1. IDENTIFICATION OF THE DEVICE AND OF THE COMPANY MANUFACTURER

1.1 Product identification

Ref.N: 600-001BLANCONE ARCUS+

Name: BLANCONE ARCUS+ – LED bleaching activation unit

Intended use: LED bleaching activation device BLANCONE ARCUS+ is designed for photoactivation of bleaching gel based on hydrogen or carbamide peroxide, intended for light activation, used in dental practice (concentrations of H2O2 or their equivalent: 0.1 – 6% (cosmetic bleaching) or above 6% (medical bleaching). It is mandatory accessory device to fulfill the intended use of light activated bleaching gels.

1.2 Manufacturer data

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2. 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.

BLANCONE ARCUS+ 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

BLANCONE ARCUS+ 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 random people nearby.
As such, use protection goggles for the operator, and for the patient goggles, cheek retractor and lip protection (apply vaseline on lips for better comfort) in conjunction with face protection paper. 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 of EN 166 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.

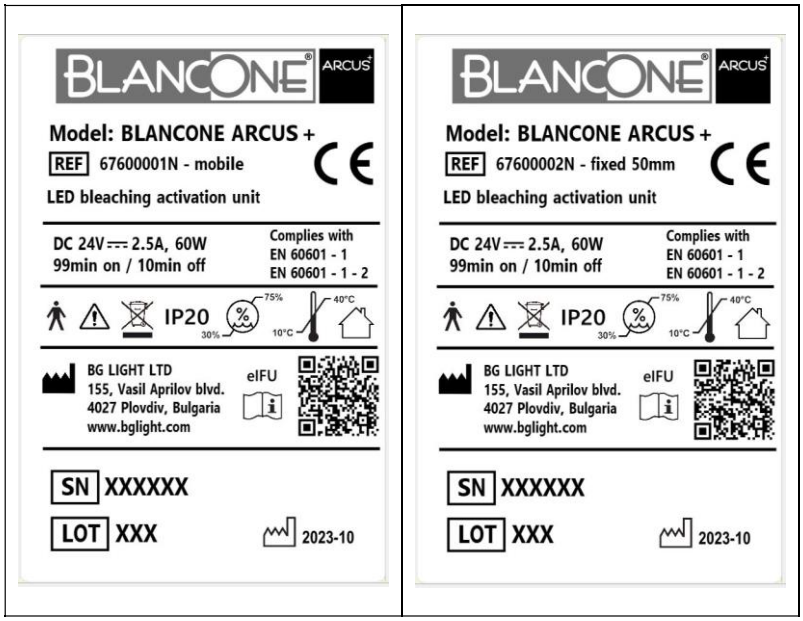
Risk of mechanical damage to the operator and the patient.

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.

3. DEVICE LABEL



4. FIRST-AID MEASURES

4.1 Description of first aid measures

General instructions: No special measures are necessary

4.2 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.

5. FIRE-FIGHTING MEASURES

5.1 Fire extinguishers

Suitable extinguishing media: Alignment of fire extinguishing measures with the environment.

5.2 Advice for firefighters

Special protective equipment: No special measures are required.

6. HANDLING AND STORAGE

6.1 Precautions for safe work

With due observance of the requirements in point VII. PREPARATION FOR OPERATION of the Operations Manual, no special measures are necessary.

6.2 Conditions for safe storage

BLANCONE ARCUS+ 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!

. Requirements: No special measures are required.

7. PERSONAL PROTECTION

During work with device: use protection goggles for the operator, and for the patient goggles, cheek retractor and lip protection (apply vaseline on lips for better comfort) in conjunction with face protection paper.

The special safety goggles from the set that meet the requirements of EN 166 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.

8. ECOLOGICAL INFORMATION

-  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!

9. REGULATORY INFORMATION

BG LIGHT LTD TECHNICAL FILE LED bleaching activation unit	**EU Declaration of conformity**	**TD 5.3** *Revision* ***03***

Manufacturer: **BG LIGHT LTD**

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CE

Product:	Product code:	Name:
Dental LED bleaching activation unit	**600-001BLANCONE ARCUS+**	**BLANCONE ARCUS+**

Intended purpose: BLANCONE ARCUS+ is designed for photoactivation (irradiation of blue light 430-490 nm) of bleaching gel based on hydrogen or carbamide peroxide (concentrations of H_2O_2 or their equivalent: 0.1 – 6% (cosmetic bleaching), intended for light activation, used in dental practice.

The manufacturer declares under his own responsibility that the described product complies with the essential requirements of the following normative acts and regulatory technical documents when used for its intended purpose and in accordance with the safety instructions:

Document	Title	Edition / date of issue
Directive 2014/35/EC	***Electrical equipment designed for use within certain voltage limits***	*26.02.2014*
Directive 2014/30/EC	***Electromagnetic compatibility (EMC)***	*26.02.2014*
Directive 2011/65/EU	***Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)***	*08.06.2011*

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

Harmonized standard	Title	Edition / date of issue
EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. IEC 60601-1:2005/ IEC 60601-1:2005/A1:2012	2006+ A1:2013;A12:2014 ;A2:2022
EN 60601-1-2	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. IEC 60601-1-2:2007	2015+ A1:2021
EN 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability. IEC 60601-1-6:2010	2010+ A1:2015; A2:2021
EN IEC 63000	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances (IEC 63000:2016)	2019
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	2016+ AC:2018; A11:2022
EN ISO 14971	Medical devices – Application of risk management to medical devices. (ISO 14971:2019)	2019+ A11:2022

The products described above comply with the essential requirements specified in Directives 2014/35/EU, 2014/30/EU and 2011/65/EU.

The declaration of conformity is issued in fulfillment of the requirements for the declaration of conformity, according to the relevant annexes of the implemented directives, based on test results - protocols No. 22.0016/02.024 - 21.12.2022 and 2EMC-23-041 / 31.03.2023, the assessed conformity and the maintained Internal production control system - Quality management system - Module A - ISO 9001:2015 certificate – No AC090 100/1971/4047/2020, ISO 13485:2016 – No AC090 MD/1971/4047/2020.

BG LIGHT LTD maintains a Technical File according to the requirements of the described directives.

01.09.2023
Plovdiv, Bulgaria

Dipl. Eng. Plamen Karaivanov
Manager
BG LIGHT LTD