Console
CHIROPRO L PREMIUM

ENG INSTRUCTIONS FOR USE.

CE 0123 RX Only

REF 2100428-0004/2025-01

Set Console CHIROPRO L US PREMIUM REF 1700463-001

CONSOLE CHIROPRO L PREMIUM
REF 1600855-001

MOT MX-i LED
REF 1600755-001

CABLE MX LED 3M
REF 1600881-001

IRRIGATION CLIP
REF 1307727-010

GALLOWS
REF 1303393-001

FOOTCTRL
REF 1600631-001

IRRIG. LINE CHIROPRO L 3.5M
REF 1501738-010

Set Console CHIROPRO L US PREMIUM WL REF 1700889-001

CONSOLE CHIROPRO L PREMIUM
REF 1600855-001

MOT MX-i LED
REF 1600755-001

CABLE MX LED 3M
REF 1600881-001

IRRIGATION CLIP
REF 1307727-010

GALLOWS
REF 1303393-001

WIRELESS FOOTCTRL + DONGLE*
REF 1601192-001

IRRIG. LINE CHIROPRO L 3.5M
REF 1501738-010

Options

IRRIG. LINE CHIROPRO L 3.5M
REF 1501738-010

IRRIGATION LINE KM (10/pkg)
REF 1501635-010

IRRIGATION CLIP
REF 1307727-010

FUSE SPT Ø5x20
REF. 1307312-010

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

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ENG

1 Symbols

1.1 Description of symbols for Console CHIROPRO L PREMIUM

Sym	Description	Sym	Description
CE 0123	CE Marking with number of the notified body.		General symbol for recovery/ recyclable.
	OFF (power).		Separate collection of electric and electronic equipment.
	ON (power).		Manufacturer.
	Fuse.		Lamp; lighting; illumination.
	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.
	Refer to instruction manual/booklet (https://dental.bienair.com/fr_ch/support/download-center/).	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.		Variability in steps.
	Data Matrix code for product information including UDI (Unique Device Identification).		Protective earth (ground).
	Temperature limitation.		Equipotency.
	Atmospheric pressure limitation.		Humidity limitation.

1.2 Description of symbols for Console CHIROPRO L PREMIUM accessories

Sym	Description	Sym	Description
	CE Marking with number of the notified body.		Thermo washer disinfectable.
	Expiration date.		General symbol for recovery/ recyclable.
	Do not reuse.		Separate collection of electric and electronic equipment.
	Sterilized with Ethylene Oxyde.		Sterilizable in autoclave up to the specific temperature.
	Electrical safety. Applied part type B.		Manufacturer.
	Catalogue number.		Serial number.
	Does not contain DEHP.		Batch code.
	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).

ENG

2 Identification & Intended Use

2.1 Identification

The CHIROPRO L PREMIUM device encompasses a table-top system allowing to control a dental micromotor which drives a dental handpiece. A peristaltic pump conveys the physiological liquid via a sterile single-use irrigation line. The console includes a user interface composed of keypad and buttons which enables to set the parameters, and a foot control used to turn on/off the pump, to navigate through the various steps of the selected procedure and to control the rotation direction of the motor. The user interface shows many parameters of the operation, such as the handpiece gear ratio, bur speed, torque value and irrigation flow setting.

2.2 Intended use

CHIROPRO L PREMIUM devices are intended to be used in dental implantology, periodontology, oral surgery and maxillo-facial surgery.

2.3 Intended patient population

The intended patient population of the CHIROPRO L PREMIUM 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 for selecting 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 Use environment

Professional healthcare facility environment.

2.6 Intended medical conditions

- Dental implantology is the treatment to replace one or more missing teeth.
- Oral surgery treatments include impacted teeth extraction, wisdom teeth extraction, non-salvageable decayed teeth extraction. Guided and not- guided bone regeneration, apicoectomy, osteotomy, sequestrectomy and hemisection.
- The main periodontology treatments include gingivitis, periodontitis.
- The main maxillofacial surgery includes procedures such as Orthognathic surgery, genioplasty and rhinoplasty.

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.

3 User and patient safety: Warnings & Precautions of Use

⚠ WARNING

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

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

⚠ WARNING

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

- 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 electric shock, the warnings below must be observed:

⚠ WARNING

- The device 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.
- The cleaning procedure defined in chapter 11.2 Cleaning & Sterilization on page 35 must be followed.
- 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 infection, the warnings below must be observed:

⚠ WARNING

- 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.
- The cleaning procedure of the device defined in chapter 9.2 Cleaning must be followed.
- Always refer to the accessories IFU for dedicated maintenance procedure.
- Always replace the irrigation line after an operation as they are single use only.
- Always ensure that the irrigation line package is intact before use.

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

⚠ **WARNING**

- If the irrigation pump is used and regulated by the device, verify that the pump is working properly before starting the treatment as well as during the treatment. The device 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 console or motor overheating, the cautions below must be observed:

⚠ **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 the device outside the range of operating temperature.
- Let the system cool down when the motor overheating alert notification is on display. See chapter 7 List of error & Troubleshooting for more details.

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

⚠ **CAUTION**

- The predefined settings contained in the device 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:

⚠ **CAUTION**

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

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

⚠ **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.

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

⚠ **WARNING**

- Place the device on a flat surface capable of bearing its weight. It may be positioned on a table, on a trolley or any other surface but in no circumstances on the floor.
- Always use Bien-Air Dental SA accessories or those recommended by Bien-Air Dental SA.

⚠ **CAUTION**

- Never connect a handpiece on a running micromotor.
- Do not switch off the device while the motor is running.
- Always check that the lid is not opened when running the irrigation pump.
- Beware of the risk of pinching when closing the irrigation valve.
- Only use original Bien-Air Dental maintenance products and parts or those recommended by Bien-Air Dental. Using other products or parts may cause operational failure and/or void the guarantee.

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

⚠ **WARNING**

- 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:

⚠ **WARNING**

- 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 Description

4.1 Console CHIROPRO L PREMIUM system overview

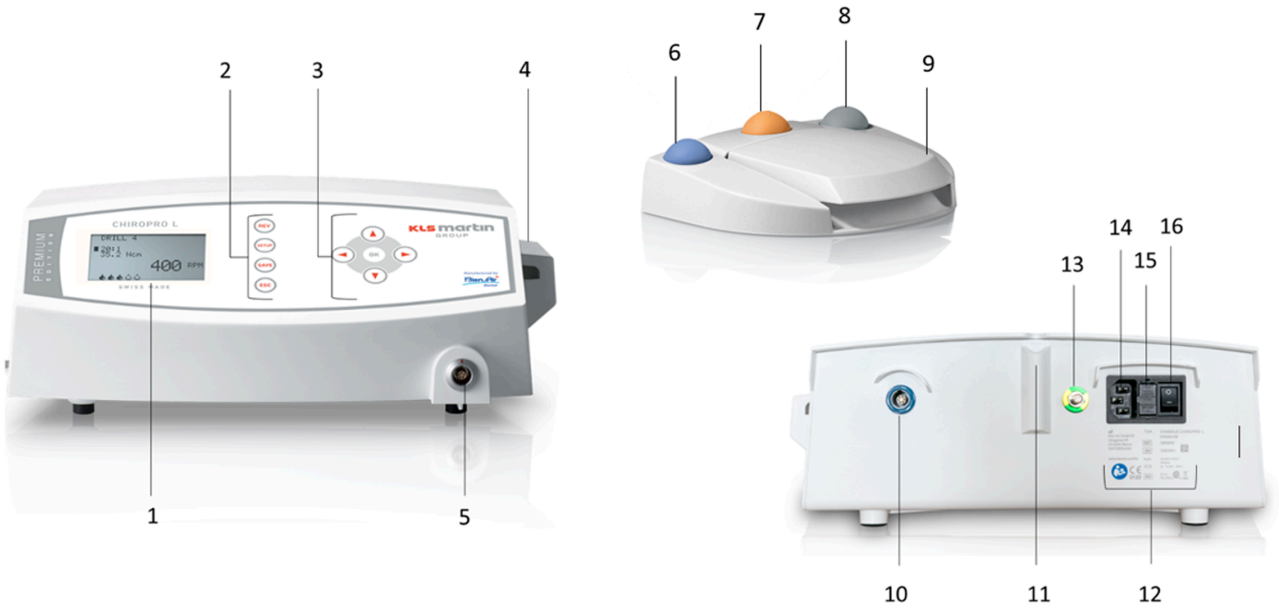


FIG. 1

(1) DEVICE SCREEN

(2) REV COMMAND TO REVERSE THE ROTATION OF THE MOTOR MX-i LED
SETUP "SETUP" MENU BACKUP KEY
SAVE PARAMETERS BACKUP KEY
ESC RETURN KEY

(3) COMMANDS DEVICE
Down key
Up key
Left key (-)
Right key (+)
OK Confirmation/selection key: next stage

(4) PERISTALTIC PUMP LID

(5) MX-LED MICROMOTOR CONNECTOR

(6) IRRIGATION ON/OFF CONTROL BUTTON ON PEDAL

(7) "PROGRAM" BUTTON ON PEDAL - Short press = next stage - Long press = previous stage

(8) BUTTON TO REVERSE THE ROTATION OF MICROMOTOR ON PEDAL

(9) VARIABLE SPEED DRIVE ON PEDAL

(10) PEDAL CONNECTOR

(11) GALLOW SUPPORT/BRACKET

(12) LABEL

(13) EQUIPOTENCY CONNECTOR

(14) MAINS CONNECTOR (100/115/230VAC)

(15) FUSE HOLDER

(16) MAIN SWITCH (ON/OFF)

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.

4.2 Sets supplied

Set CHIROPRO L US PREMIUM REF 1700463-001

Designation	REF number
Console CHIROPRO L PREMIUM	1600855-001
MOT MX-i LED	1600755-001
Cable MX LED 3m	1600881-001
FOOTCTRL	1600631-001
Irrigation line 3.5m (10/pkg)	1501738-010

Set CHIROPRO L US PREMIUM WL REF 1700889-001

Designation	REF number
Console CHIROPRO L PREMIUM	1600855-001
MOT MX-i LED	1600755-001
Cable MX LED 3m	1600881-001
WIRELESS Foot control + dongle	1601192-001
Irrigation line 3.5m (10/pkg)	1501738-010

4.3 Options

Designation	REF number
IRRIG. LINE CHIROPRO L 3.5M	1501738-001
IRRIGATION LINE KM (10/pkg)	1501635-010
IRRIGATION CLIP	1307727-010
FUSE SPT Ø5x20	1307312-010

4.4 Technical data

Dimensions L x W x H	
Console CHIROPRO L PREMIUM unit	209 x 220 x 123 mm
CHIROPRO L PREMIUM unit height (with bracket)	506 mm
Foot control (without handle)	206 x 180 x 60 mm
Foot control (with handle)	206 x 200 x 155 mm
Wireless Foot control Width x Height x Depth (without hook)	206 x 180 x 60 mm
Wireless Foot control Width x Height x Depth (with hook)	206 x 200 x 155 mm
Motor cable	L 2.0 m
Foot control cable	L 3.0 m
MOT MX-i LED	23 x 84 mm

Weight	
Console CHIROPRO L PREMIUM unit	2.7 kg
Foot control (without handle and cable)	830 g
Foot control (with handle and cable)	877 g
Wireless Foot control (without hook, two batteries included)	934 g
Bracket	115 g
Cable	105 g
MX-i LED micromotor	110 g

Electrical data	
Voltage	100 – 240 VAC
Frequency	50-60 Hz
Power demand	300 VA

Applied parts (per IEC 60601-1):	
MX-i LED micromotor	REF 1600755-001
Contra-angles (CA) & Straight handpieces (HP) compatible CA&HP	ISO 3964

Degree of ingress protection	
Unit	IP 41 (protection against insertion of objects larger than 1 mm and dripping water (vertically falling drops)).
Foot control	IP X8
Wireless foot control	IP X6

Memory

Implantology mode: Storage in memory of 8 implant fitting sequences of 10 steps each.
Surgery mode: Storage in memory of 4 separate programs.

Languages

French, German, English, Italian, Spanish, Portuguese and Russian

Bracket for physiological liquid flask

Stainless steel.

Peristaltic pump	
Pump delivery	From 30 to 130 ml/min. (5 levels)
Irrigation line	External Ø 5.60 mm
	Internal Ø 2.40 mm
Wall thickness	1.60 mm

⚠ **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 "7 List of errors & Troubleshooting".

4.5 Classification

Classification

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

Electric insulation class

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

4.6 Performance

Performance	REF 1600855-001
Motor speed regulation[1]	Accuracy ± 5%[2] in the speed range 100 - 40'000 rpm (*)
Motor torque regulation[1]	Torque adjustable from 10% to 100% of the maximum torque
Maximum motor torque	5 (±5%) Ncm (*)
Maximum motor power[1]	95 (±10%) W (*)
Max motor LED current	250 (± 10%) mA rms
Max motor LED current range	Not adjustable, always at full intensity
Power supply output limitation	< 150 W
Irrigation flow	5 levels:
	1 drop = 30ml/min
	2 drops = 60ml/min
	3 drops = 90ml/min
	4 drops = 120ml/min
	5 drops = 150ml/min
(*) Measurement realized in combination with motors MX-i LED 3rd Gen 1601008 and 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.	

[1] 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.

[2] In 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 ±10% in a highly electromagnetic disturbance environment.

4.7 Operating conditions

Operating conditions

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

ENG

4.8 Electromagnetic compatibility – emissions & immunity

This electronic control is in compliance with electrical safety standards in line with standard IEC 60601-1-6, third edition, and those governing electromagnetic compatibility in line with standard IEC 60601-1-2, fourth edition.

Guidance and manufacturer's declaration – Electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The CHIROPRO L PREMIUM 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 CHIROPRO L PREMIUM is suitable for use in any building, including residential buildings and those directly connected to the public low-voltage power supply network that supplies buildings used for residential purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Emissions due to voltage fluctuations (flicker) IEC 61000-3-3	Complie	

Guidance and manufacturer's declaration – Electromagnetic immunity

The CHIROPRO L PREMIUM is intended for use in the electromagnetic environment specified below. The customer or the user of the CHIROPRO L PREMIUM 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 CHIROPRO L PREMIUM requires continued operation during mains power interruptions, it is recommended that the CHIROPRO L PREMIUM 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	10 VRMS 0,15 MHz – 80 MHz 10 VRMS in ISM and amateur bands 0,15 MHz – 80 MHz 80% AM at 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey 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 30 cm):** 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 GSM 1800/1900: max 2W CDMA 1900: max 2 W DECT: max 2 W LTE Band 1,3,4and 25: max 2 W UMTS: max 2W Bluetooth: max 2W WILAN 802.11b/g/n: max 2 W RFID 2450:max 2W LTE Band 7: max 2W WLAN 802.11 a/n: max 0.2W Interference may occur in the vicinity of equipment marked with the following symbol: : 
	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	
	28 V/m 800-960 MHz 50% PM 18Hz	28 V/m 800-960 MHz 50% PM 18Hz	
	28 V/m 1700-1990 MHz 50% PM 217Hz	28 V/m 1700-1990 MHz 50% PM 217Hz	
	28 V/m 2400-2570 MHz 50% PM 217 Hz	28 V/m 2400-2570 MHz 50% PM 217 Hz	
	9 V/m 5100-5800 MHz 50% PM 217Hz	9 V/m 5100-5800 MHz 50% PM 217Hz	
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%.

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

5 Installation

5.1 Install the CHIROPRO L PREMIUM system

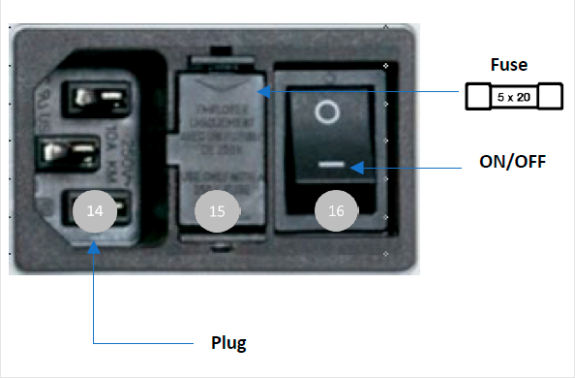


FIG. 1

A. CHIROPRO L PREMIUM may be positioned on a table, on a trolly or another surface, but in no case on the floor.
As the power plug (14) is the disconnection device. It must be easily accessible at all time in case of problems.

B. The fuse box (15) may be opened with a screwdriver.
100-240 Vac = fuse T-4.0 A L 250 VAC REF 1301560-010

C. The apparatus is powered by your line voltage (100/115/230 Vac). Connect the power cable to the plug (14).

D. The device can be safely turned off using the main switch (16).

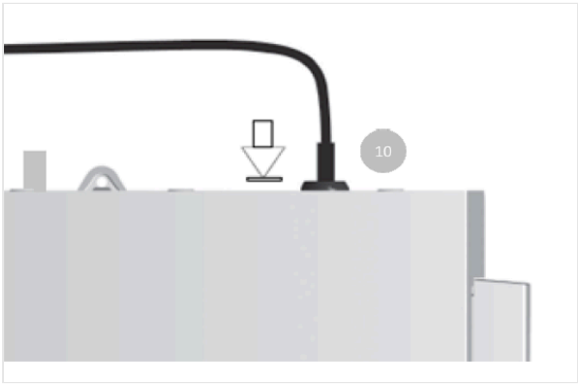


FIG. 2

E. Connect the foot control cable to the output provided on the rear panel, guiding the connector and plug by means of the index pin on the connector FIG. 2.

⚠ **CAUTION**

Do not raise the pedal using the connection cable.

⚠ **CAUTION**

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

FIG. 3

F. Connect the MX-i LED micromotor cable to the motor output on the front panel (5), guiding the connector and plus by means of the index pin and red dot on the connector FIG. 3.

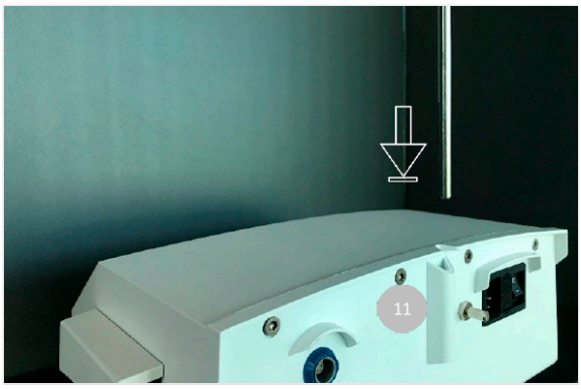


FIG. 4

G. Align and attach the bracket to the housing provided on the console's rear (11) and suspend the irrigation solution flask or bottle FIG. 4.

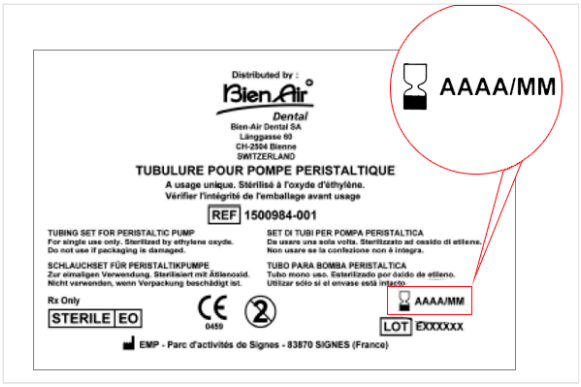


FIG. 5

H. Check the packaging integrity, as well as the expiration date of the irrigation line. Only lines supplied by Bien-Air Dental SA ensure trouble free operation. These lines are sterile and for single use. Re-use may result in microbiological contamination of the patient.

FIG. 6

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

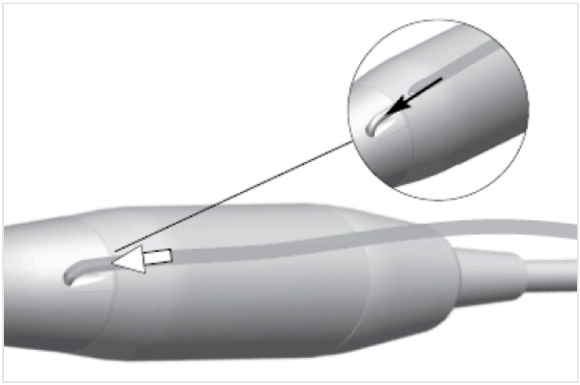


FIG. 7

Fitting on the spray tube

J. Connect the flexible hose of the irrigation line to the spray tube of the handpiece or contra-angle FIG. 7.

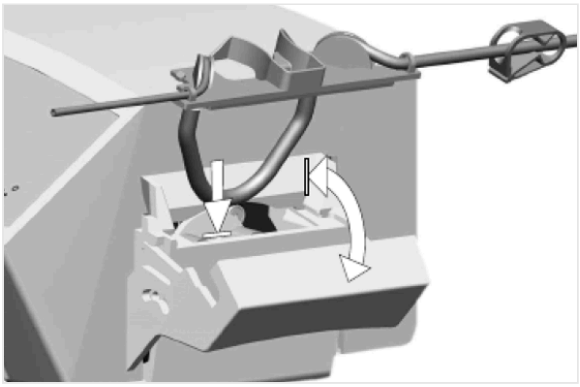


FIG. 8

Installation on the peristaltic pump

K. Install the plastic cassette in the peristaltic pump. Check that the cassette is clipped correctly. Close the pump lid, FIG. 8.
If there is resistance to closing, open the lied again and check the correct positioning of the cassette.

⚠ **CAUTION**

Do not run the pump while the lid is open to avoid risk of pinching.

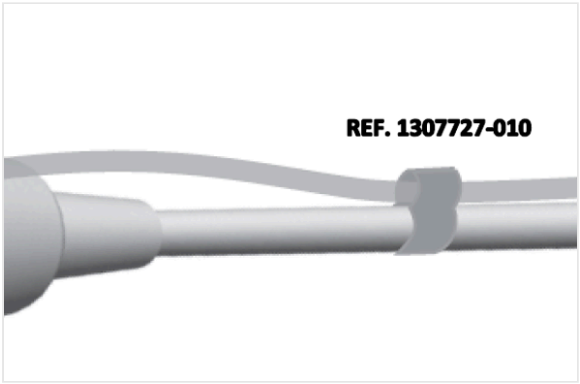


FIG. 9

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

M. Attach the irrigation line on the motor cable using the attachment collars REF 1307727-010 FIG. 9.

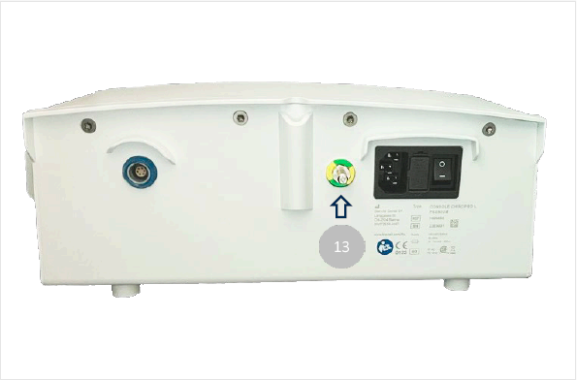
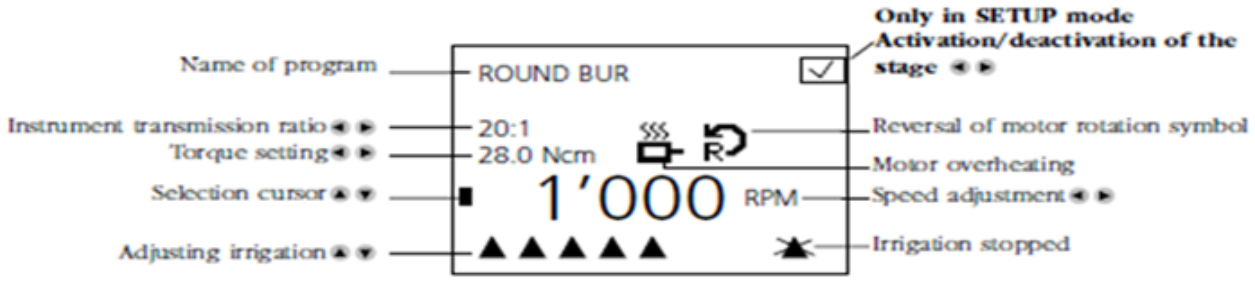


FIG. 10

N. An additional earth connector (13) is provided on the back of the device FIG. 10.

6 Interface overview

Operation mode



Note : The Operation mode is the default startup mode. Any foot control action will be ignored when the motor is running.

Starting display

Main Menu	Steps	Ratio	Speed in rpm	Torque in Ncm	Irrigation in ml/min
Implantology ▷	Round bur 1	256:1	100 – 40'000 rpm with a CA 1:1	0.58 – 5.8 Ncm with a CA 1:1	30 ml/min 20%
Surgery	Round bur 2	128:1			60 ml/min 40%
	Drill 1	64:1			90 ml/min 60%
	Drill 2	30:1	Depends on the CA	Depends on the CA	120 ml/min 80%
	Drill 3	27:1			150 ml/min 100%
	Drill 4	20:1			
	Tapping	16:1			
	Tap unscrewing	10:1			
	Implant screwing	1:1			
	Unscrewing	1:2			
		1:5			

Main Menu	Steps	Ratio	Speed in rpm	Torque in Ncm	Irrigation in ml/min
Implantology	Procedure 1	256:1	100 – 40'000 rpm with a CA 1:1	0.58 – 5.8 Ncm with a CA 1:1	30 ml/min 20%
Surgery ▷	Procedure 2	128:1			60 ml/min 40%
	Procedure 3	64:1			90 ml/min 60%
	Procedure 4	30:1	Depends on the CA	Depends on the CA	120 ml/min 80%
		27:1			150 ml/min 100%
		20:1			
		16:1			
		10:1			
		1:1			
		1:2			
		1:5			

BienAir CHIROPRO L

Available values

7 List of error & Troubleshooting

Message		Cause of error	Action
⚠ Release the pedal	The pedal is pressed when starting the device. The motor is blocked for more than 2 sec.	Safety	Release the pedal and press again.
⚠	The motor control card limits the power supplied to the motor to prevent motor overheating.	Safety	Avoid extended use. Let the system cool down.
Equipment initialisation error The following error may occur at start-up of CHIROPRO L PREMIUM			
1. Check on the integrity of the CHIROPRO L PREMIUM memory			
INIT ERROR 1	The memory is corrupt! Please contact Bien-Air Dental SA. ESC: restore	The memory data check failed	Press the ESC key to try to restore the memory. Contact Bien-Air Dental SA.

ENG

Message		Cause of error	Action
Device operating error The following errors may occur during operation of the device			
1. Loss of pedal connection			
ERROR 1	The pedal is not connected! Please check the connection. ESC: exit	The pedal is not connected correctly.	Check pedal connection. Contact Bien-Air Dental SA.
2. Peristaltic pump general error			
ERROR 3	Irrigation pump fault! Please contact Bien-Air Dental SA. ESC: exit	Peristaltic pump electrical fault / Peristaltic pump motor driver overheating.	Contact Bien-Air Dental SA.
3. Loss of motor connection			
ERROR 4	The motor is not connected! Please check the connection. ESC: exit	Loss of motor phase fault. The motor is not connected correctly.	Check motor connection. Contact Bien-Air Dental SA.
4. Motor cable fault			
ERROR 5	Motor cable fault! Please change cable. ESC: exit	Motor power fault. The motor cable may be defective.	Check motor cable. Contact Bien-Air Dental SA.
5. Motor control overheating			
ERROR 6	System overheating! Please wait for it to cool. ESC: exit	Overheating of motor control card (electrical control of motor).	Wait until the system cools. Contact Bien-Air Dental SA.
6. System electrical fault			
GEN ERROR (Error code)	System electrical fault! Please contact Bien-Air Dental SA. ESC: exit	Communication fault with motor control card: [EC100] Motor control card power supply undervoltage: [EC101] Motor control card power supply overvoltage: [EC102] Other moto control card faults: [C120]	Contact Bien-Air Dental SA.

8 Default Values

Implantology:

Default values : "Operative parameters default values for implantology., p. 35"
The table shows the default operating values for 8 different implantology sequences.

Surgery:

Default values : "Operative parameters default values for surgery., p. 35"
The table shows the default operating values for 4 different surgical sequences.

9 Maintenance and Servicing

9.1 Servicing

⚠ **CAUTION**

Never disassemble the device. For all servicing or repair operations, you are advised to contact your regular 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.

9.2 Cleaning

⚠ **CAUTION**

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

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.)

FIG. 1

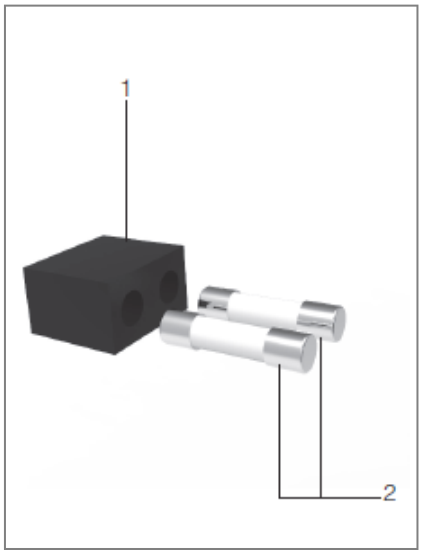


FIG. 2

9.3 Replacement of fuses

A. Switch off the CHIROPRO L PREMIUM unit "O".

B. Disconnect the main cable.

⚠ 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. 1.

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

⚠ CAUTION

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

9.4 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	

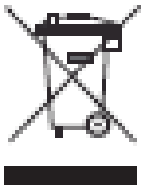
10 Transport & disposal

10.1 Transport

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

10.2 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).

ENG

11 General information

11.1 Terms of guarantee

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

Y The device is covered by this guarantee from the date of invoicing for:

- 12 months for the motor cable;
- 24 months for the CHIROPRO L PREMIUM 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.

⚠ **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.

11.2 References

Device REF	LEGEND
1600855-001	Console CHIROPRO L PREMIUM

Accessories REF	LEGEND
1600755-001	Electric micromotor MX-i LED.
1600881-001	MX-i LED cable 3 meters length.
1303393-001	Potency for attaching physiological fluid bag.
1600631-001	Foot control pedal.
1601192-001	Wireless Foot control + Dongle
1501738-010	Pack of 10 disposable sterile irrigation lines;
1501635-010	Pack of 10 disposable sterile irrigation lines compatible for Kirschner-Meyer irrigation system.
1307727-010	Pack of 10 plastic clip to allow the attachment of the irrigation line with the electric micromotor cable.
1307312-010	Pack of 10 fuses Ø5x20 T4.0AH 250 VAC high breaking capacity.

12 DEFAULT VALUES

Operative parameters default values for implantology.

⚠ CAUTION

All the pre-programmed settings are indicative and MUST be validated by the user before starting the treatment/ operation. Always follow the implant manufacturer recommendations.

SURGERY			
PROCEDURE 1 ☑	PROCEDURE 2 ☑	PROCEDURE 3 ☑	PROCEDURE 4 ☑
1:5	1:2	1:5	1:5
0.87 Ncm	2.90 Ncm	0.87 Ncm	0.87 Ncm
100'000 RPM	80'000 RPM	50'000 RPM	100'000 RPM
▲▲▲△△	▲▲▲△△	▲▲▲△△	▲▲▲△△

Operative parameters default values for surgery.

The table shows the default operating values for 4 types of surgical operations proposed by the system:

SURGERY			
PROCEDURE 1 ☑	PROCEDURE 2 ☑	PROCEDURE 3 ☑	PROCEDURE 4 ☑
1:5	1:2	1:5	1:5
0.87 Ncm	2.90 Ncm	0.87 Ncm	0.87 Ncm
100'000 RPM	80'000 RPM	50'000 RPM	100'000 RPM
▲▲▲△△	▲▲▲△△	▲▲▲△△	▲▲▲△△

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