

iOptima^{INT}

ENG Installation instructions.



Compatible Apple devices list is available on Bien-Air website :<u>https://dental.bienair.com/</u>



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1. Symbols

Symbol	Description	Symbol	Description
CE 0123	CE marking with number of the notified body	$((\cdot,\cdot))$	Non-ionizing electromagnetic radiation.
	Manufacturer	\sim	Alternating current.
REF	Catalogue number.	\bigcirc	OFF (power).
SN	Serial number.		ON (power).
Rx Only	Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.		Sound alerts.
X	Recyclable electrical and electronic material		General symbol for recovery/recyclable
Ĩ	Consult instructions for use or consult electronic instructions for use (https://dental.bienair.com/fr_ch/support/download- center/).		Movement to the stop in the direction indicated
	Data Matrix code for product information including UDI (Unique Device Identification).	MD	Medical device
\triangle	WARNING! hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.	\triangle	CAUTION! hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.
EC REP	Authorized EC Representative in the European Community.	Ť	Keep away from rain
xx*	Temperature limit.	x%X%	Humidity limitation.
X hPg	Atmospheric pressure limitation.		

2. Identification & Intended Use

2.1.Identification

Electronic control for Bien-Air Dental SA MX2, MCX and MX-i LED brushless and sensorless micromotors.

2.2.Intended use

Refer to the iOptima^{INT} IFU (Ref 2100279).

2.3.Notation

- **A**, **B**, **C**, etc. Text preceded by a letter indicates a procedure to be carried out step-by-step.
- (1), (2), (3), etc. Text preceded by a number indicates text used in conjunction with an illustration.

3. Description

3.1.System overview

Electronically controlled integrated unit for dentistry allowing operation of multiple micromotors (MX2,MCX and MX-i LED) with variable speed using the dental unit pedal. It is essential to connect a compatible iPod touch® or iPad mini® using the USB connector with the provided docking station.

3.2. Technical data

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.

Electrical and pressure data

Voltage	100-240 VAC
Frequency	.47-63 Hz
Nominal power	90 W
Max. input power	160 W
Operating voltage	32 Vdc
Operating current	Max 4.6 A
Max. input pneumatic pressure	.5 bar / 72.5 psi
Min. input pneumatic pressure	3 bar / 43.5 psi

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

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).

Important:	Consult the	Instructions f	for Use	of the	following	devices:
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Device	IFU	REF
Motor MX2	2100199	1600677-001
Motor MX-i LED	2100245	1600755-001
Hose MX2	2100223	1600809-001
Hose MX-i LED	2100163	1600606-001
Control DMX3 set	2100278	1600903-001
iOptima ^{៲ℕ}	2100279	1601074/5/6-001
Motor MCX	2100231	1600751-001

3.3. 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 device to their distributors or directly contact an approved body responsible for processing and recovering this type of equipment (European directive 2012/19/EU).

4. Installation

Before use, please read these installation instructions and the iOptimalNT operating instructions (2100279) carefully. Switch ON only when the system is ready for use.

To conform with IEC 60601-1-2 standards, consider the different routes of the wires through the unit (bend, fold, section etc) and only use the transformer provided with the kit (Refer to "5.3 DMX3 wiring").

To maintain warranty, this device must be installed with the greatest care. Follow all the necessary instructions.

4.1. Docking and bracket

A. Center the docking (1) into the bracket (2) and tighten both screws (3) using socket wrench REF 1000031-001 and M3 TORX-S Screw Head REF 3300404-001.

B. Fix the bracket onto the left or right connection bracket (4), adjust the desired angle for the device and tighten both bolts (5) using socket wrench REF 1000031-001 and M4 TORX-S Screw Head REF 1307307-001.

C. Add the caps (6) to hide the screws and the nuts.

D. Drill $2 \times \emptyset$ 3.5 to 4 mm (9/64" to 5/32") holes in the dental unit.

E. Fix the connection bracket onto the dental unit and tighten the two nuts (7). Depending on the desired distance from the unit to the iPod/iPad, fix the connection bracket onto the dental unit using the position (7.1) or (7.2).

F. Fit the iPod/iPad (8).

G. Insert the lock (9) and tighten the screw (10) using socket wrench REF 1000031-001 and M3 TORX-S Screw Head REF 3300404-001.

Note: It is possible to fit the docking station on both sides of the dental unit.







Connect either a pneumatic (0-3 bar / 0-43.5 psi) (1) or an electrical (0-5 Vdc) (2) dental unit pedal according to the following:



4.3.DMX3 wiring

Note: Refer to the corresponding diagram on the following pages.

WARNING: THE POWER MUST NOT BE CONNECTED DURING THE WHOLE INSTALLATION PROCEDURE

4.3.1. DMX3 with 1 MX2 motor procedure

A. Drill a hole of diameter 12 mm (15/32") in the unit to install the Power supply reset switch (1502568) (1).

B. Connect together: Power supply reset switch (1502568), Power Supply PMP90 (1500666) (2) and Power Outlet Cable (1300067).





FIG.4

FIG.5

C. Drill two holes of diameter 3.5 mm (9/64") in the unit to fix the electrovalve (1502523) to the dental unit using screws, washers and nuts (1502564).





D. Fix the whiteboxes (1601015 and 1502569) to the dental unit using Velcros (1502565).

E. Connect the pneumatic circuit (1502566) to the delivery unit and to the motors according to the "4.3.2 DMX3 with 1 MX2 motor diagram".

Note: Please use pneumatic pipes with an internal diameter of 2.8 mm (7/64"). F. Connect the electrovalves (1502523) to the DMX3 Whitebox (1601015) (1).

G. Connect the DMX3 Whitebox (1601015) to the motor hose following the color code (3) on the connector.

H. Connect the Power supply reset switch to the DMX3 Whitebox (1601015) (2).



I. Connect the USB Lightning cable (not provided in the set) to the DMX3 Whitebox (1601015).

J. Drill a hole of diameter 19 mm (3/4") in the unit with the hole saw (3300409). Pass the USB Lightning cable through the opening on the dental unit. To protect and avoid any USB Lightning cable movement:

- fix it inside the unit with the provided cable zip tie (1) and its Self-adhesive cable tie mount (1502535) (2),
- protect the opening with cable pass-through protection





FIG.10

K. Connect the USB Lightning cable to the Apple device.

L. Connect the power supply cable.

M. Configure the board through the App according to the iOptima application settings chapter.



4.3.2. DMX3 with 1 MX2 motor diagram

4.3.3. DMX3 with 2 MX2 motors procedure

A. Drill a hole of diameter 12 mm (15/32") in the unit to install the Power supply reset switch (1502568).

B. Connect together: Power supply reset switch (1502568), Power Supply PMP90 (1500666) (1) and Power Outlet Cable (1300067).



FIG.11

C. Drill four holes of diameter 3.5 mm (9/64") in the unit to fix the electrovalves (1502528) to the dental unit using screws, washers and nuts (1502574).



FIG.12

D. Fix the whiteboxes (1601015 and 1502569) to the dental unit using Velcros (1502572).

E. Connect the pneumatic circuit (1502573) to the delivery unit and to the motors according to the "4.3.4 DMX3 with 2 MX2 motors diagram".

Note: Please use pneumatic pipes with an internaldiameter of 2.8 mm (7/64").

F. Connect the air switches to the motor holders.

G. Connect the air switches to the DMX3 board (1).

H. Connect the electrovalves (1502528) to the dual motor whitebox (1502569) (2).





I. Connect the dual motor whitebox (1502569) to the motor hoses following the color code on the connectors. Motor 1 shall be connected to (1.1), motor 2 shall be connected to (1.2). J. Connect the Power supply reset switch to the DMX3 Whitebox (1601015) (2).



FIG.15

FIG.16

K. Connect the DMX3 Whitebox (1601015) to the dual motor whitebox (1502569) with the DMS connection (1502525) (1).



FIG.17

L. Connect the USB Lightning cable (not provided in the set) to the DMX3 Whitebox (1601015).

M. Drill a hole of diameter 19 mm (3/4") in the unit with the hole saw (3300409). Pass the USB Lightning cable through the opening on the dental unit. To protect and avoid any USB Lightning cable movement:

• fix it inside the unit with the provided cable zip tie (1) and its Self-adhesive cable tie mount (1502535) (2),

• protect the opening with cable pass-through protection.





N. Connect the USB Lightning cable to the Apple device.

O. Connect the power supply cable.

P. Configure the board through the App according to the iOptima application settings chapter.





4.3.4. DMX3 with 2 MX2 motors diagram

4.3.5. DMX3 with 1 MX2 motor and 1 MX-i LED motor procedure

A. Drill a hole of diameter 12 mm (15/32") in the unit to install the Power supply reset switch (1502568).

B. Connect together: Power supply reset switch (1502568), Power Supply PMP90 (1500666) (1) and Power Outlet Cable (1300067).



FIG.20

C. Drill two holes of diameter 3.5 mm (9/64") in the unit to fix the electrovalve (1502527) to the dental unit using screws, washers and nuts (1502564).



FIG.21

D. Fix the whiteboxes (1601015 and 1502569) to the dental unit using Velcros (1502572).

E. Connect the pneumatic circuit (1502576) to the delivery unit and to the motor according to the "4.3.6 DMX3 with 1 MX2 motor and 1 MX-i LED motor diagram".

Note: Please use pneumatic pipes with an internal diameter of 2.8 mm (7/64").

F. Connect the air switches to the motor holders.

G. Connect the air switches to the DMX3 board (1).

H. Connect the electrovalve (1502527) to the dual motor whitebox (1502569) (2)



I. Connect the dual motor whitebox (1502569) to the motor hoses following the color code on the connectors. MX2 Motor shall be connected to (1.1), MX-i LED motor shall be connected to (1.2).

J. Connect the Power supply reset switch to the DMX3 Whitebox (1601015) (2).







FIG.25

K. Drill a hole of diameter 14 mm to 15 mm (9/16" to 19/32") in the unit and mount MX-i LED Connector (1502529) with the dedicated tool (3600139) and the open-end wrench:

2

- Insert the MX-i LED Connector (1502529) (1) from inside the dental unit.
- Add the nut (2) provided with the MX-i LED Connector (1502529) outside the dental unit.
- Tighten the nut (3) using the tool (3600139) (4) and the open-end wrench.



FIG.26

L. Connect the DMX3 Whitebox (1601015) to the dual motor whitebox (1502569) with the DMS connection (1502525) (1).



FIG.27

M. Connect the USB Lightning cable (not provided in the set) to the DMX3 Whitebox (1601015).

N. Drill a hole of diameter 19 mm (3/4") in the unit with the hole saw (3300409). Pass the USB Lightning cable through the opening on the dental unit. To protect and avoid any USB Lightning cable movement:

- Fix it inside the unit with the provided cable zip tie (1) and its Self-adhesive cable tie mount (1502535) (2),
- Protect the opening with cable pass-through protection.





O. Connect the USB Lightning cable to the Apple device.

P. Connect the power supply cable.

Q. Configure the board through the App according to the iOptima application settings chapter.



4.3.6. DMX3 with 1 MX2 motor and 1 MX-i LED motor diagram

4.3.7. DMX3 with 1 Piezo Scaler procedure

Note: The Piezo scaler is an add-on of the motor(s) and can only be set on holder 3. Refer to the corresponding procedure for the motor installation :

- "4.3.1 DMX3 with 1 MX2 motor procedure"
- "4.3.3 DMX3 with 2 MX2 motors procedure"
- "4.3.5 DMX3 with 1 MX2 motor and 1 MX-i LED motor procedure"
- A. Connect the Piezo Scaler device to the DMX3 Whitebox (1601015).

B. Connect the Piezo Scaler device to the Power Supply.

Note: Refer to the Piezo scaler IFU for specific connections.



4.3.8. DMX3 with 1 Piezo Scaler diagram



4.3.9. DMX3 with peristaltic pump on Piezo Scaler output (without DMS) diagram



4.3.10. DMX3 with 1 Piezo Scaler and peristaltic pump diagram



4.3.11. DMX3 with 3 motors diagram

5. iOptima application settings

5.1. Display configuration

A. When used with an iPad mini[®], the app automatically displays accordingly to the orientation of the iPad. See CAUTION of the user IFU (REF 2100279).

B. To correct the orientation of the display if it is incorrect (e.g. if you want to change the orientation of the iPad after the app has been launched), quit the app, reposition the iPad as desired and then restart the app according to the standard procedure (see user IFU).

C. Make sure the screen's rotation lock is disabled (see user IFU).

5.2. Board configuration

A. Go to the Settings page, tap System settings and enter the password «1959» to display the System settings page.



B. Tap Board configuration to display the Board configuration page.

C. Select either No holder switch (1) or With holder switch tab (2) and set the instrument type for each holder.

Note: The instrument in use displays a green border and check mark (3).

<	System settings		• v	100%	09-41 Fri 2.34		♥ 100% ■		
	-	Board configuration	>			No holder s	witch	With holder s	witch
	•	Lock settings	>			Holder 1 MCX	l} ≬ ≬		~
						Holder 2 MX−Ů	[i] ž	6	>
						Holder 3	_		>
							Reset facto	ry settings	
	Checl Rotati	k Control Center (swipe dow ion lock shall be OFF	vn from top-right corn	ier)					
			_	1		_			(i)
			_		-				

FIG.31

5.2.1. Change instrument

A. Tap the holder with the instrument to change, select the instrument or No instrument connected.

B. Select whether the instrument is active when the holder switch is closed or open and tap to acknowledge configuration is done.

09-41 PH 2.			4 1001L	09-41 Pri 2 Jun		• 100% •	09:41 PH 2 Ju	n	• 100% •	09:41 Pit 2 Jun			+ 100% m
<	Board conf	iguration		Cancel	Holder 1		Cancel	Holder 1		< _	Board co	nfiguration	
	No holder switch	With holder swite	zh .	MX2		>		INSTRUMENT IS ACTIVE WHEN	~		No holder switch	With holder switch	
	Holder 1	-	>					the holder switch is open			Holder 1	5111-	>
	MI/K 2			MCX	13 6 6 EIII	>					IVI <i>KZ</i>		
	Holder 2	6 - EIII	>								Holder 2	=====	>
				MX-i	[4] <u>\$</u> 8− 8Ⅲ	>					Configura	tion done	
	Holder 3	-	>								Holder 3		>
				No instrument	connected								
	Reset facto	ry settings									Reset fac	tory settings	
			(i)										(T)
			J.										

FIG.32

Note: If you select MX-i LED motor you will have to select whether No Holderswitch is installed and wired (tap **without holder**) or not (tap **the holder switch is closed** or **the holder switch is open**). Software iOptimalNT interface must be in V2.7.0 or higher to support MX-I without holder.

09-41 Fri 2	aut.	P 100%
Cano	Holder 2	
	INSTRUMENT IS ACTIVE WHEN	
	the holder switch is closed	
	the holder switch is open	
	without holder	~
	FIG.33	

Note: If you select MX-i LED motor you will have to select whether a peristaltic pump is installed and wired (tap **Enable pump control**) or not (tap **Disable pump control**). Software iOptimaINT interface must be in V3.0.6 to support peristaltic pump. If required, software update is proposed when connecting iPod/iPad to the iOptimaINT and launching iOptima App V2.4.0 or higher.

OB-41 Fri 2	nut.	Holder 2	100%
	PERISTALTIC PUMP		
	Enable pump control		~
	Disable pump contro	I	
	E	G 34	
		0.34	

5.2.2. Configure Piezo Scaler

Note: Piezo Scaler can only be set on holder 3.

A. Tap the holder 3, select the Piezo Scaler then select the Power regulation.

B. Select whether the Piezo Scaler is active when the holder switch is closed or open and tap to acknowledge configuration is done.

09-41 Pri 2	an .	🕈 10014 🗰	08:41 Fri 2 Jun		P 100%	00:41 Fri 2 Jun		🕈 100% 🗰	09/41 Fri2 J	lun.	🕈 100% 🗰
<	Board configuration		Cancel	Holder 3		Cancel	Holder 3		Cance	Holder 3	
							SCALER CONTROL MODE			INSTRUMENT IS ACTIVE WHEN	
	No holder switch With holder switch		MX2		>		Power regulation 0 to 5V analog voltage	~		the holder switch is closed	 Image: A second s
	Holder 1	5					Power regulation 2.2KΩ potentiometer			the holder switch is open	
	MX2		MCX	IÇ 🖉 8 EIII	>						
	Holder 2	>									
	MX-l		MX-i		>						
	Holder 3	>									
	Reset factory settings										
			No instrument conne	cted							
		U.									
			_								

FIG.35

5.3.Lock settings

A. Tap Lock settings. input and confirm a passcode.

Note: If Lock settings is activated, it is not possible to save any user-defined data!

	09:41 Fri 2 Jun		🗢 100% 🔳	09:41 Fri 2 Jun		🗢 100% 🔳	09:41 Fri 2 Jun		÷ 100%	
	<	System settings			Lock settings	Cancel		Lock settings	Cancel	
		Board configuration	>							
	A	Lock settings	>		Fature and a			Castien unus noncosta		
					Enter a passcode			Continn your passcode		
				5 C 🕅			5 C 🕅			
	Che Che	ack Control Center (swipe down from top-rig)	t corner)	1 2 3 4	5 6 7 8	90 🗷	1 2 3 4	5 6 7 8	90 🗷	
	Rotation lock shall be OFF) ,, return	< ≤ × @ # \$	â î () (â î () /) // return		
				8+2 5 1 - % - +		1 ? , . #+=	8+2 % ¹ +		1 ? #+=	
			i	ABC		undo ABC	ABC		undo ABC	
FIG.36										

6. Integration Checklist

Please go through the following checklist

• For use on iPad mini®, check that the screen's rotation lock is disabled and make sure
the screen
displays the correct orientation according to its position (portrait or landscape orientation)
A. CHECK that overall installation is conformed with the wiring diagram
B. CHECK that all mechanical component are well fixed
Check that there is no mechanical traction on any wire
 Check that each electrical element could not be harmed by dental unit surrounding
 Check that USB Lightning cable is held by the nylon cable tie provided
 Check that there is no mechanical traction on any pneumatic tube
 Check that each pneumatic connection is correct with a light pull test
 Check that there is no squeezing or deformation on any pneumatic tube
Check that all the connectors are correctly plugged in
Check that whiteboxes are closed and fixed with Velcro
Check that electronic boards are not able to move inside the whiteboxes
Check that the hose securing cord is griped to the dental unit and that there is no
mechanical traction on the wire when the motor is held.
C. CHECK that power supply is well installed
Only allow use of the power supply inside of the dental unit
Check that there is a circuit breaker upstream power supply
D. CHECK that air flow system is well configured
Verify that an air filter is installed in the dental unit
• Verify that an input air pressure is at least 3 bar / 43.5 psi and maximum 5bar / 72.5 psi
Check that the air flow rate at the motor nose is 10NI/min (Normal Liter per minute)
Check that no air is flowing in Endo Mode
 Verify that the tubes are properly connected to the T-fittings
E. CHECK that system is functional
Check that when pulling up the motor and pressing footpedal, that it turns ON
 Check that motor LIGHT is ON when the motor is ON
Check that the rotation direction motor is consistent with the setting in the application
 (clockwise and counter clockwise)
• Check that the App configuration is consistent with the wiring (for example Motor1 = MX2 and Motor2 = MX2 in case of set 1700705)
Check on the iPod/iPad that the maximum speed reachable is 40'000rpm
Check that the power supply reset switch works
If installed, check that the peristaltic pump works: ON/OFE check, irrigation level
activation (only in SR mode)
• If installed, check that the scaler works properly; power output follows power level from
the application
 If installed, check that the scaler control mode is properly set

Note: If there is any unchecked box remaining, please do not use the system and refer to Troubleshooting procedures on the iOptima application.

In addition, the installation must be done according to electrical and insulation standard.

7. Maintenance

Use only original Bien-Air Dental SA maintenance products and parts. The use of other products or parts could void the warranty.

8. Legal and general

8.1.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.

8.2.Trademarks

ProTaper Next® is a trademark of DENTSPLY SIRONA Inc.

8.3. Terms of guarantee

Bien-Air Dental SA grants the user a warranty covering any operating fault, or material or manufacturing defect.

The device is covered by this guarantee for:

- 12 months for the hose
- 12 months for the power supply
- 12 months for the electronic boards
- 24 months for the iOptimalNT elements
- 36 months for 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 warranty becomes null and void if damage and its consequences result from incorrect servicing or modification by third parties not authorized by Bien-Air Dental SA.

Warranty requests will only be taken into consideration if the product is accompanied by a copy of the invoice or delivery note. The following information must be clearly indicated: purchase date, product reference and serial number.

The guarantee does not cover flexible "Optical fiber" 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.

9. Electromagnetic compatibility for iOptimaINT

9.1.Electromagnetic compatibility warnings

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

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.

The EMC tests have been carried out on an iOptimalNT device where neither a pump nor a piezoscaler were installed.

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.

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 integrator.

9.2. 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	Group 1	The iOptima ^{INT} uses RF energy for its interna		
CISPR 11		operation only. Therefore, its RF emissions		
		are very low and are not likely to cause any		
		interference in nearby electronic equipment.		
RF emissions	Class B	The iOptima ^{INT} is suitable for use in any		
CISPR 11		building, including residential buildings and		
Harmonic emissions	Class A	those directly connected to the public low-		
IEC 61000-3-2		voltage power supply network that supplies		
Emissions due to voltage	Conforming	buildings used for residential purposes.		
fluctuations IEC 61000-3-3				

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

Surge	±0.5 kV line to line		±0.5 kV line to line		Mains power quality should be	
IEC 61000-4-5	±1 kV line to line		±1 kV line to line		that of a commercial or hospital	
	±0.5 kV line to earth		±0.5 kV line to earth		environment.	
	±1 kV line to earth		±1 kV line to earth			
	±2 kV line to earth		±2 kV line to earth			
Voltage dips, short	0% UT for 0.5 cycle	э,	0% UT for 0.5 cycle, at		Mains power quality should be	
interruptions and	at 0°, 45°, 90°, 135°	,	0°, 45°, 90°, 135°, 180°,		that of a commercial or hospital	
voltage	180°, 225°, 270° an	180°, 225°, 270° and		d 315°	environment. If the user of the	
variations on power	315°		0% UT for 1	cycle and	iOptima ^{INT} requires continued	
supply input lines	0% UT for 1 cycle		70% UT for 2	5/30	operation during mains power	
IEC 61000-4-11	and 70% UT for		cycles at 0°		interruptions, it is recommended	
	25/30 cycles at 0°				that the iOptima ^{INT} be powered	
					from an uninterruptible power	
					supply or a battery.	
Magnetic field due to	30 A/m		30 A/m		Magnetic fields generated by the	
mains frequency (50/60					mains frequency should be at	
Hz)					levels characteristic of a typical	
IEC 61000-4-8					location in a typical commercial	
					or hospital environment.	
Conducted	3 VRMS		3 VRMS		Field strengths from fixed RF	
disturbances	0,15 MHz – 80 MHz		0,15 MHz – 80 MHz		transmitters, as determined by an	
induced by RF fields	6 VRMS in ISM		6 VRMS in ISM and		electromagnetic site survey ^a	
IEC 61000-4-6	bands		amateur bands		should be less than the	
	0,15 MHz – 80 MHz		0,15 MHz – 80 MHz		compliance level in each	
	80% AM at 1 KHz				frequency range. Interference	
Radiated RF EM fields	3 V/m		3 V/m		may occur in the vicinity of	
IEC 61000-4-3	80 MHZ – 2,7 GHZ		80 MHz – 2,7 GHz			
	80 % AM at 1 kHz		80 % AM at 1 kHz		following overhol:	
Drovimity fields from	Toot from [MU]=1	Ma		Immunity		
	Test freq. [MHZ]	IVIE	ix. power [w]	tost loval	Distance: 0.5 m	
wireless				[V/m]		
communications	385	1 9	2	27		
equipment	450	2	,	21		
IFC 61000-4-3	EC 61000-4-3 710 745 780 0.2		>	0		
	810 870 930	2	-	28		
	1720 1845 1970	2		20		
	2450	2		28		
	5240 5500 5785	2)	9		
	0270, 0000, 0100	0.2	-	0		

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 iOptimalNT is used exceeds the RF compliance level mentioned above, the iOptimalNT 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 iOptimalNT.

9.3.References

9.3.1. Set supplied (see cover page)

iOptima INT set REF 1700704-001

REF	Legend
1502475-001	iOptimaINT iDevice fixation (1x)
1600677-001	MX2 Micromotor (1x)
1600809-001	MX2 Micromotor hose (1x)
1502568-001	Power supply reset switch
1500666-001	Power supply PMP90 (1x)
1300067-001	3P cable system, US, length 2.00 m (1x)
1601074-001	1 Motor Control Boards

iOptima INT set REF 1700705-001

REF	Legend
1502475-001	iOptimaINT iDevice fixation (1x)
1600677-001	MX2 Micromotor (2x)
1600809-001	MX2 Micromotor hose (2x)
1502568-001	Power supply reset switch
1500666-001	Power supply PMP90 (1x)
1300067-001	3P cable system, US, length 2.00 m (1x)
1601075-001	Dual Motor Control Boards

iOptima INT set REF 1700706-001

REF	Legend
1502475-001	iOptimalNT iDevice fixation (1x)
1600677-001	MX2 Micromotor (1x)
1600809-001	MX2 Micromotor hose (1x)
1600755-001	MX-i LED Micromotor (1x)
1600606-001	MX-i LED Micromotor hose (1x)
1502568-001	Power supply reset switch
1500666-001	Power supply PMP90 (1x)
1300067-001	3P cable system, US, length 2.00 m (1x)
1601076-001	Dual Motor Control Boards
1303711-010	Pack of 10 attachment collars for fastening the sterile irrigation line to
	a cable

9.3.2. Optional accessories (see cover)

1502620-001	Mechanical interface iPod right mount
1502621-001	Mechanical interface iPod left mount
1502622-001	Mechanical interface iPad right mount
1502623-001	Mechanical interface iPad left mount
1502567-001	Mounting tools
1307467-001	USB / Lightning cable





Other addresses available at www.bienair.com



EC REP Bien-Air France Sàrl

19-21 rue du 8 mai 1945 94110 Arcueil France

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