OPERATING INSTRUCTIONS MANUAL

BLUEDENT POWER PEN built-in
24V / 220V

Dental LED curing light

Ref.#200-002b, #200-002m



BG LIGHT PRO
the power of light

Thank you for trusting our products!
Carefully read this Operating instructions manual before installing and operating the unit to use and maintain it successfully!
Save this Operations guide for your reference in the future.

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I. UNIT DESCRIPTION AND FUNCTION

Dental LED curing light BLUEDENT POWER PEN built-in is a medical device - specialized light source for intraoral polymerization of dental materials, sensitive to the blue part of the light spectrum.

The device is intended for use only by a qualified dental practitioner and in a dental practice.

BLUEDENT POWER PEN built-in consists of Handpiece with cable (and adapter for 220V version) and Holder for attaching to the dental chair.

BLUEDENT POWER PEN built-in is manufactured in conformity with the requirements of Regulation on medical devices MDR 2017/745 and standards ISO 13485:2016, ISO 9001:2015.

II. SYMBOLS

European Conformity
Indicates conformity with local laws and regulations within the European Economic Area.



Caution
To indicate that caution is necessary when operating the device or control close to where the symbol is placed.



Refer to instruction manual/booklet
To signify that the instruction manual/booklet must be read.



Electronic instructions for use
To indicate on product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed paper form.



Dangerous voltage
To indicate hazards arising from dangerous voltage.



Hazardous light emission
To indicate hazards arising from light radiation.



Hazardous thermal effects
To indicate hazards arising from thermal effects.



Manufacturer
Indicates the device manufacturer.



Date of manufacture
Indicates the date when the device was manufactured.



Catalogue number
Indicates the manufacturer's catalogue number so that the device can be identified.



Serial number
Indicates the manufacturer's serial number so that a specific device can be identified.



Batch code
Indicates the manufacturer's batch code so that the batch or lot can be identified.



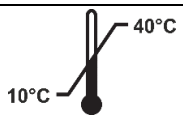
Applied part type B according to electric safety classification.

IP20
IEC - IP rating

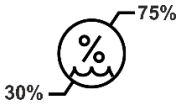
For indoor use in dry conditions.
Protection against solid objects larger than 12.5mm; no protection against water.
(Ingress Protection rating)



For indoor use only
To identify electrical equipment designed primarily for indoor use.



Temperature limit
Indicates the temperature limits to which the device can be safely exposed.



Humidity limitation
Indicates the range of humidity to which the device can be safely exposed.



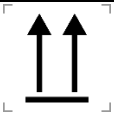
Keep away from sunlight
To indicate that transport package shall not be exposed to sunlight.



Keep away from rain
To indicate that the transport package shall be kept away from rain and in dry conditions.



Fragile; handle with care
To indicate that the contents of the transport package are fragile and the package shall be handled with care.



This way up
To indicate the correct upright position of the transport package.



Waste Electrical and Electronic Equipment (WEEE)
According to Directive 2012/19/EU, this symbol indicates that the product should not be disposed of as urban waste at the end of its operating life. It must be sent to separate collection facilities for recovery and recycling.

III. SAFETY PRECAUTIONS



GENERAL WARNINGS:

BLUEDENT is a Class I medical device and it meets the requirements of the Medical Devices Regulation - MDR (EU) 2017/745. In order to be used safely for staff and patients, the following rules must be observed:

- Do not allow unauthorized and untrained personnel to use the device to avoid risks.
- Disconnect the adapter from the power supply at the end of the working day.
- Do not use or store the device in a dusty environment.
- Do not expose the device to direct sunlight.
- Do not spray disinfectant directly into the device - only wiping with a swab soaked in disinfectant is acceptable.
- Do not get it wet and store it in a dry place to avoid electric shock or damage to the device.
- The device should not be used if any of its parameters are not within the norm.
- Strong electromagnetic fields in the building can cause interference and malfunction of the device. If their source cannot be determined, change the location of the device and plug it into another outlet or another room, even in another building.
- Opening and repairing the device may only be carried out by service technicians authorized by the manufacturer.
- When replacing defective parts, only original parts must be used. The device or any of its parts must not be disassembled while it is connected to the power supply!
-  Fragile! Use caution when transporting, using and storing the device!
- According to Directive 2012/19/EEC, this symbol indicates that the product should not be disposed as a general waste at the end of its lifespan. The product must be taken to a specialized center for the separate collection of electrical and electronic equipment according to local regulations. Proper disposal of equipment that is no longer used prevents negative consequences for the environment and human health!
- In accordance with the requirements of MDR (EU) 2017/745, user and / or the patient must report any serious accident that have occurred during us of the device to the manufacturer and the competent authority of the Member State in which the user/patient is established.
- All packaging materials of the product must be kept away from children to avoid risks of injury / suffocation.

SAFETY MEASURES AND RISKS
The device must be used in strict accordance with the Operating Instructions Manual.



1. Electrical safety

Before starting the device, make sure that the voltage and type of plug correspond to the power supply in the country. Use only the original adapter type SYS1381N-1224-W2E.
Electrical safety is ensured by class II protection against electric shock according to EN 60601-1.
The built-in device should be connected to the terminals of the dental unit with a voltage of 24VAC/DC +-20%.

BLUEDENT must only be operated indoors, under the following conditions:
- temperature from + 10 ° to + 40 ° C;
- relative humidity 30 - 75%;
- lack of dust in the room;
- atmospheric pressure 700 - 1060 hPa;
- absence of chemically active and flammable substances;
- no part of the device should be wetted or immersed in water;
- the device or any of its parts must not be disassembled while it is connected to the mains!

In case of a problem with the power adapter (for 220V model) or its cables, the device should be sent to a service center.
During thunderstorms, the device should be disconnected from the power supply (for 220V model) or the dental unit should be turned off (for 24V model).

Risk: Failure to comply with these instructions may result in electric shock to users of the device.



2. Light radiation

BLUEDENT is a source of intense light in the blue range, to which the human eye is highly sensitive. Irradiation of the eyes and skin with intense light carries a risk of

damage. This leads to the serious measures that must be taken to protect patients and medical staff.
The light should never be directed at the eyes! Irradiation should be limited to the work area. Do not irradiate soft tissues.
It is mandatory to use special filters or protective glasses that meet the requirements:
- Glasses should tightly cover the eyes and temples, even if the person is wearing optical glasses.
- be made of volumetric colored impact-resistant plastic.
- block light with a wavelength of 410 - 490 nm at least 100 times.
- have a stable mechanical structure, have no scratches, cracks or damage to its surface.

The device can only be used after medical consultation on or by persons suffering from photo-biological reactions; persons taking photosensitive medications; persons operated on for cataracts, persons with retinal diseases, etc.

<u>The risk of unlawful exposure is severe eye irritation, temporary spots in the visual field, severe vision damage in case of direct exposure, including loss of vision.</u>



3. Thermal radiation

The thermal effect is a consequence of the absorption of the energy of the blue light in the tissues, in which the energy is converted into heat. Irradiate only the dental tissue without the surrounding soft tissues. Take breaks in case of sensitivity. The risk of overheating and burning occurs only with prolonged continuous overdose of irradiation.

<u>Risk of pain, burning of soft tissues.</u>

4. Fire safety

- Keep the device away from solvents, flammable liquids and powerful heat sources.
- Do not expose to direct sunlight.
- Do not allow liquids and cleaning agents to penetrate the device, as this may cause damage or fire.

- If the product emits an odor or smoke – disconnect from the mains, do not attempt to repair it, take it to a service center.

Risk of fire and burns.

5. Prohibitions for using the device:

The device can only be used after medical consultation on or by: persons suffering from photobiological reactions; persons taking photosensitizing medications; persons having cataract surgery; persons with retinal diseases; persons with allergies; people who have recently undergone surgical or cosmetic operations on the face or lips, including hyaluronic acid or Botox injections; persons with very sensitive skin or dermatitis, etc. If photosensitizing agents or medications are being taken, check the package insert of the medicine.

IV. TECHNICAL DATA

1. Operating voltage of the device (according to the device specifications):
– 24V AC/DC +-20% of the dental unit
or with an additional mains adapter: type SYS1381N-1224-W2E with -input voltage 100-240VAC, output voltage 24VDC to the device.

2. Power consumption:
- 24V AC/DC – 0,35A
- 110-240V / 50-60Hz – 0,115A

3. Dimensions of emitting handpiece:
- diameter of handpiece – min 18 mm, max 25 mm
- Length - 245 mm

4. Weight of handpiece (incl. lightguide and protection filter) – 100g

5. Polymerization modes – RAMP mode – with soft start.

6. Light source – wideband LED module with reflector optics.

7. Emitted light – blue, visible spectrum, 410-490 nm.

8. Light intensity – up to 1300 mW/sq.cm

9. Emitting time:
- 10 / 20 / 30 sec. /±10%

10. Fiberoptic lightguide (360 degrees rotatable)

11. Working mode (1 min. work / 10 min. pause)

12. Degree of protection against electric current - applied part type B.

The manufacturer of this unit declares to provide on request all additional necessary technical documentation / information which will help the user's technical staff to service the parts of the unit which the manufacturer has claimed to be a subject for repair.

V. COMPLETE SET

1. Charging adapter SYS1381N-1224-W2E - 1 pc. (for 220V model with adapter)
2. Emitting handpiece - 1 pc.
3. Holder - 1 pc.
4. Protection filter and cap – 1 pc.
5. Operations guide - 1 pc.

Version 24V

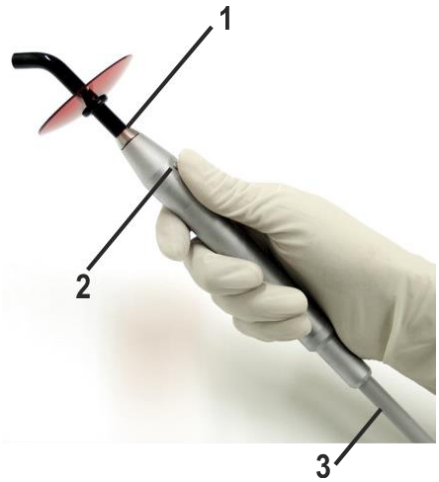


Version 220V with adapter



<u>Control and indication:</u>

1. Emitting LED module
2. Start / Stop button
3. Cable



VI. PREPARATION AND SEQUENCE OF OPERATION

BLUEDENT POWER PEN built-in is designed for use as a cable powered unit to be built-in the dental chair (version 24V) or to be powered by the mains (version 220V with adapter).

1. Take the curing light out of the packing.
A dental technician connects the cable to the 24V AC/DC terminal on the dental chair. Important – never connect the device to a higher voltage!

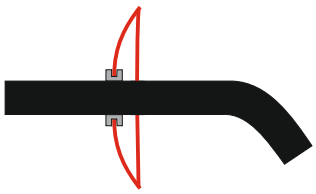
2. The holder is fixed on a suitable vertical surface with the included fasteners.

3. Mount lightguide and protection shield or protection cap.
See VII. ROUTINE CARE AND MAINTENANCE for instructions of initial cleaning and mounting.



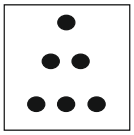


For polymerization of posterior teeth (attach as shown) - Protection cap (1)



For polymerization of anterior teeth / general application – Protection filter

4. Choosing timer mode:

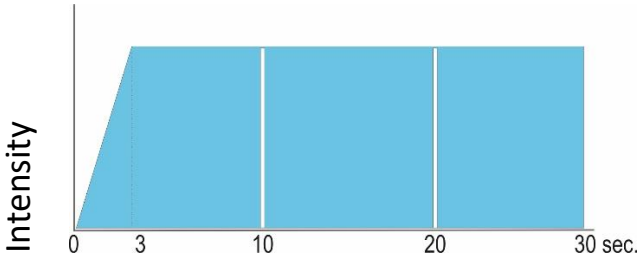
- SINGLE Press the Start / Stop button - 10 sec.	
- DOUBLE Press the Start / Stop button - 20 sec.	
- TRIPLE Press the Start / Stop button - 30 sec.	

After the set time has elapsed, the unit will turn off the output light.

If desired, the dentist can interrupt the cycle by pressing the Start / Stop button again.

During operation, the fiberoptic lightguide must be at a distance of at least 1 mm from the polymerization area.

Diagram of curing mode
RAMP - gradual increase in intensity during the first 3 seconds.



(Sound signal at 10, 20, 30 sec.)

5. Overheating protection

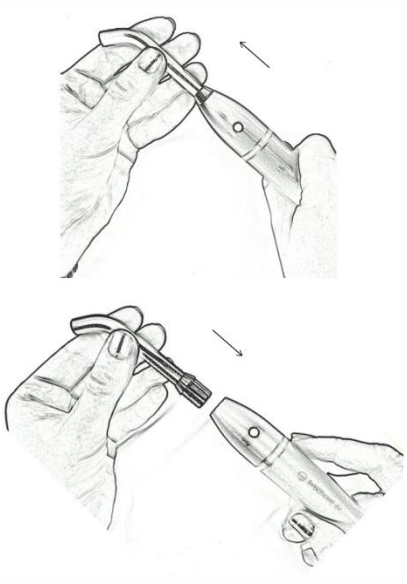
The unit is equipped with overheating protection, which is activated if the temperature of the LED module rises up to 50°C.
It is necessary to wait for device’s cooling down.

VII. ROUTINE CARE AND MAINTENANCE

1. **Examining of lightguide / protection cap.**

Lightguide and protection cap must be sterilized before every use! They are delivered in a non-sterile state and must be sterilized beforehand first use.

Before each patient, the lightguide (only it, without the handpiece) must be mechanically cleaned of adhering composite and then with a disinfectant (e.g. Desident CaviCide or another approved by the Ministry of Health) and sterilized by autoclaving at 134° C for 5 minutes.



The ligh guide is installed/dismounted by inserting/pulling and can be rotated 360 degrees.

The lightguide must be checked daily for:
- adhered photocomposite on the front of the light guide (cleaned carefully with a blunt non-metallic object)
- mechanical damage.

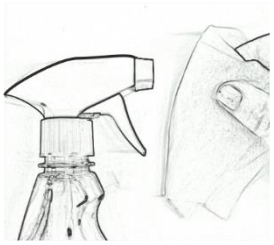
Check for light conduction: Remove the light guide and look through it at a strong light - if there are darkened areas over 10% of the area, replace it with a new one.

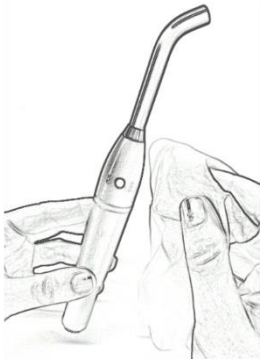
OK 

Defective 

2. **Cleaning of the device**

To disinfect the device, spray disinfectant onto a piece of cotton/soft cloth and clean the handpiece.
You can also use disinfecting wipes.





Do not use abrasives or solvents as these may damage the parts of the unit!

Do not spray directly onto handpiece or in button / USB charge connector!



VII. WARRANTY CONDITIONS

1. The warranty period for the BLUEDENT dental photopolymerization device is 24 (twenty-four) months from the date of purchase. If the date of purchase is not filled in and warranty documents are missing, the warranty begins to run from the date of manufacture.

2. During the warranty period, the replacement of defective elements is carried out free of charge by the manufacturer. The light guide is not subject to warranty service.

3. If during the warranty period the device is defective due to improper operation (mechanical, chemical, thermal, electrical damage, use not for its intended purpose), improper storage and other reasons due to the user's fault, the repair is not covered by warranty.

4. Damage and complaints due to electric shocks, thunderstorms, failure to comply with electrical safety measures are not accepted.

5. The device must be transported to the service center only in the original packaging to avoid unwanted damage. The light guide must be packed separately from the handpiece. The warranty card (this Manual, with chapter XII BLUEDENT Data completed) or a copy of the sales invoice showing the serial number of the device must be presented.

6. If repairs are carried out by unauthorized persons outside the company service center or if non-original elements and assemblies are used, the user loses the right to warranty service.

7. Disclaimer: The manufacturer is not liable for compensation and lost profits in the event of damage or incomplete functioning of the device, regardless of the cause or in the event of problems arising from failure to comply with safety measures in the event of risks (chapter III, Risks)

8. The warranty service is performed in the company service at the address:

BG LIGHT PRO Ltd
155, Vasil Aprilov blvd
4027 Plovdiv
Bulgaria
tel: +359 32 644089
office@bglight.com
www.bglight.com

9. The device's service life is set at 5 years from the date of purchase. After the end of its life cycle, the user must discontinue use of the device.
At the user's request, the life cycle can be extended. For this purpose, the device must be returned to the manufacturer BG LIGHT PRO OOD, where its characteristics must be checked and all main elements (emitters, adapter, electronic boards) tested and replaced.

10. In the event of disputes arising in connection with the application and interpretation of these Operating Instructions, they will be resolved by the Plovdiv District Court, in accordance with the current Bulgarian legislation.

IX. SERVICE DATA

X. FAQ

Problem	Solution
The button does not respond properly	Clean around the button with an alcohol swab. If the button still does not respond properly, send the device to a service center.
Weak curing effect	It is necessary to clean the front of the light guide with a non-metallic object and clean the adhered composite with alcohol. If the result is poor - send the device to the service center.
The patient experiences discomfort during the prolonged polymerization process of 20-30 sec.	It is necessary to polymerize with short cycles - 10sec or less, with short pauses 1-3sec. The sensitivity is higher if the light is close to the dental pulp and decreases with each layer.
The power cable or power adapter is damaged.	Send to service center.
Liquid entering the device	Send to service center.
After falling to the floor, the device does not work	Send to service center.

XI. DECLARATION OF CONFORMITY

BG LIGHT PRO **TECHNICAL FILE** **BLUEDENT** **LED curing light**	**EU Declaration of conformity** *Developed in conformity with MDR (EU) 2017/745*	**TD 7.2** *Revision* ***03***

Manufacturer: **BG LIGHT PRO LTD**
SRN:
Address: 155, Vasil Aprilov blvd., 4027 Plovdiv, Bulgaria
Tel.: +359 32 644089, email: office@bglight.com
BULSTAT UIC 208000520, VAT N: BG208000520

CE

Product:	Product code:	Name:
Dental LED curing light	**200-002b**	**BLUEDENT POWER PEN – built-in 24V**
	200-002m	**BLUEDENT POWER PEN – built-in 220V**

Basic UDI: 38001748200000G8
EMDN code: Q0190

Classification: Active invasive medical device of **Class I** of the Regulation on medical devices - MDR (EU) 2017/745

Intended purpose: BLUEDENT is designed for photopolymerization of composites and materials used in dental practice (irradiation of blue light 410-490 nm).

The manufacturer declares that the medical devices covered by the Declaration are in compliance with the provisions of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.

The applicable GENERAL REQUIREMENTS FOR SAFETY AND PERFORMANCE, defined in Appendix I of the normative act described below and of normative technical documents, are met when the medical device is used for its intended purpose and in accordance with the safety requirements.

Document	Title	Edition / date of issue
Regulation (EU) 2017/745	***REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL*** *of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC*	*05.05.2017* *(last change 24.04.2020)*

To achieve compliance, the requirements of the following standards are met:

EN ISO 13485:2016 +/AC:2017/ /AC:2018/ A11:2022 +/AC:2017/ /AC:2018/ A11:2022	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 9001:2015	Quality management systems - Requirements
EN ISO 60601-1:2006 /A1:2013/AC:2014/A2:2022	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
EN 60601-1-2:2015/A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+ /A1:2015 / /A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-8:2007+ /A1:2013 /A11:2017 /A2:2021	Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN ISO 10650:2018	Dentistry - Powered polymerization activators
EN 62304:2006/A1:2015	Medical device software. Software life cycle processes.

EN 62353:2014	Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment
EN 62366-1:2015+ AC:2016/ A1:2020	Medical devices. Application of usability engineering to medical devices.
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 14971:2019+/A11:2022	Medical devices – Application of risk management to medical devices.
CEN ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
Directive 2012/19/EC	Directive on waste electrical and electronic equipment (WEEE)

Classification is done by the manufacturer according to Regulation on medical devices - MDR (EU) 2017/745, Annex VIII, Rule 13. Conformity assessment procedure according to article 52, paragraph 7 of MDR (EU) 2017/745.

The declaration of conformity is issued in implementation of Annex IV “EU Declaration of conformity” of EU Regulation 2017/745, based on the results of tests carried out and assessment of compliance with the General safety and performance requirements defined in Annex I, implemented and certified Quality Management System - ISO 9001:2015 certificate – No AC090 100/2409/6029/2025, ISO 13485:2016 – No AC090 MD/0008/6029/2025 from TUV NORD Polska Sp. z o.o. (NB 2274).

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

BG LIGHT PRO LTD maintains data on the provision, evaluation and maintenance of compliance of the medical device, according to the requirements of Annex II "Technical documentation" of MDR (EU) 2017/745.

Plovdiv, Bulgaria
08.05.2025

Dipl. Eng. Plamen Karaivanov
Manager
BG LIGHT PRO LTD

XII. BLUEDENT DATA

SN:	
LOT:	
DATE OF PRODUCTION:	
QC:	
DATE OF PURCHASE:	

Last revision: 22.07.2025
Follow www.bglight.com for updated revision of this Operating instructions manual.