OPERATING INSTRUCTIONS MANUAL

BLUEDENT 12 BL
built-in telescopic

Dental LED bleaching activation unit

Ref.#600-001bt

BG LIGHT LTD

Caution! Before installing and operating with the unit, read carefully this manual!

I.UNIT DESCRIPTION AND FUNCTIONS

LED bleaching activation device BLUEDENT 12 BL is an accessory to a medical device and is designed to whiten hard dental tissues by photoactivation of a bleaching gel based on hydrogen or carbamide peroxide, intended for light activation, applied in dental practice (concentrations of H_2O_2 or their equivalent: 0.1 – 6% (cosmetic bleaching) or above 6% (medical bleaching).

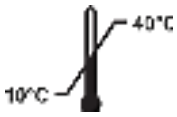
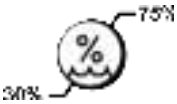
The device is intended for use only by a qualified dental practitioner and in a dental practice.

The device consists of Bleaching Head, Stand, Fixing bracket and Power Adapter.

BLUEDENT 12 BL 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

	**Caution!** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	**Consult instructions for use** Indicates the need for the user to consult the instructions for use.
	**Dangerous voltage** To indicate hazards arising 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 medical device manufacturer.
	**Date of manufacture** Indicates the date when the medical device was manufactured.
	**Medical Device** Indicates the item is a medical device.
	**Unique Device Identifier** Indicates a carrier that contains Unique Device Identifier information.
	**Catalogue number** Indicates the manufacturer's catalogue number so that the medical device can be identified.

	**Serial number** Indicates the manufacturer's serial number so that a specific medical 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.
	**Temperature limit** Indicates the temperature limits to which the medical device can be safely exposed.
	**Humidity limitation** Indicates the range of humidity to which the medical device can be safely exposed.
	**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.
	**Fragile** Indicates a medical device that can be broken or damaged if not handled carefully.
	**European Conformity** Indicates conformity with local laws and regulations within the European Economic Area.

III. SAFETY PRECAUTIONS

GENERAL WARNINGS:

BLUEDENT 12 BL is a Class I accessory to a medical device and it meets the strict 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 device from the mains after completing the procedures.
- 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 rubbing with a swab drained of disinfectant is acceptable.
- Do not get wet or drop liquid on the device, cables, adapter to avoid electric shock or damage to the device.
- Store the device in a dry place, moisture can cause electric shock and damage.
- In case of a problem, disconnect the device from the mains, do not to make attempts to repair, take the device to a service center.
- The device must not be used if any of its parameters are not normal (timer, light intensity, heat radiation).
- The bleaching head must not be covered, the cooling openings must not be closed so as not to cause the device to overheat and ignite.
- 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 socket or other room, even in another building.
- Opening and repairing the appliance may only be carried out by authorized service technicians from the manufacturer.
- Only original BLUEDENT 12 BL parts must be used when replacing defective parts. The warranty of the device does not cover the damage caused by the use of non-original spare parts. The device or any of its parts must not be disassembled while it is connected to the mains!
- Before each patient, the emitting window must be disinfected (with a disinfectant).
- Before the patient undergoes whitening, he/she must sign an Informed Consent, which describes in great detail the possible side effects of the process. Sample text can be found at www.bglight.com
- Note: It is recommended to attend a suitable training "Teeth whitening in a dental office"!

-  Fragile! Use caution when transporting, using and storing the device! When transported in an assembled condition, two persons are required to keep the moving parts. With any unevenness on the flooring, the device should only be moved by two people.
-  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 appliance, make sure that the voltage and the type of plug correspond to the mains supply in the country. Use only the original adapter type FSP060-DAAN3.
Electrical safety is ensured by class I protection against electric shock according to EN 60601-1.

BLUEDENT 12 BL 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!
To avoid the risk of electric shock, this device must only be connected to power supplies with protective earthing.
Protect the cables of the appliance from insulation damage and breakage from sharp objects, strong pulling, rodents, chemicals. If such damage is noticed on the electrical cables, it is necessary to take the device immediately to the company service. The device must not be used with damaged cables.
In case of thunderstorms, the procedures must be stopped and the plug must be disconnected from the mains.
Risk: Failure to comply with these instructions may result in electric shock to users of the device.

2. Light radiation

BLUEDENT 12 BL is a source of extremely intense light in the blue range, to which the human eye has a high sensitivity. This results in serious measures to be taken for patients, medical staff and accidentally nearby people, animals and plants.
As such, use protection goggles for the operator, and for the patient goggles, mask and high-factor sunscreen.
Irradiation of the eyes and skin with intense light carries a risk of damage from light and heat. Skin pigmentation is possible.

The light should never be directed at the eyes! Irradiation should be limited to the workplace area. The special safety goggles from the set that meet the requirements must be used:
- to cover the eyes and temples tightly, even if the person is wearing optical glasses.
- be made of volumetric colored impact-resistant plastic.
- do not transmit light with a wavelength of 380 - 600 nm.
- reduce the intensity of the blue spectrum by more than 100 times.
- have a stable mechanical structure, no scratches, cracks and damage to its surface.

The device can be used only after a doctor's consultation on or by persons suffering from photo-biological reactions; persons taking photosensitive drugs; persons undergoing cataract surgery, persons with retinal diseases, etc.
The risk of improper irradiation is severe eye irritation, temporary spots in the visual field, severe visual impairment in direct radiation, to loss of vision.

3. Thermal radiation

The thermal effect is due to the absorption of the energy of the blue light in the tissues, during which the energy is converted into heat. The risk is only with prolonged overdose.

Risk of pain, burning of soft tissues.

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 detergents to enter the device, as this may cause a short circuit and fire or cause potentially dangerous damage.
- 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, explosion and damage.

5. Danger of mechanical moving parts

- To be used in rooms with a horizontal floor surface.
- Assemble the mechanical parts, position them, lock them slowly with care.
- The device must not be used for transporting or moving people or objects.
- The counterweight must be fully screwed in order to avoid falling and injuring people and objects.
- Fix the emitting head well - at an appropriate height and distance to be stable in front of the patient's teeth during the procedure.
- Do not turn the horizontal arm by force to avoid mechanical shocks with the counterweight or the bleaching head. In the event of a mechanical shock, if the whitening head is damaged, the use of the device must not be continued. It must be taken immediately to the company service center.
- To take measures against damage to the human body by mechanical parts (movable and immovable), pinching, inertial reinforcement of the counterweight, manipulations with the device to be performed carefully to avoid injury.
- The movement of the parts of the device without prior unscrewing of the fixators can damage their locking mechanism. The wheel stoppers, if any, must be released before moving the bleach.

Risk of mechanical damage to the operator and the patient.

6. Who should not be bleached because of prohibitions and risk of burns and complications:

- The device should not be used by: pregnant and breastfeeding mothers; patients with severe periodontal pathology, with recessions, dental hyperesthesias and under 17 years of age; patients with allergies, wounds and infections, fresh scars on the face, skin infections, recently placed dental implants or surgical procedures in the oral cavity and face, fibral conditions, herpes, bleeding, bruises, burns, cancer or indications of such on the face and lips cavity, atypical warts in the area of irradiation, difficult to heal wounds; patients taking painkillers that dull the skin's sensitivity to heat; persons under the influence of alcohol or narcotics.
- The device can be used only after medical consultation on or by: persons with implanted cardiac pacemaker; persons suffering from photobiological reactions; persons taking photosensitive drugs; persons undergoing cataract surgery; persons with retinal diseases; people with allergies; people who have recently undergone cosmetic surgery on the face or lips, including injections of hyaluronic acid or botox; people with very sensitive skin or dermatitis, etc. If you are taking photosensitizers or medicines, check the package leaflet and never undergo bleaching procedure if it is indicated that it may cause photoallergic reactions, or if you are required to avoid sun exposure after taking this medicine.

Failure to follow the whitening protocol may result in pain, hypersensitivity, enamel damage, and soft tissue burns.

7. What to do before bleaching:

- Talk to the patient to clarify the patient's status and explain the prohibitions and risks and to answer any questions.
- Familiarization of the patient with the content of the "Informed Consent" and its mandatory signing by the patient.
- Isolation of soft tissues with a mask to avoid burns and skin reactions.
- Mandatory use of the safety goggles provided by the manufacturer for the operator and the patient. Do not use other types of glasses that may be dangerous to the eyes.
- Check the patient's sensitivity to light intensity. The device has 2 levels of intensity and with the distance to the teeth the optimal conditions are selected.

Testing begins with a high level of intensity "Hi" (High) and a distance of 5-6 cm and if the heat sensation after 1-2 minutes is very strong, the distance should be increased to achieve an acceptable thermal sensation.
If the heat sensation is very strong at 10-15 cm, then it is better to switch to low intensity - "Lo" (Low) and less distance to the teeth.
If the patient has no sensitivity or cannot judge the distance – it is advisable to work at a greater distance and mode "Lo".
- After selecting the appropriate intensity (HI or LO) and the distance between the device and the patient's lips between 5 and 15 cm, dentist must monitor how the patient reacts to this intensity - for example after a few minutes of irradiation. Distance should be adjusted according to the patient heat response to avoid danger of side effects - burns. The heat effect is as strong as the light effect. For example, in the summer or at high temperatures in the room, it is mandatory to increase the distance to the patient by 1-2 cm.
- To have constant control over the procedure to ensure that the distance has not changed. The patient should not be left unattended during the procedure.
- It is desirable to have a picture before and after the procedure of the teeth and soft tissues and to monitor whether there is redness or other reaction. The photo should be stored long enough to monitor the effect of whitening and possibly the soft tissue reaction.

8. What to do after bleaching:

- Examination of the patient after the procedure for redness and changes in the mucosa, if any, to give him a prescription for appropriate treatment and to keep in touch with him in the coming days until the disappearance of any problem. It is desirable for the dentist to keep in touch with a dermatologist and to be able to offer a consultation with one in case of problems with the patient.
- The patient should be warned to observe the necessary hygiene and not to undertake self-medication, which may deepen the reaction and to maintain contact with the dentist if necessary.
- The clinic (dentist) takes full responsibility for quickly and effectively solving any problems in order to ultimately obtain the desired aesthetic result without unwanted complications and consequences.

IV. TECHNICAL SPECIFICATIONS

1. Operating voltage to the power adapter - 100-240V / 50-60Hz,
to the bleaching head - 24VDC.
2. Charging adapter type FSP060-DAAN3, current consumption – 1,8 A max
3. Dimensions:
- Bleaching head
length - 220 mm
width - 155 mm
height - 95 mm
- Stand
length (assembled) - 52 cm / 80 cm with extended telescopic arm
height - 26 cm
maximum diameter of the standard fixing bracket - 50 mm. Optional fixing brackets with max. diameters 60mm, 70mm, 80mm and 90mm
4. Weight:
- Bleaching head - 640 g
- Stand - 2000 g
5. Irradiance - HI mode (100%), LO mode (50%) measured at the output window
6. Operation time - 10 sec. - 30 min / ± 5% /
7. Emitted light - blue 430 - 490 nm.
8. Light source - 10 LED modules x 5W = 50W
9. Fan air cooling.
10. Ability to start and stop the Bleaching Head at any time.
11. Maximum continuous operation time 99 min – every 99 minutes of continuous operation should have at least 10 minutes rest.
12. Degree of protection against electric current - applied part type B.

The manufacturer of this device will provide upon request the necessary additional technical documentation / information necessary for the technical staff of the user to repair those parts of the device that the manufacturer has specified as subject to repair.

V. PACKAGING / COMPONENTS

1. Power cord 24 V DC to the Bleaching Head
2. Straight arm
3. Telescopic arm
4. Telescopic fixator locking mechanism
5. Angular Arm
6. Fixing bracket
7. Bleaching head positioning mechanism
8. Bleaching head
9. Dental unit vertical arm
10. Control panel
10A. "+" Timer or "Pause" button
10B. "-" Timer or "Pause" button
10C. Start / Stop button
10D. Display
11. Cable retaining clip
12. Cables and connectors
13. Safety glasses - 2 pcs.
14. Power Adapter 100-240V AC / 24V DC

Fine positioning is done by turning the Bleaching head so that the light is perpendicular to the patient's teeth and centered on them.

If the movement of the Bleaching head is difficult or it does not hold the selected position it is necessary to adjust the Bleaching head positioning (7) and Telescopic fixator locking mechanism (4).

VI. INSTALLATION

BLUEDENT 12 BL BUILT-IN is designed to be mounted with a fixing bracket to the vertical arm of the dental unit.

1. Unpack the transport box, remove the components and initially assemble the fixing bracket to the dental unit. Make sure the diameter of the bracket matches the diameter of the dental unit vertical arm. Soft PVC tape strips are provided in the case that there is a need to compensate for small difference in the two diameters. Tighten the two screws with a 4 mm Allen key (included in the package).	
2. Tighten the stop/safety screw with a 3 mm Allen key (included in the package).	
3. Insert the cable through the small opening of the fixing bracket and place the angular arm in it.	

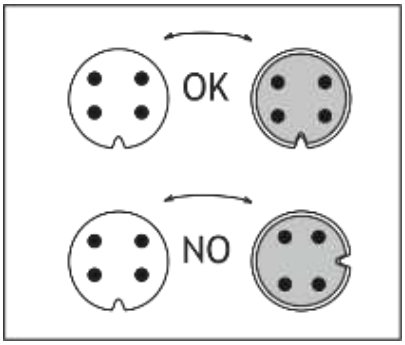
4. Attach the straight arm. Tighten the stop/safety screw with a 4 mm Allen key (included in the package). Make sure that the straight arm can be moved up and down for precise positioning.

5. Altering the force required to move the straight arm up and down is done by adjusting the screw (located on the back of the central position locking mechanism) with a 5 mm Allen key (included in the package).

6. Mount the bleaching head by turning clockwise the positioning fixator located on the telescopic arm.
By turning the conical fixator located on the straight arm, the telescopic arm is firmly fixed.

7. Connect the cable from the top of the angular arm to the one coming from the bleaching head using the connectors (see figure). Note: the device will not work if the cable connectors are incorrectly coupled.

8. Connect the cable on the bottom of the angular arm with the power adapter using the connectors (see figure). Note: the device will not work if the cable connectors are incorrectly coupled.



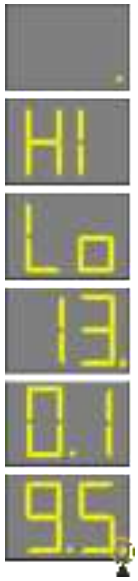
9. Plug the power cord into the power network, SHUKO socket.

VII. PREPARATION FOR OPERATION

1.BLUEDENT 12 BL bleaching activation device should be placed in a suitable position around the patient and the dental unit. See the positioning examples (Section X).

The bleaching head must be in the same vertical plane and parallel with the arc of the teeth with a distance between 5-15 cm. See the positioning examples (Section X).

2. Plug the power adapter into the power network. Only one point/dot on the display lights up. Press START / STOP button and then the "Hi" (High) or "Lo" (Low) intensity indication appears.



3. The display shows "HI" - a high intensity level. If you want to switch to the "Lo" (Low) intensity mode, press the TIMER / MODE (+ / -) button once. Then the display will show "Lo". Every time before setting the required time, you will be able to select the Hi or Lo intensity level.

4. Press the START / STOP button once again and set time option will be displayed. Note that the device will save the timeframe used in the latest bleaching procedure. Required time frame for operation is set by pressing TIMER + (increasing time) and TIMER- (reducing time):
The display on the bleaching head will indicate timeframes between 10 sec. and 9 min. and 50 sec. with a dot between the two digits.
Examples:
Display indicates: 13. This means the timeframe is set to 13 min.
Display indicates: 0.1. This means the timeframe is set to 10 sec.
Display indicates: 9.5. This means the timeframe is set to 9 min. and 50 sec.
The display on the bleaching head will indicate timeframes between 10 min. and 30 min. without a dot between the two digits.

5. Press the START / STOP button one final time and the device will start to emit light. A flashing dot on the display will indicate that the device is working properly.

6. If either of the TIMER / MODE (+ / -) buttons is pressed during operation, the unit switches to Pause mode. A blinking display with the remaining time will indicate that the device is paused. Operation is resumed by pressing any TIMER / MODE (+ / -) button again.

7. To Stop the bleaching device at any time press the START / STOP button. If the device is not manually stopped it will stop after the selected time has elapsed. Note that the fan will continue to work for some time in order to cool down the unit.

8. At the end of the day turn off the device by holding down the Start / Stop button for 3-4 seconds or by disconnecting it from the power network.

9. In case of overheating the thermal protection is triggered and the device will cease to emit light. The display will indicate "Oh" and the fans will turn on for 1 minute. After cooling, the device will continue its normal operation, but stays in Pause mode. Overheating can only happen in an emergency situation or by accidental clogging of the cooling vents. For this reason the cooling vents located on the bottom of the bleaching head must always be unobstructed in order to allow air circulation.

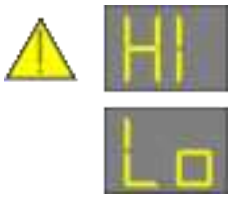
VIII. DAILY CARE AND MAINTENANCE

1. Disinfection of the PVC window of the bleaching head
For each patient, the emitting window is cleaned with a cotton swab soaked in an alcohol solution.

2. Cleaning the device:
To disinfect the device and its parts, spray disinfectant on a piece of soft cloth or cotton and clean.
Do not use abrasives or solvents, as this may damage parts of the device!

IX. PREPARATION FOR WORK WITH PATIENTS

1. Before starting work with the bleaching activaton device, insulate the patient’s non-calcified soft tissue, place a cover or protective napkin on the face, apply protective UV cream and put on protective glasses. Bleaching gel is applied to the teeth surface according to the directions for use outlined by the gel manufacturer.



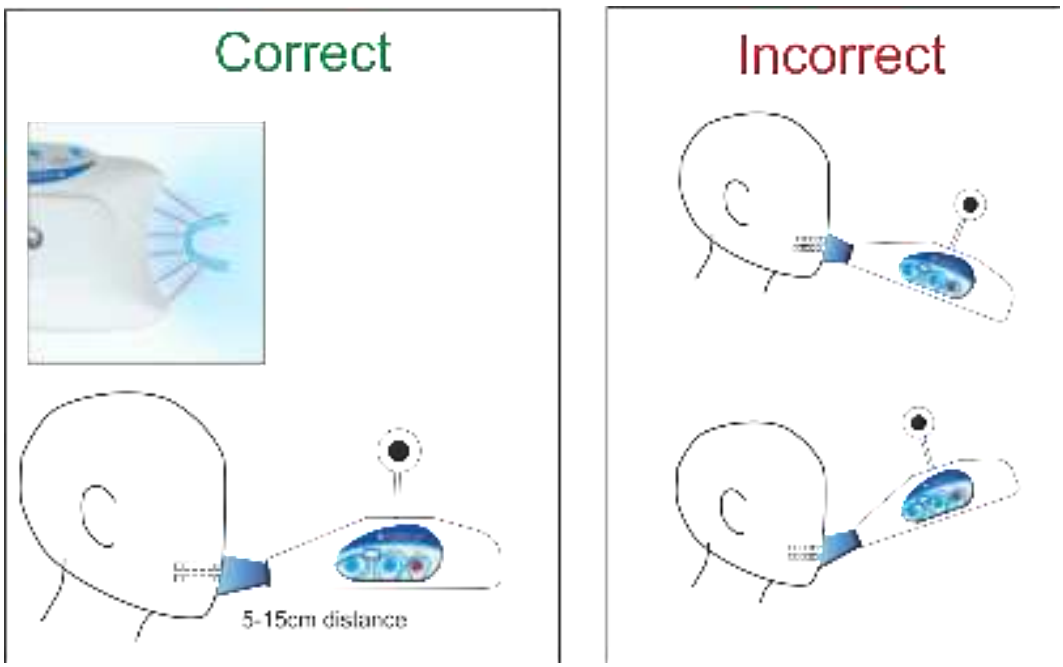
The patient should be under constant supervision by the dentist during the bleaching process in order to avoid discomfort and to ensure all safety and technological procedures are applied.

2. It is desirable to check the individual sensitivity of the patient. The device has two levels of intensity (high HI and low LO) and the optimal conditions are selected by adjusting the distance of the device to the patient's teeth.

Testing starts with a high intensity "Hi" and a distance of 5 cm and if the heat sensation is very strong, the distance is increased to achieve an acceptable thermal sensation.

If the acceptable distance is more than 10 cm, it is better to switch to a mode with low intensity - "Lo" (Low) and put the bleaching head closer to the teeth to obtain optimal distance.

X. POSITIONS OF BLEACHING HEAD AGAINST PATIENT'S TEETH



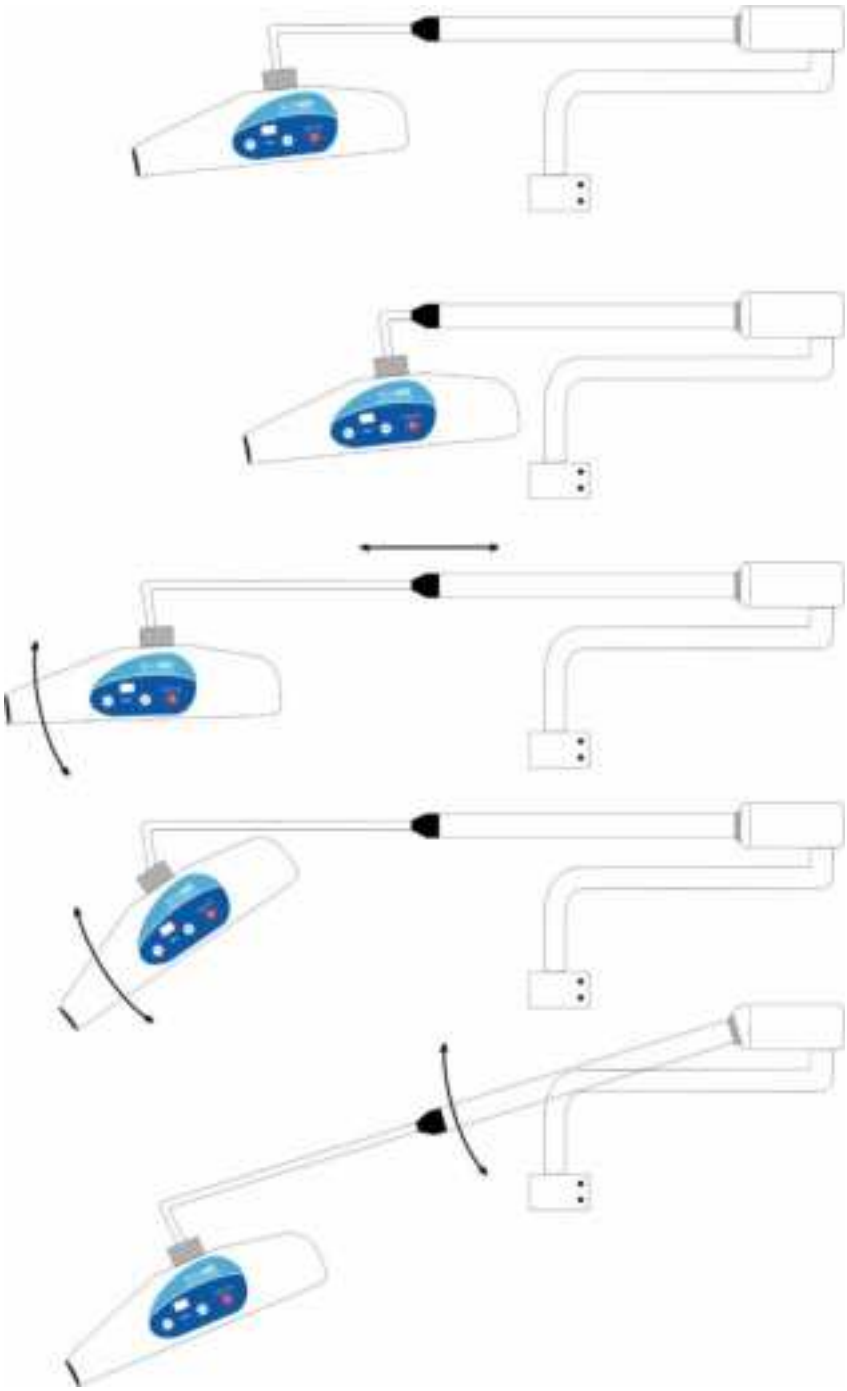
POSSIBLE LAMP POSITIONING WITHIN DENTAL UNIT

BLEACHING

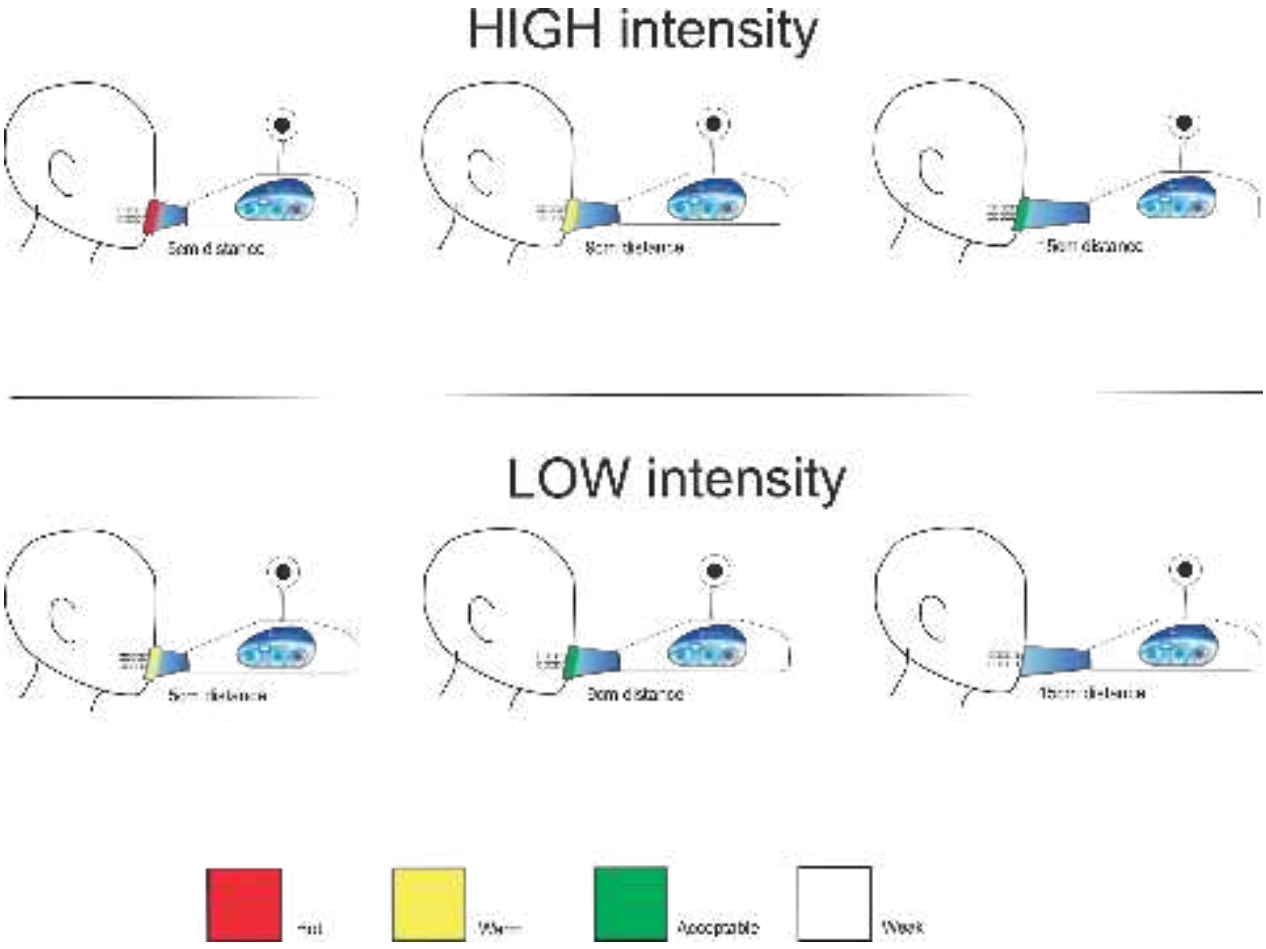
STAND-BY

STAND-BY

BLEACHING ACTIVATION UNIT OPERATIVE POSITIONING



XI. DETERMINATION OF DISTANCE TO PATIENT'S TEETH



XII. PROBLEMS AND SOLUTIONS

The device does not work.
Check if the power cord from the adapter is plugged into the power network and all cable connectors are correctly coupled. Use only the original adapter type FSP060-DAAN3.

Damaged power cord.
Do not use the device! Switch it off and replace the cable with new one or take the device to the service facility.

Unpleasant or irritating thermal sensation by the patient.
Increase the distance of the device to the patient's teeth to 10-15 cm. If the thermal sensation is still unpleasant at this distance switch to low intensity- "Lo" (Low) and shorten the distance to the teeth.

The display is blinking and no light is emitted.
The device is in PAUSE mode. To resume operation, press either (+) or (–) TIMER button.

The Bleaching Head cannot be fixed.
Tighten the fixing ball until the desired head position is reached (see Chapter V., point 5).

The display only shows "Oh".
The device has protection against overheating, and is activated if the temperature in the emitting head rises. Then the light stops, the display shows "Oh" - Overheating - and the fans work for 1 minute. After cooling, the device returns to normal operation. Overheating can only occur in an emergency or when the cooling openings are blocked. Therefore, the cooling openings in the lower part of the radiating head must always be free for air circulation.

For all other questions regarding installation and operation of the BLUEDENT 12 BL, contact the manufacturer or your local dealer.

XIII. WARRANTY

1. The warranty period of the BLUEDENT 12 BL bleaching activation device is 24 (twenty-four) months from the date of purchase. If the purchase date is not filled in, the warranty begins on the date of production.

2. During the warranty period, the replacement of the defective elements is carried out free of charge by the manufacturer. Note - LED modules have a 6-month warranty.

3. The device and its components must only be used as intended by the manufacturer purpose outlined in this Operating instruction. Any other use will void the warranty and the manufacturer is not liable for any damages or damages caused by it.

4. If during the warranty period the device fails due to improper operation (mechanical, chemical, thermal, electrical), non-intended use, inappropriate storage etc.., warranty will be void and the repair cost will be at the expense of the user.

The device should not be used with damaged cables. If any such damages are noticed switch off the device and immediately take it to the service facility.

If liquids such as water and solvents, aggressive or flammable substances and their vapors, watering or wiping the device with them, insects or rodents enter the device, the device must be taken immediately to the service facility. Damages from the above will void the warranty.

No claims shall be accepted for damages arising from electrical shocks, thunderstorms, non-compliance with electrotechnical safety measures or insufficient protection of patients, staff, other people, animals, plants, and objects from light radiation.

The manufacturer does not owe any compensation for lost profits during the period when the device is damaged or malfunctioned, no matter what the reason.

Claims for damages and claims due to of non-compliance with the bleaching procedure are not accepted. Including but not limited to: shorter or longer time period use of the device with the bleaching material set by the gel manufacturer; unsatisfactory bleaching result; patient's harms from the bleaching material; overdosage; insufficient insulation

of patient's non-calcified soft tissue; improper protection of the patient and staff; inappropriate, expired, intended for another wavelength and/or with unsuitable concentration bleaching material.

The warranty is forfeited and no claims shall be accepted for damages as a result of incorrect or insufficient care and attention for protection during transport, unpacking, moving, handling and storage of the device.

In the event of disputes arising out of the application and interpretation of this Operating Instructions Manual, those will be settled by the courts in the city of Plovdiv, under the current Bulgarian legislation.

5. The warranty of the device will be forfeited if any repairs or modifications are done by unauthorized personnel outside of the manufacturer's service facilities and/or non-original spare parts are used.

6. The manufacturer recommends that customers should check whether the device parameters are within the permissible limits once a year. Technical condition tests and verifications may only be carried out at the manufacturer's service facilities or by an authorized representative.

7. Sending for repair to the company service must be done in the original packaging of the product.

8. All repairs must be done at the manufacturer's service facilities with the following address:

BG LIGHT LTD
155, Vasil Aprilov blvd., 4027 Plovdiv, BULGARIA
tel.: +359 32 644089, +359 32 641913
www.bglight.com
office@bglight.com

XIV. SERVICE DATA

XV. DECLARATION OF CONFORMITY

BG LIGHT LTD **TECHNICAL FILE** **BLUEDENT 12 BL** **LED bleaching activation unit**	**EU Declaration of conformity** *Developed in conformity with MDR (EU) 2017/745*	**TD 7.2** *Revision* ***02*** *Page* ***26*** *of* ***28***

Manufacturer: **BG LIGHT LTD**
SRN: BG-MF-000019812
Address: 155, Vasil Aprilov blvd., 4027 Plovdiv, Bulgaria
Tel.: +359 32 644089, +359 888 809256, email: office@bglight.com
BULSTAT UIC 115841960, VAT N: BG115841960

CE

Product:	Product code:	Name:
Dental LED bleaching activation unit	**600-001bt**	**BLUEDENT 12 BL – built-in telescopic**

Basic UDI: 3800501374600000XK
EMDN code: Q0190

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

Intended purpose: BLUEDENT 12 BL is designed to bleach the solid tooth tissue by photoactivation (irradiation of blue light 430-490 nm) of dental bleaching gel. BLUEDENT 12 BL is accessory for a medical device as described in article 2, p.(2) as it performs its intended purpose together with dental bleaching gel.

The manufacturer declares under its own responsibility that the specified medical device complies with the applicable GENERAL SAFETY AND PERFORMANCE REQUIREMENTS, defined in Annex I of the normative act described below and normative technical documents, when 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 - certificates No: AC090 100/1971/4047/2020, AC090 MD/1971/4047/2020 from TUV NORD Polska Sp. z o.o. (NB 2274).

BG LIGHT 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
01.01.2023

Dipl. Eng. Plamen Karaivanov
Manager
BG LIGHT LTD

XVI. LED BLEACHING ACTIVATION UNIT DATA

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

Last revision: 01.01.2023

Please follow www.bglight.com to download the latest updated revision of this Operating instructions manual.