



BLANCONE

ARCUS

LED BLEACHING SYSTEM UNIT

rev. 0 (08/08/2016)



ATTENTION!

*Before installation and starting work with the unit, carefully read this guide!
This unit is intended for use only by dentist in the dental office*

INDICE:

- I. UNIT DESCRIPTION AND FUNCTION
- II. TECHNICAL DATA
- III. ACCESSORIES AND SPARES
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- V. PREPARATION AND SEQUENCE OF OPERATION
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I. UNIT DESCRIPTION AND FUNCTION

ARCUS BLANCONE BLEACHING SYSTEM is intended to whiten the hard dental tissue by activating bleaching gel used in dental practice.

The device consists of Bleaching head and Stand.

ARCUS BLANCONE BLEACHING SYSTEM is produced in conformity with MDD 93/42 CEE .



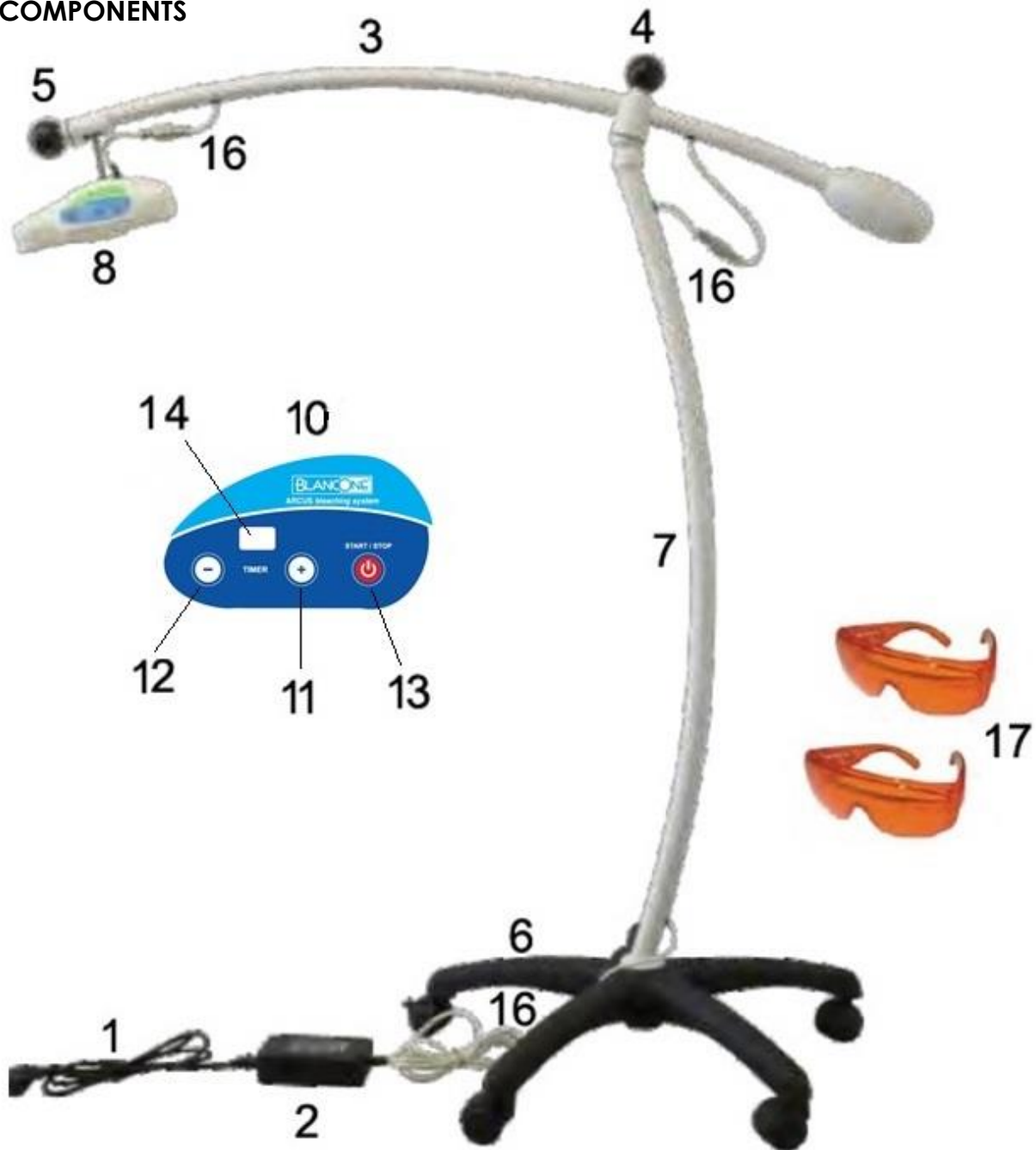
II. TECHNICAL DATA

1. Operating Voltage – 100-240V / 50-60Hz (see unit label)
2. Power consumption – 0,4-0,2 A
3. Dimensions:
 - Bleaching head
length – 220 mm
width – 155 mm
height – 95 mm
 - stand
length (in assembled state) – 1300 mm
4. Weight:
 - Bleaching head – 1200 g
 - Stand – 8500 g
5. Light intensity over 600 mW/s.q.cm. at 1 distance from polycarbonate
6. Emitting time: 10 sec.-99 min. ($\pm 5\%$)
7. Emitting light – blue, 430-490 nm
8. Light source – 10 LED modules
9. Microfan cooling
10. Audible signal every 1 min.
12. Possibility for start and stop of Bleaching head at any moment
13. Working mode (99 min. / 10 min.)

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



III. COMPONENTS



- 1. power cable
- 2. adapter 100-240VCA/24VCC
- 3. horizontal arm
- 4. central fixator
- 5. front fixator
- 6. 5 wheel lower carrier
- 7. vertical support
- 8. light emitting unit
- 9. counterweight

- 10. front panel
- 11. "+" timer button or "pause"
- 12. "-" timer button or "pause"
- 13. Start/Stop button
- 14. timer display
- 15. emitting part
- 16. cables and connectors
- 17. protection goggles

IV. SAFETY PRECAUTIONS

As with all technical devices, the proper function and safe operation of this unit depend on the user's compliance with the standard safety procedures as well as the specific safety recommendations described in this Operations guide.

1. The unit must be used in strict accordance with the operations guide. The manufacturer accepts no liability for any damage resulting from the use of this unit for any other purposes.

2. Before start-up of the unit make sure that the operating voltage indicated on the unit label corresponds to the mains voltage. Operation of the unit at the different voltage may damage the unit.

Electrical safety is ensured by Protection class against electrical current damages according to EN 60601-1-1990+A1:1993+A2:1995+A13:1996. The devices must be plugged in standard electrical network, power voltage 100-240VCA/50-60Hz.

Mains outlet where the device is plugged in must be grounded "SHUKO" type.

ARCUS BLEACHING SYSTEM should be operated in indoor premises in the following conditions:

- temperature: + 10° – +40°C;
- atm, pressure: 700 – 1060 hPa;
- relative humidity: 30 – 75%.

The device must not contact liquids, such as water and solvents, aggressive or flammable substances and their vapors, also pouring or wiping the device with the same.

- Absence of chemically active or flammable substances

3. ARCUS BLEACHING SYSTEM is a source of exceptionally intensive light in blue-green range, to which human eye is high sensitive. That is why serious measures must be taken towards patients, medical personnel and nearby people, animals and plants. As measures can be used: protection goggles for operator and goggles, mask and high factor sun protection cream for patient.

Irradiation of the eyes bears certain risk for their damage. Therefore the light must not be directed toward the eyes! Exposure must be restricted to the working area.



*ATTENTION! The emitted light is in the wavelength range 430-490 nanometers
During work use protection goggles and/or protection shield!*

4. The unit must not be applied to pregnant women and suckling mothers, patients aged under 17. The unit can be used only doctor's advice by or in persons with heart pacemakers implant; persons with photobiological reactions; persons currently taking photosensitive medication; persons with cataract surgery; persons with retinal diseases, etc.

5. Solvent, flammable liquids and powerful heat sources must not be kept near the unit as exposure to one of these factors may damage the plastic parts of the unit.


6. Cleaning agents should not enter the unit as this may feel pain, hypersensitivity, enamel damage, soft tissues burning.

7. Device's cables must be kept safe from treading and isolation damage, breaking by sharp object, heavy pulling, rodent, chemicals. If any damages are noticed, it is necessary that the device is taken to manufacturer's service. The device must not be heavily twisted to avoid mechanical blows with counterweight or bleaching head. In cases of mechanical blow, if bleaching head is damaged, the device must not be used. It must be brought immediately to manufacturer's service. Before moving the arm in vertical direction or change position of bleaching head, it is necessary that sphere fixators are released first unscrewing. Fixing is done by the reverse screwing. Moving the above mentioned parts without unscrewing the sphere fixators can damage their mechanism. Before moving the bleaching unit, make sure that wheel stoppers are released.

8. Only factory-authorized it open and repair the unit.

9. Only original ARCUS BLEACHING SYSTEM spare parts should be used to replace defective parts. The unit warranty does not cover any damage resulting from the use on non-original replacement parts. The unit or any of its parts should not be disassembled while it is connected to the mains!

10. Before the patient the polycarbonate window should disinfected (by disinfecting agent)

11.  **FRAGILE!** Be extremely careful during transportation, storage and handling of the unit! During transportation in assembled state, two persons should accompany the unit, supporting the movable parts.

If there are any unevenness on the floor the device in assembled state on slope floorings.

Measures must be taken against injuries on the human body parts (movable or still), pinching, inertia speeding of counterweight. Each manipulation with device must be done carefully to avoid damage on human limbs.

12. Before the patient undergoes teeth bleaching he/she must sign informed consent, in which all side effects of the process must be fully described.

Note: We recommend that the dentist takes a suitable course on the subject: "Techniques of In-office teeth bleaching"!



13. Pursuant to Directive CE/2002/96, this symbols shows that the product must not be disposed of as urban waste at the end of its operating life. The product must be taken to centers specialized in separate collection of electrical and electronic equipment. Correct disposal of the equipment, which is no longer used, prevents negative consequences for the environment and human health!

V. PREPARATION AND SEQUENCE OF OPERATION

ARCUS BLEACHING SYSTEM UNIT is designed for use as a free-standing unit. The unit must be used only in premises with horizontal flooring. ARCUS BLEACHING SYSTEM UNIT has the following principle of action: 12 pcs. Hi-tech single LED modules, emitting blue cold light in 430-490 nm spectrum, are used as light source.

ASSEMBLING/INSTALLATION

1. *Unpack the transport box, take out the component parts and first mount the lower carrier with the 5 wheels*

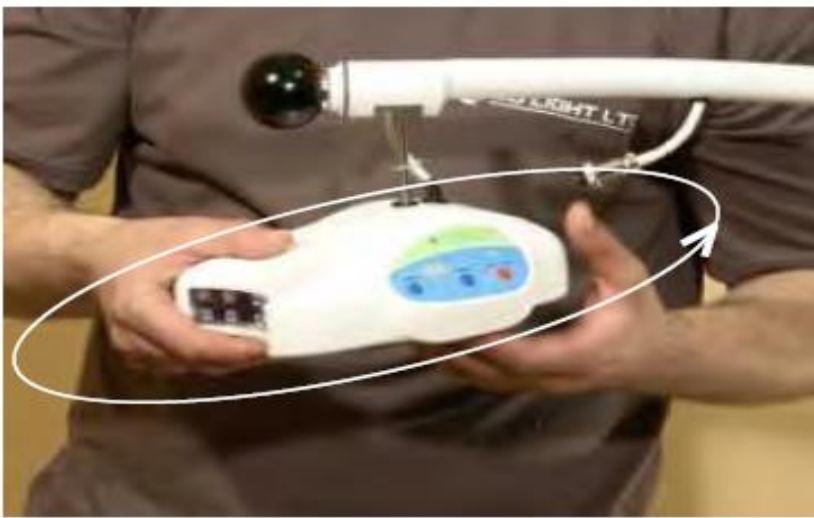
2. *Assemble the vertical support to the center of the lower carrier*

3. *Mount the horizontal arm of the stand and fix with side stopping screw, using the inbus key enclosed.*



4. Mount the counterweight at the bottom part of the horizontal arm

5. Mount the bleaching head at the front part of horizontal arm – screw around the stick with normal effort until tightened. It is desirable to fix the position of the stick by tightening/screwing the front fixator.



For units without front fixator (ball) position of the stick must be fixed using the same imbus key. Unwind the cover cap – tighten as needed and wind the cap back.



6. With help of the two fixators fix
The horizontal arm in a suitable
position



7. Connect the cables by the power jacks



8. Examine all moving parts for omissions

9. The mains plug of the power cable is
switched into the adapter

10. The power cable is switched into mains
outlet "SHUKO" type.



PREPARATION BEFORE START OF WORK

1. Take LED bleaching unit ARCUS BLEACHING SYSTEM out of the packing and assemble it by following the above steps. Place the unit on a horizontal surface.

2. Connect the power adapter to the mains outlet

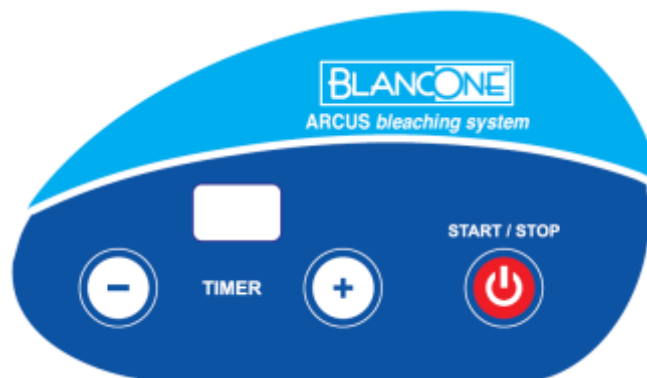
3. Before starting to work with bleaching unit ARCUS BLEACHING SYSTEM soft dental tissues must be isolated, patient's face must be covered by protection napkin, protection goggles must be put on patient's face and bleaching gel has to be applied on teeth surface, according to the respective bleaching gel manufacturer's instructions.

4. Timer is set by pressing buttons **TIMER +** (increase of time) e **TIMER -** (decrease of time), as:

- from 10 sec. to 10 min. timer has 10-sec. step adjustment (example: 2,3 = 2 min. 30 sec.)

- from 10 sec. to 99 min. timer has 1-min. step adjustment (example: 13 min.)

After desired time is chosen (written on the display), **START/STOP** button shall be pressed and the device is started.



5. If during work any of the buttons **TIMER +** / **TIMER -**, is pressed, the device is paused. Work is resumed by repeated pressing of **TIMER +** / **TIMER -** button.

Final stopping of bleaching unit can be done at any time by pressing of **START/STOP**. If **START/STOP** is not pressed again, the device will stop after expiring of chosen time.

6. Switching off of bleaching unit in the end of the day shall be done by unplugging of mains plug from the wall socket.

Overheating

The unit is equipped with overheating protection, which is activated if the temperature of the Bleaching handpiece rises up to 65°-70°C

When overheating protection is activated, audible signal is heard, indicator displays "On" and microcooling fan works continuously for 1 min. After cooling work can be resumed.

ARCUS BLEACHING SYSTEM Unit has built-in micro fan cooling and overheating protection should be activated only in emergency situations if the fan stops working, if the vents of the fan become obstructed, etc.

VI. ROUTINE CARE AND MAINTENANCE

1. Cleaning of polycarbonate window on bleaching head

For each patient the polycarbonate window must be disinfected by cotton soaked in alcohol solution.

2. Cleaning of the unit

For disinfection of the unit, spray the disinfection agent onto a piece of soft cloth / cotton and clean the handpiece and power adapter. Do not use abrasives or solvents as these may damage the plastic parts of the unit!

3. Troubleshooting

If, after connecting the unit to the mains, display is not lit and/or the Led indicator on the adapter does not flash, the reason might be lack of electricity – in this case check if the mains plug is correctly plugged in the mains socket and if the connectors are fixed together correctly. If, after your check, the device does not work properly, please contact the company service!

OPERATING PROTOCOL (BLEACHING CYCLES)

Before proceeding to bleaching, read user instruction within the BlancOne kit packaging or in professional area on www.blancone.eu web site.

ACTIVATION THROUGH BLANCONE ARCUS

Use the BlancOne ARCUS arc light to activate gel on both arches simultaneously. Position the head of the light 5-10 cm from the teeth and activate according the BlancOne treatment selected (see below Table).

Treatment	Applications (min-max)	Minimum Time	Maximum Time
BlancOne CLICK	1	10'	15'
BlancOne TOUCH	4-5	5'	8'
BlancOne ULTRA	4-6	2'	3'

When used according to BlancOne protocols, the ARCUS whitening lamp is safe for teeth and gums. Protect the lips with Oralsan NBF emulsion or lip balm. The lamp generates heat on the skin similar to a tanning lamp. If the patient feels a little bother, especially if room temperature is high, move the lamp slightly away from the mouth.

VII. WARRANTY CONDITIONS

1. Warranty period of the ARCUS LED BLEACHING SYSTEM, is 24 (twenty four) months from the date of purchase. If date of purchase is not written, warranty starts at date of production
2. During the warranty period the replacement of defective parts (LED MODULES – 6 months warranty) is done free of charge by manufacturer's service.
3. The device and its component parts must be used only according to use provided by the manufacturer. In any other use warranty invalid and manufacturer is not responsible for caused harms and damages. / The devices should not be used for any other purpose such as: lighting, furniture, means for moving people, animals or object.

4. If, during the warranty period, the lamp is damaged (mechanical, chemical, thermal or electric) due to incorrect operation, the repair of such damage caused by incorrect use and storage or any other reason attributable to the user, will be borne by the latter.

5. This warranty becomes null and void if any repair to or servicing of the product is performed by any unauthorized party or if other than original ARCUS LED BLEACHING SYSTEM spare parts are used therefore. If any damage is noticed on electric cables, the device must be brought immediately to manufacturer's service. The device must not be used if cables are damaged.

If liquids, such as water and solvent, aggressive or flammable substances and their vapors, also pouring or wiping the device with the same, insect or rodents have entered the device, it must be brought immediately to manufacturer's service. In such cases warranty is lost. Damages and claims are not accepted due to electric shocks, thunder storms, non-following of measures for electric safety or insufficient protection of patients, personnel or other persons toward light irradiation.

The manufacturer does not owe compensation for lost benefits in cases of defects or imperfect functioning of the device regardless of the cause. The manufacturer does not accept damages and claims due to non-observance with teeth bleaching procedure shorter or longer irradiation time than prescribed by bleaching materials manufacturer, insufficient effect or patient harm by bleaching procedure shorter or longer irradiation time than prescribed by bleaching material manufacturer, insufficient effect or patient harm by bleaching materials, overdose and insufficient isolation, incorrect patient and personnel protection. Also damages caused by improper bleaching material with expired term of use, suitable for another wavelength or with unsuitable concentration.

No claims and damages are accepted due to incorrect security and attention for protection during and attention for protection during transportation, unpacking, moving, work and preservation of device. Warranty becomes null and void if any of the above mentioned happens. If a dispute arises on the application and interpretation of this Operations guide, it shall be the court of jurisdiction.

6. The manufacturer recommends that the users check once a year (or if there is an incident-immediately) in the manufacturer's service if the parameters: output light intensity and heat radiation of their units are in the admissible range. This check-up is done free of charge in the manufacturer's service.

7. The warranty servicing is performed at the manufacturer's service at the following address:

IDS S.p.A.

Via Valletta San Cristoforo 28/10
17100 Savona SV - ITALY
Tel 019 862080 - Fax 019 2304865
www.ids dental.it - info@ids dental.it

VIII. BLANCONE ARCUS BLEACHING SYSTEM DATA

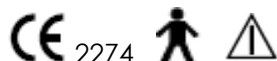
SERIES NUMBER:

LOT:

DATE OF PRODUCTION:

PACKER:

DATE OF PURCHASE:

**IX. SIMBOLS**

Manufacturer

BG LIGHT LTD, 155, Vasil Aprilov Bul., 4027 Plovdiv, Bulgaria



Pursuant to Directive CE/2002/96, this symbols shows that the product must not be disposed of as urban waste at the end of its operating life.



Pay attention to the instructions accompanied by this symbol.



Fragile !



Product with CE mark



Applied part type B

Ω	Ohm (electric resistance unit)
s	Second (time unit)
W	Watt (unita di alimentazione)
Hz	Hertz (frequency unit)
mm	Millimeter (lenght unit)
A	Amper (electric current unit)
V	Volt (electric voltage unit)
Pa	Pascal (atmosphere pressure unit)
°C	Degrees Centigrade (temperature unit)
g	Gram (weight unit)
SN	Serial number
LOT	Lot

DECLARATION OF CONFORMITYDirective Agreement with
93/42/CEEManufacturer: **BG LIGHT LTD**Address: 155, Vasil Aprilov Blvd., 4027 Plovdiv, Bulgaria
Tel.: +359 32 644089, Fax: +359 32 641913
BULSTAT 115841960, Tax N: 1165887138Product: **BLUEMENT 12 BL- bleaching unit**
Classification: Active device in Class IIa of the Medical Device Directive 93/42/EEC+AC:2007

Classification is done by the manufacturer according to Medical Device Directive 93/42/EEC+AC:2007, Rule 9, Annex IX.



Notified body: TUV NORD Polska Sp. z o.o., ul.Mickiewicza 29, 40-085 Katowice, Poland.

This Declaration of conformity is valid only in combination with our certificates of Notified body TUV NORD Polska Sp. z o.o..

The manufacturer declares under its sole responsibility that the products are developed and produced in conformity with MDD 93/42/EEC+AC:2007 and the following applicable standards:

- EN 60601-1 Electrical safety,
- EN 60601-1-2 Electromagnetic compatibility
- EN 62304 Medical device software. Software life cycle processes.
- EN 62353 Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment
- EN 62366 Medical devices. Application of usability engineering to medical devices.
- EN ISO 14155-1 Clinical investigation of medical devices for human subjects. General requirements.
- EN ISO 14155-2 Clinical investigation of medical devices for human subjects. Clinical investigation plans.
- EN ISO 14971 Medical devices – Application of risk management to medical devices
- EN ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EN 1041 Information supplied by the manufacturer with medical devices
- EN ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Dipl. Eng. Plamen Karaivanov
Manager
BG LIGHT LTD20.03.2014
Plovdiv, Bulgaria

Изготвил: 	20.03.2014 г.	Утвърдил: 
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