

Console CHIROPRO L PREMIUM

ENG Instructions for use.

Other languages available on www.bienair.com/ifu



CE
0123

Rx Only

REF 2100428-0003/2024.02

Set Console CHIROPRO L 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

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



























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ENG INSTRUCTIONS FOR USE

1. Symbols

1.1 Description of symbols for CHIROPRO L PREMIUM

Symbol	Description	Symbol	Description
	CE with Marking 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/).		Serial number.
	Consult instructions for use or consult electronic instructions for use.		Catalogue number.
	Authorized EC Representative in the European Community.		Medical Device.
	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 CHIROPRO L PREMIUM accessories

Symbol	Description	Symbol	Description
	CE Marking with number of the notified body.		Thermo washer disinfectable (graved on the MX-i LED Micromotor).
	Expiration date (on the irrigation line package).		General symbol for recovery/recyclable.
	Do not reuse (on the irrigation line package).		Separate collection of electric and electronic equipment (on the foot control label).
	Sterilized with Ethylene Oxide (on the irrigation line package).		Sterilizable in autoclave up to the specific temperature (graved on the MX-i LED Micromotor).
	Electrical safety. Applied part type B (graved on the MX-i LED Micromotor).		Manufacturer.
	Catalogue number.		Serial number.
	Does not contain DEHP (on the irrigation line package).		Batch code.
	Do not use if package is damaged (on the irrigation line package).		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. 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 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 surgeon.

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 side effects

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.

WARNING

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



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.

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 CHIROPRO L PREMIUM 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 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.
- 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 bone overheating, the warnings below must be observed:



WARNING

- If the irrigation pump is used and regulated by the CHIROPRO L PREMIUM, verify that the pump is working properly before starting the treatment as well as during the treatment. The CHIROPRO L PREMIUM 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 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 CHIROPRO L PREMIUM outside the range of operating temperature.

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



CAUTION

- The predefined settings contained in the CHIROPRO L PREMIUM 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 risk of injury and/or material damage the cautions below must be observed:



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.

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:



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.

4.1 Electromagnetic compatibility – emissions & immunity

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.

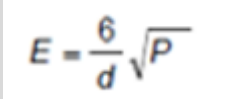

Emission test	compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The CHIROPRO L PREMIUM uses RF energy for its internal operation only. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

RF emissions CISPR 11	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 IEC 61000-3-3	Complies	

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 ±1 kV for lines no input/output	Main 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	Main 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 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°	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: 

Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 3 GHz 80 % AM at 1 kHz	Distance: 0.3 m Minimum separation distance shall be calculated by following equation:  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	

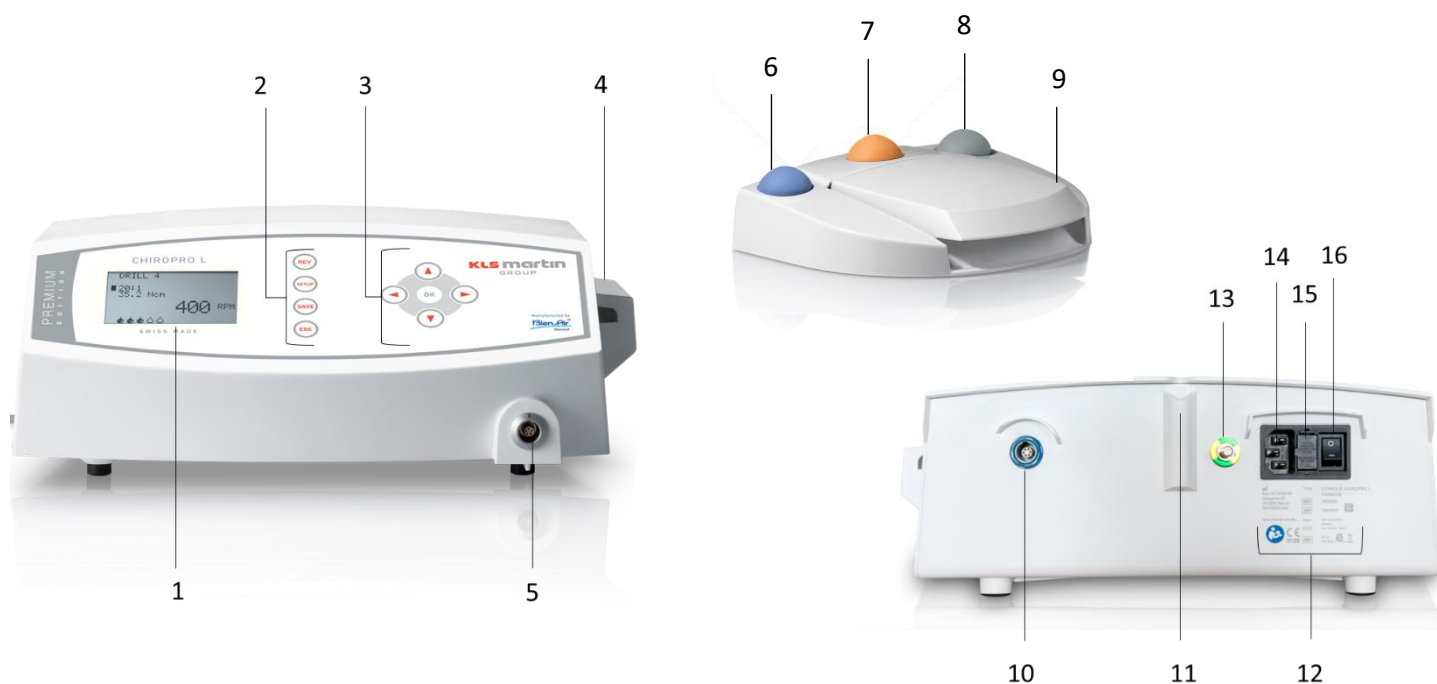
NOTE: U_T is the AC mains voltage prior to the application of the test level.

Essential performance per IEC 60601-1: The essential performance is to maintain in normal condition the visual luminous intensity of the LED at $\pm 30\%$ and the motor speed with a maximum speed deviation at $\pm 10\%$.


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. Description

5.1 CHIROPRO L PREMIUM system overview



1 DEVICE SCREEN

2  COMMAND TO REVERSE THE ROTATION OF THE MOTOR MX-i LED

 "SETUP" MENU BACKUP KEY


 PARAMETERS BACKUP KEY

 RETURN KEY


3 COMMANDS DEVICE

 Down key

 Up key

 Left key (-)

 Right key (+)

 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.

5.2 Sets supplied

Set CHIROPRO L 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

5.3 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	1307313-010

5.4 Technical data

Dimensions L x W x H

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
Motor cable	L 3.0 m
Foot control cable	L 2.9 m
MOT MX-i LED	23 x 84 mm

Weight

CHIROPRO L PREMIUM	2.7 kg
Foot control (without handle and cable)	830 g
Foot control (with handle and cable)	877 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)	ISO 3964 compatible CA&HP

Degree of ingress protection (in accordance with IEC 60529).

Unit	IP 41 (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)

Memory

Implantology mode: Storage in memory of 8 implant fitting sequences of 10 steps each.

Surgery mode: Storage in memory of 4 separate programs.

Interface languages

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

Bracket for physiological liquid flask

Stainless steel.

Peristaltic pump

Pump deliver 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

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 “8 List of errors & Troubleshooting” on page 20.

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 part:

Type B applied parts in accordance with IEC 60601-1 standard

5.6 Performances




Performance	REF 1600755-001
Motor speed regulation ¹	Accuracy $\pm 5\%^2$ in the speed range 100 - 40'000 rpm
Motor torque regulation	Torque adjustable from 10% to 100% of the maximum torque
Maximum motor torque ¹	5 ($\pm 5\%$) Ncm
Maximum motor power ¹	95 ($\pm 10\%$) W
Max motor LED current	250 ($\pm 10\%$) 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

¹Measurement 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%]
	Atmospheric pressure limitation:	[700 hPa; 1060 hPa] [525 mmHg; 795 mmHg]

CAUTION

Do not use CHIROPRO L PREMIUM outside the range of operating temperature.

6. Installation

6.1 Install the CHIROPRO L PREMIUM system

	Installation
<p>Fig. 1</p>	<p>A. CHIROPRO L PREMIUM may be positioned on a table, on a trolley 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.</p> <p>B. The fuse box (15) may be opened with a screwdriver.</p> <p>100-240 Vac = fuse T-4.0 A L 250 VAC REF 1301560-010</p> <p>C. The apparatus is powered by your line voltage (100/115/230 Vac). Connect the power cable to the plug (14).</p> <p>D. The device can be safely turned off using the main switch (16).</p>
<p>fig. 2</p>	<p>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.</p> <p> Do not raise the pedal using the connection cable.</p>
<p>fig. 3</p>	<p>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.</p>

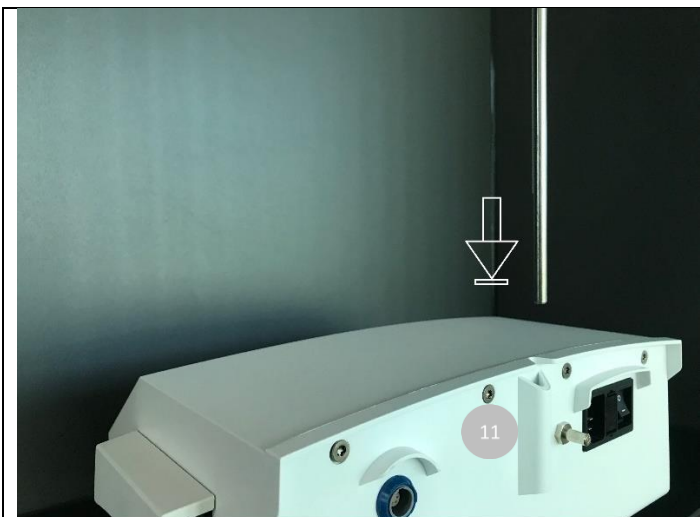


fig. 4

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.

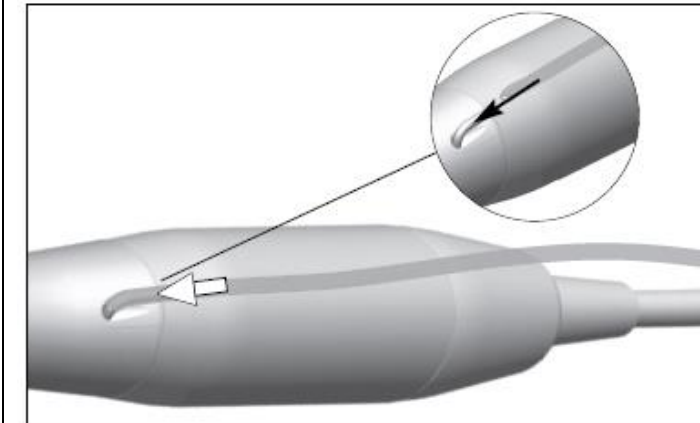


fig. 7

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**.

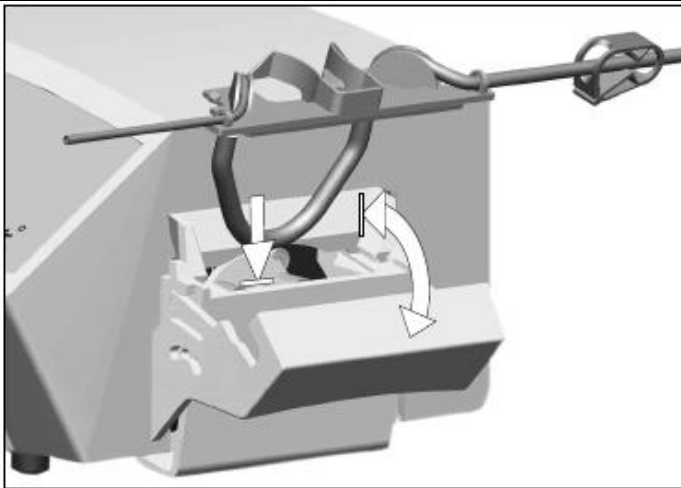


fig. 8

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 lid again and check the correct positioning of the cassette.



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

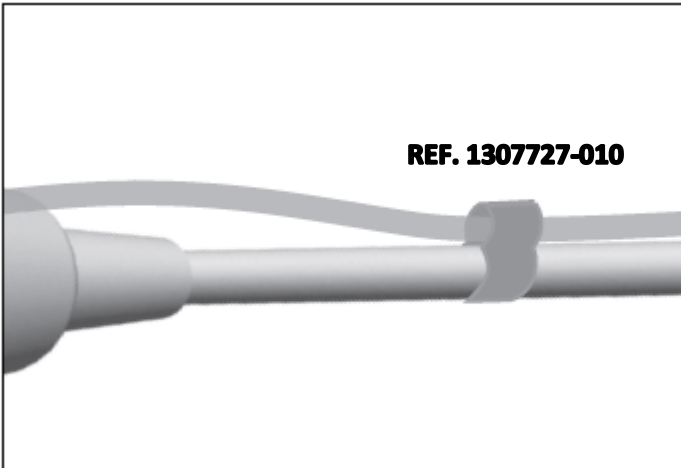


fig. 9

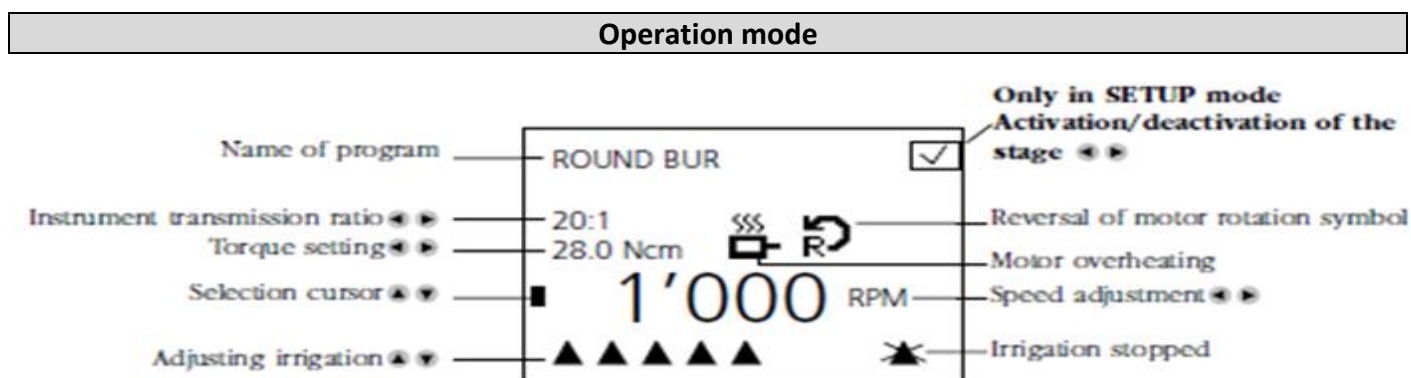
- L. Perforate the cap of the physiological liquid flask with the pointed end of the irrigation line after removing the protective cap.
M. Attach the irrigation line on the motor cable using the attachment collars REF 1307727-010 **fig. 9**.



Fig. 10

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

7. Interface overview



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 Surgery	Round bur 1	256:1	100 – 40'000 rpm with a CA 1:1 Depends on the CA	0.58 – 5.8 Ncm with a CA 1:1 Depends on the CA	30 ml/min 20%
	Round bur 2	128:1			60 ml/min 40%
	Drill 1	64:1			90 ml/min 60%
	Drill 2	30:1			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 Surgery	Procedure 1	256:1	100 – 40'000 rpm with a CA 1:1 Depends on the CA	0.58 – 5.8 Ncm with a CA 1:1 Depends on the CA	30 ml/min 20%
	Procedure 2	128:1			60 ml/min 40%
	Procedure 3	64:1			90 ml/min 60%
	Procedure 4	30:1			120 ml/min 80%
		27:1			150 ml/min 100%
		20:1			
		16:1			
		10:1			
		1:1			
		1:2			
		1:5			



Available values

8. 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.
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.
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.

9. Default Values

Implantology:

Default values page 25

The table shows the default operating values for 8 different implantology sequences.

Surgery:

Default values page 25

The table shows the default operating values for 4 different surgical sequences.

10. Maintenance and Servicing

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.

10.1 Servicing

CAUTION

Never disassemble the device. For any modification and repair, we recommend that you 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.

10.2 Cleaning

CAUTION

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

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.)

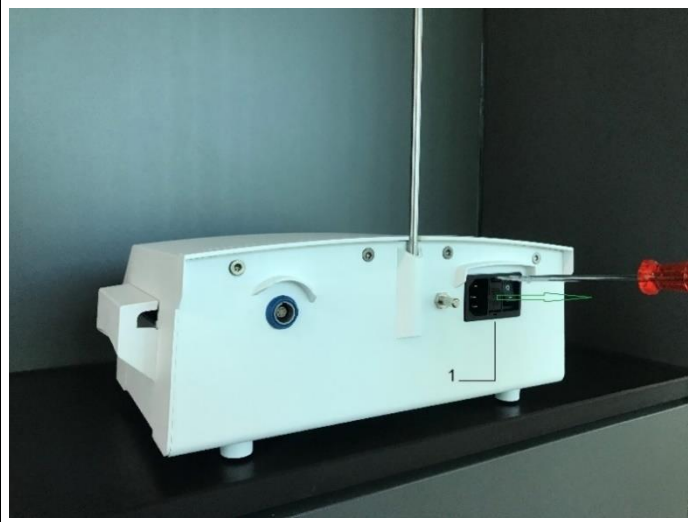


FIG. 1

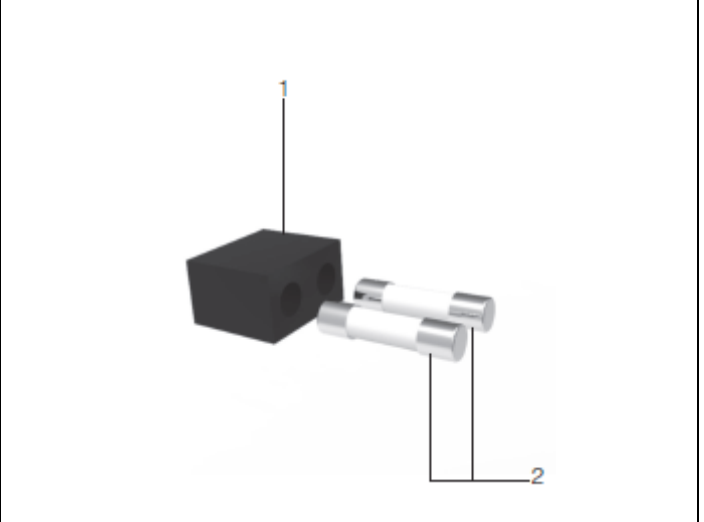


FIG. 2

10.3 Replacement of fuses

- A. Switch off the CHIROPRO L PREMIUM unit.
- 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.





10.4 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	

11. Transport & Disposal

11.1 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	

11.2 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).

12. General information

12.1 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 CHIROPRO L PREMIUM unit and Foot Control;
- 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.

12.2 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.
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.

DEFAULT VALUES

Operative parameters default values for implantology.

 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.

The table shows the default operating values for the 8 implantology systems pre-programmed in the system:

Implant PRG1 / PRG8	Implant PRG2	Implant PRG3	Implant PRG4	Implant PRG5	Implant PRG6	Implant PRG7
ROUND BUR 1 <input checked="" type="checkbox"/>	ROUND BUR <input checked="" type="checkbox"/>	ROUND BUR <input checked="" type="checkbox"/>	ROUND BUR <input checked="" type="checkbox"/>	ROUND BUR <input checked="" type="checkbox"/>	ROUND BUR <input checked="" type="checkbox"/>	PILOT DRILL 1 <input checked="" type="checkbox"/>
20:1	20:1	20:1	20:1	20:1	20:1	20:1
28.7 Ncm	28.7 Ncm	28.7 Ncm	28.7 Ncm	28.7 Ncm	35.7 Ncm	28.7 Ncm
1'000 RPM	2'000 RPM	1'000 RPM	1'200 RPM	1'500 RPM	1'500 RPM	800 RPM
▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲
ROUND BUR 2 <input checked="" type="checkbox"/>	PILOT DRILL <input checked="" type="checkbox"/>	DRILL 1 <input checked="" type="checkbox"/>	DRILL 1 <input checked="" type="checkbox"/>	DRILL 1 <input checked="" type="checkbox"/>	DRILL 1 <input checked="" type="checkbox"/>	PILOT DRILL 2 <input checked="" type="checkbox"/>
20:1	20:1	20:1	20:1	20:1	20:1	20:1
28.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	28.7 Ncm
1'000 RPM	800 RPM	800 RPM	800 RPM	500 RPM	1'500 RPM	800 RPM
▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲
DRILL 1 <input checked="" type="checkbox"/>	DRILL 1 <input checked="" type="checkbox"/>	DRILL 2 <input checked="" type="checkbox"/>	DRILL 2 <input checked="" type="checkbox"/>	DRILL 2 <input checked="" type="checkbox"/>	DRILL 2 <input checked="" type="checkbox"/>	DRILL 1 <input checked="" type="checkbox"/>
20:1	20:1	20:1	20:1	20:1	20:1	20:1
35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm
800 RPM	800 RPM	800 RPM	800 RPM	500 RPM	1'500 RPM	600 RPM
▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲
DRILL 2 <input checked="" type="checkbox"/>	DRILL 2 <input checked="" type="checkbox"/>	DRILL 3 <input checked="" type="checkbox"/>	DRILL 3 <input checked="" type="checkbox"/>	DRILL 3 <input checked="" type="checkbox"/>	DRILL 3 <input checked="" type="checkbox"/>	DRILL 2 <input checked="" type="checkbox"/>
20:1	20:1	20:1	20:1	20:1	20:1	20:1
35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm
600 RPM	800 RPM	800 RPM	800 RPM	500 RPM	1'500 RPM	500 RPM
▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲
DRILL 3 <input checked="" type="checkbox"/>	DRILL 3 <input checked="" type="checkbox"/>	DRILL 4 <input checked="" type="checkbox"/>	DRILL 4 <input checked="" type="checkbox"/>	DRILL 4 <input checked="" type="checkbox"/>	DRILL 4 <input checked="" type="checkbox"/>	DRILL 3 <input checked="" type="checkbox"/>
20:1	20:1	20:1	20:1	20:1	20:1	20:1
35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm
500 RPM	800 RPM	800 RPM	800 RPM	500 RPM	1'500 RPM	400 RPM
▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲
DRILL 4 <input checked="" type="checkbox"/>	DRILL 4 <input checked="" type="checkbox"/>	DRILL 5 <input checked="" type="checkbox"/>	DRILL 5 <input checked="" type="checkbox"/>	DRILL 5 <input checked="" type="checkbox"/>	DRILL 5 <input checked="" type="checkbox"/>	SHAPING DRILL <input checked="" type="checkbox"/>
20:1	20:1	20:1	20:1	20:1	20:1	20:1
35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm
400 RPM	800 RPM	800 RPM	800 RPM	500 RPM	1'500 RPM	250 RPM
▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲	▲▲▲▲
TAPPING <input checked="" type="checkbox"/>	TAPPING <input checked="" type="checkbox"/>	TAPPING <input checked="" type="checkbox"/>	TAPPING <input checked="" type="checkbox"/>	TAPPING <input checked="" type="checkbox"/>	TAPPING <input checked="" type="checkbox"/>	TAPPING <input checked="" type="checkbox"/>
20:1	20:1	20:1	20:1	20:1	20:1	20:1
35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm
15 RPM	15 RPM	15 RPM	15 RPM	15 RPM	20 RPM	20 RPM
△△△△	△△△△	△△△△	△△△△	△△△△	△△△△	△△△△
TAP UNSCREWING <input checked="" type="checkbox"/>	TAP UNSCREWING <input checked="" type="checkbox"/>	TAP UNSCREWING <input checked="" type="checkbox"/>	TAP UNSCREWING <input checked="" type="checkbox"/>	TAP UNSCREWING <input checked="" type="checkbox"/>	TAP UNSCREWING <input checked="" type="checkbox"/>	TAP UNSCREWING <input checked="" type="checkbox"/>
20:1	20:1	20:1	20:1	20:1	20:1	20:1
42.6 Ncm	42.6 Ncm	42.6 Ncm	42.6 Ncm	42.6 Ncm	42.6 Ncm	42.6 Ncm
15 RPM REV	15 RPM REV	15 RPM REV	15 RPM REV	15 RPM REV	15 RPM REV	20 RPM REV
△△△△	△△△△	△△△△	△△△△	△△△△	△△△△	△△△△
IMPLANT SCREWING <input checked="" type="checkbox"/>	IMPLANT SCREWING <input checked="" type="checkbox"/>	IMPLANT SCREWING <input checked="" type="checkbox"/>	IMPLANT SCREWING <input checked="" type="checkbox"/>	IMPLANT SCREWING <input checked="" type="checkbox"/>	IMPLANT SCREWING <input checked="" type="checkbox"/>	IMPLANT SCREWING <input checked="" type="checkbox"/>
20:1	20:1	20:1	20:1	20:1	20:1	20:1
35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm	35.7 Ncm
15 RPM	15 RPM	15 RPM	15 RPM	15 RPM	15 RPM	15 RPM
△△△△	△△△△	△△△△	△△△△	△△△△	△△△△	△△△△
UNSCREWING <input checked="" type="checkbox"/>	UNSCREWING <input checked="" type="checkbox"/>	UNSCREWING <input checked="" type="checkbox"/>	UNSCREWING <input checked="" type="checkbox"/>	UNSCREWING <input checked="" type="checkbox"/>	UNSCREWING <input checked="" type="checkbox"/>	UNSCREWING <input checked="" type="checkbox"/>
20:1	20:1	20:1	20:1	20:1	20:1	20:1
54.8 Ncm	54.8 Ncm	54.8 Ncm	54.8 Ncm	54.8 Ncm	54.8 Ncm	54.8 Ncm
15 RPM REV	15 RPM REV	15 RPM REV	15 RPM REV	15 RPM REV	15 RPM REV	15 RPM REV
△△△△	△△△△	△△△△	△△△△	△△△△	△△△△	△△△△

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 <input checked="" type="checkbox"/>	PROCEDURE 2 <input checked="" type="checkbox"/>	PROCEDURE 3 <input checked="" type="checkbox"/>	PROCEDURE 4 <input checked="" type="checkbox"/>
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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