

iChiropro iChiropro Surgery

ENG INSTRUCTIONS FOR USE.







* For instructions for use of the wireless foot control, please refer to the Quick Guide REF 2100443



REF 1303711-010

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ENG INSTRUCTIONS FOR USE

1 Symbols

1.1 Description of symbols used

Sym	Description	Sym	Description
CE 0123	CE Marking with number of the notified body.	ÊÞ	General symbol for recovery/ recyclable.
\bigcirc	OFF (power).	X	Separate collection of electric and electronic equipment.
	ON (power).		Manufacturer.
⊕	Fuse.	-Ċ-	Lamp; lighting; illumination.
\sim	Alternating current.		Sound alerts.
	CAUTION! hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed.	Rx Only	Warning: in accordance with federal law (USA), this device is only available for sale upon recommendation by an accredited practitioner.
	WARNING! hazard that could result in serious injury or damage to the device if the safety instructions are not correctly followed.	.	CSA marking – Complies with U.S and Canadian standards.
8	Refer to instruction manual/booklet (<u>https://dental.bienair.com/fr_ch/</u> <u>support/download-center/</u>).	SN	Serial number.
	Refer to instruction manual/booklet (https://dental.bienair.com/fr_ch/ support/download-center/).	REF	Catalogue number.
MD	Medical Device.	EC REP	Authorized EC Representative in the European Community.
[]	Keep away from rain.	200	Variability in steps.
	Data Matrix code for product information including UDI (Unique Device Identification).		Protective earth (ground).
x, x	Temperature limitation.	\bigtriangledown	Equipotency.
, y)	Atmospheric pressure limitation.	,	Humidity limitation.

1.2 Description of symbols for iChiropro and iChiropro Surgery accessories

Sym	Description	Sym	Description
<u>C</u> E	CE Marking with number of the notified body.	」 本	Thermo washer disinfectable.
	Expiration date.	Ê	General symbol for recovery/ recyclable.
2	Do not reuse.	X	Separate collection of electric and electronic equipment.
(FER.LE)	Sterilized with Ethylene Oxyde.	135℃ ↓↓↓	Sterilizable in autoclave up to the specific temperature.
¥	Electrical safety. Applied part type B.		Manufacturer.
REF	Catalogue number.	SN	Serial number.
DEHP	Does not contain DEHP.	LOT	Batch code.
8	Do not use if package is damaged.		CAUTION! hazard that could result in light or moderate injury or damage to the device if the safety instructions are not correctly followed (on the foot control label).

2.1 Identification

The ICHIROPRO are tabletop devices allowing to drive a dental micromotor by using a foot control, under the guidance of an iPad as display, connected to the main console via a docking station. The system includes the iChiropro console, with the foot control and the peristaltic pump, and the associated software application running on the iPad. The peristaltic pump inside the console conveys the physiological liquid to the surgical site via a disposable sterile irrigation line, preventing liquid contamination. The software application allows to control the operation settings, such as the handpiece gear ratio, bur speed, torque value, irrigation flow, and motor light intensity, which are all shown on the iPad screen.

2.2 Intended use

iChiropro device is intended to be used in dental offices and hospitals for dental implantology and oral surgery. The consoles are designed to operate a specific dental micromotor that drives dental handpieces fitted with appropriate tools to cut hard and soft tissues in the mouth and to screw dental implants.

2.3 Intended patient population

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

2.4 Intended User

Product intended for professional use only. Used by dentists, dental professionals and oral surgeons.

2.5 User environment

Professional healthcare facility environment.

2.6 Intended medical conditions

- Dental implantology is the treatment to replace one or more missing teeth.
- The main oral surgery treatments include:
 - impacted teeth extraction
 - wisdom teeth extraction
 - non salvageable decayed teeth extraction
 - guided and not-guided bone
 - regeneration
 - apicoectomy
 - osteotomy
 - sequestrectomy
 - hemisection

2.7 Patient contra-indications and warnings

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

2.8 In case of accidents

If an accident occurs, the device must not be used until repairs have been completed by a qualified, authorized and trained technician in a repair center. If any serious incident occurs in relation to the device, report it to a competent authority of your country, as well as the manufacturer through your regional distributor. Observe relevant national regulations for detailed procedures.

Any use other than that for which this device is intended is prohibited and may be dangerous.

3 User and patient safety: Warnings & Precautions of use

The device must be used by qualified dental 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, coolant failure, excessive vibration, abnormal heating, unusual noise 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 and have the service personnel carry out repair work.
- 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.
- Any modification of the medical device is strictly forbidden.

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

- The iCHIROPRO must be connected only to a supply main with a protective earth.
- Always ensure that there is no water under the unit before switching it on.
- All connectors must be dry before use. Ensure the absence of residual moisture due to cleaning.
- Never simultaneously touch the patient and the electrical connection of the unit. The system must never be touched by the patient.
- Never attempt to open the device while it is connected to the electrical mains.
- The power plug must be always easily accessible as it may be used for disconnection in case of problems.

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

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

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

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

- If the irrigation pump is used and regulated by the iCHIROPRO, verify that the pump is working properly before starting the treatment as well as during the treatment. The iCHIROPRO has neither been conceived for controlling the working status of the pump nor for detecting possible failures of the pump.
- There is no detection of empty physiological liquid flask. Always check the content of the flask before operating.
- Never run the pump without the irrigation line being securely fastened.

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

- To avoid any risk of contamination, only control the device via the foot control during surgical procedures. Never touch the device during a clinical operation.
- Always replace the irrigation line after an operation as they are single use only.
- The cleaning procedure defined in §10 must be followed.
- Always refer to the accessories IFU for dedicated maintenance procedure.
- Always ensure that the irrigation line package is intact before use.

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

\triangle caution

- Never connect a handpiece on a running micromotor.
- Always check that the lid is not opened when running the irrigation pump.
- Beware of the risk of pinching when closing the irrigation valve.
- Always use Bien-Air Dental SA accessories or those recommended by Bien-Air Dental SA.
- Do not handle the iPad outside the touch screen during clinical procedures.

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

\triangle caution

- The predefined settings contained in the iChiropro are indicative only. Bien-Air Dental SA cannot be held liable for them.
- The predefined torque and speed values are only intended as a guide. The drill values used must be adapted according to the implant manufacturer instructions. Always refer to the implant manufacturer specifications to set up the console settings.
- Always verify that the configured parameters correspond to your medical application. The predefined parameters may be subject to modification without notice.

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

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

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

\triangle caution

- Always ensure that both the cable and the motor are in good condition.
- Ensure that the micromotor hose is not bent.
- Do not use iChiropro outside the range of operating temperature.

To prevent any wireless connection loss, the cautions below must be observed:

\triangle caution

- Ensure that there are no obstructions, such as clutter, furniture, or other items, between the foot control and the console. The foot control and the console must always be in the same room.
- The foot control emits a red signal when the battery is low. In this case, it is recommended to complete the ongoing operation and change the batteries before starting a new operation.

4 Electromagnetic Compatibility

To avoid any risk of electromagnetic interference that could affect active implantable medical devices, and sustainable life devices, the warning below must be observed:

- The device must not be placed in the vicinity (30cm) of other sustainable life devices.
- 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.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- The device is not intended to be used in the vicinity of High Frequency surgical equipment.

To avoid any risk of electromagnetic interference that could affect the performance of the device the warnings below must be observed:

- Since compliance with the international standard IEC 60601-1-2 does not guarantee immunity against 5G worldwide (due to the different frequency bands used locally), avoid the presence of devices equipped with 5G broadband cellular networks in the clinical environment or ensure that the network functionality of these devices is disabled during the clinical procedure.
- Radio transmitting equipment, cellular phones, etc., should not be used in the immediate vicinity of the device, since this could affect its operation. Special precautions should be taken when using strong emission sources such as high-frequency surgical equipment and other similar devices, to ensure that HF cables are not routed above or near the device. If in doubt, please contact a qualified technician or Bien-Air.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by Bien-Air, may result in increased emissions or decreased immunity.

4.1 Electromagnetic compatibility – emissions & immunity

Guidance and manufacturer's declaration – Electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR11	Group 1	The iChiropro and iChiropro Surgery uses RF energy for its internal operation only. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Class B	The iChiropro and iChiropro Surgery is suitable for use in any building, including
Harmonic emissions IEC 61000-3-2	Not applicable	connected to the public low-voltage power supply network that supplies buildings used
Emissions due to voltage fluctuations (flicker) IEC 61000-3-3	Not applicable	for residential purposes.

Guidance and manufacturer's declaration – Electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for other lines	±2 kV for power supply lines ± kV for lines no input/output	Mains power quality should be that of a commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV line to line ±1 kV line to line ±0.5 kV line to earth ±1 kV line to earth ±2 kV line to earth	±0.5 kV line to line ±1 kV line to line ±0.5 kV line to earth ±1 kV line to earth ±2 kV line to earth	Mains power quality should be that of a commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT for 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles at 0° 0% UT for 250 cycles at 0°	0% UT for 0.5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles at 0° 0% UT for 250 cycles at 0°	Mains power quality should be that of a commercial or hospital environment. If the user of the iChiropro requires continued operation during mains power interruptions, it is recommended that the iChiropro be powered from an uninterruptible power supply or a battery.
Magnetic field due to mains frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields generated by the mains frequency should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted disturbances induced by RF fields IEC 61000-4-6	3 VRMS 0,15 MHz – 80 MHz 6 VRMS in ISM bands 0,15 MHz – 80 MHz 80% AM at 1 kHz	3 VRMS 0,15 MHz – 80 MHz 6 VRMS in ISM bands 0,15 MHz – 80 MHz 80% AM at 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ¹ should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance	
Radiated RF EM fields IEC 61000-4-3	3V/m 80MHz - 2,7GHz 80% AM at 1 kHz	10V/m 80MHz - 3GHz 80% AM at 1 kHz	Distance: 0.3 m Minimum separation distance shall be calculated by following equation: $E = \frac{6}{d}\sqrt{P}$ E= is the immunity test level in [V/m] d is the minimum separation in [m] P is the maximum power in [W]	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	27 V/m 380-390MHz 50% PM 18Hz	27 V/m 380-390MHz 50% PM 18Hz	RF wireless equipment maximum output power and separation distance tested (at	
	28V/m 430-470MHz FM +/- 5kHz Deviation, 1kHz sine 9V/m 704-787MHz 50% PM 217 Hz	28V/m 430-470MHz FM +/- 5kHz Deviation, 1kHz sine 9V/m 704-787MHz 50% PM 217 Hz	TETRA 400: max1.8 W GMRS 460 FRS 460: max 2 LTE band 13 and 17, max 0.2 GSM 800/900 max 2 W TETRA 800 : max 2 W iDEN 820: max 2 W CDMA 850: max 2 W LTE Band 5: max 2 W	
	28 V/m 800-960 MHz 50% PM 18Hz	28 V/m 800-960 MHz 50% PM 18Hz	CDMA 1900: max 2W CDMA 1900: max 2 W DECT: max 2 W LTE Band 1,3,4and 25: max 2 W	
	28 V/m 1700-1990 MHz 50% PM 217Hz	28 V/m 1700-1990 MHz 50% PM 217Hz	UMTS: max 2W Bluetooth: max 2W WILAN 802.11b/g/n: max 2 W RFID 2450:max 2W	
	28 V/m 2400-2570 MHz 50% PM 217 Hz	28 V/m 2400-2570 MHz 50% PM 217 Hz	LTE Band 7: max 2W WLAN 802.11 a/n: max 0.2W Interference may occur in the vicinity of equipment marked	
	9 V/m 5100-5800 MHz 50% PM 217Hz	9 V/m 5100-5800 MHz 50% PM 217Hz	with the following symbol:	
Proximity magnetic fields IEC 61000-4-39	30kHz/CW/ 8 A/m 134.2kHz/PM 2.1kHz/65 A/m 13.56 MHz/PM 50kHz /7.5 A/m	30kHz/CW/ 8 A/m 134.2kHz/PM 2.1kHz/65 A/m 13.56 MHz/PM 50kHz /7.5 A/m		

Note : U_T is the AC mains voltage prior to the application of the test level. Essential performance per IEC 60601-1: The essential performance is to maintain in normal condition the visual luminous intensity of the LED at ±30% and the motor speed with a maximum speed deviation at ±10%.

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.

5 Description

5.1 iChiropro system overview



- (1) Peristaltic pump lid
- (2) Foot control connector
- (3) Adapter for
- (4) Bracket support
- (5) Main switch
- (6) Fuse box
- (7) Mains connector
- (8) MX-i micromotor

- acknowledge high speed steps warnings
- Button to reverse the rotation of the MX-i
- "Program" button (Short press: next step. Long press: next implant placement or next surgery procedure)
- (12) MX-i micromotor connector

Note : The technical specifications, illustrations and dimensions contained in these instructions are given merely as an indication. They may not give rise to any claim. The original language of those instructions for use is English. For any further information, please contact Bien-Air Dental SA at the address given on the back cover.

5.2 Sets supplied

Set iChiropro REF 1700439-001

Designation	REF number
Console iChiropro	1600784-001
MOT MX-i LED	1600755-001
FOOTCTRL	1600631-001
Cable MX LED	1600606-001
Sterile protect film (2/pkg)	1501746-002
Irrigation line (10/pkg)	1500984-010

Set iChiropro CA REF 1700440-001

Designation	REF number
Set iChiropro	1700439-001
CA 20:1 L Micro-Series	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.

Set iChiropro CA 20:1 L WL REF 1700892-001

Designation	REF number
Console iChiropro	1600784-001
MOT MX-i LED	1600755-001
Wireless foot control + Dongle	1601192-001
Cable MX LED	1600606-001
Sterile protect film (2/pkg)	1501746-002
Irrigation line (10/pkg)	1500984-010
CA 20:1 L Micro-Series	1600692-001

Set iChiropro surgery REF 1700485-001*

Designation	REF number
Console iChiropro Surgery	1600883-001
Mot MX-i LED	1600755-001
FOOTCTRL	1600631-001
Cable MX LED 3m	1600881-001
Sterile protect film (2 pack)	1501746-002
Irrigation lines 3.5m (10/pkg)	1501738-010

*Set is available in the USA and Canada only

Set iChiropro Surgery HP REF 1700484-001*

Designation	REF number
Set iChiropro Surgery	1700485-001
PM 1:2	1600436-001

*Set available in the USA and Canada only

5.3 Options

Designation	REF number
Sterile protect film	1501746-010
Sterile protect film	1501746-002
Irrigation sys KM 20:1L (10/pkg)	1501621-010
Bur Guards HP1:2 (100 PCES)	1501317-100
Irrigation line (10/pkg)	1500984-010
Irrigation line Chiropro L 3.5m (10/pkg)	1501738-010
Irrigation line KM (10/pkg)	1501635-001
Handpiece/ support holder	1301575-001
Fuse SPT ø5x20	1307312-010
iPad 10 adapter	1308761-001
iPad Air 5 adapter	1308964-001
Philips screwdriver	1305436-001
Irrigation clip	1303711-010

5.4 Technical data

Dimensions L x W x H

Dimensions	L x W x H
iChiropro unit	242 x 244 x 102 mm
iChiropro unit (with bracket)	242 x 244 x 482 MM
Foot control	205 x 205 x 54 mm
Foot control (with handle)	205 x 205 x 144 mm
Wireless Foot control Width x Height x Depth (without hook)	206 x 180 x 60 mm/td>
Wireless Foot control Width x Height x Depth (with hook)	206 x 200 x 155 mm/td>
Motor cable (REF 1600606)	L 2.0 m
Motor cable (REF 1600881)	L 3.0 m
Foot control cable	L 2.9 m
MX-i LED micromotor	23 x 84 mm

Weight

Weight	
iChiropro unit	2.8 kg
Foot control (without handle and cable)	830 g
Wireless Foot control (without hook, two batteries included)	934 g
Foot control	877 g
Bracket	115 g
Cable	105 g

Electrical data

Electrical data	
Voltage	100 – 240 VAC
Frequency	50-60 Hz

Operating mode

Operating mode	
Intermittent	ON: 5 MIN OFF: 40 MIN

Applied parts (per IEC 60601-1):

Applied parts	
MX-i LED micromotor	REF 1600755-001
Contra-angles (CA) & Straight handpieces (HP)	SO 3964 compatible CA&HP

Degree of ingress protection (In accordance with IEC 60529)

Degree of ingress protection	
Unit	IP 40 (Protection against insertion of objects larger than 1 mm and dripping water (vertically falling drops)).
Foot control	IP X8 (Water protection against continuous immersion at 1m or more)
Wireless foot control	IP X6

Memory

Memory implantology mode:

- Storage of 8 users;
- Storage of 30 implant manufacturers (user-defined);
- Storage of 50 different settings for each implant manufacturer (user defined)
- storage of 12 steps per setting including adjustment of speed, torque, irrigation, ligiting and handpiece of each step;
- Storage of 8 implants per operation in planned mode
- 30 minutes recording length per implant.

Interface Languages

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

Bracket for physiological liquid flask

Stainless steel.

Peristaltic pump

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

\triangle caution

The use of the system with other handpieces than those supplied by Bien-Air Dental SA has not been validated/certified (performances values are not guaranteed in this case).

List of errors & Troubleshooting

See chapter "List of errors & Troubleshooting"

5.5 Classification

Classification

Class IIa in accordance with European Regulation (EU) 2017/745 concerning medical devices. Class 1 in accordance with American regulation to the Food & Drug Administration (FDA) concerning medical devices.

Electric insulation class

Class I per IEC 60601-1 (apparatus protected against electric shocks). Applied parts: Type B applied parts in accordance with IEC 60601-1 standard.

5.6 Performance

Performance	REF 1600995
Motor speed regulation	Accuracy \pm 5% in the speed range 100 - 40'000 rpm (*)
Motor torque regulation	Torque adjustable from 10% to 100% of the maximum torque
Maximum motor torque	5.2 (±5%) Ncm (*)
Maximum motor power	130 (±10%) W (*)
Max motor LED current range	Range adjustable 11 steps each 10% from 0% to 100% of max current value
Power supply output limitation	< 200 W/
	< 300 W
	5 levels:
	5 levels: 1 drop = 30ml/min
Irrigation flow	<pre>5 levels: 1 drop = 30ml/min 2 drops = 60ml/min</pre>
Irrigation flow	5 levels: 1 drop = 30ml/min 2 drops = 60ml/min 3 drops = 90ml/min
Irrigation flow	5 levels: 1 drop = 30ml/min 2 drops = 60ml/min 3 drops = 90ml/min 4 drops = 120ml/min

(*) Measurement realized in combination with motor MX-i LED 1600755, contra-angle CA 20:1 L Micro Series 1600692 and/or handpiece PML 1121 1600156. The maximum torque is measured at 1000 rpm with irrigation stopped and it corresponds to a maximum torque of 80 Ncm at the rotative tool if the motor is combined with the contra-angle CA 20:1 L Micro Series 1600692. 2In accordance with 80601-2-60, no essential performance is linked to this dental equipment. According to IEC 60601-1-2, essential performances are to maintain motor speed with a maximum speed deviation at $\pm 10\%$ in a highly electromagnetic disturbance environment.

5.7 Operating conditions

Operating conditions

	Temperature limit:	[+10°C; +35°C] [+50°F; +95°F]
	Relative humidity range:	[30%; 80%]
6-6 	Atmospheric pressure limitation:	[700 hPa; 1060 hPa] [525 mmHg; 795 mmHg]

\triangle caution

Do not use iChiropro outside the range of operating temperature.

22

6 Installation









FIG. 2



FIG. 4

FIG. 5



FIG. 6



FIG. 7

FIG. 8



FIG. 9



FIG. 10



FIG. 11





FIG. 12

6.1 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 : The iPad must be correctly connected to the Internet before the App Store C is opened; refer to Apple's user guide for appropriate use of the iPad.

6.2 Install the iChiropro system

A. If necessary, use the Phillips screwdriver to change the installed iPad adapter.

FIG. 1

Replace the iPad adapter with the desired one, paying attention not to force the adapter during insertion to avoid damaging the connector.

Note : For a safe insertion of the iPad adapter onto the device, before reaching the end of the stroke, slightly press the centre of the adapter towards the device to align the connector with the hole provided on the adapter itself. Once the connector has found the hole, then complete the insertion until the adapter is fully engaged.

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

\triangle 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 T4.0AH 250 VAC REF 1307312-010. To replace a fuse, see chapter "12.4 Fuses replacement".

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

Note : The equipment is powered by the mains power supply (100 - 240 Vac).

\triangle caution

The power plug is the device used for disconnection in case of problems, it must always 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.

\triangle 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.

If a wireless foot control is used, please follow the IFU/Quick Start Guide REF. 2100443.

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

H. Check the packaging integrity, as well as the expiry date of the irrigation line on the label (1).

A WARNING

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.

\triangle caution

Do not run the pump while the lid is open.

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.

6.3 Installation of the iPad on the iChiropro

O. 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, paying attention not to force it to avoid damaging the connector.

Note : For certain iPad models battery saving options can be activated in the iPad Settings. If this is the case, battery charge level will be limited accordingly, and will therefore not reach 100%.

6.4 On/off procedure

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

7 Interface overview

FIG. 1

7.1 iChiropro application

The iChiropro system can be operated in two modes : implantology and oral surgery.

7.1.1 Compatibility

Please refer to www.bienair.com for updated iPad model compatibility. iPad models with USB-C connector are compatible only from application 2.6.1 version. The user should protect iPad access with a strong password as described in the iPad user manual.

7.1.2 Nomenclature

In the interest of clarity , in this manual, interface devices «iPad®» and «iPad Air®» are referred to as «iPad».

7.2 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-frequency 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		

7.3 iPad and iChiropro connection / disconnection conditions

7.3.3 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.

${\rm \ensuremath{\underline{\wedge}}}$ 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.

7.3.4 Connection

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

${\rm \ensuremath{\underline{\wedge}}}$ caution

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

7.3.5 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 foot control (iChiropro app in operative mode).



8 Getting started

8.1 Back up data

Use 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, or iCloud.

8.2 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 as described in Apple's user manual for the specific iPad model, in order not to disrupt the operation:
- 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 "8.9.5 iChiropro App update").
- E. Tap the app icon (5) to launch the iChiropro application.

\triangle caution

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

8.3 Terms of service

FIG. 2

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

\triangle caution

Do not update iOS unless it is recommended by Bien-Air. See also chapter "11.1 Safety alert (operating)". For more information go to the App Store © under "what's new" of the selected application. B. Tap OK (2) to acknowledge disclaimer message.

8.4 Welcome screen and disclaimer

A. When opening iChiropro application for the first time, Terms of service must be validated.

B. Make sure you accept "Terms of service" by sliding the cursor (3) and tapping on I AGREE (4).

✤ The Home page screen is displayed.

See chapter "8.5 Home page screen.



8.5 Home page screen

FIG. 4

- A. Tap (1)(4) to open the Information screen. See chapter "8.10 Information" for details.
- B. Tap 💿 (2) to create a new user profile. See chapter "8.6 Create user profile" for details.
- 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 "8.6 *Create user profile*" for details.

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

🌭 The User page screen is displayed.

FIG. 5

A. Tap IM (5) to enter the implantology mode.

See chapter "9.1 Enter implantology mode" for details.

B. Tap SR (1) to enter the surgery mode. 🖭

See chapter "10.1 Enter surgery mode" for details.

Note : In the USA and Canada, the surgery mode is available only on the iChiropro Surgery unit (REF 1600883-001).

- C. Tap *Patients* (2) to open the Patients list popup ^Q. See chapter "8.8 Patients" for details.
- D. Tap *Operations history* (4) to open the *Operations history* screen. See chapter "8.9 Operations history" for details.
- E. Tap i (3) to open the *Information* screen. (i) See chapter "8.10 Information" for details.

8.6 Create user profile

A. From the Home page screen (FIG. 4), tap 😔 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 : 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:



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

Note : *FDI* is defined as the default teeth numbering system.

• Planning software (3)

Note : CoDiagnostiX[™] is selected as the default planning software.
Fields marked with an asterisk are mandatory fields.
C. Tap Save (1) to create the new user profile.

Note : It is possible to create up to 8 users.

(Г	
2	2	



8.7 Edit or remove user profile

FIG. 7

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

Solution 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.





8.8 Patients

FIG. 9

From the user page screen, tap *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).

8.8.1 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.

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
- D. Tap Save (1) to validate or Back (or Cancel, if creating a patient) (9) to discard changes. *Note : Fields marked with an asterisk are mandatory fields.*
- E. Tap Close (4) (see FIG. 10) to close the Patients list popup.

Note : Fields marked with an asterisk are mandatory fields.

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

Note : In case mandatory fields are empty, saving is not possible until these fields are filled in. Empty mandatory fields blink on the screen.

In case the patient number already exists, a popup window is displayed when saving:

Patient nbr. not unique This patient number already exists. Do you want to use the existing patient ? Demo Patient Patient nbr.:123456 Date of birth: 01.01.00

Use this patient

Cancel

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



8.8.2 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 : 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 are two or more patients in the list.

₲ A message box opens: *Delete patient*

Delete patient Patient and all related data will be lost ! Cancel Delete

B. Tap *Cancel* or *Delete* to validate.

8.8.3 Consult patients' history

FIG. 11

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

Note : It is only possible to consult a patient's history when accessing the Patients list popup from the user page screen.

The number of operations found for the selected patient is indicated (4, FIG. 11).

Solution The Operations history screen is displayed.

See chapter "8.9 Operations history" for details.



8.8.4 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

P

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

Merge patients

Do you want to merge selected patients with this patient ?

Demo Patient Patient nbr.:123456 Date of birth: 01.01.00

Cancel

Merge

D. Tap *Merge* to validate or *Cancel* to discard changes and cancel merging process.

Patients and their corresponding operations are merged.



FIG. 14

FIG. 15

8.9 Operation database

8.9.5 Operation 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 "9.4 Import an operation" 48).

Note : If the operation has been imported, the corresponding planning software icon is displayed.

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.
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 user only) or 🚨 (all users) (11);
- Find specific information in the list with the Search button (1) (*see chapter "8.9.1 Search operations history"*);
- 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 "8.9.4 Export all operations reports"*);
- Sort patients names and operations dates by tapping on their respective columns' titles (2).

Note : Patients names column is replaced by a non-sortable **Tooth number** column when accessing the **Operations history** screen from the **Patient** popup window.

- A. 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 : Operations recorded by other users are marked either with the symbol *It is not possible to modify information for these operations. See chapter "8.9.2 Operation data".*

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

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

Note : By patient name and By patient number are only available if the search popup was accessed from the User page screen.

• 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

8.9.6 Operation report

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 "8.9.3 Export report"), add Notes (3) and go back (4) to the previous page.

Note : If the operation has been imported, the corresponding planning software icon is displayed.

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.

Patient data tab

FIG. 17

11-

4

3

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

Note : Values with "" can be modified and saved during and also after an operation.*

Tap \square to modify the patient's information (See chapter "8.8.1 Add or edit patient" for details).

Implants data tab

FIG. 18

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 "8.11 ISQ values readings".

Note : If information is modified Cancel and Save buttons are displayed

Implant brand and *Implant type* can only be modified during operation, before the foot control 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.

This page differs whether the operation concerns implantology or surgery and whether the implant information has been scanned or filled-in manually.

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.

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	Chemic Patient Present rice reserved Chemic of terms 01.01.00	аль 🖲 🖪	× Sho
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FIG. 20

8.9.7 Operation report export

A. From the *Operation data* page, tap 1 to export the operation data.

s 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.
- s 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.
- \clubsuit The corresponding app popup is displayed.

Note : It is only possible to export as a mail if a mail account is already created and configured on the iPad.

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

8.9.8 Export all operations reports

FIG. 21

- A. From the *Operations history* page screen tap (1) (2) to export all operations displayed in the filtered list in a .zip file.
- s A popup window allows to choose the export format.



Note : When the Operations history screen is accessed from the Patient popup window, only recorded operations related to the corresponding patient are exported.

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.



s 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.
- 🥾 The corresponding app popup is displayed.

Note : It is only possible to export as a mail if a mail account is already created and configured on the iPad.

\triangle caution

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



8.9.9 iChiropro App update

FIG. 22

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 : This function is active only when the iPad is connected to the internet.

- *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).



8.10 Information

FIG. 23

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

FIG. 24

🔖 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 : 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 emails, printer or any other supported export target.

- Catalogue (3) (open online catalogue (pdf file));
- Web TV(4) (opens Bien-Air web TV);
- About (5) (See chapter "8.10.1 About");
- Contact us (6) (opens email application with predefined email address iChiropro@bienair.com);
- Implants update (7) (displays updated implants / protocols list, FIG. 26).

Note : Latest News, Catalogue, Web TV and Contact us functions are greyed out when the iPad is not connected to the internet.

8.10.10 About

FIG. 25

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 Surgery;
- Interface board name and firmware version (5);
- MX-i micromotor drive type and firmware version (6).



8.10.11 Implants update

FIG. 27

The Implants update screen displays the automatically updated implants and protocols. Type of update is indicated with the following symbols:

- + for the added implants;
- $^{\bigcirc}$ for the implants with existing protocols which have been updated;
- \times for the removed implants.

8.11 ISQ values readings

FIG. 28

By default ISQ values readings area (1) displays only the 🕘 (3) button. It is possible to add up to five ISQ

editable fields by tapping the (3) button and to *Delete* (2) them.

Tap (1) (4) to access a popup with explanations on the ISQ or tap the button (5) to display a graph (FIG. 29) of the different ISQ readings in relation to time.



9 Operation – Implantology mode

9.1 Enter implantology mode

FIG. 1

Tap IM ^[M] to enter the implantology mode.

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

Steep page screen is displayed.

9.2 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:

(1) Search field (to find specific information in the planned operations list)

(2) Import an operation from a planning software (see "9.4 Import an operation")

(3) Back to the previous screen

(4) Direct operation area

(5) Plan a new operation (see "9.3 Plan an operation")

(6) *Planned* operations area

Note : Patients' names and operation's dates can be sorted by tapping on their respective columns titles (6).

9.3 Plan an operation

A. From the *Setup* screen, tap 🕒 *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.



- C. Tap on the desired patient line to select the patient.
- D. See section "8.8.1 Add or edit patient" 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).
- E. Tap the following operation fields to fill them in, FIG. 3:
- Operation date*(2);
- Bone density (from 1 to 4, or unknown) (3).

Fields marked with an asterisk must be filled in before saving.

F. Tap 🔋 (4) to select an implant.

🔖 The *Implant brand selection* popup window is displayed.

Note : In case any implant among the favorite ones has been updated or a new brand has been added, the *Implants update* popup window is displayed:



Added implants are marked with the + symbol, implants with updated protocols are marked with the

symbol and removed implants are marked with the X symbol. Implant updates are possible only when the iPad is connected to the internet.Tap Close to acknowledge.

G. Tap a *Brand* to access the implants types window or tap *Close* (1) to go back.

₲ The *Implant type selection* popup window is displayed.

See section "9.11 Bookmark or remove brands" to bookmark or remove brands or see "9.10.1 Add implant" if the desired brand is not present. FIG. 6

Note : User-defined implants are represented by **L** *. Default implants are represented by* **L** *.* **H.** When available, choose between *Guided* (implant) and *Non-guided* (1).

I. Tap the desired implant system (3) and its diameter (2).

If the desired implant is not available, see"9.10 Add, edit or remove implants".

✤ The app navigates back to the *Operation setup* page screen.



J. Tap 🕮 (7) to scan an implant barcode.

🔖 The camera is activated, and the Scan page screen is displayed.

FIG. 8

K. Align the yellow rectangle with the barcode.

₲ The *Scan completed!* popup is displayed when the barcode has been read successfully:



L. 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 : Only Code 128, QR code, and DataMatrix barcodes are supported.

It is also possible to fill these fields in manually by tapping on them.

It is possible to add up to 8 implants. Each implant is numbered in the jaw representation according to the operation order. The last implant type used for the operation is proposed by default for additional implants.

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

- 💺 The selected tooth is replaced by a blue highlighted implant (3).
- N. Tap (9) to add other implants to the operation or tap \times (1) to remove implants from the operation.

Note : It is possible to add up to 8 implants. Each implant is numbered in the jaw representation according to the operation order. The last implant type used for the operation is proposed by default for additional implants.

Long tap on implants icons and move them to reorganize order.

0. Tap or slide *Notes* (5) to write comments in relation to the operation.

Note : *Position of the Notes is automatically saved.*

P. Tap Save (4) to validate.

 $\mathbf{U}_{\mathbf{V}}$ The operation appears on the planned operations list.

Note : In case mandatory fields are empty, saving is not possible until these fields are filled in. Empty mandatory fields blink on the screen.

Q. Tap \checkmark to go back to the Setup page screen or tap \blacktriangleright to start the operation.

Note : Starting an operation is not possible if the implant's position and information is not defined. Empty mandatory fields blink on the screen.

See section "9.6 Start or resume a planned operation" to start a planned operation.

9.4 Import an operation

- A. From the *Setup* screen, tap 🕙 *Import from [Planning software logo]* to import an operation from corresponding planning software.
- 🔖 The camera is activated, and the Planning code scan page is displayed.

Note : The user must have enabled the import feature in the Profile popup window to import an operation from a planning software (see section "8.8.1 Add or edit patient"). FIG. 9

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. 10

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 : 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 "8.8.4 Merge patients").



The following operation information is automatically defined for each step and cannot 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 : Fields marked with an asterisk must be filled in before saving.

F. Tap 📖 (10) to scan an implant barcode.

🔖 The camera is activated and the Scan page screen is displayed.

FIG. 10

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 : The *Reference* field is replaced by a *GTIN* field when *GTIN* code is available in the barcode data. Only Code 128, QR code, and DataMatrix barcodes are supported.

It is also possible to fill these fields in manually by tapping on them.

I. Tap or slide *Notes* (7) to write comments in relation to the operation.

Note : Position of the *Notes* is automatically saved.

J. Tap *Save* (6) to validate.

🔖 The operation appears on the planned operations list.

Note : If the operation has been imported, the corresponding planning software icon is displayed

K. Tap \checkmark to go back to the *Setup* page screen or tap \blacktriangleright to start the operation.

See section "9.6 Start or resume a planned operation" to start a planned operation.



9.5 Remove an operation FIG. 12

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.

9.6 Start or resume a planned operation

FIG. 13

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 : 17 In case mandatory fields are empty, saving is not possible until these fields are filled in. Empty mandatory fields blink on the screen. FIG. 14

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

Note : Starting an operation is not possible if the implant's position and information is not defined. Empty mandatory fields blink on the screen.

\triangle caution

If the foot control 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 foot control is released and pressed again.

\triangle 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. 15

\triangle caution

When accessing the *Operative* page screen for the first time, a popup is displayed to introduce the foot control'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 foot control to adjust the MX-i micromotor speed. If needed, tap 🔤 (1) to record step.

Note : Real-time speed and torque values are displayed when the MX-i micromotor is running. 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.

\triangle 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 foot control's orange button or tapping the Navigation area (9) to go to the next step;
- Tapping the desired step icon (4).

Note : *Refer to the corresponding handpiece IFU if a tool change is needed.*

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 foot control's blue button to acknowledge the popup warning and allow the MX-i micromotor to start.

The implant placement step icon is marked with the 🖤 symbol in the upper-right corner.

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

- Note : Surgical protocol visualization is only available for operations imported from coDiagnostiX[™].
- F. If necessary, tap 🔍 (3) to visualize the position of the tool to be used for the current step in the cassette.

Note : Tool visualization in the cassette may not be available for all implant systems.

See chapter "9.9 Tool visualization in cassette" for details.

G. Adjust the operative parameters (7) if necessary.

See section "9.8 Operative parameters".

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



FIG. 15

Note : *Refer to the corresponding handpiece IFU if a tool change is needed.*

- 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 "8.9.2 Operation data" for details.

- K. Tap the Finish button (6) to end the operation.
- 🍇 A message box opens: *Finish operation* .
- L. Tap *Finish* to confirm the end of operation or *Cancel* to continue operation.



9.7 Start a direct operation

The direct operation mode allows realizing an operation without any planning. FIG. 16 $\,$

- A. From the *Setup* page screen, tap (2) in the *Direct* operation area to select implant brand and type,
- 🍫 The *Implant brand selection* popup window is displayed.

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

✤ The *Operative* page screen is displayed.

FIG. 17

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

₲ The *Implant type selection* window is displayed.

See section "9.10.1 Add implant" if the desired brand is not present or see "9.11 Bookmark or remove brands" to manage brands.

Note : User-defined implants are represented by 👤 . Default implants are represented by ២ .

- C. When available, choose between *Guided* (implant) and *Non-guided* (1).
- D. Tap the implant system (2) and its diameter (3) to select the desired implant.
- E. If the desired implant is not available, see "9.10 Add, edit or remove implants".

₲ The app navigates back to the *Setup* page screen.

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

${\rm \ensuremath{\underline{\wedge}}}$ caution

If the foot control 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 foot control is released and pressed again.

\triangle 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. 18.

\triangle caution

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

	<i>(</i>				
		4			
Don't show me again					

G. Operate by pressing the foot control to adjust the MX-i micromotor speed. If needed, tap 🔤 (1) to record step.

Note : Real-time speed and torque values are displayed when the MX-i micromotor is running. 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.

\triangle caution

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

H. Navigate through the operation steps by:

- I. Short pressing the foot control's orange button or tapping the Navigation area (7) to go to the next step;
- J. Tapping the desired step icon (3).

Note :

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

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 foot control's blue button to acknowledge the popup warning and allow the MX-i micromotor to start.

The implant placement step icon is marked with the 🔘 symbol in the upper-right corner.

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

Note : Tool visualization in the cassette is only available for operations using Straumann[™] non-guided implants.

See chapter "9.9 Tool visualization in cassette" for details. L. Adjust the operative parameters (6) if necessary.

See section "9.8 Operative parameters".

- M. Select the bone density (8); it is possible to set or modify the bone density value at any time during the operation (? = unknown).
- N. Tap *Data* (4) to modify patient's data if necessary.
- 🔖 The *Operation data* page screen is displayed.

See section "8.9.2 Operation data" for details.

- **O**. Tap the Finish button (5) to end the operation.
- & A message box opens: *Finish operation* .
- P. 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 "8.9.2 Operation data" for details.



9.8 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.

9.8.1 MX-i micromotor Speed & Torque

FIG. 19.

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 : The max. reached torque value is represented by the green arrow (1). Slide to adjust the maximum speed and torque values.

Or tap the icons 🖄 💽 to activate the keypad for fine adjustment.

FIG. 20.

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

9.8.2 MX-i micromotor rotation direction

FIG. 21.

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

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

Note : The operative screen always displays the selected rotation direction.

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

The operative screen always displays the selected handpiece ratio.

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

The operative screen always displays the selected light intensity value.



9.8.3 Irrigation Level

FIG. 22.

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.

9.8.4 Handpiece ratio

FIG. 23.

Tap and select to modify the handpiece ratio.

Verify that the handpiece corresponds to your selection.

Note : The operative screen always displays the selected handpiece ratio.

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

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

9.8.5 Light intensity

FIG. 24.

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



9.9 Tool visualization in cassette

FIG. 25.

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

 \mathbf{b} The tool visualization page screen is displayed.

FIG. 26.

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

(1) Complete / Basic switch

Note : The **Basic** tab allows to display simplified tools identification table and cassette picture (not available for all Straumann[™] implants).

- (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.

9.10 Add, edit or remove implants

9.10.6 Add implant

FIG. 27.

A. From the *Implant type selection* popup window tap \oplus (2) to create a copy of a factory implant, or

tap + (1) to create an implant named after an existing Implant Brand, with operation parameters assigned by default.

Note : User-defined implants are represented by lacksquare . Default implants are represented by lacksquare .

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.

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).

It is also possible to automatically fill-in the *Brand name* field by tapping on the icon of one of the existing Implant Brands.

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

₲ The app navigates back to the *Drill protocol* page screen.



FIG. 30.

- E. When available, choose between *Guided* (implant) and *Non-guided* (9).
- F. Fill in or modify the *Implant type* (1) and *Diameter* (2) fields.
- **G.** Change the *Step name* (7) and the operative parameters (6) if necessary. *See section "9.8 Operative parameters".*
- H. Tap \blacksquare (5) to record step by default.

\triangle 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 : It is possible to add up to 12 steps for each drill protocol.

The implant placement step icon is marked with the 🖤 symbol. 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.

J. Tap *Save* (4) to validate.

Solution 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 : The Implant brand and Implant type fields must be filled in before saving.



9.10.7 Edit (user-defined) implant

FIG. 31.

- A. From the *Implant type selection* popup window, tap $^{(0)}$ (1) on the user-defined implant to be modified.
- 🔖 The *Drill protocol* page screen is displayed.
- B. Change the desired operative parameters.

See section "9.8 Operative parameters".

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

9.10.8 Remove (user-defined) implant

Swipe left to remove the desired user-defined implant:



9.11 Bookmark or remove brands

FIG. 32.

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 : When displaying the Implant brand selection popup window for the first time, the favorite brands tab (2) is selected. When no brand is bookmarked in the favorite brands tab (2), a tutorial explaining how to bookmark brands is displayed.

- 🔖 The brands icons are greyed out when the bookmark or remove brand function is activated.
- B. Tap 🖄 (5) to bookmark a brand or tap 🔟 (4) to remove a brand.

Note : The brands present by default in the app (factory ones) cannot be removed.

C. Tap *Done* (3) to validate or *Cancel* (6) to discard changes. Bookmarked brands are displayed in the favorite brands tab (1).

To unbook mark brands, apply reverse procedure (possible on both *ALL* and favorite brands tab).



10 Operation – Surgery mode

10.1 Enter surgery mode FIG. 1

A. Tap 🖭 to enter the surgery mode.

✤ The Setup page screen is displayed.

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

Note : In the USA and Canada, the surgery mode is available only on the iChiropro Surgery unit (REF 1600883-001).

10.2 Setup screen description

FIG. 2

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

(1) Search field (to find specific information in the planned operations list)

- (2) Plan a new operation (see "10.3 Plan an operation")
- (3) Back to the previous screen
- (4) *Direct* operation area
- (5) *Planned* operations area

Note : Patients' names and operation's dates can be sorted by tapping on their respective columns' titles (6).

10.3 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 \bigcirc (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 "8.8.1 Add or edit patient" if the desired patient is not present or to modify patient's data. 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 : Fields marked with an asterisk must be filled in before saving.

E. Tap 🔳 (4) to choose the procedure.

✤ The *Procedure* popup window is displayed.

FIG. 5

Note : User-defined procedures are represented by . Default procedures are represented by . F. Tap the desired procedure or tap *Close* (1) to go back.

₲ The app navigates back to the *Operation setup* page screen.

See "10.8.1 Add procedure" to create an user-defined procedure.



G. In the jaw representation, tap the desired tooth emplacement to affect the procedure to it.

Solution The tooth is highlighted in blue (4).

H. Tap \oplus (5) to add other procedures to the operation, or tap \times (1) to remove procedures from the operation.

Note : It is possible to add up to 8 procedures per operation. Each procedure is numbered in the jaw representation according to the operation order.

Long tap on procedure icons and move them to reorganize order.

I. Tap or slide *Notes* (3) to write comments in relation to the operation.

Note : *Position of the Notes is automatically saved.*

J. Tap *Save* (2) to go back to the *Setup* page screen.

 \clubsuit The operation appears on the planned operations list.

Note : In case mandatory fields are empty, saving is not possible until these fields are filled in. Empty mandatory fields blink on the screen

See section "10.5 Start or resume an operation" to launch a planned operation.



10.4 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.

10.5 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 : *Starting an operation is not possible if the procedure is not defined.*

\triangle caution

If the foot control 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 foot control is released and pressed again.

\triangle 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

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 foot control to adjust the MX-i micromotor speed. If needed, tap 🔤 (1) to record step.

Note : Real-time speed and torque values are displayed when the MX-i micromotor is running. 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.

D. Navigate through the operation steps by:

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

Note : Refer to the corresponding handpiece IFU if a tool change is needed. E. Adjust the operative parameters (6) if necessary.

See section "9.8 Operative parameters".

- 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 foot control's orange button to perform the operation's other planned surgery procedures.

Note : *Refer to the corresponding handpiece IFU if a tool change is needed*

H. Tap *Data* (4) to modify patient's data if necessary.

Solution The *Operation data* page screen is displayed.

See section "8.9.2 Operation data" for details.

I. Tap the Finish button (5) to end the operation.

- 🍇 A message box opens: *Finish operation* .
- J. Tap *Finish* to confirm the end of operation or *Cancel* to continue operation.





10.6 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 : User-defined procedures are represented by* 📥 .

Default procedures are represented by \blacktriangleright . Or tap \triangleright (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.

₲ The app navigates back to the *Setup* page screen.

See chapter "10.8.1 Add procedure" to create an user defined procedure.

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

If the foot control 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 foot control is released and pressed again.

\triangle 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

\triangle 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 foot control to adjust the MX-i micromotor speed. If needed, tap 🔤 (1) to record step.

Note : Real-time speed and torque values are displayed when the MX-i micromotor is running. 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.

E. Navigate through the operation steps by:

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

Note : Refer to the corresponding handpiece IFU if a tool change is needed. F. Adjust the operative parameters (6) if necessary.

See section "9.8 Operative parameters".

- 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 "8.9.2 Operation data" for details.

I. Tap the *Finish* button (5) to end the operation.

🍫 A message box opens: *Finish operation* .

J. Tap *Finish* to confirm the end of operation or *Cancel* to continue the operation.

🔖 The *Operation data* page screen is displayed. Fill the necessary information in and tap *Save* .

See section "8.9.2 Operation data" for details.



10.7 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.

10.7.1 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 20 to activate the keypad for fine adjustment.

FIG. 15

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

10.7.2 MX-i micromotor rotation direction

FIG. 16

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

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

Note : The operative screen always displays the selected rotation direction.

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



10.7.3 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.

10.7.4 Handpiece ratio

FIG. 18

Tap and select to modify the handpiece ratio.

\triangle warning

Verify that the handpiece corresponds to your selection.

Note : The operative screen always displays the selected handpiece ratio.

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

10.7.5 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 : The operative screen always displays the selected light intensity value.



10.8 Add, edit or remove procedures

10.8.6 Add procedure

FIG. 20

- A. From the *Procedure* popup window, tap + (1) to create a procedure from scratch. Or tap \oplus (2) to create a copy of a factory procedure.
- 🔖 The *Procedure Protocol* page screen is displayed.

Note : User-defined procedures are represented by . Default procedures are represented by EIG. 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 "10.7 Operative parameters".

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

E. Tap (6) to add steps or tap \times (1) to remove steps from the procedure protocol. Change their position by dragging and releasing them.

Note : It is possible to add up to 12 steps for each procedure.

F. Tap *Save* (2) to validate.

✤ The new procedure can be found in the *Procedure* popup window.

Note : The Procedure name field must be filled in before saving.

10.8.7 Edit (user-defined) procedure

FIG. 22

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

🔖 The *Procedure protocol* page screen is displayed.

B. Change the desired operative parameters.

See section "10.7 Operative parameters".

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



FIG. 23

10.8.8 Remove (user-defined) procedure

FIG. 23

Swipe left to remove the user-defined procedure.

11 List of errors & Troubleshooting

11.1 Safety alerts (operating)

Warning description	Message	Cause of warning	Action
Foot control to be released	⚠ Please release pedal	Foot control is pressed when accessing operative page. Foot control remains pressed when acknowledging any system notification. Motor is jammed for more than 2 seconds.	Release foot control and press it again.
Motor torque limitation active	9	Motor drive limits delivered torque to prevent motor overheating.	Avoid extended use. Let system cool down.
Low to high speed drilling transition	₩ ¹ /2 = # ₩ 15 6m ≪Opm	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 volume on your iPad and set it to an appropriate level according 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 system 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.	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.

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Error description	Message	Cause of error	Action
ERROR 1: Loss c	of pedal connection		
Foot control connection missing	Foot control is not connected! Please check foot control connection.	Foot control is not connected correctly.	 Check pedal connection If problem persists, contact Bien-Air Dental SA
ERROR 2: Perist	altic pump general error		
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 3: Loss r	notor connection		
Motor connection missing	Motor is not connected! Please check motor connection.	Loss of motor phase fault. Motor is not properly connected.	 Check motor connection. If problem persists, contact Bien-Air Dental SA.
ERROR 4: Motor	cable fault		
Motor cable failure	Motor cable fault! Please replace motor cable.	Motor control card failure. Motor cable may be defect.	1. Replace motor cable 2. If problem persists, contact Bien-Air Dental SA.
ERROR 5: Motor control overheating			
Motor drive over temperature	Overall system overheating! Please wait until cool.	Overheating of motor control card.	 Wait for system cooling If problem persists contact Bien-Air Dental SA.
GEN ERROR [FailCode] : System electrical fault			
System electrical failure	 Switch OFF unit Disconnect iPad device from unit Close application Switch unit back ON Reconnect iPad device to unit Restart application 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	 Switch OFF unit Disconnect iPad device from unit Close iChiropro application Switch unit back ON Reconnect iPad device to unit Restart iChiropro application If problem persists contact Bien-Air Dental SA.

11.2 iOS compatibility errors (disclaimer screen)

color	iOS version (identifier digit change)	Text version	Restriction (reommendations)
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 	Currently installed iOS x.y.z text section is displayed in red color.	• Configuration in use is significantly different from recommended configuration.
	to iOS verified during app validation		The current configuration should NOT be used!



FIG. 1

12 Maintenance and servicing

\triangle caution

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

12.1 Servicing

\triangle caution

Never dismantle the device. For all servicing or repair operations, you are advised to contact your usual supplier or Bien-Air Dental SA directly.

Service period

The device was tested by simulating 10,000 clinical procedures (corresponding to a service period of 6 to 10 years). If the actual use of the device exceeds the tested service period, preventive maintenance of the device is recommended.

12.2 Cleaning

\triangle caution

- Do not immerse in disinfectant solution.
- Not designed for an ultrasonic bath.

\triangle warning

- Use a new sterile irrigation line for each patient.
- Use a new sterile protective sheet for each patient.

Clean the unit including the bracket and the foot control by gently rubbing it with a clean cloth soaked in a suitable product (i.e. Bien-Air Dental Spraynet or isopropyl alcohol for about 15 sec.)



12.3 Replacement of fuses

A. Switch off the iChiropro unit "O".

B. Remove the iPad from the adapter.

\triangle caution

The power cable must be disconnected at least 10 seconds before opening the fusebox.

C. Remove the fuse box (1) with a flat screwdriver FIG. 2.

D. Replace the fuses (2) by the new ones and put the fuse box back (1) in place FIG. 3.

\triangle caution

Only use fuses T4.0AH 250 VAC REF 1307312-010.

12.4 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.
- D. Open the peristaltic pump lid and uninstall the peristaltic cassette in it.
- E. Tilt the iChiropro unit to approximately 45° and remove both screws (2). FIG. 1
- F. Remove the iPad support (s1) and install the needed one, paying attention not to force it to avoid damaging the connector.

12.5 Packaging and Storage

Storage conditions		
**	Temperature range:	[0°C; +40°C] [+32°F; +104°F]
	Relative humidity range:	[10%; 80%]
	Atmospheric pressure limitation:	[650 hPa; 1060 hPa] [490 mmHg; 795 mmHg]
(†)	Keep away from rain	

13 Transport & disposal

13.1 Transport

Transport		
**	Temperature range:	[-20°C; +50°C] [-4°F; +122°F]
" ⁽²⁾	Relative humidity range:	[5%; 80%]
	Atmospheric pressure limitation:	[650 hPa; 1060 hPa] [490 mmHg; 795 mmHg]
Ť	Keep away from rain	

13.2 Disposal



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



This device must be recycled. 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 2012/19/ EU).

14 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.

14.1 Limitation of liability

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.

14.2 Trademarks

iPad Air®, iPad Pro® and iPad® are registered trademarks of Apple Inc.

14.3 Terms of guarantee

Bien-Air Dental SA grants the user a guarantee covering all functional defect, or material or manufacturing faults. The device is covered by this guarantee from the date of invoicing for:

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

In the event of a justified claim, Bien-Air Dental SA or its authorized representative will repair or replace the product free of charge.

All other claims of any kind whatsoever, particularly claims for damages, 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.

\triangle caution

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.

14.4 References

Device REF	LEGEND
1600784-001	Console iCHIROPRO
ACCESSOFIES REF	LEGEND
1600755-001	Electric micromotor MX-i LED.
1600881-001	MX LED cable 3 meters length.
1600606-001	MX LED cable
1303393-001	Potency for attaching physiological fluid bag
1600631-001	Foot control pedal
1601192-001	Wireless foot control + Dongle
1501746-002	Sterile protect film
1501738-010	Irrigation line 3.5m
1500984-010	Irrigation line
1501621-010	Irrigation sys KM 20:1L
1307312-010	Pack of 10 fuses ø5x20 T4.0AH 250 VAC high breaking capacity.
1501317-100	Bur Guards HP1:2 (100 PCES)
1501635-001	Irrigation line KM (10/pkg)
1301575-001	Handpiece/ support holder
1308761-001	iPad 10 adapter
1308964-001	iPad Air 5 adapter
1501635-001	Irrigation line KM (10/pkg)



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