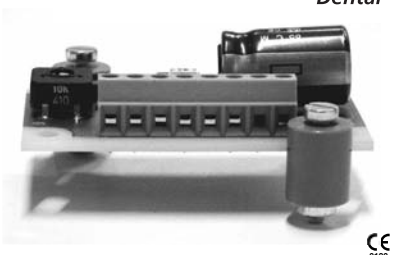
PL Light Plus



Instruction

REF 2100226-ENG/08.11

CE 0120

English

Medical devices entirely made in Switzerland by Bien-Air Dental SA.

Type
These electronics allow all the bulbs to be supplied with a maximum power of 3.5 W and with a voltage of between 2.5 and 4 Vdc. Factory setting: 3.8 Vdc (or 3.5 Vdc at the bulb, due to loss on line).

Intended use

Product intended for professional use only. Use in dentistry for prophylaxis, general dentistry and endodontic work.
Any use other than that for which this device is intended is prohibited and may prove dangerous.

Technical data and assembly

Dimensions
54 x 34 x 19.5 mm.

Weight
20 g.

Output current: bulb
0.8 A max.
• The light output is protected against short circuits.

Output voltage: bulb
3.8 Vdc (default value) adapted to the length of a standard 1.7-m tube.

Voltage
12 to 28 Vac / 50 or 60 Hz or 17 to 40 Vdc

Setting with trimmer fig. 1 and fig. 2
From 2.5 Vdc to 4 Vdc, adjustable by the trimmer.

Setting with potentiometer fig. 3
From 2.5 Vdc to the value regulated by the trimmer.

Assembly fig. 4 and fig. 5
① Positive feed.
② Negative feed.
③ Blue wire (mass pole)
④ Brown wire (positiv pole)

Note!
In order to conform to the CEI 60601-1-2 standards, take into account the different routes of the wires through the unit (bend, fold, section etc...) and use a transformer with double insulation and separate coils. This device must be installed with the greatest care, with all the necessary insulation and by a person with the necessary, adequate knowledge of electricity.

Electromagnetic compatibility
Corresponds to the electromagnetic compatibility in accordance with CEI 60601-1-2. Declaration by the manufacturer regarding electromagnetic compatibility: refer to the tables on pages 2-3.

Information
The technical specifications, illustrations and dimensions contained in these instructions are given only as a guide. They may not be the subject of any claim. The manufacturer reserves the right to make technical improvements to its equipment, without amending these instructions. For all additional information, please contact Bien-Air Dental SA at the address indicated on the back cover.

Disposal

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 2002/96/EC).

Maintenance

Only use maintenance products and components from Bien-Air Dental. The use of other products and components can void the guarantee.

Servicing
Never disassemble the device. For any modification and repair, we recommend that you contact your regular supplier or Bien-Air Dental directly.
Bien-Air Dental asks the user to have its dynamic instruments checked or inspected at least once a year.

Environment
Working
- Temperature: +10°C (50°F) to +40°C (104°F)
- Relative humidity: 30% to 80%, including condensation
- Atmospheric pressure: 700 hPa to 1060 hPa

Transport and storage
Environmental conditions for a period of max. 15 weeks
- Temperature: -25°C (-13°F) to +70°C (158°F)
- Relative humidity: 10% to 100%, including condensation
- Atmospheric pressure: 500 hPa to 1060 hPa

Other precautions for use

The device must be used by a qualified person in accordance with the current legal provisions concerning industrial safety, health and accident prevention measures, and these working instructions. In accordance with these requirements, the operators:
- must only use operating devices that are in perfect working order; in the event of irregular functioning, excessive vibration, abnormal heating or other signs indicating malfunction of the device, the work must be stopped immediately; in this case, contact a repair centre that is approved by Bien-Air Dental;
- must ensure that the device is used only for the purpose for which it is intended, must protect themselves, their patients and third parties from any danger, and must avoid contamination through the use of the product.

The device is intended for medical treatment only; any use other than that for which this product is intended is unauthorised and may be dangerous. The medical device meets all the current legal requirements.

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

Avoid any contact with liquids.

Guarantee

Terms of guarantee
Bien-Air Dental grants the user a guarantee covering all functional defects, material or production faults. The device is covered by this guarantee for 12 months from the date of invoicing.

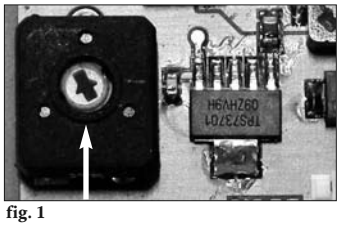


fig. 1

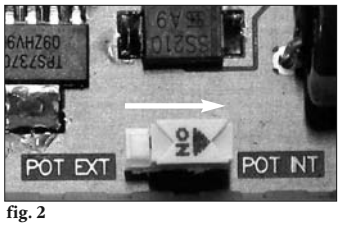


fig. 2

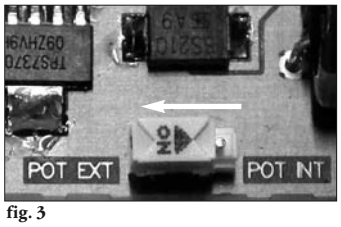


fig. 3

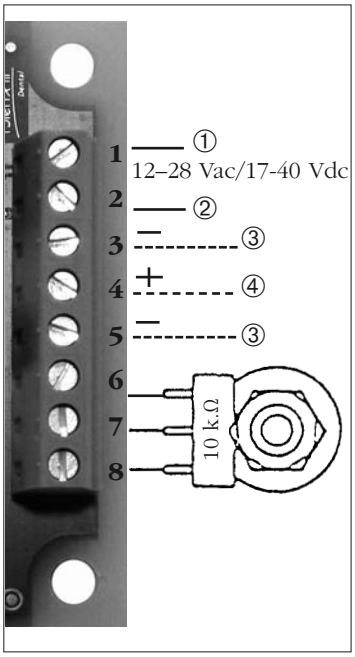


fig. 4

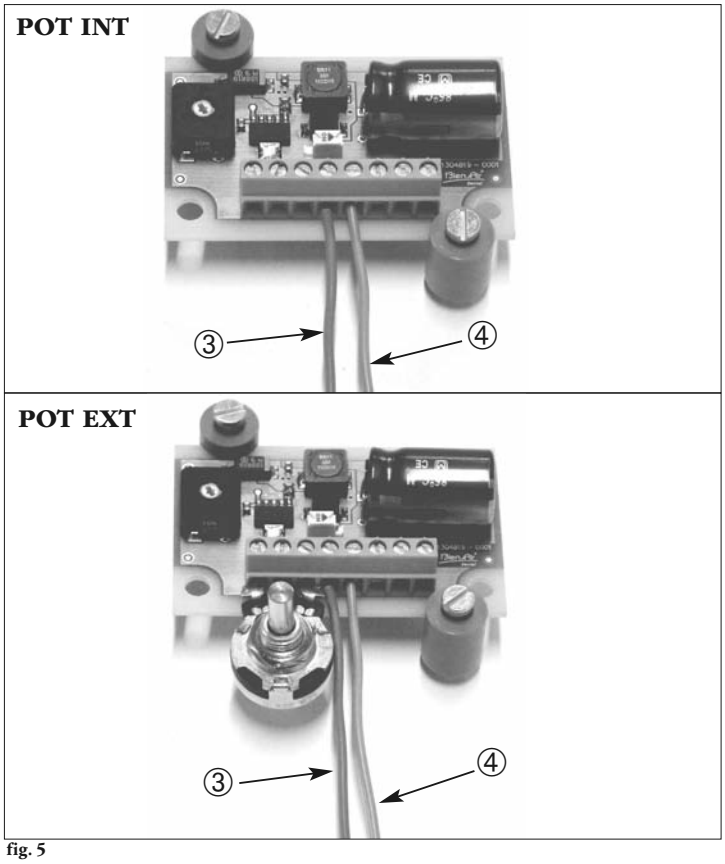


fig. 5

Bien-Air Dental offers a 24-month guarantee for the glass-bar light conductors.

In the event of justified claim, Bien-Air Dental or its authorised representative will fulfil the company's obligations under this guarantee by repairing or replacing the product free of charge. Any other claims, of whatever nature, in particular in the form of a claim for damages and interest, are excluded.

Bien-Air Dental shall not be held responsible for damage or injury and the consequences thereof, resulting from:
- excessive wear and tear
- improper use
- non-observance of the instructions for installation, operation and maintenance
- unusual chemical, electrical or electrolytic influences
- poor connections, whether of the air, water or electricity supply.

The guarantee does not cover flexible "fibre optic" type conductors, or any parts made of synthetic materials.

The guarantee shall become null and void if the damage and its consequences are due to improper manipulation of the product, or modifications to the product carried out by persons not authorised by Bien-Air Dental.

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.

Precautions regarding Electromagnetic Compatibility (EMC)
Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the user's manual and in the present document.

The PL Light Plus complies with the EMC requirements according to CEI 60601-1-2. Radio transmitting equipment, cellular phones, etc. shall not be used in close proximity to the device since this could influence the performance of the device. Particular precaution must be considered during use of strong emission sources such as High Frequency surgical equipment and similar so that e.g. the HF cables are not routed on or near the device. If in doubt, please contact a qualified technician or Bien-Air Dental.

The PL Light Plus should not be used adjacent or stacked with other equipment. If adjacent to or stacked use is necessary, the PL Light Plus should be observed to verify normal operation in the configuration in which it will be used.

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

Guidance and manufacturer's declaration – electromagnetic emissions
The PL Light Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the PL Light Plus should assure that it is used in such an environment.

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

Guidance and manufacturer's declaration – electromagnetic immunity
The PL Light Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the PL Light Plus should assure that it is used in such an environment.

Immunity test	Test level CEI 60601	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) CEI 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact N.A.	The floors should be wood, concrete or ceramic tiles. If floors are covered in synthetic material, the relative humidity should be at least 30%.
Fast transient burst CEI 61000-4-4	±2 kV for electrical supply lines ±1 kV for input/output lines	±2 kV for electrical supply lines N.A.	The quality of the electrical supply network should be equivalent to that of a typical commercial or hospital environment.
Voltage spike CEI 61000-4-5	±1 kV between phases ±2 kV between phases and earth	N.A. N.A.	The quality of the electrical supply network should be equivalent to that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on input power ports CEI 61000-4-11	<5 % U_T (>95 % dip in U_T) during 0,5 cycle 40 % U_T (60 % dip in U_T) during 5 cycles 70 % U_T (30 % dip in U_T) during 25 cycles <5 % U_T (>95 % dip in U_T) during 5 s	N.A. N.A. N.A. N.A.	The quality of the electrical supply network should be equivalent to that of a typical commercial or hospital environment. If the user of the PL Light Plus requires continuous operation during the interruptions to the electrical supply network, it is recommended that the PL Light Plus is powered by an uninterruptible power supply or a battery.
Power network frequency (50/60 Hz) magnetic field test EN 61000-4-8	3 A/m	3 A/m	The levels of the magnetic fields at the power network frequency should be equivalent to those of a representative location in a typical commercial or hospital environment.

NOTE U_T is the voltage of the alternating network before the application of a test level.
Essential performance: The essential performance is the maintaining of the visual lighting intensity of the LED.

Guidance and manufacturer's declaration – electromagnetic immunity
The PL Light Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the PL Light Plus should assure that it is used in such an environment.

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

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and lan 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 PL Light Plus is used exceeds the applicable RF compliance level above, the PL Light Plus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PL Light Plus.

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

Recommended separation distances between portable and mobile RF communications equipment and the PL Light Plus

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

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

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

NOTE 1
At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

REF	Legend
1600774-001	PL Light Plus without housing, for lighting power, controlled electrically
249.28.05	Holder
1304658-001	Potentiometer

List of Bien-Air Dental SA registered trade mark products ®:

Aquilon®
Bora®
Boralina®
ChiroPro®
Eolia®
Gyro®
Gyrolina®
Isolite®
Lubrifluid®
Lubrimed®
MX®
PowerCare®
Prestilina®
Spraynet®

In these instructions, "Device" corresponds to the product described in the heading "Type". For example, turbine, contra-angle, handpiece, micromotor, tube, electronics, connectors, station etc.

Symbols

Manufacturer.

CE Marking with number of the notified body.

Recyclable electrical and electronic materials.

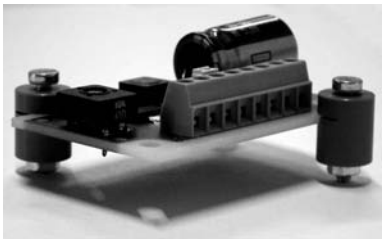
Move in the direction indicated.

Move fully to the stop, in the direction indicated.

This product may be covered by one or more of the following patents:
EP Europe: 745358 / 688539 / 948294 / 1145688 / 1563800 / 1563801 / 1675523 / 1753360
DE Germany: 29616023.7
DK Denmark: 9600315
FR France: 2722972
CH Switzerland: 693922
CN China: 100528099 / 100522100 / 100522099 / 100553584
JP Japan: 3892485 / 4298933 / 7000419
US United States: 5453008 / 6033220 / 6319003 / 7214060 / 7448870
RU Russia: 2361540 / 2361541 / 2372046

REF 1600774-001 BOARD PL Light Plus

Set supplied



REF 1600774-001

Optional accessories

REF 1304658-001

REF 249.28.05

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