

ICHIROPRO, ICHIROPRO SURGERY

ENG INSTRUCTIONS FOR USE.



Set iChiropro REF 1700439-001





REF 1303393-001 REF 1600755-001



REF 1600606-001



REF 1600631-001









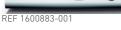


Set iChiropro CA REF 1700440-001



Set iChiropro Surgery REF 1700485-001*







REF 1600755-001













REF 1306547-001

Set iChiropro Surgery HP REF 1700484-001*



* Set is available in the USA and Canada only.

Options



1600755-001

































REF 1500984-010









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1 Symbols

1.1 Description of symbols for iChiropro and iChiropro Surgery units

Symbol	Description	Symbol	Description
C € 0120	CE Marking with number of the notified body.		Recyclable materials.
	Main switch - Power OFF.		Separate collection of electric and electronic equipment.
	Main switch - Power ON.	***	Manufacturer.
5 x 20	Fuse Ø 5 x 20 mm.		Light.
~	Alternating current.		Sound alerts
$\Big(\!\big((\bullet)\big)\!\Big)$	RF emitting device (Interference may occur in the vicinity of equipment marked with this symbol).	Rx Only	Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.
<u> </u>	CAUTION! Consult accompanying documents. Provides an instruction that should be observed for safety reasons.	c ® us	CSA marking – Complies with U.S. and Canadian standards
	Refer to the accompanying documents (www.bie-nair.com/ifu).	SN	Serial number.
REF	Reference number.		

1.2 Description of symbols for iChiropro and iChiropro Surgery accessories

Symbol	Description	Symbol	Description
€ 0120	CE Marking with number of the notified body.	溪	Machine washable.
\subseteq	Expiration date.		Recyclable materials.
PHT	Product containing phthalates.	X	Separate collection of electric and electronic equipment.
2	Do not reuse.	135°C	Sterilizable in autoclave up to the specified temperature.
STERILE EO	Sterilized with Ethylene Oxyde.	***	Manufacturer.
†	Electrical security. Applied part type B.	SN	Serial number.
REF	Reference number.		







FIG. 1 FIG. 2 FIG. 3

2 Identification, Intended use and Notation

2.1 Identification

Electronically controlled tabletop device for dentistry allowing operation of a dental handpiece via an MX-i micromotor with variable speed control by a pedal.

A peristaltic pump conveys the physiological liquid via a disposable irrigation line without being contaminated.

It is essential to connect a compatible iPad to the device using the connector provided for this purpose.

See section "6.1.1 Compatibility" on page 14 for details.

The implant fitting parameters are defined before the operation using the iChiropro application installed on the iPad.

△ CAUTION

The pre-recorded settings of Implant Brands are informative only and must be updated according to the Instructions for use from Implant Brands.

2.2 Intended use

The system is to be used by dentists and surgeons in dental offices and hospitals. The system is designed to control a dental MX-i micromotor which can drive a dental hand-piece fitted with appropriate tools to cut hard and soft tissues in the mouth and to screw dental implants.

The system is intended for use in dentistry for implantology and dental surgery.

Any use other than that for which this product is intended is unauthorized and may be dangerous.

The system meets all the current legal requirements for medical devices.

iChiropro and iChiropro Surgery dental units are intended for use in dental implantology and dental surgery.

Two applications are available to control these systems:

- The iChiropro application, deployed on the App Store © worldwide except United States and Canada;
- The iChiropro US application, deployed on the App Store © in United States and Canada only.

The iChiropro US application allows both implantology and surgery procedures only when the iPad is connected to an iChiropro Surgery unit. When the iPad is connected to an iChiropro unit, only implantology procedures may be accessed by the user.

FIG. 1

iChiropro US application is connected to iChiropro Surgery unit: in the application user interface, both implantology (IM) and surgery (SR) procedures selection buttons are available.

FIG. 2

iChiropro US application is connected to iChiropro unit: in the application user interface, only implantology (IM) procedures selection button is available.

2.3 Notation and chapter links

• A B C etc

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

· 6

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**.

FIG. 3

• 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 (1) links the user directly to the table of content, regardless of the reading position in the text.

3 Warnings & Precautions of Use

△ CAUTION

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

△ CAUTION

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

↑ CAUTION

Never connect a handpiece on a running MX-i micromotor.

△ CAUTION

The iPad must never be disconnected from the iChiropro dental unit during operation.

△ CAUTION

Any modification of the medical device is strictly forbidden.

△ CAUTION

The device is not designed for use in an explosive atmosphere (anaesthetic gas).

△ CAUTION

Do not attempt to open the device when it is connected to the electric mains.

Risk of electrocution.

△ CAUTION

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

Note 1

NOTES

 $\boldsymbol{1}$. The predefined parameters may be subject to modification without notice.

4 Description

4.1 iChiropro system overview



- (1) Peristaltic pump lid
- (2) Pedal connector
- (3) Label
- (4) Bracket support
- (5) Main switch
- (6) Fuse box
- (7) Mains connector

- (8) MX-i micromotor
 - (9) Button to start/stop irrigation and to acknowledge high speed steps warnings
 - (10) Button to reverse the rotation of the MX-i micromotor on pedal
 - (11) "Program" button on pedal (Short press: next step, Long press: next implant placement or next surgery procedure)
 - (12) MX-i micromotor connector
 - (13) Adapter for iPad

4.2 Sets supplied

4.2.1 iChiropro sets

iChiropro set REF 1700439-001

Designation	REF number
iChiropro unit (1x)	1600784-001
MX-i LED micromotor (1x)	1600755-001
3-button pedal (1x)	1600631-001
Cable for MX-i LED micromotor 2 m (1x)	1600606-001
2 single-use sterile iPad protective sheets (1x)	1501746
Pack of 10 disposable sterile irrigation lines (1x)	1500984-010
iPad Air 2 adapter (1x)	1306547-001
iPad Air adapter (1x)	1306205-001
Philips screwdriver (1x)	1305436-001
10 attachment collars for fastening the sterile irrigation line to a cable (1x)	1303711-010
Bracket for fluid bottle (1x)	1303393-001
Handpiece support (1x)	1301575-001
3P cable system, US/Asia, length 2m (1x)	1300067-001
3P cable system, Europe, length 2.5 m (1x)	1300066-001
3P cable system, Switzerland, length 2 m (1x)	1300065-001
Quick Start Guide (1x)	2100247

iChiropro CA set REF 1700440-001

Designation	REF number
iChiropro set (1x)	1700439-001
Contra-angle handpiece CA 20:1 L Micro- Series (light) (1x)	1600692-001

In the interests of clarity, only the iChiropro CA set (REF 1700440-001) is illustrated in these instructions for use. However, the explanations apply to all other iChiropro and iChiropro Surgery sets.

4.2.2 iChiropro Surgery sets

iChiropro Surgery set REF 1700485-001*

Designation iChiropro Surgery unit (1x) MX-i LED micromotor (1x) 3-button pedal (1x)	REF number 1600883-001 1600755-001 1600631-001
MX-i LED micromotor (1x) 3-button pedal (1x)	1600755-001
3-button pedal (1x)	
·	1400431 001
	1000031-001
Cable for MX-i LED micromotor 3 m (1x)	1600881-001
2 single-use sterile iPad protective sheets (1x)	1501746
Pack of 10 disposable sterile lines 3.5 m (1x)	1501738-010
iPad Air 2 adapter (1x)	1306547-001
iPad Air adapter (1x)	1306205-001
Philips screwdriver (1x)	1305436-001
10 attachment collars for fastening the sterile irrigation line to a cable (1x)	1303711-010
Bracket for fluid bottle (1x)	1303393-001
Handpiece support (1x)	1301575-001
3P cable system, US/Asia, length 2m (1x)	1300067-001
3P cable system, Europe, length 2.5 m (1x)	1300066-001
3P cable system, Switzerland, length 2 m (1x)	1300065-001
Quick Start Guide (1x)	2100247

^{*} Set is available in the USA and Canada only.

iChiropro Surgery HP set REF 1700484-001 *

Designation	REF number
iChiropro Surgery set (1x)	1700485-001
Straight handpiece HP 1:2 (1x)	1600436-001

^{*} Set is available in the USA and Canada only.

4.3 Options

4.3.1 iChiropro options

Designation	REF number
3-button pedal	1600631-001
MX-i LED micromotor	1600755-001
Contra-angle handpiece CA 20:1 L KM Micro-Series (light)	1600786-001
Contra-angle handpiece CA 20:1 L KM (light)	1600785-001
Contra-angle handpiece CA 20:1 L Micro-Series (light)	1600692-001
Contra-angle handpiece CA 20:1 L (light)	1600598-001
Straight handpiece HP 1:2	1600436-001
Straight handpiece PM 1:1 Micro-Series	1600052-001
Packets of 10 single-use sterile iPad protective sheets	1501746-010
Pack of 10 disposable sterile lines 3.5 m	1501738-010
Kirschner/Meyer pack of 10 disposable sterile lines	1501635-010
Kirschner/Meyer type detachable irrigation set for CA 20:1 L KM and CA 20:1 L KM Micro-Series, comprising 10 rings and 10 tubes	1501621-010
Box of 100 sterile Bur Guards	1501317-100
Pack of 10 disposable sterile lines	1500984-010
Bracket for fluid bottle	1303393-001
Handpiece support	1301575-001
Cable for MX-i LED micromotor 3 m	1600881-001
Cable for MX-i LED micromotor 2 m	1600606-001
3P cable system, US/Asia, length 2m	1300067-001
3P cable system, Europe, length 2.5 m	1300066-001
3P cable system, Switzerland, length 2 m	1300065-001
10 attachments collars for fastening the sterile irrigation line to a cable	1303711-010
10x Fuse T4.0A L 250 VAC breaking capacity 40A	1301560-010

4.4 Technical data

Dimensions L x W x H

iChiropro unit	. 242 x 244 x 102 mm
iChiropro unit (with bracket)	. 242 x 244 x 482 mm
Pedal	. 250 x 205 x 54 mm
Pedal (with handle)	. 250 x 205 x 144 mm
Motor cable (REF 1600606)	. L 2.0 m
Motor cable (REF 1600881)	. L 3.0 m
Pedal cable	L 2.9 m

The pedal is waterproof (IP X8 in accordance with CEI 60529).

Weight

iChiropro unit	2.8 kg
Pedal	830 g
Bracket	
Cable	105 g
Electrical data	
Voltage	100 – 240 VA0
Frequency	50-60 Hz

Environmental conditions

Environmental conditions	Operating	Transport and storage (max. 15 weeks)
Temperature	+10°C (50°F) to +25°C (77°F)	-25°C (-13°F) to +70°C (158°F)
Relative humidity (including condensation)	30% to 80%	10% to 100%
Atmospheric pressure	700 hPa to 1060 hPa	500 hPa to 1060 hPa

△ CAUTION

Do not use iChiropro 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).

Applied parts (per IEC 60601-1):

MX-i LED micromotor	REF	1600755-001
Straight handpiece 1:1	REF	1600052-001
Straight handpiece 1:2	REF	1600436-001
CA 20:1 L	REF	1600598-001
CA 20:1 LMicro-Series	REF	1600692-001
CA 20:1 L KM	REF	1600785-001
CA 20:1 L KM Micro-Series	REF	1600786-001
Irrigation lines	REF	1500984-010
KM Irrigation lines	REF	1501635-010
Sterile Bur Guards	REF	1501317-100

Degree of ingress protection

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

Memory

- Memory storage of 8 users;
- Memory storage of 30 implant manufacturers (user-defined):
- Memory storage of 50 different settings for each implant manufacturer (user-defined);
- Memory storage of 12 steps per setting including adjustment of speed, torque, irrigation, lighting and handpiece for each step;
- 30 minute recording length per implant.

Languages

French, German, English, Italian, Spanish, Portuguese, Japanese Russian and Chinese.

Bracket for physiological liquid flask

Stainless steel.

Peristaltic pump

Pump delivery	From 30 to 150 ml/min.
	(5 levels)
Hose for pump	External Ø 5.60 mm
Internal	Ø 2.40 mm
Wall thickness	1.60 mm

Intended for use with:	See instructions for use
MX-i LED micromotor	REF 2100245
Cable for micromotor	REF 2100163
Contra-angle CA 20:1 L, light	REF 2100209
Contra-angle CA 20:1 L	
Micro-Series, light	REF 2100209
Contra-angle CA 20:1 L KM, light	REF 2100209
Contra-angle CA 20:1 L KM	
Micro-Series, light	REF 2100209
Straight Handpiece 1:1	
Straight Handpiece 1:2	REF 2100103

△ CAUTION

The use of the system with other handpieces, motors or cables has not been validated/certified (speed and torque values are not guaranteed in this case).

List of errors & Troubleshooting

See chapter "10 List of errors & Troubleshooting" on page 50.

4.5 Environmental protection and information for disposal



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



Separate collection of electric and electronic equipment and accessories in view of recycling.

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

4.6 Limitation of liability

△ CAUTION

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

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

To ensure the appropriate working of the whole device, make sure to use your iChiropro application only with iOS version validated by Bien-Air Dental SA.

4.7 Electromagnetic compatibility (technical description)

Precautions regarding Electromagnetic Compatibility (EMC)

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

△ CAUTION

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

△ CAUTION

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

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

△ CAUTION

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

Guidance and manufacturer's declaration - electromagnetic emissions

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

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

Emissions test	Compliance	Electromagnetic environment - guidance	
RF emissions CISPR 11	Group 1	iChiropro uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B		
Harmonic emissions IEC 61000-3-2	Compliant	iChiropro is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	for domestic purposes.	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance	
Electrostatic discharge (ESD)	±6 kV contact	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.	
IEC 61000-4-2	±8 kV air	±8 kV air		
Electrical fast transient burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for lines no input/output	±2 kV for power supply lines ±1 kV for lines no input/output	Mains power quality should be that of a typical commercial or hospital environment.	
Shock waves IEC 61000-4-5	±0.5 kV line to line ±1 kV line to line ±0.5 kV line to earth ±1 kV line to earth ±2 kV line to earth	±0.5 kV line to line ±1 kV line to line ±0.5 kV line to earth ±1 kV line to earth ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance	
Voltage dips and outages	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T	Mains power quality should be that of a typical commercial or hospital environment. If the user of iChiropro requires continued operation during power mains interruptions, it is recommended that iChiropro be powered from an uninterruptible power supply or a battery.	
IEC 61000-4-11	$\begin{array}{l} (30\% \ dip \ in \ U_T) \\ for \ 25 \ cycles \\ <5\% \ U_T \\ (>95\% \ dip \ in \ U_T) \\ for \ 5 \ sec \end{array}$	$\begin{array}{l} (30\% \ dip \ in \ U_T) \\ \text{for } 25 \ \text{cycles} \\ <5\% \ U_T \\ (>95\% \ dip \ in \ U_T) \\ \text{for } 5 \ \text{sec} \end{array}$		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.	

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

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

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

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the iChiropro is used exceeds the applicable RF compliance level above, the iChiropro should be observed to verify normal operation.

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

Note 1 - 2

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

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

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

	Separation distance according to frequency of transmitter [m]			
Rated maximum output power of transmitter [W]	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
transmitter [11]	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

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

Note 1 - 2

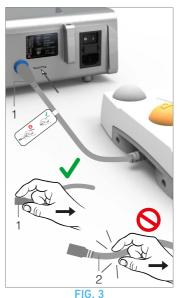
NOTES

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

5 Installation

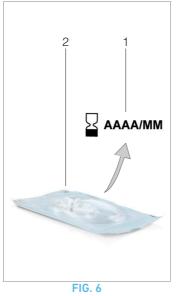


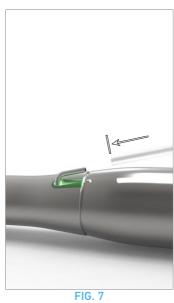






















5.1 Install the iChiropro app

- A. Open the App Store ©, tap the corresponding icon on the iPad.
- **B.** Tap Search to find the iChiropro application.
- **C.** Install the iChiropro application designed by Bien-Air Dental.

Note 1

5.2 Install the iChiropro system

A. If necessary, use the Phillips screwdriver to change the adapter for the iPad model being used (see chapter "11.5 iPad adapter change" on page 52).

FIG. 1

B. Place the iChiropro on a flat surface capable of bearing its weight.

△ CAUTION

It may be positioned on a table, on a trolley or any other surface but in no circumstances on the floor.

FIG. 2

C. The fuse box may be opened with a screwdriver. 100 - 240 Vac = fuse T-4.0 A L 250 VAC REF 1301560-010.

To replace a fuse, see chapter "11.6 Fuses replacement" on page 53.

D. Connect the power cable (1) to the connector (2).

Note 2

△ CAUTION

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

FIG. 3

E. Connect the pedal cable to the output provided on the rear panel, guiding the connector and plug by means of the index pin on the connector.

△ CAUTION

Do not lift the pedal holding the connection cable.

To disconnect the pedal cable pull the cable socket connector (1). Do not pull the cable (2) without disconnecting the cable socket before.

FIG. 4

F. Connect the MX-i micromotor cable to the motor output, guiding the connector and plug by means of the index pin on the connector.

FIG. 5

G. Align and attach the bracket to the housing provided on the rear of the console and suspend the flask or bottle.

FIG. 6

 $\mathbf{H}.$ Check the packaging integrity, as well as the expiry date of the irrigation line on the label (1).

△ CAUTION

The medical device must be used only with lines supplied by Bien-Air Dental to ensure trouble-free operation. These lines are sterile and for single use. Re-use may result in microbiological contamination of the patient.

I. Remove the single-use sterile irrigation line (2) from its pouch.

FIG. 7

J. Connect the flexible hose of the irrigation line to the spray tube of the handpiece or contra-angle.

FIG. 8

K. Install the peristaltic cassette (1) in the peristaltic pump (2). Check that the cassette is clipped correctly.

FIG. 9

L. Close the pump lid (3). If there is resistance to closing, open the lid again and check the correct positioning of the cassette. When the lid is correctly closed, the user should hear a click sound.

⚠ CAUTION

Do not run the pump while the lid is open.

△ CAUTION

Risk of pinching!

FIG. 10

M. Perforate the cap of the physiological liquid flask with the pointed end of the irrigation line after removing the protective cap.

FIG. 11

N. Attach the irrigation line on the motor cable using the attachment collars (1) REF 1303711-010.

5.3 Installation of the iPad on the iChiropro

0. Remove the single-use sterile protection sheet for iPad from its pouch and stick it on the screen. Refer to the instructions on the back of the pouch.

FIG. 12

P. Connect the iPad to the iChiropro by sliding it carefully along the adapter.

5.4 On/off procedure

The device can be switched on and off in complete safety using the main switch on the iPad and iChiropro.

NOTES

- 1 The iPad must be correctly connected to the Internet before the App Store © is opened; refer to Apple's user guide for appropriate use of the iPad.
- 2 The equipment is powered by the mains power supply (100 240 Vac).



FIG. 1

6 Interface overview

6.1 iChiropro application

The iChiropro system is intended for use in dental implantology and dental surgery.

6.1.1 Compatibility

The iChiropro application is compatible with iPad 2nd generation and higher.

6.1.2 Notation

In order to simplify the notation, in this manual, interface devices «iPad 2», «iPad 3», «iPad 4», «iPad Air®» and «iPad Air 2®» are referred to as «iPad».

6.2 Sound alerts



Sound alert	Description
One short beep	Activating irrigation, going to next step, and changing rotation direction
Two short beeps	Deactivating irrigation, and changing rotation direction
One high-fre- quency beep	Going to next implant placement or next surgery procedure
One long beep	Entering in implantology or surgery operative, going to first step of operative sequence
Alternate short beeps	Warning notifications
Alternate medium beeps	Micromotor REVERSE running indicator
Alternate long beeps	System failure notification

6.3 iPad and iChiropro connection / disconnection conditions

6.3.1 Disconnection

If the iPad is disconnected, the iChiropro system is in standby mode (MX-i micromotor stopped). The iChiropro app remains accessible when the iPad is disconnected. The user is able to navigate through the application and also to modify/create his own settings.

△ CAUTION

The iPad must never be disconnected from the iChiropro dental unit during operation! If the iPad is disconnected during an operation, the MX-i micromotor stops immediately.

6.3.2 Connection

The MX-i micromotor can start only when the iPad is connected and the application is in operative mode (implantology or surgery).

△ CAUTION

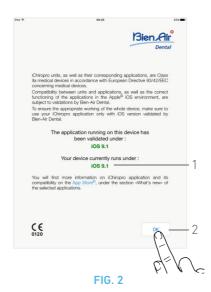
If the footpedal is pressed before entering in operative mode, the MX-i micromotor will not start to run.

6.3.3 iChiropro unit switched ON

If the iChiropro app is running and the iPad is plugged to the iChiropro (switch ON):

- The iPad will charge up (even if the app is not running);
- The MX-i micromotor can be operated with the pedal (iChiropro app in operative mode).







7 Getting started

7.1 Back up data

Use iTunes or iCloud to automatically back up your iChiropro application user-defined settings (user profiles, implant brands, implant parameters and all operations data).

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

7.2 Launch iChiropro app

FIG. 1

- **A.** Make sure that the sound volume on your iPad is ON and set to an appropriate level according to the ambient noise of the room:
 - Volume down (3) and up (2).
- **B.** Close all other applications in order not to disrupt the operation:
 - Double-click the home button (4) 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 Auto-lock and all alerts. Refer to Apple's user guide for appropriate use of the iPad.
- **D.** Ensure that the latest application updates have been installed (see chapter "7.10 iChiropro App update" on page 24).
- **E.** Tap the app icon (5) to launch the iChiropro application.

△ CAUTION

If not using your iPad, press the Sleep/Wake button (1) to lock it.

7.3 Welcome screen and disclaimer

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

FIG. 2

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

△ CAUTION

Do not update iOS unless it is recommended by Bien-Air. See also chapter "10.1 Safety warning (operating)" on page 50.

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. 3

- **C.** Make sure to have set all steps of disclaimer (3) and tap **OK** (4).
- ♥ The Home page screen is displayed.

See chapter "7.4 Home page screen" on page 16.

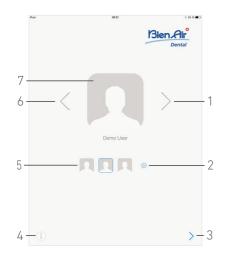






FIG. 4 FIG. 5 FIG. 6

7.4 Home page screen

FIG. 4

A. Tap (4) to open the *Information* screen. See chapter "7.11 Information" on page 24 for details.

B. Tap (+) (2) to create a new user profile. See chapter "7.6 Create user profile" on page 16 for details.

 ${f C.}$ Tap a thumbnail (5) or use the arrows (1 or 6) to select a user profile.

D. Tap the profile photo (7) to edit or remove a user profile. See chapter "7.7 Edit or remove user profile" on page 17 for details.

E. Tap (3) to validate the profile choice.

♥ The User page screen is displayed.

7.5 User page screen

FIG. 5

A. Tap *IM* (5) to enter the implantology mode. See chapter "8.1 Enter implantology mode" on page 26 for details.



B. Tap *SR* (1) to enter the surgery mode. See chapter "9.1 Enter surgery mode" on page 40 for details.



Note 1

C. Tap *Patients* (2) to open the Patients list popup. See chapter "7.8 Patients" on page 18 for details.



D. Tap *Operations history* (4) to open the *Operations history* screen



See chapter "7.9 Operations history" on page 20 for details.

E. Tap *i* (3) to open the *Information* screen. See chapter "7.11 Information" on page 24 for details.



7.6 Create user profile

A. From the Home page screen (FIG. 4), tap $^{\bigoplus}$ to create a new user profile.

The **Profile** popup window is displayed.

FIG. 6

B. Fill in the following parameters fields:

• Picture (from camera or library) (7)

Note 2

- Title (6)
- Last Name* (5)
- First Name* (4)
- Teeth numbering system (Universal, FDI) (2)

Note 3

• Planning software (3)

Note 4 - 5

C. Tap Save (1) to create the new user profile.

Note 6 - 7



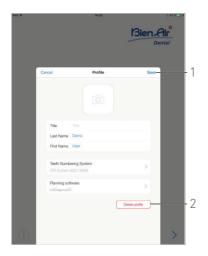


FIG. 7 FIG. 8

7.7 Edit or remove user profile

FIG. 7

A. From the Home page screen, tap the profile photo (1) to edit or remove user profile.

♣ The Profile popup window is displayed.

FIG. 8

B. Change the desired parameters and tap *Save* (1) to validate the changes on profile, or tap *Delete profile* (2) to remove profile.

🔖 If removing profile, a message box opens: *Delete profile*.



C. Tap Cancel or Delete to acknowledge.

NOTES

- $1\,$ $\,$ In the USA and Canada, the surgery mode is available only on the iChiropro Surgery unit (REF 1600883-001).
- **2** A *No access to camera* popup window is displayed if the app does not have access to camera. Tap OK to acknowledge and go to the iPad settings to allow the app to access camera:



- 3 FDI is defined as the default teeth numbering system.
- **4** CoDiagnostiX[™] is selected as the default planning software.
- 5 Fields marked with an asterisk are mandatory fields.
- 6 It is possible to create up to 8 users.
- 7 In case mandatory fields are empty, saving is not possible until these fields are filled in. Empty mandatory fields blink on the screen





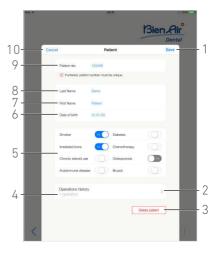


FIG. 10 FIG. 11

7.8 Patients

FIG. 9

From the user page screen, tap ${\it Patients}$ to open the Patients list popup.

FIG. 10

The Patients list popup displays all the recorded patients with the following information (3):

- · Patient's first and last names;
- · Patient's number;
- · Patient's date of birth.

This popup also allows to find patients in the list with the **Search** *in patients list* field (1).

7.8.1 Add or edit patient

FIG. 10

A. Tap + (2) to create a new patient, or tap on the desired patient line to access and modify the specific information.

Note 8

🖔 The *Patient* popup window is displayed.

FIG 11

- **B.** Tap the patient's identity fields to fill them in or to modify them:
 - Patient number (9);
 - Last Name* (8):
 - First Name* (7);
 - Date of birth (6).
- **C.** Swipe right or left (or tap) to answer by **Yes** or **No** to their medical history (5) (the selector is set by default in the middle position meaning unknown):
 - Smoker
 - Irradiated bone
 - · Chronic steroid use
 - Autoimmune disease
 - Diabetes
 - Chemotherapy
 - Osteoporosis
 - Bruxist

Note 9

D. Tap *Save* (1) to validate or *Back* (or *Cancel*, if creating a patient) (9) to discard changes.

Note 10 - 11

E. Tap Close (4) (see FIG. 10) to close the Patients list popup.

7.8.2 Remove patient

FIG. 11

A. Tap *Delete patient* (3) or from the Patients list popup, swipe left and tap *Delete* (1) (see FIG. 12) to remove the desired patient.

Note 12

🔖 A message box opens: Delete patient



B. Tap Cancel or Delete to validate.

7.8.3 Consult patients history

FIG. 11

A. Tap *Operations history* (4) to consult the patient's operations history.

Note 13 - 14

 $\$ The **Operations history** screen is displayed.

See chapter "7.9 Operations history" on page 20 for details.

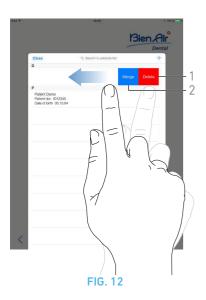




FIG. 13

7.8.4 Merge patients

Patient identity is unique. When the iChiropro app is updated, or when an operation is imported from a planning software, a check on the patients already existing in the database is performed. If two or more patients share first name, last name, date of birth and patient number, they are automatically merged.

If only some of these fields are coincident, a manual merge is still possible:

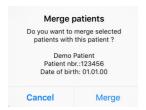
FIG. 12

A. From the Patients list popup, swipe left and tap Merge (2).

Note 12

FIG. 13

- **B.** Tap the lines of the patients that need to be merged with the selected patient.
- $\$ A check symbol $\$ is displayed on each of the selected patients lines.
- C. Tap Done (1) to validate.
- 🔖 A message box opens: *Merge patients*



- ${\bf D.}$ Tap ${\it Merge}$ to validate or ${\it Cancel}$ to discard changes and cancel merging process.
- Spatients and their corresponding operations are merged.

NOTES

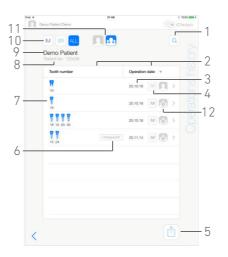
- ${\bf 8}$ If accessing from ${\it Operation\ setup}$ page, tap \bigodot to access and modify information.
- 9 Fields marked with an asterisk are mandatory fields.
- 10 In case mandatory fields are empty, saving is not possible until these fields are filled in. Empty mandatory fields blink on the screen.
- 11 In case the patient number already exists, a popup window is displayed when saving:



Tap *Use this patient* to use the already existing patient's information, or tap *Cancel* to discard changes.

- 12 The *Delete* button is only available when accessing the Patients list popup from the User page screen. The *Merge* button is only available when accessing the Patients list popup from the User page screen and when there is two or more patients in the list.
- **13** It is only possible to consult a patient's history when accessing the Patients list popup from the user page screen.
- **14** The number of operations found for the selected patient is indicated (4, FIG. 11).





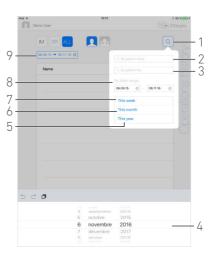


FIG. 14 FIG. 15 FIG. 16

7.9 Operations history

The *Operations history* screens can differ whether they are displayed from the User page screen (see FIG. 14) or the *Patient* popup window (see FIG. 15).

This page displays all the recorded operations with the following information:

FIG. 14

- Patient's first and last names (8);
- Patient's number (7);
- Patient's date of birth (6);
- Operation's date (3);
- Operation type (implantology or surgery) (4);
- Planning software used (9) (see chapter "8.4 Import an operation" on page 28).

Note 15

FIG. 15

- Patient's first and last names (9);
- Patient's number (8):
- Operation's date (3);
- Operation type (implantology or surgery) (4);
- Operation recorded by another user (12);

Note 16

- Placed implants identification numbers or surgery operations and their teeth positions (7);
- Planning software used (6) (see chapter "8.4 Import an operation" on page 28).

Note 15 and 17

FIG. 14 & FIG. 15

This page also allows to:

- Filter operations by type, by tapping IM (implantology), SR (surgery) or ALL (surgery and implantology) (10);
- Filter operations by user, by tapping (current use
- Find specific information in the list with the **Search** button (1) (see chapter "7.9.1 Search operations history" on page 20);
- Export all filtered operations data in a .zip file containing .csv or .pdf data for each operation, with the Export all button (5) (see chapter "7.9.4 Export all operations reports" on page 22);
- Sort patients names and operations dates by tapping on their respective columns titles (2),

Note 18

E. Tap on the desired operation line to access and modify the specific information through the *Operation data* page.

🖔 The *Operation data* page screen is displayed.

Note 16

See chapter "7.9.2 Operation data" on page 21.

only) or (all users) (11);

7.9.1 Search operations history

FIG. 16

Tap (1) to display the search popup showing the following fields:

- By patient name (2);
- By patient number (3);

Note 19

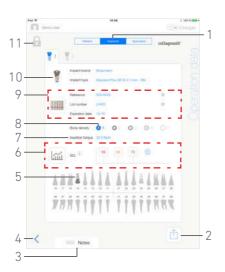
• By date range (start – end) (8).

These fields can be edited in order to define search criteria (4).

In addition to this, it is possible to automatically filter operations displaying only those performed:

- This week (7);
- This month (6);
- This year (5).





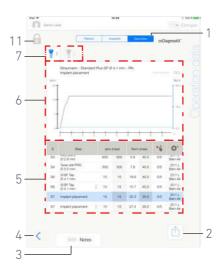


FIG. 17 FIG. 18 FIG. 19

7.9.2 Operation data

FIG. 17, FIG. 18 and FIG. 19

These three pages are available either during or after an operation. It is possible to switch through these pages with the *Patient, Implants* and *Operation* tab switch (1).

The common page footer allows to export the operation report (2) (See chapter "7.9.3 Export report" on page 22), add **Notes** (3) and go back (4) to the previous page.

Note 15 - 16

Patient data tab

FIG. 17

This page allows to view the operation date (9), the patient identity* (8) and his medical history* (7).

Note 20 - 21

Implants data tab

FIG. 17

This page allows to consult the *Implant brand* and *Implant type* (10) and the implant position (5) in details. As well as the *Bone density* (8) and the *Insertion torque* (7).

It is possible to modify the implants **Reference***, **Lot number*** and **Expiration date*** (9), and the **ISQ*** (6) values readings.

For more information about ISQ values readings, See chapter "7.12 ISQ values readings" on page 25.

Note 22, 22, 23 and 24

Operation data tab

FIG. 19

This page allows to consult the operations in detail.

- (5) Operation summary table for each implant, including step number, step name, max. reached speed, max. set speed, max. reached torque, max. set torque, motor rotation direction, irrigation level and instrument type
- (6) Graphic with torque and speed as a function of operation time for each implant and for each operative step
- (7) Implant selection icons.

NOTES

- **15** If the operation has been imported, the corresponding planning software icon is displayed.
- 16 Operations recorded by other users are marked either with

the symbol (12, FIG. 15) or (11). It is not possible to modify information for these operations.

- 17 When the *Operations history* screen is accessed from the *Patient* popup window, only recorded operations related to the corresponding patient are displayed.
- **18** Patients names column is replaced by a non-sortable **Tooth number** column when accessing the **Operations history** screen from the **Patient** popup window.
- 19 By patient name and By patient number are only available if the search popup was accessed from the User page screen.
- **20** Values with ****** can be modified and saved during and also after an operation.
- 21 Tap to modify the patient's information (See chapter "7.8.1 Add or edit patient" on page 18 for details).
- 22 If information is modified *Cancel* and *Save* buttons are displayed.
- 23 Implant brand and Implant type can only be modified during operation, before the footpedal is pressed in the implant placement step. In this case, the first procedure step of the newly selected implant is selected when going back to the Operative page screen. If imported from a planning software it is not possible to modify data.
- **24** This page differs whether the operation concerns implantology or surgery and whether the implant information has been scanned or filled-in manually.





FIG. 20 FIG. 21

7.9.3 Export report

- **A.** From the *Operation data* page, tap to export the operation data.
- 🖔 A popup window allows to choose the export format:



- B. Tap Export as .pdf or Export as .csv.
- The Operation report screen (export as pdf) or the operation data table (export as csv) is displayed.

FIG. 20

- **C.** Tap the Export report button (1) to choose the export target.
- 🔖 A popup window allows to choose the export target (2).
- **D.** Choose the export target among the available web file storages or the installed apps supporting the csv or pdf files.
- \$\text{\$\subset\$ The corresponding app popup is displayed.}

Note 25

Or tap *Close* (or *Done*, for csv export) (3) to go back.

7.9.4 Export all operations reports

FIG. 21

- **A.** From the *Operations history* page screen tap (2) to export all operations displayed in the filtered list in a .zip file.
- 🖔 A popup window allows to choose the export format.



Note 26

- B. Tap Export as .pdf or Export as .csv.
- The export progress bar popup is displayed (export might take some time depending on the amount of operations):



The **EXPORT COMPLETE** popup is displayed when the .zip file containing .pdf or .csv data for each operation has been created successfully:



- C. Tap anywhere on the screen to acknowledge message.
- 🔖 A popup window allows to choose the export target (1).
- **D.** Choose the export target among the available web file storages or the installed apps supporting the .zip files.
- \$\to\$ The corresponding app popup is displayed.

Note 25

△ CAUTION

If the generated zip file is large, it might not be possible to export it with the procedure described above.

In this case, see "Export all reports procedure with iTunes" on page 23

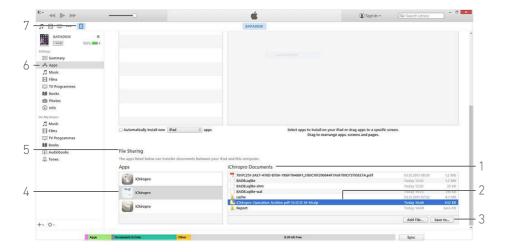


FIG. 22

Export all reports procedure with iTunes

- A. Connect the iPad to a computer via USB cable.
- **B.** Tap *Trust* if the *Trust This Computer?* popup window is displayed on the iPad.
- C. Launch iTunes app on the computer.

FIG. 22

- **D.** Click the connected iPad icon (7).
- ${\bf E.}$ Click ${\it Apps}$ (6) and scroll down until reaching ${\it File Sharing}$ area (5).
- **F.** Click on the iChiropro app line (4).
- **G.** Click on the *iChiropro Operation Archive format-dd.mm.yy hh-mm.zip* line (2), in the *iChiropro Documents* area (1).
- H. Click Save to (3) and choose the desired saving path.

NOTES

- 25 It is only possible to export as a mail if a mail account is already created and configured on the iPad.
- **26** When the *Operations history* screen is accessed from the *Patient* popup window, only recorded operations related to the corresponding patient are exported.







FIG. 23

7.10 iChiropro App update

FIG. 23

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

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

Note 27

- 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).

7.11 Information

FIG. 24

A. Tap 1 to open the *Information* screen (it is also possible to access it from the home page screen).

FIG. 25

🔖 This screen allows to navigate to the following pages:

- Latest news (1) (opens Bien-Air website latest news page);
- *User manual* (2) (application detects the language of the iPad and downloads the User Manual in the same language);

Note 28 - 29

- Catalogue (3) (opens online catalogue (pdf file));
- Web TV (4) (opens Bien-Air web TV);
- *About* (5) (See chapter "7.11.1 About" on page 25);
- *Contact us* (6) (opens email application with predefined email address iChiropro@bienair.com).

Note 30



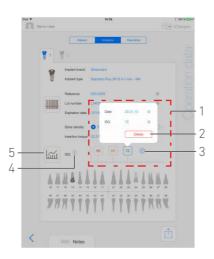




FIG. 26 FIG. 27 FIG. 28

7.11.1 About

FIG. 26

The **About** screen displays the following information:

- Manufacturer contact details (1);
- Application name and version (2);
- iPad model and iOS version (3);
- Compatible dental units (4);
 - iChiropro;
 - iChiropro Gnatus;
 - iChiropro Surgery;
 - OsseoCareTM Pro;
- Interface board name and firmware version (5);
- MX-i micromotor drive type and firmware version (6).

7.12 ISQ values readings

FIG. 27

By default ISQ values readings area (1) displays only the $\stackrel{\textcircled{+}}{=}$ (3) button. It is possible to add up to five ISQ editable fields by tapping the $\stackrel{\textcircled{+}}{=}$ (3) button and to **Delete** (2) them.

Tap \odot (4) to access a popup with explanations on the ISQ or tap the button (5) to display a graph (FIG. 28) of the different ISQ readings in relation to time.

NOTES

- 27 This function is active only when the iPad is connected to the internet.
- **28** If the User Manual is not available in the correct language, the English manual is downloaded.
- **29** The user can export the User Manual to targets such as e-mails, printer or any other supported export target.
- **30** Latest News, Catalogue, Web TV and Contact us functions are available only if the iPad is connected to the internet.



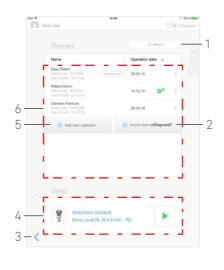




FIG. 2 FIG. 3

8 Operation - Implantology mode

8.1 Enter implantology mode

FIG. 1

Tap **IM** to enter the implantology mode.

The implantology mode allows to perform operations consisting of placing up to 8 implants. Each implant placement is made up of several steps that can be edited by the user.

🖔 The *Setup* page screen is displayed.

8.2 Setup screen description

FIG. 2

The **Setup** screen allows to plan an operation, start a planned operation or select a single implant for direct placement:

- Search field (to find specific information in the planned operations list)
- (2) Import an operation from a planning software (see "8.4 Import an operation" on page 28)
- (3) Back to the previous screen
- (4) Direct operation area
- (5) Plan a new operation (see "8.3 Plan an operation" on page 26)
- (6) Planned operations area

Note 1

8.3 Plan an operation

A. From the **Setup** screen, tap \bigoplus **Add new operation** to add a new operation.

🖔 The *Operation setup* page screen is displayed.

FIG. 3

B. Tap (6) to access the Patients list popup.

The Patients list popup is displayed.







FIG. 4 FIG. 5 FIG. 6

FIG. 4

C. Tap on the desired patient line to select the patient.

See section "7.8.1 Add or edit patient" on page 18 if the desired patient is not present or to modify patient's data.

- The *Operation setup* page screen is displayed again, and the following patient information fields are automatically filled in, FIG. 3:
 - First and last names* (7);
 - Date of birth (1);
 - Patient Number (5).
- **D.** Tap the following operation fields to fill them in, FIG. 3:
 - Operation date* (2);
 - Bone density (from 1 to 4, or unknown) (3).

Note 2



(4) to select an implant.

The *Implant brand selection* popup window is displayed.

FIG 5

- **F.** Tap a \it{Brand} to access the implants types window or tap \it{Close} (1) to go back.
- 🖔 The *Implant type selection* popup window is displayed.

See section "8.10.1 Add implant" on page 36 if the desired brand is not present or see "8.11 Bookmark or remove brands" on page 38 to bookmark or remove brands.

FIG. 6

Note 3

- ${\bf G.}$ When available, choose between ${\it Guided}$ (implant) and ${\it Non-guided}$ (1).
- H. Tap the desired implant system (3) and its diameter (2).

If the desired implant is not available, see "8.10 Add, edit or remove implants" on page 36.

NOTES

- 1 Patients' names and operation's dates can be sorted by tapping on their respective columns titles (6).
- 2 Fields marked with an asterisk must be filled in before saving.

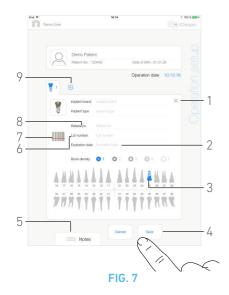


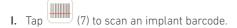




FIG. 8 FIG. 9

FIG. 7

Note 4



- 🖔 The camera is activated and the Scan page screen is displayed.
- J. Align the yellow rectangle with the barcode.
- The Scan completed! popup is displayed when the barcode has been read successfully:



K. If correct, tap *Done* or the *Scan completed!* popup itself.

The following implant information fields are automatically filled in:

- Reference / GTIN (8):
- Lot number (6);
- Expiration date (2) if available.

Note 5 - 6 - 7

L. Define the implant position by tapping the corresponding tooth in the jaw representation.

🔖 The selected tooth is replaced by a blue highlighted implant (3).

M. Tap $\stackrel{(+)}{\oplus}$ (9) to add other implants to the operation, or tap \times (1) to remove implants from the operation.

Note 8 - 9

 $\mathbf{N.}$ Tap or slide Notes (5) to write comments in relation to the operation.

O. Tap Save (4) to validate.

 $\$ The operation appears on the planned operations list.

Note 10

P. Tap < to go back to the *Setup* page screen or tap to start the operation.

Note 11

See section "8.6 Start or resume a planned operation" on page 30 to start a planned operation.

8.4 Import an operation

Note 4

 $\ensuremath{\mathfrak{t}}\xspace$ The camera is activated and the Planning code scan page is displayed.

Note 12

FIG. 8

 ${f B.}$ Align the yellow rectangle with the desired QR code from a planning software.

The **Scan completed!** popup is displayed when the QR code has been read successfully.

FIG. 9

C. If correct, tap *Done* (1) or the *Scan completed!* popup itself.

The operation information is imported and the *Operation setup* page screen is displayed.

Note 13

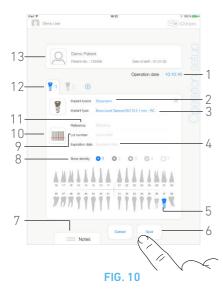


FIG. 10

The following operation information is automatically defined for each step and can not be modified:

- Implants placement order (12)
- Implant brand (2)
- Implant type (3)
- Implant position (5)
- **D.** If necessary, modify the automatically filled in patient's general information (13) and *Bone density* (8).
- E. Tap the *Operation date** field (1) to define the operation date.

Note 14

- F. Tap (10) to scan an implant barcode.
- \$\triangle\$ The camera is activated and the Scan page screen is displayed.
- **G.** Align the yellow rectangle with the barcode.
- The Scan completed! popup is displayed when the barcode has been read successfully:



- H. If correct, tap *Done* or the *Scan completed! popup* itself.
- The following implant information fields are automatically filled in:
 - Reference / GTIN (11);
 - Lot number (9);
 - Expiration date (4) if available.

Note 5 - 6 - 7

- **I.** Tap or slide **Notes** (7) to write comments in relation to the operation.
- J. Tap Save (6) to validate.
- 🖔 The operation appears on the planned operations list.

Note 15

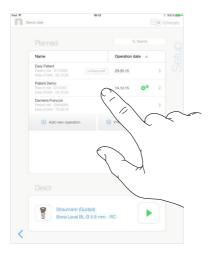
K. Tap < to go back to the *Setup* page screen or tap to start the operation

See section "8.6 Start or resume a planned operation" on page 30 to start a planned operation.

NOTES

- 4 The barcode and QR code scanning function is available only on iPad 3rd generation and higher.
- 5 The *Reference* field is replaced by a *GTIN* field when GTIN code is available in the barcode data.
- 6 Only Code 128 and DataMatrix barcodes are supported.
- ${f 7}$ It is also possible to fill these fields in manually by tapping on them
- **8** It is possible to add up to 8 implants. Each implant is numbered in the jaw representation accordingly to the operation order. The last implant type used for the operation is proposed by default for additional implants.
- $\boldsymbol{9}$ $\,$ Long tap on implants icons and move them to reorganize order.
- 10 In case mandatory fields are empty, saving is not possible until these fields are filled in. Empty mandatory fields blink on the screen.
- 11 Starting an operation is not possible if the implant's position and information is not defined. Empty mandatory fields blink on the screen.
- **12** The user must have enabled the import feature in the *Profile* popup window to import an operation from a planning software (see section "7.8.1 Add or edit patient" on page 18).
- 13 When imported patient information corresponds to an already existing patient information (same *First name, Last name, Date of birth* and *Patient number*), patients are automatically merged. If only some of these fields are coincident, a manual merge is still possible (see section "7.8.4 Merge patients" on page 19).
- 14 Fields marked with an asterisk must be filled in before saving.
- **15** If the operation has been imported, the corresponding planning software icon is displayed.





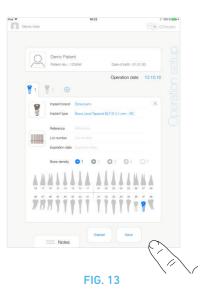


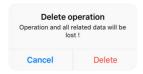
FIG. 11 FIG. 12

8.5 Remove an operation

FIG. 11

A. From the Setup page screen, swipe left and tap Delete (1) to remove the desired operation.

A message box opens: Delete operation.



B. Tap Cancel or Delete to acknowledge.

8.6 Start or resume a planned operation

FIG. 12

A. From the *Setup* page screen, in the *Planned* operations area, tap the operation that needs to be started or tap an operation marked with the symbol to resume it and go directly to step C.

The Operation setup page screen (start operation) or the Operative page screen (resume operation) is displayed.

Note 16

FIG. 13

B. Check if the operation's information is correct and tap to access the *Operative* page screen.

Note 17

△ CAUTION

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

△ CAUTION

If the sound volume is OFF before entering in operative mode, a warning message «Please switch ON sound volume on your iPad and set it to an appropriate level according to the ambient noise level in your practice room.» will be displayed.

The MX-i micromotor will not start to run until the sound volume is $\ensuremath{\mathsf{ON}}$

FIG. 14

△ CAUTION

When accessing the *Operative* page screen for the first time, a popup is displayed to introduce the footpedal's orange button behavior. Tap anywhere on the screen to close the popup or tap *Don't show me again* to acknowledge:



C. Operate by pressing the footpedal to adjust the MX-i micromotor speed.

If needed, tap (1) to record step.

Note 18 - 19

△ CAUTION

Recording steps is only possible with the contra angle handpiece CA 20:1 L designed by Bien-Air Dental SA.

- **D.** Navigate through the operation steps by:
 - Short pressing the footpedal's orange button or tapping the Navigation area (9) to go to the next step;
 - Tapping the desired step icon (4).

Note 21 - 22 - 23

E. Tap (2) to visualize the surgical protocol generated by the planning software, if necessary.

Note 24

F. If necessary, tap (3) to visualize the position of the tool to be used for the current step in the cassette.

Note 25

See chapter "8.9 Tool visualization in cassette" on page 36 for details.

G. Adjust the operative parameters (7) if necessary. See section "8.8 Operative parameters" on page 34.

H. Long tap on the implant icons (11) or long press the footpedal's orange button to perform the other planned implants placement.

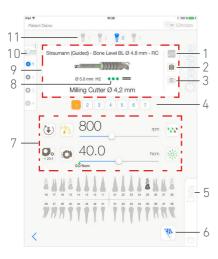


FIG. 14

Note 21

- **I.** Select the bone density (10) for the current implant position; it is possible to set or modify the bone density value at any time during the operation (? = unknown).
- J. Tap Data (5) to modify patient's data if necessary.
- ♣ The Operation Data page screen is displayed.
 See section "7.9.2 Operation data" on page 21 for details.
- K. Tap the Finish button (6) to end the operation.
- 🔖 A message box opens: *Finish operation*.
- $\mbox{\bf L.}$ Tap $\mbox{\it Finish}$ to confirm the end of operation or $\mbox{\it Cancel}$ to continue operation.

NOTES

- 16 In case mandatory fields are empty, saving is not possible until these fields are filled in. Empty mandatory fields blink on the screen.
- 17 Starting an operation is not possible if the implant's position and information is not defined. Empty mandatory fields blink on the screen.
- **18** Real-time speed and torque values are displayed when the MX-i micromotor is running.
- 19 When the power demand of the MX-i micromotor is excessive,

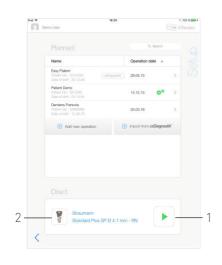
the Operative screen displays the overheating symbol . In this case the iChiropro unit lowers the torque automatically in order to avoid overheating of the MX-i micromotor. To restore 100% torque, allow the motor to idle or stop for a few seconds.

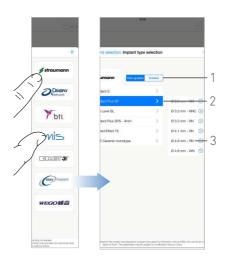
- **20** The specific guided surgery information (8) is displayed for operations imported from coDiagnostiX TM with Straumann TM guided implants
- 21 Refer to the corresponding handpiece IFU if a tool change is needed.
- 22 For safety reasons, the speedometer and the step icon of high speed steps are highlighted in orange. The following popup warning is displayed when switching from low speed to high speed (≥ 100 RPM) drilling:



Tap \it{OK} or short press the footpedal's blue button to acknowledge the popup warning and allow the MX-i micromotor to start.

- 23 The implant placement step icon is marked with the symbol in the upper-right corner.
- 24 Surgical protocol visualization is only available for operations imported from coDiagnosti X^{TM} .
- **25** Tool visualization in the cassette is only available for operations using Straumann™ non-guided implants.





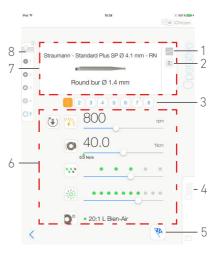


FIG. 15 FIG. 16 FIG. 17

8.7 Start a direct operation

The direct operation mode allows realizing an operation without any planning.

FIG. 15

A. From the **Setup** page screen, tap (2) in the **Direct** operation area to select implant brand and type,

Or tap (1) if the desired implant selection is already displayed and go directly to step E.

\$\to\$ The **Operative** page screen is displayed.

FIG. 16

B. Tap a brand to access the *Implant type selection* window.

🖔 The *Implant type selection* window is displayed.

See section "8.10.1 Add implant" on page 36 if the desired brand is not present or see "8.11 Bookmark or remove brands" on page 38 to manage brands.

Note 26

- C. When available, choose between Guided (implant) and Non-guided (1).
- $\mathbf{D}.$ Tap the implant system (2) and its diameter (3) to select the desired implant.

If the desired implant is not available, see "8.10 Add, edit or remove implants" on page 36.

\$\to\$ The app navigates back to the **Setup** page screen.

E. Tap (1) to access the *Operative* page screen, FIG. 15.

△ CAUTION

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

△ CAUTION

If the sound volume is OFF before entering in operative mode, a warning message «Please switch ON sound volume on your iPad and set it to an appropriate level according to the ambient noise level in your practice room.» will be displayed.

The MX-i micromotor will not start to run until the sound volume is $\ensuremath{\mathsf{ON}}.$

FIG. 17

△ CAUTION

When accessing the *Operative* page screen for the first time, a popup is displayed to introduce the footpedal's orange button behavior. Tap anywhere on the screen to close the popup or tap *Don't show me again* to acknowledge.



F. Operate by pressing the footpedal to adjust the MX-i micromotor speed.

If needed, tap (1) to record step.

Note 27 - 28

△ CAUTION

Recording steps is only possible with the contra angle handpiece CA 20:1 L designed by Bien-Air Dental SA.

- **G.** Navigate through the operation steps by:
 - Short pressing the footpedal's orange button or tapping the Navigation area (7) to go to the next step;
 - Tapping the desired step icon (3).

Note 29 - 30 - 31

H. If necessary, tap (2) to visualize the position of the tool to be used for the current step in the cassette.

Note 32

See chapter "8.9 Tool visualization in cassette" on page 36 for

- **I.** Adjust the operative parameters (6) if necessary. See section "8.8 Operative parameters" on page 34.
- **J.** Select the bone density (8); it is possible to set or modify the bone density value at any time during the operation (? = unknown).
- K. Tap Data (4) to modify patient's data if necessary.
- 🔖 The *Operation data* page screen is displayed.

See section "7.9.2 Operation data" on page 21 for details.

- L. Tap the Finish button (5) to end the operation.
- A message box opens: Finish operation.
- $\mathbf{M}.$ Tap Finish to confirm the end of operation or Cancel to continue operation.
- The Operation data page screen is displayed. Fill the necessary information in and tap Save.

See section "7.9.2 Operation data" on page 21 for details.

NOTES

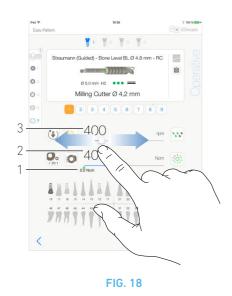
- **27** Real-time speed and torque values are displayed when the MX-i micromotor is running.
- 28 When the power demand of the MX-i micromotor is excessive,

- 29 Refer to the corresponding handpiece IFU if a tool change is needed.
- **30** For safety reasons, the speedometer and the step icon of high speed steps are highlighted in orange. The following popup warning is displayed when switching from low speed to high speed (\geq 100 RPM) drilling:



Tap **OK** or short press the footpedal's blue button to acknowledge the popup warning and allow the MX-i micromotor to start.

- **31** The implant placement step icon is marked with the symbol in the upper-right corner.
- ${\bf 32}$. Tool visualization in the cassette is only available for operations using Straumann $^{\text{TM}}$ non-guided implants.



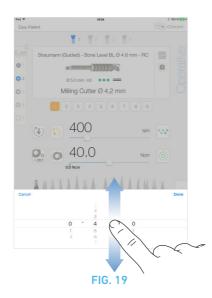




FIG. 20

8.8 Operative parameters

The operative parameters disposition can slightly differ whether it is displayed from a direct operation, a planned operation or a procedure protocol. However, the procedures given in this chapter are valid for all kinds of operations. All operation parameters can be temporarily changed during an operation, on the *Operative* screen.

8.8.1 MX-i micromotor Speed & Torque

FIG. 18

Maximum reachable speed (3) and torque (2) values are displayed when the MX-i micromotor is not running. Real-time speed (3) and torque (2) values are displayed when the MX-i micromotor is running.

Note 33

Slide to adjust the maximum speed and torque values.

Or tap the icons to activate the wheel scroller for fine adjustment.

FIG. 19

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

8.8.2 MX-i micromotor rotation direction

FIG. 20

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

- Forward (clockwise)
- Reverse (counter clockwise)

Note 34 - 35

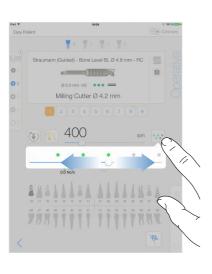






FIG. 21 FIG. 22 FIG. 23

8.8.3 Irrigation Level

FIG. 21

Slide or tap the appropriate dot to set up the irrigation level. 6 levels of adjustment are possible:

irrigation OFF, 30ml/min, 60ml/min, 90ml/min, 120ml/min, 150ml/min.

8.8.4 Handpiece ratio

FIG. 22

Tap and select to modify the handpiece ratio.

△ CAUTION

Verify that the handpiece corresponds to your selection.

Note 36 - 37

8.8.5 Light intensity

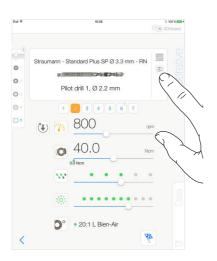
FIG. 23

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 38

- **33** The max. reached torque value is represented by the green arrow (1).
- ${\bf 34}$ $\,$ The operative screen always displays the selected rotation direction.
- **35** In reverse mode (CCW), the symbol flashes and there is a sound alert (alternate medium beeps).
- **36** The operative screen always displays the selected handpiece ratio
- **37** The handpiece ratio is red-colored for multiplication gears, blue-colored for direct-drive, and green-colored for reduction gears.
- **38** The operative screen always displays the selected light intensity value.





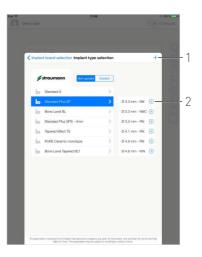


FIG. 24 FIG. 25 FIG. 26

8.9 Tool visualization in cassette

FIG. 24

From the *Operative* screen, tap to visualize the position of the tool to be used for the current step in the cassette.

\$\text{\$\text{The tool visualization page screen is displayed.}}

FIG. 25

This page allows to locate the needed tool in the cassette:

(1) Complete / Basic switch

Note 39

- (2) Current step tool to be used
- (3) Tools identification table
- (4) Cassette picture
- (5) Close button
- **A.** Find the current step tool number (2) in the tools identification table (3). If necessary, swipe down or up to access the tool in the tools identification table (3).
- **B.** Locate the current step tool number in the cassette picture (4).
- C. Tap Close to go back to the Operative page screen.
- 🦴 The *Operative* page screen is displayed.

8.10 Add, edit or remove implants

8.10.1 Add implant

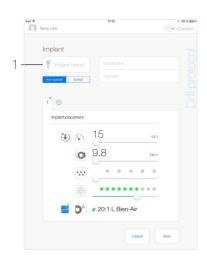
FIG. 26

A. From the *Implant type selection* popup window tap $\stackrel{\leftarrow}{+}$ (2) to create a copy of a factory implant, or tap $\stackrel{\leftarrow}{+}$ (1) to create an implant named after an existing Implant Brand, with operation parameters assigned by default.

Note 40

It is also possible to add a new brand by tapping + in the *Implant* brand selection popup window.

The **Drill protocol** page screen is displayed. If creating an implant as a copy of a factory implant or named after an existing Implant Brand, go directly to step E.



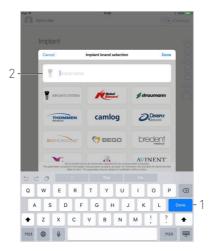




FIG. 27 FIG. 28 FIG. 29

FIG. 27

- **B.** Tap the *Implant brand* button (1).
- 🔖 The *Implant brand selection* popup window is displayed again.

FIG. 28

C. Type the brand name in the **Brand name** field (2).

Note 41

- D. Tap Done (1) to validate.
- 🔖 The app navigates back to the *Drill protocol* page screen.

FIG. 29

- E. When available, choose between *Guided* (implant) and *Non-quided* (9).
- F. Fill in or modify the *Implant type* (1) and *Diameter* (2) fields.
- ${f G.}$ Change the ${\it Step\ name}$ (7) and the operative parameters (6) if necessary.

See section "8.8 Operative parameters" on page 34.

H. Tap (5) to record step by default.

△ CAUTION

Recording steps is only possible with the contra angle handpiece CA 20:1 L designed by Bien-Air Dental SA.

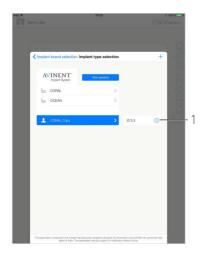
I. Tap \oplus (8) to add steps or tap \times (3) to remove steps from the drill protocol. Change their position by dragging and releasing them.

Note 42 - 43 - 44

- J. Tap Save (4) to validate.
- The new implant can be found in the *Implant type selection* popup window, into its corresponding brand. If a brand has been created, it is now present in the *Implant brand selection* popup window.

Note 45

- **39** The *Basic* tab allows to display simplified tools identification table and cassette picture (not available for all Straumann TM implants).
- **41** It is also possible to automatically fill-in the *Brand name* field by tapping on the icon of one of the existing Implant Brands.
- 42 It is possible to add up to 12 steps for each drill protocol.
- **43** The implant placement step icon is marked with the symbol.
- **44** By default, when a new implant is created from scratch, only the implant placement step is present. This step cannot be removed, its recording is active by default and cannot be deactivated.
- **45** The *Implant brand* and *Implant type* fields must be filled in before saving.



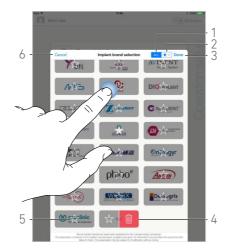


FIG. 30 FIG. 31

8.10.2 Edit (user-defined) implant

FIG. 30

A. From the *Implant type selection* popup window, tap \bigcirc (1) on the user-defined implant to be modified.

The **Drill protocol** page screen is displayed.

B. Change the desired operative parameters. See section "8.8 Operative parameters" on page 34.

C. Tap Save to validate or Cancel to discard changes.

8.10.3 Remove (user-defined) implant

Swipe left to remove the desired user-defined implant:



8.11 Bookmark or remove brands

FIG. 31

A. From the *Implant brand selection* popup window, long tap on a brand in the *ALL* tab (1) to activate the bookmark or remove brands function.

Note 46

The brands icons are greyed out when the bookmark or remove brands function is activated.

B. Tap (5) to bookmark a brand or tap (4) to remove a brand.

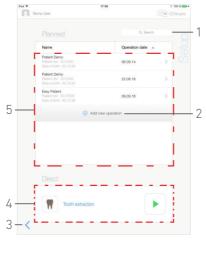
Note 47

C. Tap *Done* (3) to validate or *Cancel* (6) to discard changes.

Bookmarked brands are displayed in the favorite brands tab (1). To unbookmark brands, apply reverse procedure (possible on both ALL and favorite brands tab).

- **46** When displaying the Implant brand selection popup window for the first time, the favorite brands tab (2) is selected. In this case, a tutorial explaining how to bookmark brands is displayed.
- ${\bf 47}^{\,\,}$ The brands present by default in the app (factory ones) cannot be removed.





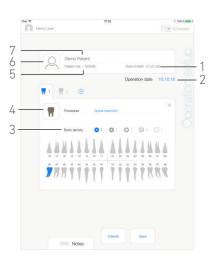


FIG. 2

FIG. 3

9 Operation - Surgery mode

9.1 Enter surgery mode

FIG. 1

Tap SR sungar

to enter the surgery mode.

Note 1

The surgery mode allows to perform operations which do not include implants placement.

The **Setup** page screen is displayed.

9.2 Setup screen description

FIG. 2

The **Setup** screen allows to plan an operation, start a planned operation or start a direct operation:

- Search field (to find specific information in the planned operations list)
- (2) Plan a new operation (see "9.3 Plan an operation" on page 40)
- (3) Back to the previous screen
- (4) Direct operation area
- (5) Planned operations area

Note 2

9.3 Plan an operation

A. From the **Setup** screen, tap \oplus to add a new operation.

The *Operation setup* page screen is displayed.

FIG. 3

B. Tap (6) to access the patients list.

The Patients list popup is displayed.

FIG. 4

C. Tap on the desired patient line to select the patient.

See section "7.8.1 Add or edit patient" on page 18 if the desired patient is not present or to modify patient's data.

 $\ensuremath{\mbox{\ensuremath{\mbox{ψ}}}}$ The following patient information fields are automatically filled in, FIG. 3:

- First and last names* (7);
- Date of birth (1);
- Patient Number (5).
- **D.** Tap the following operation fields to fill them in:
 - Operation date* (2);
 - Bone density (from 1 to 4, or unknown) (3).

Note 3

E. Tap (4) to choose the procedure.

The **Procedure** popup window is displayed.

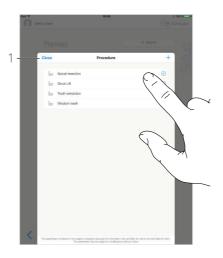
FIG. 5

Note 4

F. Tap the desired procedure or tap *Close* (1) to go back.

See "9.8.1 Add procedure" on page 48 to create an user-defined procedure.





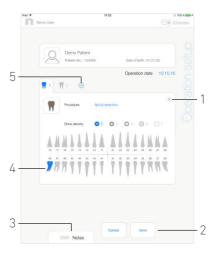


FIG. 4 FIG. 5 FIG. 6

FIG. 6

- $\textbf{G.}\ \ \ \$ In the jaw representation, tap the desired tooth emplacement to affect the procedure to it.
- **H.** Tap \oplus (5) to add other procedures to the operation, or tap \times (1) to remove procedures from the operation.

Note 5 - 6

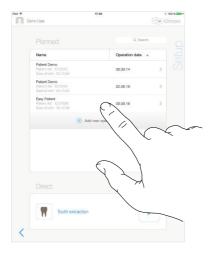
- ${\bf l.}$ Tap or slide ${\it Notes}$ (3) to write comments in relation to the operation.
- J. Tap Save (2) to go back to the Setup page screen.
- $\$ The operation appears on the planned operations list.

Note 7

See section "9.5 Start or resume an operation" on page 42 to launch a planned operation.

- $1\,$ $\,$ In the USA and Canada, the surgery mode is available only on the iChiropro Surgery unit (REF 1600883-001).
- 2 Patients' names and operation's dates can be sorted by tapping on their respective columns titles (6).
- 3 Fields marked with an asterisk must be filled in before saving.
- **5** It is possible to add up to 8 procedures per operation. Each procedure is numbered in the jaw representation accordingly to the operation order.
- ${\bf 6} \quad \mbox{Long tap on procedure icons}$ and move them to reorganize order.
- 7 In case mandatory fields are empty, saving is not possible until these fields are filled in. Empty mandatory fields blink on the screen.





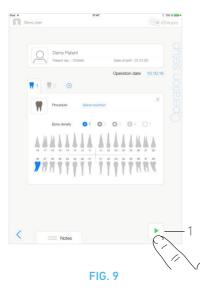


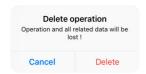
FIG. 7 FIG. 8

9.4 Remove an operation

FIG. 7

A. From the **Setup** page screen, swipe left and tap **Delete** to remove the desired operation:

A message box opens: Delete operation.



B. Tap Cancel or Delete to acknowledge.

9.5 Start or resume an operation

FIG. 8

A. From the *Setup* page screen, in the *Planned* operations area, tap the operation that needs to be started or tap an operation marked with the symbol to resume it and go directly to step C.

The Operation setup page screen (start operation) or the Operative page screen (resume operation) is displayed.

FIG. 9

B. Check if the operation's information is correct and tap (1) to access the *Operative* page screen.

Note 8

△ CAUTION

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

△ CAUTION

If the sound volume is OFF before entering in operative mode, a warning message «Please switch ON sound volume on your iPad and set it to an appropriate level according to the ambient noise level in your practice room.» will be displayed.

The MX-i micromotor will not start to run until the sound volume is ON.

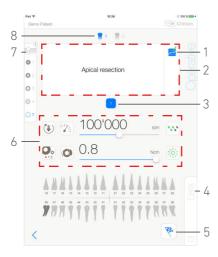


FIG. 10

FIG. 10

△ CAUTION

When accessing the *Operative* page screen for the first time, a popup is displayed to introduce the orange button behavior. Tap anywhere on the screen to close the popup or tap *Don't show me again* to acknowledge:



C. Operate by pressing the footpedal to adjust the MX-i micromotor speed.

If needed, tap (1) to record step.

Note 9 - 10

- **D.** Navigate through the operation steps by:
 - Short pressing the footpedal's orange button or tapping the Navigation area (2) to go to the next step;
 - Tapping the desired step icon (3).

Note 11

- **E.** Adjust the operative parameters (6) if necessary. See section "9.7 Operative parameters" on page 46.
- **F.** Select the bone density (7); it is possible to set or modify the bone density value at any time during the operation.
- **G.** Tap the teeth icons (8) or long press the footpedal's orange button to perform the operation's other planned surgery procedures.

Note 11

- H. Tap Data (4) to modify patient's data if necessary.
- 🖔 The *Operation data* page screen is displayed.

See section "7.9.2 Operation data" on page 21 for details.

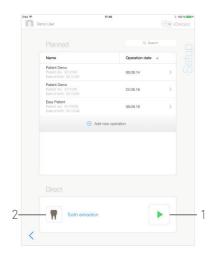
- I. Tap the Finish button (5) to end the operation.
- 🔖 A message box opens: *Finish operation*.
- ${\bf J.}\ {\bf Tap}\ {\it Finish}\ {\bf to}\ {\it confirm}\ {\it the}\ {\it end}\ {\it of}\ {\it operation}\ {\it or}\ {\it Cancel}\ {\it to}\ {\it continue}\ {\it operation}.$

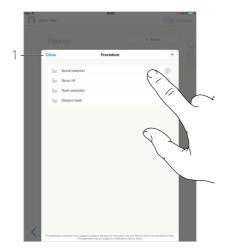
NOTES

- 8 Starting an operation is not possible if the procedure is not defined.
- **9** Real-time speed and torque values are displayed when the MX-i micromotor is running.
- 10 When the power demand of the MX-i micromotor is excessive,

the Operative screen displays the overheating symbol . In this case the iChiropro unit lowers the torque automatically in order to avoid overheating of the MX-i micromotor. To restore 100% torque, allow the motor to idle or stop for a few seconds.

11 Refer to the corresponding handpiece IFU if a tool change is needed.





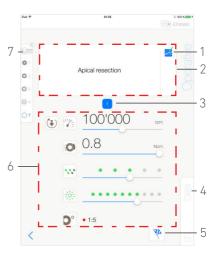


FIG. 11 FIG. 12 FIG. 13

9.6 Start a direct operation

The direct operation mode allows realizing an operation without any planning.

FIG. 11

A. From the **Setup** page screen, tap (2) in the **Direct** operation area to select surgery procedure. The **Procedure** popup window is displayed.

Note 12

Or tap (1) if the desired operation is already displayed and go directly to step E.

🔖 The *Operative* page screen is displayed.

FIG. 12

B. Tap the desired procedure or tap Close (1) to go back.

\$\to\$ The app navigates back to the **Setup** page screen.

See chapter "9.8.1 Add procedure" on page 48 to create an user-defined procedure.

C. Tap (1) to access the *Operative* page screen, FIG. 11.

△ CAUTION

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

△ CAUTION

If the sound volume is OFF before entering in operative mode, a warning message «Please switch ON sound volume on your iPad and set it to an appropriate level according to the ambient noise level in your practice room.» will be displayed.

The MX-i micromotor will not start to run until the sound volume is ON.

FIG. 13

△ CAUTION

When accessing the *Operative* page screen for the first time, a popup is displayed to introduce the orange button behavior. Tap anywhere on the screen to close the popup or tap *Don't show me again* to acknowledge:



D. Operate by pressing the footpedal to adjust the MX-i micromotor speed.

If needed, tap (1) to record step.

Note 13 - 14

E. Navigate through the operation steps by:

- Short pressing the footpedal's orange button or tapping the Navigation area (2) to go to the next step;
- Tapping the desired step icon (3).

Note 15

F. Adjust the operative parameters (6) if necessary. See section "9.7 Operative parameters" on page 46.

- **G.** Select the bone density (7); it is possible to set or modify the bone density value at any time during the operation.
- H. Tap Data (4) to modify patient's data if necessary.
- The *Operation data* page screen is displayed.

 See section "7.9.2 Operation data" on page 21 for details.
- I. Tap the Finish button (5) to end the operation.
- A message box opens: Finish operation.
- ${\bf J.}~{\bf Tap}~{\it Finish}~{\bf to}~{\bf confirm}~{\bf the}~{\bf end}~{\bf of}~{\bf operation}~{\bf or}~{\it Cancel}~{\bf to}~{\bf continue}~{\bf the}~{\bf operation}.$
- The Operation data page screen is displayed. Fill the necessary information in and tap Save.

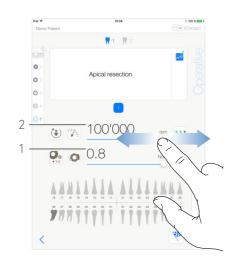
See section "7.9.2 Operation data" on page 21 for details.

NOTES

- ${f 13}$ Real-time speed and torque values are displayed when the MX-i micromotor is running.
- 14 When the power demand of the MX-i micromotor is excessive,

the Operative screen displays the overheating symbol . In this case the iChiropro unit lowers the torque automatically in order to avoid overheating of the MX-i micromotor. To restore 100% torque, allow the motor to idle or stop for a few seconds.

15 Refer to the corresponding handpiece IFU if a tool change is needed.





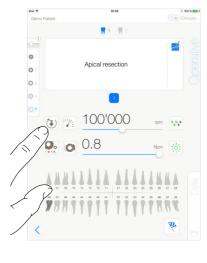


FIG. 14

FIG. 16

9.7 Operative parameters

The operative parameters disposition can slightly differ whether it is displayed from a direct operation, a planned operation or a procedure protocol. However, the procedures given in this chapter are valid for all kinds of operations. All operation parameters can be temporarily changed during an operation, on the *Operative* screen.

9.7.1 MX-i micromotor Speed & Torque

FIG. 14

Maximum reachable speed (2) and torque (1) values are displayed when the MX-i micromotor is not running. Real-time speed (2) and torque (1) values are displayed when the MX-i micromotor is running

Slide to adjust the maximum speed and torque values.

Or tap the icons to activate the wheel scroller for fine adjustment.

FIG. 15

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

9.7.2 MX-i micromotor rotation direction

FIG. 16

Tap (to select the rotation mode of the MX-i micromotor:

- Forward (clockwise)
- Reverse (counter clockwise)

Note 16 - 17





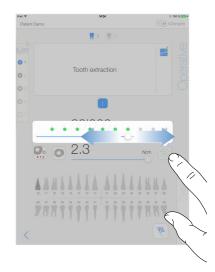


FIG. 17 FIG. 18 FIG. 19

9.7.3 Irrigation Level

FIG. 17

Slide or tap the appropriate dot to set up the irrigation level. 6 levels of adjustment are possible:

irrigation OFF, 30ml/min, 60ml/min, 90ml/min, 120ml/min, 150ml/min.

9.7.4 Handpiece ratio

FIG. 18

Tap and select to modify the handpiece ratio.

△ CAUTION

Verify that the handpiece corresponds to your selection.

Note 18 - 19

9.7.5 Light intensity

FIG. 19

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 20

- **16** The operative screen always displays the selected rotation direction.
- 17 In reverse mode (CCW), the symbol flashes and there is a sound alert (alternate medium beeps).
- **18** The operative screen always displays the selected handpiece ratio.
- 19 The handpiece ratio is red-colored for multiplication gears, blue-colored for direct-drive, and green-colored for reduction gears.
- ${\bf 20}\,\,$ The operative screen always displays the selected light intensity value.



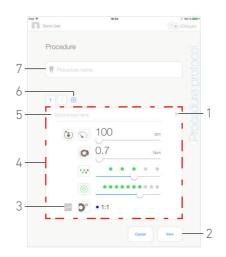




FIG. 20 FIG. 21 FIG. 22

9.8 Add, edit or remove procedures

9.8.1 Add procedure

FIG. 20

A. From the **Procedure** popup window,, tap + (1) to create a procedure from scratch.

Or tap (+) (2) to create a copy of a factory procedure.

Note 21

The **Procedure Protocol** page screen is displayed.

FIG. 21

B. Fill in or modify the *Procedure name* field (7).

C. Change the *Optional step name* (5) and the operative parameters (4) if necessary.

See section "9.7 Operative parameters" on page 46.

D. Tap (3) to record step by default.

E. Tap $\stackrel{\textcircled{+}}{\oplus}$ (6) to add steps or tap $\stackrel{\textstyle \times}{\times}$ (1) to remove steps from the procedure protocol. Change their position by dragging and releasing them.

Note 22

F. Tap Save (2) to validate.

 $\begin{tabular}{ll} \begin{tabular}{ll} \beg$

Note 23

9.8.2 Edit (user-defined) procedure

FIG 22

A. From the **Procedure** popup window, tap \bigcirc (1) on the user-defined procedure to be modified.

The **Procedure protocol** page screen is displayed.

B. Change the desired operative parameters.

See section "9.7 Operative parameters" on page 46.

C. Tap Save to validate or Cancel to discard changes.



9.8.3 Remove (user-defined) procedure

FIG. 23 Swipe left to remove the user-defined procedure.

- 22 It is possible to add up to 12 steps for each procedure.
- 23 The Procedure name field must be filled in before saving.

10 List of errors & Troubleshooting

10.1 Safety warning (operating)

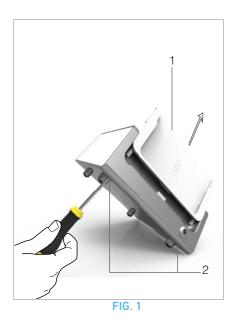
Warning description	Message	Cause of warning	Action	
Footpedal to be released	Please release pedal	Pedal is pressed when accessing operative page. Pedal remains pressed when acknowledging any system notification. Motor is jammed for more than 2 seconds.	Release footpedal and press it again.	
Motor torque limitation active		Motor drive limits delivered torque to prevent motor overheating.	Avoid extended use. Let system cool down.	
Low to high speed drilling transition	15 rpm 400 rpm	User switches from low speed to high speed (≥ 100 RPM) drilling during implant procedure.	Confirm transition and acknowledge message.	
iPad speaker OFF	Please switch ON sound vol- ume on your iPad and set it to an appropriate level accord- ing to the ambient noise level in your practice room.	iPad speaker was switched OFF, or sound volume was disabled by user. It is necessary to have iPad speaker turned ON so that sys- tem sound notifications and alarms may be heard distinctly.	Turn iPad speaker ON and set sound volume to an appropriate level.	
Non-verified iOS version in use	It is NOT recommended to use app (x, y, z) with IOS x, y. 200 — 20 —	iOS version installed on the iPad has not been verified according to Bien-Air validation protocols. Therefore it is NOT recommended to use the system with this configuration.	Do NOT update iPad with new iOS versions unless Bien-Air recommends to do so. If the iPad has been updated with a new iOS version despite everything, do not use the system until Bien-Air has verified and approved the new iOS version.	
User Manual has been updated	User Manual has been updated, and may be consulted in the Information page.	An update of the User Manual is available on Bien-Air website, and has been automatically downloaded on the iPad.	It is highly recommended to consult the updated User Manual before using the system.	

10.2 Device operating error

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

10.3 iOS compatibility errors (disclaimer screen)

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



11 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.

11.1 Servicing

Never disassemble the device. For any modification and repair, we recommend that you contact your regular supplier or Bien-Air Dental directly.

Note 1

11.2 Information

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.

11.3 Cleaning-disinfection

- Disinfect the surfaces of the iChiropro unit and footpedal by gently rubbing with a clean cloth soaked in a suitable product (i.e. Bien-Air Dental Spraynet or isopropyl alcohol for about 15 sec.)
- Do not immerse in disinfectant solution.
- Not designed for an ultrasonic bath.
- Use a new sterile irrigation line for each patient.
- Use a new sterile protective sheet for each patient.

11.4 Important

For maintenance:	.See instructions for use
MX-i LED micromotor	.REF 2100245
Cable for micromotor	.REF 2100163
Contra-angle CA 20:1 L, light	.REF 2100209
Contra-angle CA 20:1 L	
Micro-Series, light	.REF 2100209
Contra-angle CA 20:1 L KM, light	.REF 2100209
Contra-angle CA 20:1 L KM	
Micro-Series, light	.REF 2100209
Straight Handpiece 1:1	.REF 2100046
Straight Handpiece 1:2	.REF 2100103

11.5 iPad adapter change

- A. Switch off the iChiropro unit «O».
- **B.** Remove the iPad from the adapter.
- **C.** Remove the bracket support and unplug all the cables on the iChiropro unit.
- ${f D}.$ Open the peristaltic pump lid and uninstall the peristaltic cassette in it.

FIG. 1

- **E.** Tilt the iChiropro unit to approximately 45° and remove both screws (2).
- **F.** Remove the iPad support (1) and install the needed one by following the steps above reversely.

See chapter "4.2 Sets supplied" on page 6 for details on the available adapters.

See chapter "5.2 Install the iChiropro system" on page 13 for details on installation.



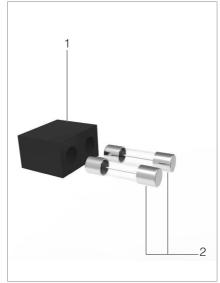


FIG. 2

FIG. 3

11.6 Fuses replacement

- A. Switch off the iChiropro unit «O».
- **B.** Remove the iPad from the adapter.

FIG. 2

C. Remove the fuse box (1) with a flat screwdriver.

FIG. 3

 ${\bf D}.$ Replace the fuses (2) by the new ones and put the fuse box back (1) in place.

△ CAUTION

Only use fuses T-4.0 A L 250 VAC REF 1301560-010.

NOTES

1 Bien-Air Dental SA recommends the user to have its dynamic instruments regularly checked or inspected.

12 General information and guarantee

12.1 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.

12.2 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 from the date of invoicing for:

- 12 months for the hose;
- 24 months for the iChiropro unit and CA 20:1 L Micro-Series;
- 36 months for the MX-i micromotor.

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:

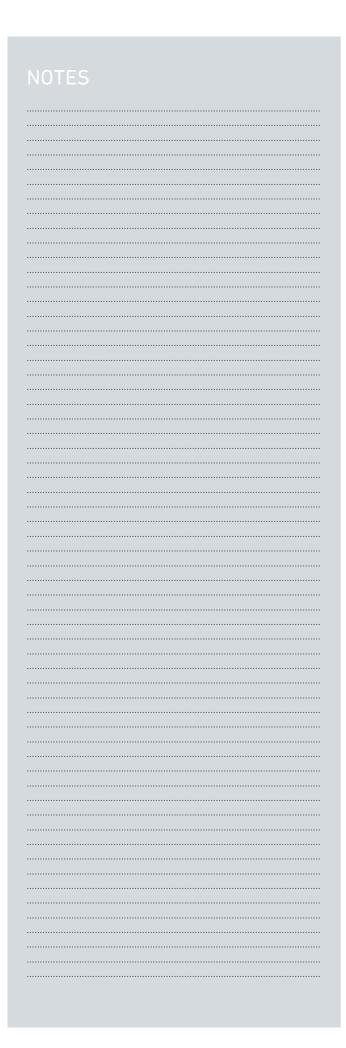
- excessive wear and tear
- improper use
- non-observance of the instructions for installation, operation and maintenance
- unusual chemical, electrical or electrolytic influences
- poor connections, whether of the air, water or electricity supply.

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.

Please refer to the General Terms and Conditions of Sale on www.bienair.com.





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