

iOptima^{INT}

ENG INSTALLATION INSTRUCTIONS.



REF 2100320-0000/2018.06

Set iOptima^{INT} REF 1700704-001



Set iOptima^{INT} REF 1700705-001



Set iOptima^{INT} REF 1700730-001



Set iOptima^{INT} REF 1700731-00°



Options







1x REF 1502621-001



1x REF 1502622-001



REF 1502623-001



1x REF 3300409-001



1x REF 3300404-001



1x REF 3300403-001



1x REF 1000031-001



ix

REF 1502567-001



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ENG Installation instructions

1 Symbols

	7		
C € ₀₁₂₀	CE Marking with number of the notified body.		Refer to the accompanying documents for the correct use of the product.(www.bienair.com/ifu.)
**	Manufacturer.	SN	Serial number.
REF	Reference number.	X	Separate collection of electric and electronic equipment.
<u>\(\)</u>	CAUTION! Consult accompanying documents. Provides an instruction that should be observed for safety reasons.		Light.
$\left(\left(\underbrace{(\bullet)}_{\blacktriangle}\right) \right)$	RF emitting device (Interference may occur in the vicinity of equipment marked with this symbol).	0	Recyclable materials.

2 Identification and Intended use

2.1 Identification

Electronic control for Bien-Air Dental SA MX2 brushless and sensorless micromotor.

2.2 Intended use

This product is intended solely for professional use. It is intended for use in dentistry for restorative and endodontics procedures. Any use other than that for which this product is intended is prohibited and may prove dangerous.

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 Electromagnetic compatibility for iOptima INT

3.1 Electromagnetic compatibility warnings

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

⚠ CAUTION

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

Special precautions should be taken when using strong emission sources such as high-frequency surgical equipment and other similar devices, to ensure that HF cables are not routed above or near the device. If in doubt, please contact a qualified technician or Bien-Air.

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

⚠ CAUTION

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

▲ CAUTION

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

3.2 Electromagnetic compatibility – emissions & immunity

Guidance and manufacturer's declaration – Electromagnetic emissions

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

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

Guidance and manufacturer's declaration - Electromagnetic immunity

The iOptima $^{\rm INT}$ is intended for use in the electromagnetic environment specified below. The customer or the user of the iOptima $^{\rm INT}$ 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 ?	$\begin{array}{c} 0\% \ U_T \ for \ 0.5 \ cycle, \\ at \ 0^\circ, 45^\circ, 90^\circ, 135^\circ, \\ 180^\circ, 225^\circ, 270^\circ \\ and \ 315^\circ \\ 0\% \ U_T \ for \ 1 \ cycle \\ and \\ 70\% \ U_T \ for \ 25/30 \\ cycles \ at \ 0^\circ \end{array}$	$\begin{array}{c} 0\% \ U_T \ for \ 0.5 \ cycle, \\ at \ 0^\circ, 45^\circ, 90^\circ, 135^\circ, \\ 180^\circ, 225^\circ, 270^\circ \\ and \ 315^\circ \\ 0\% \ U_T \ for \ 1 \ cycle \\ and \\ 70\% \ U_T \ for \ 25/30 \\ cycles \ at \ 0^\circ \end{array}$	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.

Immunity test	IEC 60601 test level		Compliance level		Electromagnetic environment - guidance	
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V _{RMS} 0,15 MHz – 80 6 V _{RMS} in ISM 0,15 MHz – 80 80% AM at 1	D MHz I bands D MHz WHz 0,15 M		S 1Hz – 80 MHz _S in ISM and eur bands 1Hz – 80 MHz M at 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ¹ should be less than the compliance level in each frequency range.	
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz – 2,7 80 % AM at 1		3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz		Interference may occur in the vicinity of equipment marked with the following symbol: ((•)))	
	Test freq. [MHz]	Max. p [W]	ower	Immunity test level [V/ m]		
	385	1.8		27		
Proximity	450	2		28		
fields from RF wireless	710, 745, 780	0.2		9	Distance: 0.3 m	
ns equipment IFC 61000-4-3	810, 870, 930	2		28	bistance. 0.3 m	
125 01000-4-3	1720, 1845, 1970	2		28		
	2450	2		28		
	5240, 5500, 5785	0		9		

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

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

1. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and mobile field radios, amateur radios, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the iOptima INT is used exceeds the RF compliance level mentioned above, the iOptima INT should be observed to verify that it is operating normally. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the iOptima INT.

4 Description

4.1 System overview

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

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

4.2 Technical data

△ CAUTION

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

Environmental conditions	Operating	Transport and storage (max. 15 weeks)			
Temperature	+10°C (50°F) to +35°C (77°F)	-25°C (-13°F) to +70°C (158°F)			
Relative humidity	30% to 80%	30% to 80%			
Atmospheric pressure	700 hPa to 1060 hPa	500 hPa to 1060 hPa			
Altitude	0 to 3'000 m (0 to 9'842 ft)	-			

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).

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

Device	IFU	REF
Motor MX2 LED	2100199	1600677-001
Hose MX2	2100223	1600809-001
Control DMX3 set	2100278	1600903-001

4.3 Environmental protection and information for disposal



This device must be recycled. Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards. The user can return the device to its dealer or directly enlist the services of a firm accredited for the processing and recovery of this type of equipment (European Directive 2002/96/EC).

5 Installation

△ CAUTION

Before use, please read these installation instructions and the iOptima^{INT} operating instructions (2100279) carefully. Switch ON only when the system is ready for use. To conform with IEC 60601-1-2 standards, take into account the different routes of the wires through the unit (bend, fold, section etc) and only use the transformer provided with the kit or the unit's power supply (Refer to "5.3 DMX3 wiring" on page 10). To maintain warranty, this device must be installed with the greatest care. Follow all the necessary instructions.

5.1 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 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.

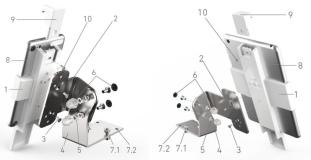


FIG. 1

FIG. 2

5.2 Dental unit pedal connection

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:

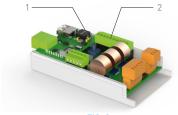


FIG. 3

5.3 DMX3 wiring

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

 Δ THE POWER MUST NOT BE CONNECTED DURING THE WHOLE INSTALLATION PROCEDURE.

5.3.1 DMX3 with 1 MX2 motor procedure

A. Drill a hole of diameter 12 mm 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).



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

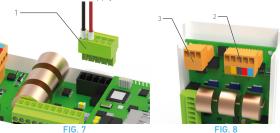


FIG. 6

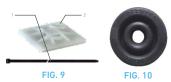
- ${\bf D}.$ Fix the whiteboxes (1601015 and 1502569) to the dental unit using Velcros (1502565).
- **E.** Connect the pneumatic circuit (1502566) to the delivery unit and to the motors according to the "5.3.2 DMX3 with 1 MX2 motor diagram" on page 12.

Note: Please use pneumatic pipes with an internal diameter of 2.8 mm.

- 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 (2) on the connector.
- H. Connect the Power supply reset switch to the DMX3 Whitebox (1601015) (3).

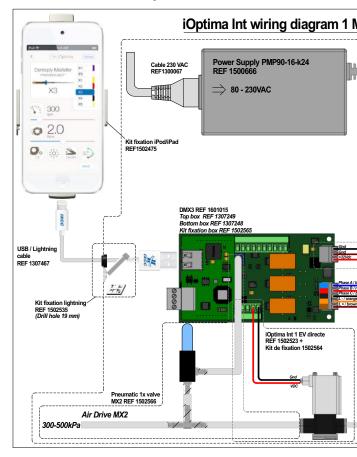


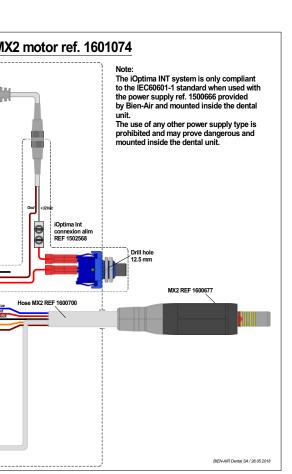
- I. Connect the Apple USB Cable (not provided in the set) to the DMX3 Whitebox (1601015).
- **J.** Drill a hole of diameter 19 mm in the unit with the hole saw (3300409). Pass the Apple USB cable through the opening on the dental unit. To protect and avoid any USB cable movement:
 - fix it inside the 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.



- K. Connect the Lightning cable to the Apple device.
- L. Connect the power supply cable.
- $\mathbf{M.}$ Configure the board through the App according to the iOptima application settings chapter.

5.3.2 DMX3 with 1 MX2 motor diagram





5.3.3 DMX3 with 2 MX2 motors procedure

A. Drill a hole of diameter 12 mm 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 in the unit to fix the electrovalves (1502528) to the dental unit using screws and nuts (1502574).



FIG. 12

- ${\bf D}.$ 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 "5.3.4 DMX3 with 2 MX2 motors diagram" on page 16.

Note: Please use pneumatic pipes with an internal diameter of 2.8mm.

- $\textbf{F.} \ \ \text{Connect the air switches to the motor holders}.$
- G. Connect the air switches to the DMX3 board (1).
- H. Connect the electrovalves (1502528) to the dual motor whitebox (1502569) (2).

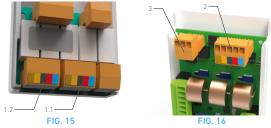


FIG. 13



FIG. 14

- 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).



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

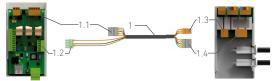
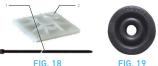


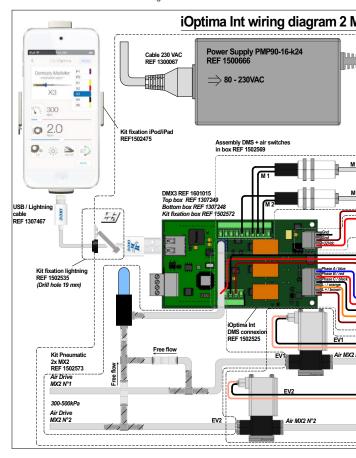
FIG. 17

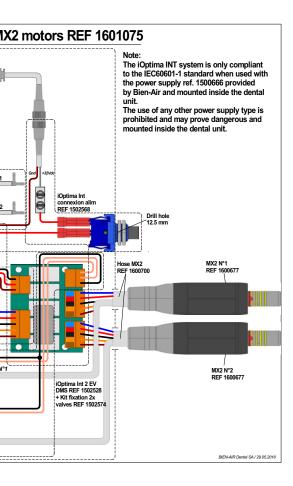
- L. Connect the Apple USB Cable (not provided in the set) to the DMX3 Whitebox (1601015).
- M. Drill a hole of diameter 19 mm in the unit with the hole saw (3300409). Pass the Apple USB cable through the opening on the dental unit. To protect and avoid any USB cable movement:
 - fix it inside the unit 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 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.

5.3.4 DMX3 with 2 MX2 motors diagram





6 iOptima application settings

6.1 Display integrator's menus

A. Go to the **Settings** page and swipe up to display the integrator's menus.



FIG. 20

6.2 Board configuration

A. Tap *Board configuration* and enter the password «1959» to display the *Board configuration* page.

B. Select either *Single motor* (4) or *Multiple motors* tab (5) and set the motor type for each holder.

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

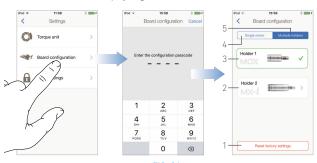


FIG. 21

6.2.1 Change motor

 $\ensuremath{\mathbf{A}}.$ Tap the holder with the motor to change, select the motor or No motor connected.

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



FIG. 22

6.3 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!

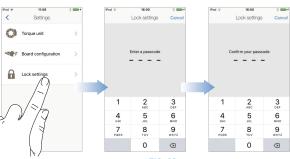


FIG. 23

7 Integration checklist PLEASE ANSWER THE FOLLOWING QUESTIONS:

Α.	CHECK that overall installation is conformed with the wiring diagram
B.	CHECK that all mechanical component are well fixed
٠	Check that there is no mechanical traction on any wire
•	Check that each electrical element could not be harmed by dental unit surrounding
٠	Check that USB Lightning cable is held by the nylon cable tie provided
٠	Check that there is no mechanical traction on any pneumatic tube
٠	Check that each pneumatic connection is correct with a light pull test
٠	Check that there is no squeezing or deformation on any pneumatic tube
٠	Check that all the connectors are correctly plugged in
٠	Check that whiteboxes are closed and fixed with Velcro
٠	Check that electronic boards are not able to move inside the whiteboxes
C.	CHECK that power supply is well installed
٠	Only allow use of the power supply inside of the dental unit
٠	Check that there is a circuit breaker upstream power supply
D.	CHECK that air flow system is well configured
٠	Verify that an air filter is installed in the dental unit.
٠	Verify that an input air pressure is at least 3 bar / $43.5\ \mathrm{psi}$ and maximum 5bar / $72.5\ \mathrm{psi}.$
•	Check that the air flow rate at the motor nose is 10Nl/min (Normal Liter per minute)
E.	CHECK that system is functional
٠	Check that when pulling up the motor and pressing footpedal, that it turns ON
٠	Check that motor is LIGHT is ON when the motor is ON
٠	Check that the rotation direction motor is clockwise when in RESTO
۰	Check that the App configuration is consistent with the wiring (for example Motor1 = MX2 and Motor2 = MX2 in case of set 1700705).
٠	Check on the iPod/iPad that the maximum speed reachable is 40'000rpm
٠	Check that the power supply reset switch works

Note: If you answered NO to any of the above questions, please do not use the system and refer to Troubleshooting procedures on the iOptima application.

8 Maintenance

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

9 General information, guarantee and references

9.1 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.

9.2 Terms of guarantee

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

The device is covered by this guarantee for:

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

from the date of invoicing.

In case of justified claim, Bien-Air Dental SA or its authorized representative will fulfill the company's obligations under this guarantee by repairing or replacing the product free of charge.

Any other claims, of whatever nature, in particular in the form of a claim for damages and interest, are excluded.

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

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

The guarantee does not cover flexible "fiber optic" type light conductors, or any parts made of synthetic materials. The guarantee shall become null and void if the damage and its consequences are due to improper manipulation of the product, or modifications to the product carried out by persons not authorized by Bien-Air Dental SA.

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

9.3 References

9.3.1 Set supplied (see cover page)

Toptima Set ILL 1700704 001				
REF				
1502475-001	iOptima ^{INT} iDevice fixation (1x)			
1600677-001	MX2 Micromotor (1x)			
1600809-001	MX2 Micromotor hose (1x)			
1502568-001	Power supply reset switchs			
1500666-001	Power supply PMP90 (1x)			
1300067-001	3P cable system, US/Asia, length 2.00 m (1x)			
1601074-001	1 Motor Control Boards			

iOptima^{INT} set REF 1700705-001

iuptima set KEF 1700705-001				
REF	Designation			
1502475-001	iOptima ^{INT} iDevice fixation (1x)			
1600677-001	MX2 Micromotor (2x)			
1600809-001	MX2 Micromotor hose (2x)			
1502568-001	Power supply reset switchs			
1500666-001	Power supply PMP90 (1x)			

1300067-001	3P cable system, US/Asia, length 2.00 m (1x)
1601075-001	Dual Motor Control Boards

iOptima^{INT} set REF 1700730-001

optima se	TREF 1/00/30-001
1600809-001	MX2 Micromotor hose (1x)
1502568-001	Power supply reset switch
1500666-001	Power supply PMP90 (1x)
1300067-001	3P cable system, US/Asia, length 2.00 m (1x)
1601074-001	1 Motor Control Boards

iOptima^{INT} set REF 1700731-001

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

9.3.2 Optional accessories (see cover page)

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



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