FIG.34

It is only possible to access the CA ENDO mode with the iOptimaINT system.

Tap [WaveOne RECIPROC ENDODONTICS] to enter the CA ENDO mode.Predefined endo file systems foreseeing the reciprocating movement need activation on the iOptimaINT system. In case the movement wasn't previously activated, tapping it leads to the activation page.

9.8.1 Activation page

FIG.35

A. Tap *More information* and follow the instructions displayed.
B. Input the code obtained and tap *Activate* (2).
C. If activated the app navigates to the operative screen.

9.8.2 Operative screen

FIG.36

The pedal symbol (3) invites the user to press it.
Press the dental unit pedal to switch ON the micromotor.
FIG.37

The movement symbol (4) displays the tool progression.
Note 28 – 30

⚠️CAUTION
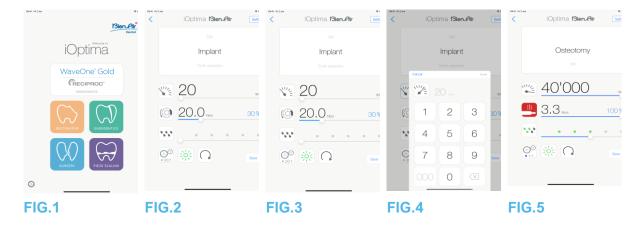
- Valid only with Bien-Air CA ENDO.
- CA ENDO must be used only with specific files.

NOTES
24 New systems and brands can also be created directly from the system screen.
25 Maximum storage of 10 user-defined brands and 10 systems per brand, if reached the icon disappears.
26 Restore ALL default system settings from the Brands screen.
27 It is only possible to delete user-defined brands
28 If an ENDO file system foreseeing the reciprocating movement is selected, speed, torque, motor direction, light, pedal mode disappear and the gear ratio is fixed.

29 When the power demand of the MX2 micromotor is excessive, the operative screen displays the overheating symbol (5). In this case the iOptimalNT 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.

30 If stress is excessive on the file, the file stress alert message appears (6).

| FIG.1 | FIG.2 | FIG.3 | FIG.4 | FIG.5 |

10. Operation - Surgery mode

It is only possible to access the surgery mode with the iOptimaINT and MX-i micromotor system. To set a holder with the MX-i micromotor, please contact a service engineer certified by Bien Air Dental SA. If only one holder is set, it will not be possible to access any other mode.

10.1 Enter Surgery mode

FIG.1

Tap [icon] to enter the surgery mode.

Note : If the MX-I motor don't have an holder integrated on the dental unit. The user can operate the motor by pressing foot control pedal. Predefined oral surgery 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

10.2 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) MX-i micromotor rotation mode: FORWARD and REVERSE
(4) Save (customize settings)
(5) Light intensity
(6) Handpiece ratio
(7) Maximum MX-i micromotor torque in Ncm, indicative percentage of maximum torque that can be delivered is also displayed (or according to settings, see chapter "7.6 Settings)
(8) Maximum MX-i micromotor speed in rpm
(9) Back to the previous screen
(10) Irrigation level

Note 2- 3

See chapter "10.3 Standard Use - Operating mode (Start)".

10.2.1 MX-i micromotor Speed & Torque

FIG.3

Slide to adjust the maximum speed and torque values.

Or tap the icons to enter a precise value.

FIG.4

Enter the motor speed and torque values and tap **Cancel** or **Done** to validate.

Note 4

FIG.6   **FIG.7**

FIG.5
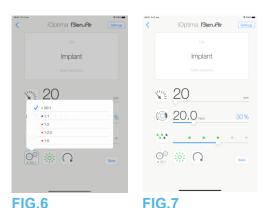
When the power demand of the MX-i micromotor is excessive, the operative screen displays

the overheating symbol . In this case the iOptimaINT unit automatically lowers the torque in order to avoid overheating of the MX-i micromotor. To restore maximum torque, allow the motor to idle or stop for a few seconds.

10.2.2 Handpiece ratio

FIG.6

Tap and select the handpiece ratio.

⚠️CAUTION

Verify that the handpiece corresponds to your selection.

Note 5 – 6

10.2.3 Irrigation level

FIG.7

Slide or tap the appropriate dot to set up the irrigation level. 6 levels of adjustment are possible from 0 ml/min (OFF) to 120 ml/min.

Note 3 - 7 – 8

NOTES

1 Save and create ➕ buttons are disabled if a lock is set (see chapter "7.7 Settings").

2 All parameters can be changed and saved directly in the operative screen (except if a lock is set).

3 Irrigation level button is hidden if pump control kit is not installed. To install it, please contact a service engineer certified by Bien-Air Dental SA.

4 If the entered value is out of range, the maximal or minimal value will be indicated.

5 The handpiece ratio is red-colored for multiplication gears and blue-colored for direct-drive, and green-colored for reduction gears.

6 The operative screen always displays the selected handpiece ratio.

7 The irrigation value is set for each operation. The default value of the irrigation level is irrigation OFF for Implant operation.

8 The operative screen always displays the selected irrigation level value. For example correspond to an irrigation level value of 60%.

FIG.8   **FIG.10**   **FIG.11**   **FIG.12**

10.2.4 Light intensity

FIG.8

Slide or tap the appropriate dot to set up the light intensity of the MX-i 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 9 – 10

10.2.5 MX-i micromotor rotation direction

Tap to change the rotation mode of the MX-i micromotor:

- **Forward** (clockwise)
- **Reverse** (counterclockwise).

Note 11 – 12

10.3   Standard Use - Operating mode (Start)

FIG.10

A. Tap [icon] to enter the SURG mode, the operative screen opens.
Note 13
FIG.11
B. Tap Settings to open the Operations screen.
Note 14
FIG.12
C. Tap to select an operation type.

The App navigates back to the operative screen.
D. Press the dental unit pedal to switch ON the MX-i micromotor.
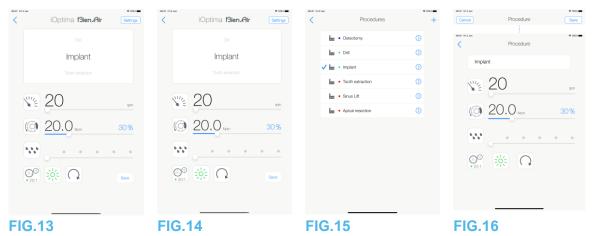
⚠️CAUTION

If the footpedal is pressed before entering in operative mode, an alert message «Please release pedal…» will be displayed. The MX-i micromotor will not start to run until the footpedal is released and pressed again. If a micromotor else than MX-i is unhooked, the previous operative mode used with that motor is displayed, so far as an operative mode has already been defined for that motor. If not, Home page will be displayed instead.
FIG.13
Note 15 - 16

- Slide to adjust the MX-i micromotor speed and torque values of the selected operation.

FIG.13   **FIG.14**   **FIG.15**   **FIG.16**

- Adjust the handpiece ratio, light intensity or rotation direction of the selected operation.
- Tap *Save* (3) to validate the new settings.

Note 17

E. Tap the operation type above (1) or below (2) the selected operation type to navigate to the operation respectively preceding or following the current one in the predefined operation list.

See chapter "10.4.3 Sort operations" to sort operations in the list.

10.4   Customize default operations

FIG.14

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

FIG.15

B. Tap ⊘ 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 👤 (custom settings).

E. Select an operation.
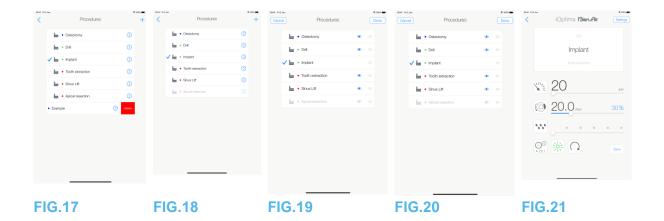
↳ The app navigates back to operative screen.

NOTES

9 The light intensity value is set for each operation. The default value of the light intensity is 100%.

10 The operative screen always displays the selected light intensity value.

11 In reverse mode (CCW), the symbol flashes and there is a sound alert (alternate medium beeps).

12 The operative screen always displays the selected rotation direction.

13 Each time you pull a motor from a holder (from the Homepage), the operative mode previously used with that motor is displayed by default.

14 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.

15 When the MX-i 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.

16 All parameters can be directly modified in the operative screen (only when the footpedal is released).

17 Modifications are discarded when leaving the operative screen without saving.

FIG.17   **FIG.18**   **FIG.19**   **FIG.20**   **FIG.21**

10.4.1 Restore (default) and delete (userdefined) operations

FIG.17

Swipe left to restore or delete.

Note 18 – 19

10.4.2 Default Operations

FIG.18

⚠ CAUTION

The parameters contained in the dental procedures are given for information ONLY. Bien-Air Dental cannot be held liable for them.

Note 20

10.4.3 Sort operations

FIG.19

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

10.4.4 Hide / Show operations

FIG.20

A. Do a long tap on an operation which is not hidden to activate the hide function and display the icons (2) and (3).
B. To hide an operation, tap it in the list, the icon (2) will pass to (3).
C. To show an operation, tap it in the list, the icon (3) will pass to (2).
D. Tap Done (1) to validate.***Note 21***

10.5   Create new operations (user-defined)

FIG.21

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

FIG.22

B. Tap to create a new operation type.

⇗ The Operations screen opens.

Note 22

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

FIG.22   **FIG.23**   **FIG.24**

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

E. Set handpiece ratio and operation settings.

F. Tap *Cancel* or *Save* (2) to validate user-defined operation and tap back, FIG. 23.
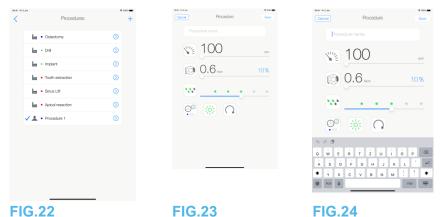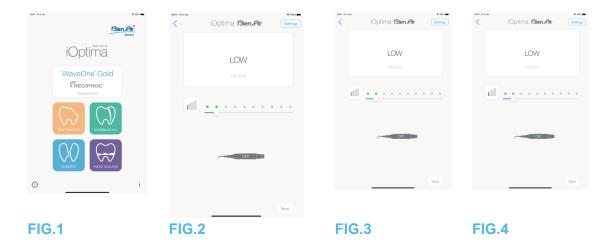
⇗ If saved, the new operation is displayed in the *Operations* screen (5) with the symbol 👤 (user-defined) beside it, FIG. 20.

G. Select an operation.

⇗ The app navigates back to operative screen.

NOTES

18 Predefined SURG operations can not be deleted. But it is possible to restore the default values if modified. Only user-defined operations can be deleted.

19 Custom and user-defined operations are represented by 👤 . Default operations are represented by 🏭 .

20 The predefined factory parameters may be subject to modification following application update

21 When an operation is hidden, it doesn't show anymore in the operative screen, so the user can show only the operation that he wants to use.

22 Maximum storage of 20 user-defined operations, if exceeded the icon ＋ disappears.

FIG.1   **FIG.2**   **FIG.3**   **FIG.4**

11.   Operation – Piezo scaling mode

It is only possible to access the piezo scaling mode with the iOptimaINT and piezo scaler system. To set a holder with the piezo scaler, please contact a service engineer certified by Bien-Air Dental SA. Multiple holder must be set to access to this mode.

11.1   Enter Piezo scaling mode

FIG.1

Tap [icon] to enter the piezo scaling mode. Predefined piezo scaling 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

11.2   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) Piezo scaler status
(4) ***Save*** (customize settings)
(5) Power level
(6) Back to the previous screen
Note 2
See chapter "11.3 Standard Use - Operating mode (Start)".

11.2.1 Power level

FIG.3

Slide to adjust the power level value.

11.3   Standard Use - Operating mode (Start)
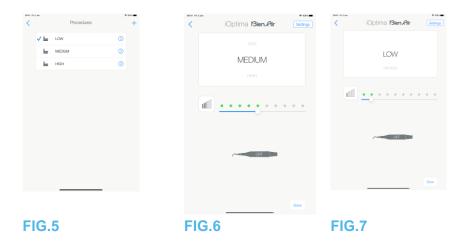
Note 3
FIG.4

A. Tap Settings to open the Operations screen.
FIG.5

B. Tap to select an operation type.

👆 The App navigates back to the operative screen.

C. Press the dental unit pedal to switch ON the piezo scaler.

FIG.5   **FIG.6**   **FIG.7**

⚠CAUTION

If the footpedal is pressed before entering in operative mode, an alert message «Please release pedal…» will be displayed. The piezo scaler will not start to run until the footpedal is released and pressed again. If a micromotor else than piezo scaler is unhooked, the previous operative mode used with that motor is displayed, so far as an operative mode has already been defined for that motor. If not, Home page will be displayed instead.

FIG.6

Note 4

- Slide to adjust the piezo scaler power level value of the selected operation.
- Tap Save (3) to validate the new settings.

Note 5

D. Tap the operation type above (1) or below (2) the selected operation type to navigate to the operation respectively preceding or following the current one in the predefined operation list. *See chapter "11.4.3 Sort operations" to sort operations in the list.*

11.4   Customize default operations

FIG.7

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

NOTES

1 Save and create ➕ buttons are disabled if a lock is set (see chapter "7.7 Settings" on).

2 All parameters can be changed and saved directly in the operative screen (except if a lock is set).

3 Each time you pull a motor from a holder (from the Home page), the operative mode previously used with that motor is displayed by default.

4 All parameters can be directly modified in the operative screen (only when the footpedal is released).

5 Modifications are discarded when leaving the operative screen without saving.

FIG.8   **FIG.9**   **FIG.10**   **FIG.11**   **FIG.12**
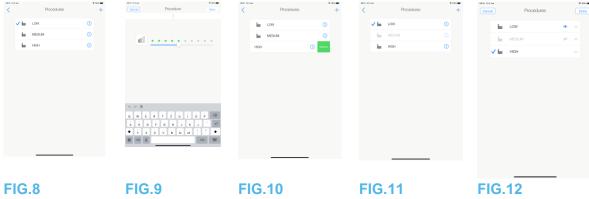
FIG.8

B. Tap ⊘ to customize an operation type.

↳ The Operation screen opens.

FIG.9

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 👤 (custom settings).

E. Select an operation.

↳ The app navigates back to operative screen.

11.4.1 Restore (default) and delete (userdefined) operations

FIG.10

Swipe left to restore or delete.
Note 6 – 7

11.4.2 Default Operations

FIG.11

⚠️CAUTION

The parameters contained in the dental procedures are given for information ONLY. Bien-Air Dental cannot be held liable for them.
Note 8

11.4.3 Sort operations

FIG.12

A. Do a long tap on an operation to activate the drag and drop function and display the icons (2).

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

C. Tap Done (1) to validate.
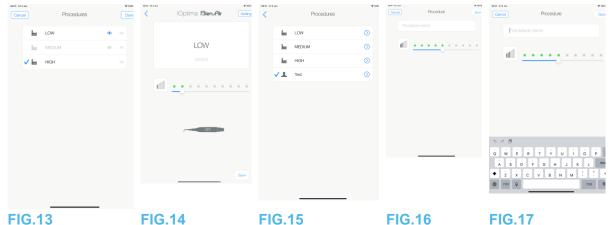
11.4.4 Hide / Show operations

FIG.13

A. Do a long tap on an operation which is not hidden to activate the hide function and display the icons (2) and (3).

B. To hide an operation, tap it in the list, the icon (2) will pass to (3).
C. To show an operation, tap it in the list, the icon (3) will pass to (2).
D. Tap Done (1) to validate.
Note 9

11.5   Create new operations (user-defined)

FIG.14
A. From the operative screen, tap Settings to open the Operations screen.
FIG.15
B. Tap to create a new operation type.

The Operations screen opens.
Note 10
FIG.16
C. Tap in the Operation name text field (1) to display the onscreen
keyboard.
FIG.17
D. Type the new Operation name (3) and tap Done (4).
E. Set power value setting.
F. Tap Cancel or Save (2) to validate user-defined operation and tap back, FIG. 16.

If saved, the new operation is displayed in the Operations screen (5) with the symbol
(user-defined) beside it, FIG. 15.
G. Select an operation.

The app navigates back to operative screen.

NOTES

6 Predefined PIEZO operations can not be deleted. But it is possible to restore the default values if modified. Only user-defined operations can be deleted.

7 Custom and user-defined operations are represented by .Default operations are

represented by .

8 The predefined factory parameters may be subject to modification following application update

9 When an operation is hidden, it doesn't show anymore in the operative screen, so the user can show only the operation that he wants to use.

10 Maximum storage of 20 user-defined operations, if exceeded the icon ＋ disappears.

12. List of errors & Troubleshooting

12.1 Alert messages (Operating)

Description	Message	Cause of alert	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		Motor drive limits delivered torque to prevent motor overheating.	Avoid extended use. Let system cool down.
iPod touch®/iPad mini® speaker OFF	Please switch ON sound volume on your iPod touch®/iPad mini® and set it to an appropriate level according to the ambient noise level in your practice room.	iPod touch®/iPad mini® speaker was switched OFF, or sound volume was disabled by user. It is necessary to have iPod touch®/iPad mini® speaker turned ON so that system sound notifications and alarms may be heard distinctly.	Turn iPod touch®/iPad mini® speaker ON and set sound volume to an appropriate level.
Non-verified iOS version in use		iOS version installed on the iPod touch®/iPad mini® 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 touch®/iPad mini® with new iOS versions unless Bien-Air recommends to do so. If the iPod touch®/iPad mini® 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 touch®/iPad mini®.	It is highly recommended to consult the updated User Manual before using the system.
Motor torque threshold limit reached, file stress condition encountered		System detects that motor torque threshold limit is reached.	Release file pressure. Slow down treatment.

12.2 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.	1. Check motor connection. 2. 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.	1. Replace motor cable. 2. 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.	1. Wait for system cooling. 2. 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 (see section 12.3.5 for iOptima^{INT} and section 6.3.4 B for iOptima) 2. Disconnect iPod touch®/iPad mini® device from unit 3. Close iOptima application 4. Switch unit back ON 5. Reconnect iPod touch®/iPad mini® device to unit 6. Restart iOptima application 7. If problem persists, contact Bien-Air Dental SA.

12.3 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 x.y.z text section is displayed in red color.	• Configuration in use is significantly different from

- Currently installed iOS was updated for major or at least significant changes compared to iOS verified during app validation

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

13. 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.

13.1 Servicing

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

Service period

The device was tested by simulating more than 6,000 clinical procedures (corresponding to a service period of 4 to 6 years).

Note 1

13.2 Cleaning

- Clean the surfaces of the iOptima unit / iOptimaINT dock-in 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).
- Do not immerse in disinfectant solution.
- Do not immerse in an ultrasonic bath.

13.3 Important

For maintenance of micromotors and hoses: See IFU

Product	Micromotor	IFU	Hose	IFU
iOptima & iOptimaINT	MX2 LED	2100199	MX2	2100223
iOptimaINT	MCX LED	2100231	MCX	2100230
iOptimaINT	MX-i	2100245	MX-i	2100163

13.4 iOptimaINT

Refer to the iOptimaINT installation manual

⚠️CAUTION

Only a qualified service engineer is permitted to open the dental unit and repair the iOptimaINT system.

14.   Legal and general

14.1   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.

14.2   Trademarks

ProTaper Next® is a trademark of DENTSPLY SIRONA Inc.
WaveOne®, WaveOne® Gold and Reciproc® are registered trademarks of DENTSPLY SIRONA Inc.
DENTSPLY MAILLEFER® is a trademark of DENTSPLY SIRONA Inc.
Reciproc® is registered trademarks of VDW GmbH

14.3   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
- 12 months for integrable electronic boards
- 24 months for the iOptima/iOptimaINT unit
- 36 months for series 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.

14.4   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 2012/19/EU).

Limitation of liability

Bien-Air Dental SA shall not be held liable for any non-compliant use of the iPod touch® or iPad mini®.
The conditions for and restrictions on use set by Apple must be respected (jailbreak, hardware modification, etc.).
To ensure optimum operation of the iOptima application, iOS updates must be according to version used during validation of the application.

15. Electromagnetic compatibility (technical description) for iOptimaINT

15.1.1 Electromagnetic compatibility precaution for use

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. EMC tests have been performed for the iOptimaINT system REF 1601076, while micromotors MX2 and MX-i LED were connected but without additional devices (piezo-scalers or irrigation pump). The verification of the electromagnetic compatibility according to IEC 60601-1-2 of the final installed configuration is under the responsibility of the unit-integrator. 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.

15.1.2 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.

Emission 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	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.
Harmonic emissions IEC 61000-3-2	Class A	
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 ±2 kV air ±4 kV air ±8 kV air ±15 kV air	±8 kV contact ±2 kV air ±4 kV air ±8 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.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT for 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles at 0°	0% UT for 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles at 0°	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 recommended 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 VRMS 0,15 MHz – 80 MHz 6 VRMS in ISM bands 0,15 MHz – 80 MHz 80% AM at 1 kHz	3 VRMS 0,15 MHz – 80 MHz 6 VRMS in ISM and amateur bands 0,15 MHz – 80 MHz 80% AM 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	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	

Proximity fields from RF wireless communications equipment IEC 61000-4-3	Test freq. [MHz]	Max. power [W]	Immunity test level [V/m]	Distance: 0.3 m
	385	1.8	27	
	450	2	28	
	710, 745, 780	0.2	9	
	810, 870, 930	2	28	
	1720, 1845, 1970	2	28	
	2450	2	28	
	5240, 5500, 5785	0.2	9	

NOTE: UT 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 ±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 iOptimaINT is used exceeds the RF compliance level mentioned above, the iOptimaINT 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 iOptimaINT.

iOptima description

16. Symbols

16.1 Description of symbols for iOptima unit

Symbol	Description	Symbol	Description
CE 0123	CE Marking with number of the notified body.	$((\cdot))$	Non-ionizing electromagnetic radiation.
(Manufacturer symbol)	Manufacturer.	$\sim$	Alternating current.
REF	Catalogue number.	$\bigcirc$	OFF (power).
SN	Serial number.		ON (power).
MD	Medical Device.	(Data Matrix)	Data Matrix code for product information including UDI (Unique Device Identification).
Rx Only	Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.	(speaker)	Sound alerts.
⚠	WARNING: hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.	⚠	CAUTION: hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.
(crossed-out bin)	Separate collection of electric and electronic equipment.	(rotation arrow)	Movement to the stop in the direction indicated.
📖 i	Consult instructions for use or consult electronic instructions for use (https://dental.bienair.com/fr_ch/support/download-center/).	(4-hole connector)	4-hole connection and 4 electric (4VLM).
♻	General symbol for recovery/recyclable.	EC REP	Authorized EC Representative in the European Community.
(thermometer)	Temperature limit.	(humidity)	Humidity limitation.
(umbrella with rain)	Keep away from rain.	(pressure)	Atmospheric pressure limitation.

16.2 Description of symbols for iOptima accessories

Symbol	Description	Symbol	Description
CE XXXX	CE Marking with number of the notified body.		Separate collection of electric and electronic equipment.
	Manufacturer.	SN	Serial number.
REF	Catalogue number.		Electrical safety. Applied part type B.
MD	Medical Device.		Data Matrix code for product information including UDI (Unique Device Identification).
EC REP	Authorized EC Representative in the European Community.	Rx Only	Warning: in accordance wit federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.
135°C	Sterilization up to the specified temperature.		

17.   Identification, Intended use and Notation

17.1   Identification

iOptima

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

The iOptima unit charges the iPod touch® battery when connected.

The restorative, endodontics parameters are defined before operation using the iOptima application installed on the iPod touch®.

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 operating systems (iOS & iPadOS).

⚠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.

17.2   Intended use

Product intended for professional use only. The iOptima systems are intended for use in restorative dentistry, endodontics, dental prophylaxis, and orthodontics by dentists and dental professionals in a dental office.

FIG.1

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

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

Note 1

17.3   Notation

- **A**, **B**, **C**, etc.

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

- ⇩

    Indicates a procedure result.

- **(1)**, **(2)**, **(3)**, etc.

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

- *OK*, *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*.

> **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.

18.   User and Patient safety: Warnings & Precautions of Use

To prevent any risk of explosion, the warning below must be observed:

⚠️WARNING

According to IEC 60601-1:2005+A12012/AnnexG, electrified devices (motors, control units, couplers and attachments), can be safely used in a medical environment in which potentially explosive or flammable mixtures of anaesthetic substances are delivered to the patient only if:

3. The distance between the motor and the anaesthetic breathing circuit exceeds 25 cm.
4. The motor is not used simultaneously to the administration of the anaesthetic substances to the patient.

To prevent any risk of electric shock, the warning below must be observed:

⚠️WARNING

- The iOptima unit must be connected only to a power supply network provided with a protective earth.

To prevent any risk of motor overheating, the cautions below must be observed:

⚠️CAUTION

- Ensure that the micromotor hose is not bent.

- The iPod touch® must never be disconnected from the iOptima dental unit during operation.

To prevent any risk of injury (damage to bone, teeth, tissue) the caution below must be observed:

⚠️CAUTION

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

- The parameters contained in the dental procedures are indicative only. Bien-Air Dental SA cannot be held liable for them.

To prevent any risk of injury and/or material damage the cautions below must be observed:

⚠️CAUTION

- Never connect a handpiece on a running micromotor.

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

Note 1

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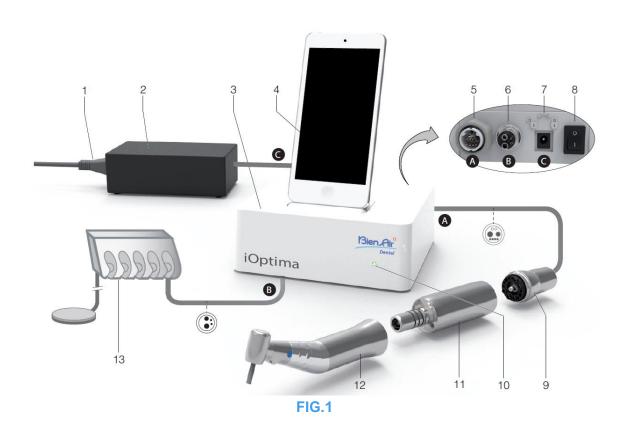
1 The predefined parameters may be subject to modification without notice.

19. Description

19.1 iOptima system overview

The iOptima system consists of:
- iOptima unit (3) with docking station for iPod touch® (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**).

FIG.1

(1)	Power supply cord	**(8)**	Main power switch
(2)	Power Supply **(C)**	**(9)**	MX2 micromotor hose* **(A)**
(3)	iOptima unit	**(10)**	iOptima status light (green power on)
(4)	iPod touch® [not provided in set]	**(11)**	MX2 micromotor*
(5)	MX2 micromotor hose output **(A)**	**(12)**	Handpiece* [not provided in set]
(6)	4-way connector input, air and water inlet from your pneumatic unit **(B)**	**(13)**	Dental unit with pedal **(B)** [not provided in set]
(7)	Power input connector (with lock) **(C)**		*Applied parts (per IEC 60601-1)*

19.2   iOptima system table

Summary of the iOptima functions and technological features.

Product	Device	Technology	Motor	Restorative	Endodontics	Oral surgery	Implantology	Prophylaxis
iOptima	iPod touch®	DMX2	MX2	X	X	-	-	X

19.3   Set supplied

19.3.1 iOptima system

iOptima set REF 1700563-001

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, lengfh 2.00 m (1x)	1300067-001
iOptima bracket	1501988-001

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, lengfh 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, lengfh 2.00 m (1x)	1300067-001

19.4   Options

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

19.5   Technical data

Dimensions L x W x H
iOptima unit.. 125 x 145 x 75 mm
iOptima unit (with iPod touch®)... 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 g

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	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 "12 List of errors & Troubleshooting".

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

Product	Micromotor	IFU	Hose	IFU
iOptima	MX2 LED	2100199	MX2	2100223

19.6   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 2012/19/EU).

Limitation of liability

Bien-Air Dental SA shall not be held liable for any non-compliant use of the iPod touch®.
The conditions for and restrictions on use set by Apple must be respected (jailbreak, hardware modification, etc.).
To ensure optimum operation of the iOptima application, iOS updates must be according to version used during validation of the application.

FIG.1   **FIG.2**   **FIG.3**   **FIG.4**

20.   Installation

20.1   Install the iOptima app

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

20.2   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 «O».

⚠ 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.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 your dental unit instructions).
H. Switch ON the iOptima (1) («I» = ON).

⇪ The led (4) turns green (power ON).

I. Once it has been switched ON, connect the interface device «iPod touch®» (2) to the iOptima carefully sliding it along the lightning adapter (3).

⇪ The iOptima is ready for use.

See chapter "20 Interface overview".

NOTES	
1	The iPod touch® must be correctly connected to a Wi-Fi network before the App Store is opened; refer to Apple's user guide or appropriate use of the iPod touch®..
	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" 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.
3	The equipment is powered by your mains power supply (100- 240 VAC).

21. Interface overview

21.1 iOptima application

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

⚠️CAUTION

Always verify that the latest version of the software is used. It is recommended to connect the unit to the Internet periodically to detect if an app update is available.

21.1.1 Compatibility

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

21.1.2 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».

21.2 Sound alerts

Sound alert	Description
One short beep	Enterring ENDO or RESTORATIVE with micromotor REVERS
	Selecting micromotor REVERS
Alternate short beeps	Alert message notifications (see chapter 12)
Alternate medium beeps	Micromotor REVERSE running indicator
	ENDO mode when the micromotor is running in reverse
Alternate long beeps	System failure notification (see chapiter 12)

21.3 iPod touch® and iOptima connection / disconnection conditions

21.3.1 Disconnection

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

21.3.2 Connection

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

⚠️CAUTION

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

21.3.3 iOptima unit switched ON

If the iOptima app is running and the iPod touch® plugged to the iOptima (switch ON):
- The iPod touch® 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).

FIG.1

21.3.4 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 "19.1 Install the iOptima app" for details.

21.4 Electromagnetic compatibility (technical description) for iOptima
21.4.1 Electromagnetic compatibility warnings

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

⚠ CAUTION

The iOptima 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, 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.

21.4.2 Electromagnetic compatibility – emissions & immunity

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.

Emission test	compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The iOptima 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	The iOptima 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.
Harmonic emissions IEC 61000-3-2	Class A	
Emissions due to voltage fluctuations IEC 61000-3-3	Conforming	

Guidance and manufacturer's declaration – Electromagnetic immunity

The iOptima is intended for use in the electromagnetic environment specified below. The customer or the user of the iOptima 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 ±2 kV air ±4 kV air ±8 kV air ±15 kV air	±8 kV contact ±2 kV air ±4 kV air ±8 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.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT for 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles at 0°	0% UT for 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles at 0°	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 recommended that the iOptima 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	3 VRMS 0,15 MHz – 80 MHz	3 VRMS 0,15 MHz – 80 MHz	Field strengths from fixed RF transmitters, as determined by an

induced by RF fields IEC 61000-4-6	6 VRMS in ISM bands 0,15 MHz – 80 MHz 80% AM at 1 kHz	6 VRMS in ISM and amateur bands 0,15 MHz – 80 MHz 80% AM at 1 kHz	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	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	

Proximity fields from RF wireless communications equipment IEC 61000-4-3	Test freq. [MHz]	Max. power [W]	Immunity test level [V/m]	Distance: 0.3 m
	385	1.8	27	
	450	2	28	
	710, 745, 780	0.2	9	
	810, 870, 930	2	28	
	1720, 1845, 1970	2	28	
	2450	2	28	
	5240, 5500, 5785	0.2	9	

NOTE: UT 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 ±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 is used exceeds the RF compliance level mentioned above, the iOptima 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.

Note 1 – 2

NOTES	
1	The predefined parameters may be subject to modification without notice.
2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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