English

OWNER´S MANUAL

Curing Light Optilight Max

DABI ATLANTE

Cód.: 77000001081 - Rev.:03

PRESENTATION OF MANUAL

INSTRUCTIONS FOR USE

Technical Name: Equipment for dental bleaching and photopolymerization of resins
Trade Name: Curing Light Optilight
Model: Max
Brand: Dabi Atlante

Manufacturer/Distribuitor:
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ATTENTION

For greater safety:
Read and understand all the instructions contained in these instructions for use before installing or operating this equipment.
Note: These instructions for use must be read by all the operators of this equipment.

INDEX

IDENTIFICATION OF EQUIPMENT

Dear Customer

This manual is a general presentation of your product and it will give you important details to help you to solve possible problems.
Please, read it and keep this with you.

IDENTIFICATION

Technical Name: Equipment for dental bleaching and photopolymerization of resins
Trade Name: Curing Light Optilight
Model: Max

IDENTIFICATION OF EQUIPMENT

Indication of the equipment

This equipment is exclusively for dental use, having to be employed and handled by a capacitated person (professional duly regulated, as per the local legislation of the country) observing the instructions contained in this manual.
The user is obliged to only use the equipment in perfect conditions and protect himself/herself, patients and third parties against possible hazards.

Physical Principle used by the Equipment

The physical principle is the emission of a cold light to polymerize photosensitive substances, as the equipment is endowed with a cold light emitter (LED) with a wavelength between 420 and 500nm (blue light), which has an ideal intensity for being integrated with the canforoquinone.

Purpose of the equipment

This equipment is exclusively for dental use, with the objective of polymerizing photosensitive substances through the emission of blue light.
It was developed to be used in several dental procedures such as: restoring procedures, bonding braces and activating photoactivated materials as sealers, lining bases.

Description of Equipment

The Optilight Max is the latest generation of the appliances of photoactivation by LED light. This short name is the acronym for Light Emitting Diode, a totally different manner of emitting light, when compared with the conventional appliances of halogen light. As opposed to the traditional appliances, which generate light in a wide wave spectrum with great heat, this technology allows a cold light to be emitted, in the precise wavelength for activating the different dental products to which it applies.
LED technology, recently introduced in Dentistry, has brought countless advantages to the curing light appliances for direct restorations in composite resin. Besides being infinitely more durable, the LEDs have made the appliances more compact, ergonomic and easy to install and transport. The emission of cold light at a precise wavelength ensures the polymerization of composites activated by the canforoquinone, without risks of dental heating, pulpal injury or discomfort for operator and patients.
The safety and efficiency of the LEDs, now with high emission power, are available for all the clinical procedures which require power of light for photoactivation.
The wavelength of 420nm - 500nm associated with the high power emitted by the Optilight Max makes the multifunctionality of this appliance feasible:
• Direct restoring procedures: composite resins, ionomers and adhesives.
• Indirect restorations: adhesive cementing of laminates, inlays, esthetic pegs and metal-free crowns.
• Activation of photoactivated materials as sealers, surgical cements and lining bases.
Planned and built using cutting-edge technology, to provide results within the specifications stipulated by the leading world dental authorities.
Endowed with an automatic bivolt switch power supply which allows one to use the equipment at any power supply voltage between 100 and 240V~ - 50/60Hz.
Digital control in the display on the handpiece itself.
Variance of choice of operating time (5,10,15 and 20 seconds).
It has 3 application modes: Continuous, Ramp and Pulsating:
• Continuous: Maximum and continuous mode of light intensity (same luminosity from start to finish of the polymerization).
• Ramp: Gradual mode of light intensity; it increases gradually.
• Pulsed: Pulsing mode consisting of cycles which oscillate at a fixed frequency.

IDENTIFICATION OF EQUIPMENT

Advantages offered by Optilight Max:
- More spectrally-selective light than conventional lamps.*
- Cold light, it doesn't heat up the resin nor the tooth.**
• Light compact equipment that provides handling comfort.
• Low power consumption.
• Longer useful life of the light emitting diode (equivalent to 36.000.000 cycles of 10 seconds).
• It does not use optical filter.
• It does not require forced ventilation, thus avoiding noise emission.

* We noted that the light emitted by the Optilight Max is completely contained within the absorption interval of the photo starter, therefore it's 100% used, whereas the conventional equipment running on halogen lamps has non-used wave-length regions.

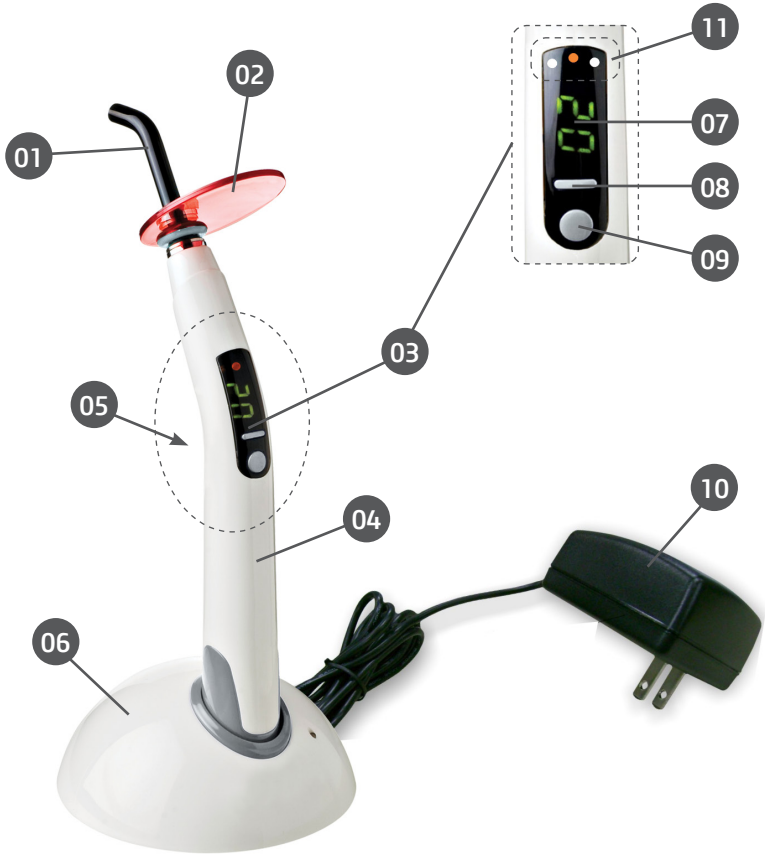
** The Optilight Max doesn't generate heat since it uses light emitting diodes.

The light conductor is removable, made out of high resistance polymer and of easy maintenance.

Light conductor with fiber optics, rotating, removable and easy to sterilize, with a front protector of the tip against scratches and the accumulation of undesirable residue. The reduced weight of the penand its anatomic design ensure that the professional's work is more comfortable and practical.

Support for the handpiece, which ensures easy access and handling.

MODULES, ACCESSORIES, OPTIONS AND MATERIALS OF CONSUMPTION



01 – Light Conductor
02 – Light Protection Shield
03 – Control Panel
04 - Handpiece
05 – Button to turn on the equipment and activate / interrupt operation
06 – Charging base
07 – Display Window
08 – Time adjustment button
09 – Application mode selection button
10 – Power supply source
11 – Application mode: Continuous, Ramp and Pulsed

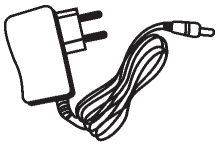
MODULES, ACCESSORIES, OPTIONS AND MATERIALS OF CONSUMPTION

Accessories which come with the product:

Charging base

Light Protection Shield

Light Conductor



Power supply source

The content of this page is for informative purpose, so the equipment can present itself different from the illustration. Therefore, when buying the product, verify the technical compatibility between the equipment, coupling and accessories.

The use of any part, accessory or material neither specified nor foreseen in those use operation instructions and it is of the user's entire responsibility.

TECHNICAL SPECIFICATIONS

General features

Power Supply
Ve: 100 - 240V~ - 50/60Hz Vs: 5V - 1,5 A
Frequency
50/60Hz
Source Power
6VA
Light Source
1 LED
Light Power
Light power: 1200 mW/cm^2 ± 200 mW/cm^2 Semi-conductor LED (InGaN)
Wavelength
420nm - 500nm
Timer
5,10,15 and 20 seconds
Time Sounder
a “beep” every 05 seconds
Activation
Through the handpiece button
Light Conductor
Optics fiber 100% coherent which guarantees the passage of light without loss
Handpiece body
Injected in ABS
Net weight
0,39 kg
Gross weight
0,98 kg
Classification of the Product
As per standard NBR IEC 60601-1
Type of protection against electric shocks
Class II Equipment

TECHNICAL SPECIFICATIONS

Applied part
Type B
Degree of protection against harmful penetration of water
IP00
Degree of saf ety of application in the presence of an anesthetic mixture inf lammable with air, oxygen or nitrous oxide
It is not suitable
Battery of Li-ion
DC 3.7V 2200mAh.
Approximate time for recharging battery
3h

TECHNICAL SPECIFICATIONS

Electromagnetic emission

1) * This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
2) * Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3) * Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation.
4) * Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Electromagnetic emission

The device is intended for use in the electromagnetic environment specified below. The customer of the user of the device should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The device use 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 emission CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

TECHNICAL SPECIFICATIONS

Guidance and manufacture's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is 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, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floor 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 input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	±1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage ips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5 cycle at 0°,45°,90°, 135°, 180°, 225°, 270°, 315° 0% UT ; 1 cycle 70% UT; 25/30 cycle 0% UT; 250/300 cycle	0% UT; 0.5 cycle at 0°,45°,90°, 135°, 180°, 225°, 270°, 315° 0% UT ; 1 cycle 70% UT; 25/30 cycle 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m 50/60Hz	30 A/m 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE Ut is the a.c. mains voltage prior to application of the test level

TECHNICAL SPECIFICATIONS

Guidance and manufacture's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 3 V RMS outside the ISM band, 6 V RMS in the ISM bands	3 Vrms 150 kHz to 80 MHz 3 V RMS outside the ISM band, 6 V RMS in the ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=0.35\sqrt{p}$ $d=1.2\sqrt{p}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	80MHz to 800MHz $d=1.2\sqrt{p}$ 800MHzto 2.7GHz $d=2.3\sqrt{p}$ 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. 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: 

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 land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.
b - Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

TECHNICAL SPECIFICATIONS

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

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz d= 1,2√p	80 MHz to 800 MHz d= 1,2√p	800 MHz to 2.7 GHz d= 2,3√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.

TECHNICAL SPECIFICATIONS

Guidance and manufacturer's declaration - electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device, should assure that it is used in such an environment.

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	Immunity teste level (V/m)
385	380 - 390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800/900 TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 - 5 800	WLAN 802. 11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE if necessary to achieve the immunity test level, the distance between the transmitting antenna and the me equipment or me system may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

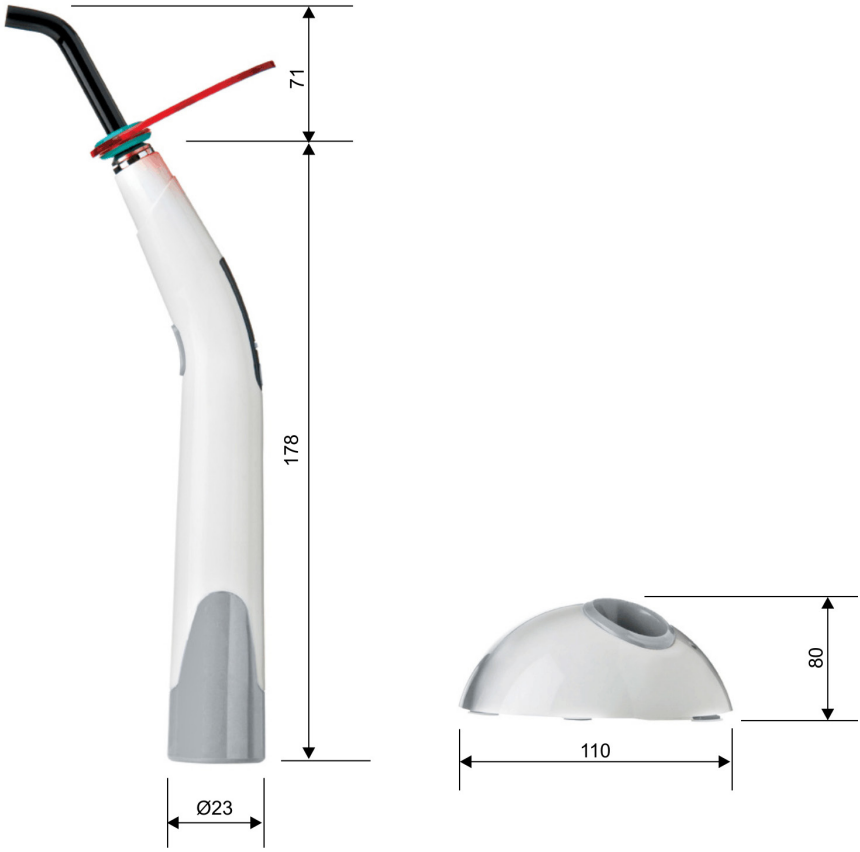
The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation:

$$E = \frac{6}{d}\sqrt{P}$$

Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.

TECHNICAL SPECIFICATIONS

Dimensions (mm)



TECHNICAL SPECIFICATIONS

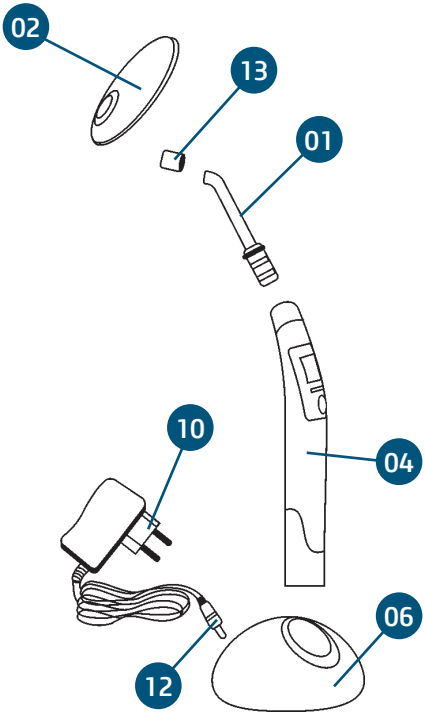
Packing symbols

	Stacking Limit by number		Keep dry
	This side Up		Keep away from sunlight
	Fragile, handle with care		Temperature limitation

Product symbols

	Type B		General warning
	Attention		Recyclable
	Refer to the instruction manual		Grounding (at several points of the equipment) indicates the condition of being grounded
SN	Serial number	#	Model Number
	Manufacturing date		Manufacturer
MODEL	Model		

INSTALLATION OF THE EQUIPMENT



• For your safety the Optilight Max has an automatic bivolt power supply source of 100V~ - 240V~ - 50/60Hz.

• Connect the cable of the power supply source (12) to the charging base (06) and the power supply source (10) in the socket.

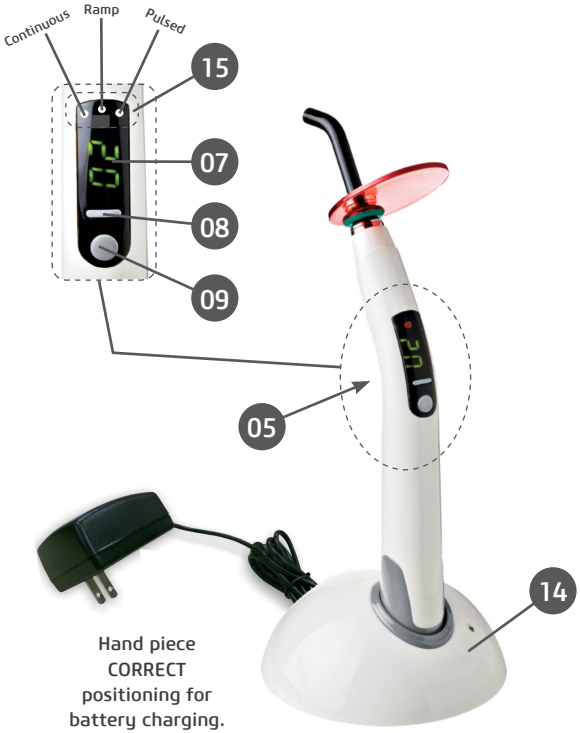
• Insert the light conductor (01) in the handpiece (04).

• Remove the protection cover (13) from the light conductor.

• Insert the light protection shield (02) in the light conductor and place the assembled equipment in the charging base.

⚠ Charge the battery during 08 hours before using the equipment for the first time.

OPERATION OF EQUIPMENT



Hand piece
CORRECT
positioning for
battery charging.

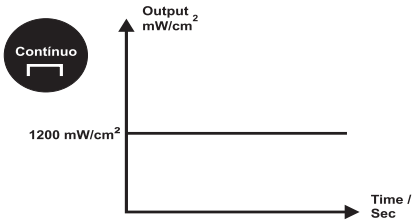
Hand piece
INCORRECT
positioning for
battery charging.

• Press the button (05) to turn on the equipment.
• Select the application mode pressing the selection button (09), of which the variations are:
- Continuous: Maximum and continuous mode of light intensity (same luminosity from start to finish of the polymerization).
- Ramp: Gradual mode of light intensity; it increases gradually.
- Pulsed: Pulsing mode consisting of cycles which oscillate at a fixed frequency.
The application mode chosen will be viewed in the sequence of LEDs (15).
• In order to schedule the time press the button (08) and choose the time 5 thru 20 seconds, which will be viewed in the display (07).
• After selecting the mode of application and the choice of time, take the handpiece to the patient's mouth and position the light guide at a safe distance.
• In order to start the polymerization cycle, press the start button (05). To interrupt it Just activate it again.

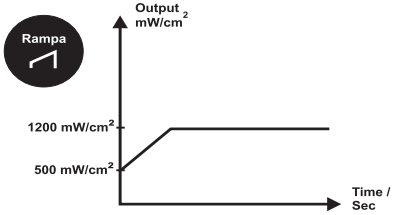
OPERATION OF EQUIPMENT

ATTENTION:
- Recharge the battery when one of the LED continuous, ramp and pulsed are blinking;
- Keep the handpiece in the charging base (connected to the mains power) when not using;
- When the LED of the charging base (14) is indicating red, the battery is being charged;
- The approximate recharging time is 3 hours. After recharging the LED in the charging base (14) it will change to green, indicating the complete recharging;
- The battery does not have a memory effect and can be recharged even if it is not completely discharged.

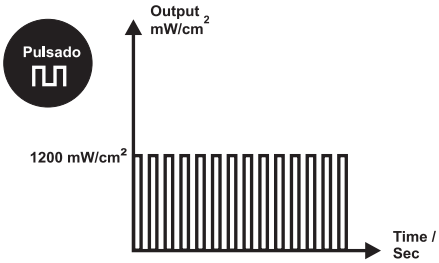
Application types: Continuous, Ramp and Pulsed



- **Continuous:**
  Maximum and continuous mode of light intensity (same luminosity from start to finish of the polymerization).
- **Maximum power** = 1200 mW/cm²*



- **Ramp:**
  Gradual mode of light intensity, it increases gradually.
- **Gradual increase =** 500 - 1200 mW/cm²*



- **Pulsed:**
  Pulsing mode consisting of cycles which oscillate at a fixed frequency.
- **On/off every 1sec. maximum power** = 1200 mW/cm²*

* Tolerance is ± 200 mW/cm²

OPERATION OF EQUIPMENT

Automatic disconnection:
The equipment will be turned off automatically to save energy. Thus, if the appliance is not on the charging base and the user doesnot use it within 3 minutes, the appliance turns off automatically. In order to turn it on again, press the on/off button.

WARNING:
- Never point the blue beam of light at anybody's eyes;
- Protect the visual field using the Light Protection Shield;
- The Light Protection Shield aims to filter only the blue light which acts in the photopolymerization of resins to protect one's vision and also allows the ambient illumination to go to the operating field.
- After use always maintain the light conductor protected by the protection cover.

PRECAUTIONS, RESTRICTIONS AND WARNINGS

Recommendations for the equipment's conservation

Your equipment has been designed and improved following modern technology standards. All devices need special care, which a lot of times are forgotten for several reasons and circumstances, because of that, here are some important reminders for your everyday.
Seek to observe these little rules that incorporated to the job's routine, will provide a big time economy and will avoid unnecessary expenses.

Transport conditions, warehousing and operation

This equipment must be transported and stored observing the following directions:
- Avoid falls and impacts;
- Keep it dry, do not expose it to rain, water drops or wet floor;
- Keep it away from water and direct sunlight, and in it original wrapping;
- Don't move it over irregular surfaces, protect it from rain and observe the maximum stack quantity specified in the packaging;

Environmental condition for transportation or storage:
- Room temperature range for transportation or storage -10ºC to +55ºC.
- Relative humidity range for transportation or storage ≤93%.
- Atmospheric pressure range 50 - 106KPa.

Environmental operation condition:
- Room temperature range for functioning +10ºC to +40ºC.
- Relative humidity range for functioning 10% to 80%.
- Atmospheric pressure range 70 - 106KPa.

Attention

The Equipment maintains its condition of safety and efficacy, provided that it is maintained (stored) as mentioned in this instruction of use. Thus, the equipment will not lose or alter its physical and dimensional features.

PRECAUTIONS, RESTRICTIONS AND WARNINGS

Sensitivity to predictable environmental conditions in ordinary situations of use

- The equipment has been designed not to be sensible to interferences as magnetic fields, external electrical influences, electrostatic discharges, the pressure or the variation of pressure, since the equipment is installed and kept clean, conserved, transported and operated conforming this operation instruction.

Precautions and warnings “during the installation” of the equipment

- Check the voltage of the equipment upon executing the electrical installation.
- Position the equipment in a place where it will not get wet.
- Install the equipment in a place where it will not be damaged by the pressure, temperature, humidity, direct sunlight, dust, salts, or sulfur compounds.
- The equipment must not undergo inclination, excessive vibrations, or blows (including during transportation and handling).
- This equipment was not planned for use in an environment where vapors, anesthetic mixtures inflammable with air, or oxygen and nitrous oxide can be detected.
- Before the first use and/or after long interruptions from work such as vacations, clean and disinfect the equipment.
- This equipment is not sensitive to electrical, electrostatic and pressure interference, provided that the items of cleaning, maintenance, transportation and operation of this Manual are observed. However, an electromagnetic environment can interfere with its normal operation.

Precautions and warnings “during the use” of equipment

- The equipment should only be operated by duly enabled and trained technicians (Dental Surgeons, Capacitated Professionals).
- If any maintenance should be required, only use services of the Alliage Authorized Technical Assistance.
- Do not expose the plastic parts to contact with chemical substances, use in the routines of dental treatment, such as: acids, mercury, acrylic liquids, amalgams, etc.
- Avoid the light conductor to terminal to touch the resin to be polymerized.
- When using the equipment check if the light conductor output doesn’t have residues that might obstruct the light beam.
- Use suitable techniques to minimize the effects of the contracting of the photopolymerized material and also of the temperature in the region applied. These techniques consist of spacing proportional to the effect desired, i.e., withdrawing the tip from the activated region the power and temperature tend to diminish.
- A minimum distance of 10mm between the tip and the tooth is advisable.

Manufacturer shall not be responsible for:

- Use of the equipment differing from that for which it is intended.
- Damages caused to the equipment, the professional and/or the patient by the incorrect installation and erroneous procedures of maintenance, differing from those described in these Instructions for use which come with the equipment or by the incorrect operation of it.

PRECAUTIONS, RESTRICTIONS AND WARNINGS

Precautions and warnings “after” the use of equipment

- Turn the equipment off while in not in use for a long time.
- Carry out the cleaning and disinfection after the use of the equipment, including in the first use.
- Do not change any part of the equipment. Do not disconnect the cable or other connections unnecessarily.
- When observing the presence of irremovable stains, cracks or fissures on the light conductor and ocular protection, provides the replacement of the damaged components.

Precautions and warnings during “cleaning and disinfection” of the equipment

- When disinfecting the handpiece, remove the light conductor; use neutral soap or alcohol 70% vol. Never use povidone iodine, glutaraldehyde or chlorinated products, which with time can produce superficial attacks over the instrument’s body. Never soak the instrument in disinfection baths.
- The conductor must be clean and sterilized at 134ºC before being used in the next patient.
- Before cleaning the equipment, disconnect it from the electricity.
- Avoid spilling water or other liquids inside the equipment, what might cause short circuits.
- Do not use micro-abrasive material or scouring pad in cleaning, do not use organic solvents or detergents that can contain solvents like ether, stain remover, etc.

Precautions in case of alteration in the functioning of equipment

- If the equipment has any abnormality, check if the problem is related to any item listed in the topic of unforeseen events (failures, causes and solutions). If it is not possible to resolve the problem, turn off the equipment, remove the power supply cable from the socket and contact your representative (Alliage).

Precautions for the Reduction of the Environment Impact

Alliage S/A aims to achieve an environmental policy that encourages the environmentally conscious supply of medical products that continuously minimize environmental impact and are more environmentally friendly and human health friendly.

To keep a minimum impact on the environment, observe the following recommendations:

- After installation, forward the recyclable materials for the recycling process.
- During the life circle of the equipment, turn it off when it is not being used.

The biomedical waste comprises nonhigh material susceptible to cause disease or house pathogenic organisms that must be stored in a yellow bag properly labeled with the symbol of biological hazard, or stored in a container resistant to perforation, tight and even collection and incineration.

The packaging consists of cardboard, plastic and expanded polystyrene (EPS) which are 100% recyclable materials.

Dimensions:
Main unit: 0,250 X 0,190 X 0,070 / MASS: About: 0,825 Kg.

Precautions to be adopted against foreseeable or uncommon risks, related to the deactivation and abandoning of equipment

In order to avoid environmental contamination or undue use of the Equipment after it has become useless, it should be discarded in the suitable place (as per the local legislation of the country).
- Pay attention to the local legislation of the country for the conditions of installation and disposal of residue.

CORRECTIVE AND PREVENTIVE MAINTENANCE AND PRESERVATION

Cleaning ,Disinfection and Sterilization

Attention
Cleaning, disinfection, and sterilization have limited impact on the reusable parts of the equipment. Therefore, the number of repeated procedures should not exceed 20 times.

Preparation for use
Immediately after use, the reprocessing equipment is immersed in <40 °C tap water (drinking water quality, 'water' mentioned in this chapter, which is required to meet this standard) to remove dirt. Do not use a fixed detergent or warm water (>40 ° C) as this will cause the residue to be fixed and affect the effect of repeated treatment.
Transport: Transport to the post-processing area for safe storage to avoid any damage and environmental pollution.

Preparation before cleaning
Remove the body light guide from the main unit and place it in a stainless steel box.
Decontamination preparation (pre-cleaning):
Rinse the body light guide with running tap water (<40 °C) until all visible residue is removed.

Manual cleaning
Rinse the body light guide with running tap water (<40 ° C) and gently wipe the visible dirt with a soft brush;
Place the body light guide in a multi-enzyme cleaner and soak for 10 minutes to decompose the contaminants. Follow the instructions of the cleaning agent manufacturer;
The body light guide was placed under running tap water for at least 1 minute to remove the residue of the cleaning agent.

Attention
We recommend the use of proven Lilcon® multi-enzyme cleaning solutions or multi-enzyme cleaning solutions that comply with local regulations (eg CE, FDA approval).

Manual disinfection
Place the body light guide in a dish containing the cleaning and disinfecting solution for 10 minutes for immersion disinfection.
The body light guide was rinsed with running tap water (<40 ° C) for at least 1 min to remove residuals from the disinfectant.
Disinfectant: It is recommended to use Ronso O-Benzaldehyde Disinfectant (OPA), no need to match.

Attention
1) If other disinfectant is used, use a disinfectant that complies with local national regulations (such as CE certification, FDA certification), and follow the instructions provided by the manufacturer of the disinfectant.
2) In order to prevent the disinfectant from corroding the device, the time of immersion disinfection should not be too long (<30min).

CORRECTIVE AND PREVENTIVE MAINTENANCE AND PRESERVATION

Dry
Dry the fiber rod with a lint-free cotton cloth.

Inspection and maintenance
After cleaning and disinfecting, the body light guide is visually inspected for cleanliness. No visible contaminants are considered to be clean. If the body light guide is found to be corroded and rusted, stop using it immediately.

package
Immediately after drying, place the body light guide in a steam sterilization bag for sealed packaging.

Attention
Steam sterilization bags in accordance with ISO 11607-1 should be used and the packaging must be sealed with a sealing machine.

Sterilization
Use a high pressure steam sterilizer in accordance with EN 13060 for sterilization.
Sterilization in an autoclave according to ISO 17665-1.
1) sterilizable parts: body light guide;
2) Sterilization method: high pressure steam sterilization method;
3) Sterilization conditions: at 134 ° C, not less than 18 min.

Attention
The body light guide can be autoclaved, and no other parts are available.

Storage
Store the sterilization equipment in a dry, clean, dust-free environment at a suitable temperature of 10°C to 40°C.

CORRECTIVE AND PREVENTIVE MAINTENANCE AND PRESERVATION

Preventive Maintenance

The equipment must suffer routinely measurements, following the current legislation of the country. But, never with a period superior to 3 years.
For protecting your equipment, look for a Alliage technical assistance for periodic reviews as preventive maintenances.

Corrective Maintenance

The supplying of the circuits' diagram, Part lists or any other information that permits the technical assistance by the user, can be requested, since previously agreed between the buyer and Alliage.

Attention

In case of the equipment presents any abnormality; check if the problem is related to some of the listed items under the item Unpredictable (situation, cause and solution).
If it's not possible to solve the problem, shutdown the equipment and demand the presence of a Alliage' technician from the nearest resale, or ask through the Attendance Service Alliage: + 55 (16) 3512-1212.

UNFORESEEN EVENTS – SOLUTION OF PROBLEMS

⚠ Upon coming across any problem in operation, follow the instructions below to check and repair the problem, and/or get in touch with your representative.

Problem	Probable cause	Solution
- The Curing Light does not work.	- Battery in the handpiece without charge. - Overheating protection activated “error code: oU. - LED damaged “error code: Er.	- Recharge the handpiece on the base for 3 hours. - Wait a few minutes. - Get in touch with the Alliage technical assistance.
- The equipment is not polymerizing the resins.	- Resin not appropriate for the wavelength range of the LED curing lights. - Light conductor fastened incorrectly. - Residue of resin in the light conductor. - Light conductor with protection cover.	- Acquire the appropriate resin for the wavelength of the curing light, i.e., which contain photoinitiators with canforoquinone. - Fasten the light conductor correctly. - Clean the light conductor. - Remove the protection cover from the light conductor.
- Inadequate luminous power.	- Light conductor fastened incorrectly. - Problems with the light conductor. - Reduced capacity of the battery.	- Fasten the light conductor correctly. - Replace the light conductor. - Get in touch with the Alliage technical assistance.

EQUIPMENT'S WARRANTY

This equipment is covered by the warranty periods, terms and conditions contained in the Warranty Certificate that comes with the product.

FINAL CONSIDERATIONS

Among the care you have to take with your equipment, the most important is regarding of the spare parts replacement.

To ensure the lifetime of your device, only replace original spare parts from Alliage. They have the assurance of the standards and technical specifications required by the Alliage representative.

We call your attention to our authorized resellers' chain. Only this chain will keep your equipment constantly new, because it has trained technical assistant and specific tools for the correct maintenance of your device.

Whenever you need, demand the presence of a Alliage' technician from the nearest resale, or ask through the Attendance Service Alliage: + 55 (16) 3512-1212.

REGISTRATION ANVISA #: 10069210081

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