



BLANCONE

ARCUS

BLEACHING SYSTEM

(build-in version for 24VAC)

rev. 0 (15/07/2016)

**ATTENTION!**

Before installation and starting work with the unit, carefully read this guide!

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I. UNIT DESCRIPTION AND FUNCTION

LED bleaching unit BlancOne is intended to whiten the hard dental tissue by activating bleaching gel used in dental practice.

The device consists of Bleaching head, Stand and Fixing bracket.

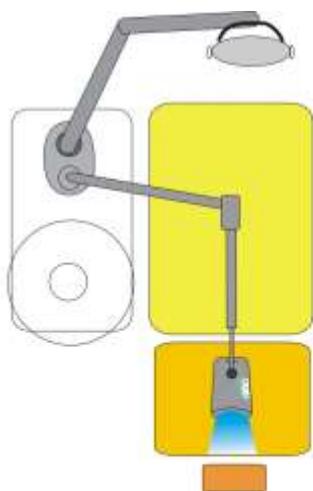
II. TECHNICAL DATA

1. Operating voltage - 24VAC / 50-60Hz ($\pm 10\%$) (see label) - it uses 24VAC from dental unit's power supply
2. Power consumption - 1,2A (during bleaching mode) - 0,1 A (during stand-by mode)
3. Dimensions:
 - Bleaching head
 - length - 220 mm
 - width - 155 mm
 - height - 95 mm
 - Stand
 - length (in assembled state) - min 52 cm / max 80 cm (with extended telescopic arm),
 - height - 26cm,
 - fixing bracket - up to 50 mm diameter
4. Weight - 2640 g total weight of device:
 - Bleaching head - 640 g
 - Stand - 2000 g
5. Light intensity over 200 mW/sq.cm. at 1 cm distance from polycarbonate window
6. Emitting time - 10 sec.- 99 min. / $\pm 5\%$ /
7. Emitted light - blue, 430 - 490 nm

8. Light source - 10 LED modules x 5W = 50W
9. Cooling fan
10. Possibility for start and stop of Bleaching head at any moment.
11. Working mode (99 min. Work / 10 min. stand-by)

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.

POSSIBLE LAMP POSITIONING WITHIN DENTAL UNIT

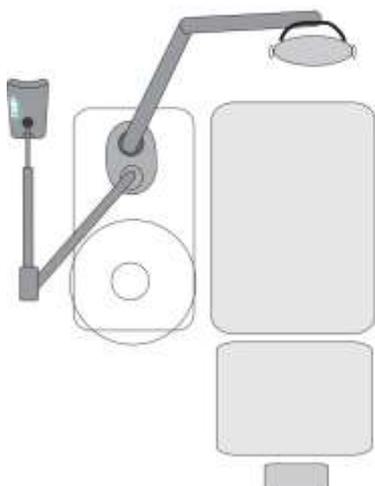


BLEACHING



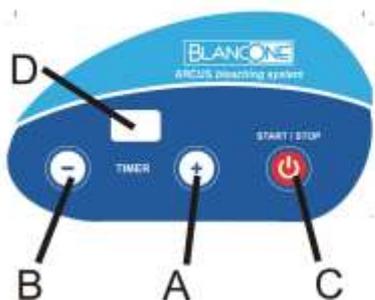
STAND-BY

STAND-BY

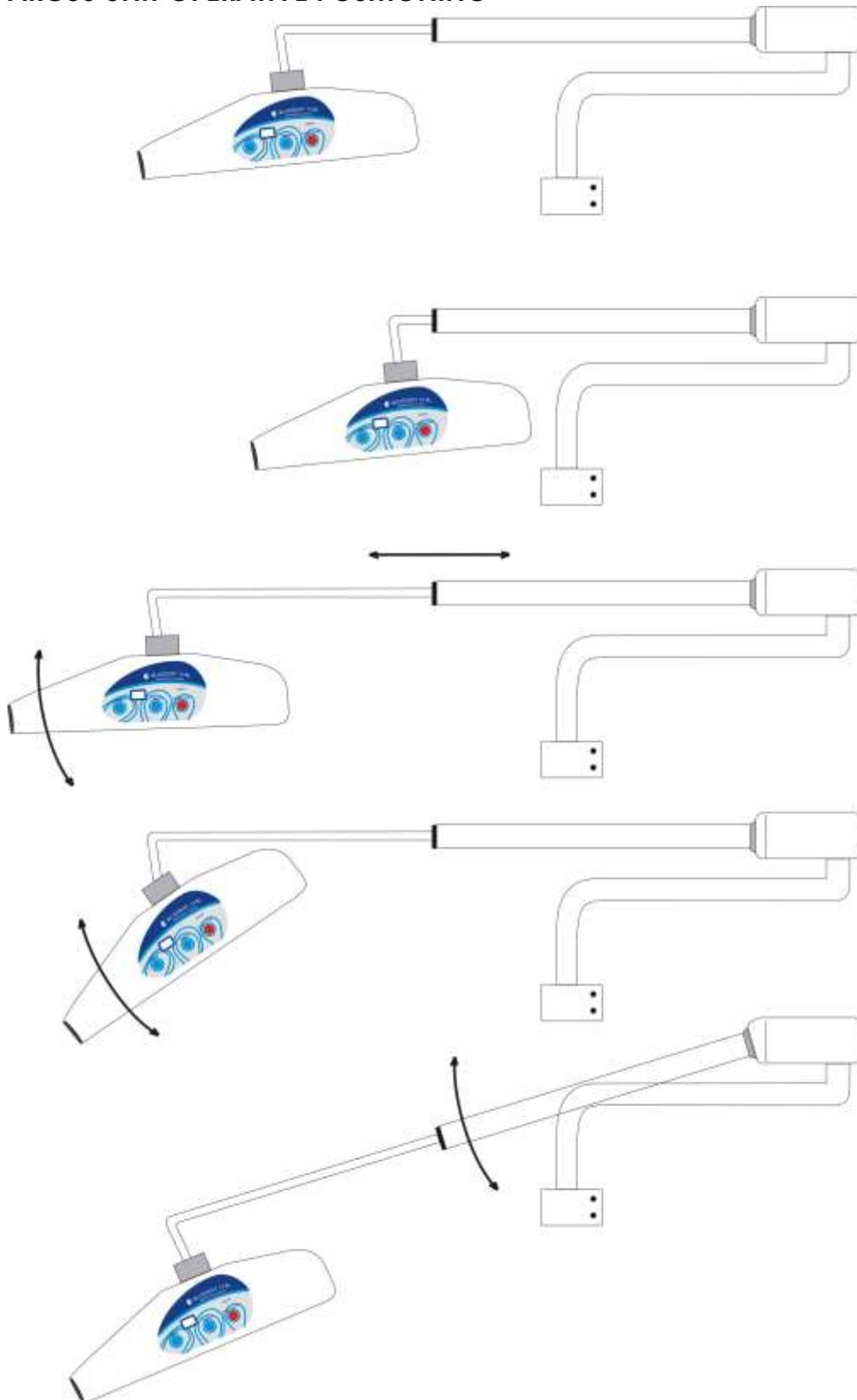


III. COMPONENTS

1. power cable to 24VAC
2. straight arm
3. telescopic arm.
4. central fixator
5. angle arm
6. fixing bracket
7. positioning assembly
8. light emitting unit
9. vertical pipe of dental unit
10. front panel
- A. "+" timer button or "Pause"
- B. "-" timer button or "Pause"
- C. Start/Stop button
- D. timer display
11. cable holder
12. cables and connectors
13. protection goggles



ARCUS UNIT OPERATIVE POSITIONING



IV. SAFETY PRECAUTIONS

As with all technical devices, the proper function and safe operation of this unit depends on user's compliance with the standard safety procedures as well as 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 supplied voltage. Operation of the unit at a different voltage may damage the unit.

Electrical safety is ensured by Protection class I against electrical current damages according to EN 60601-1.

The device must be connected to 24VAC in dental unit,

BlancOne should be operated in indoor premises in the following conditions:

- temperature +10° - +40° C;
- relative air humidity - 30 - 75%; The device must not be used in premises with high air humidity, condense or water on floor, walls or ceiling. 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.
- atm. pressure 700 - 1060 hPa;
- absence of chemically active or flammable substances.

3. BlancOne 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 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!

Protection goggles are required to:

- cover tightly eye and temple even if the person wears optical glasses
- be made of impact-resistant plastic colored volume
- transmit light in wavelength above 600 nm
- reduce light intensity of blue spectrum over 100 times
- have stable mechanical construction, no scratches and damages to the surface.

4. The unit must not be applied to pregnant women and suckling mothers, patients with oncologic diseases, severe parodontal pathology, recessions, dental hyperesthesia and 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. Solvents, 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 cause malfunction of device.

7. Device's cables must be kept safe from isolation damage, breaking by sharp objects, 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 used if cables are damaged.

In case of mechanical hit of the device, if bleaching head is damaged, device should no longer be used.

Bleaching unit must be taken immediately to manufacturer's service for inspection.

8. Only the manufacturer or manufacturer-authorized companies are entitled to open and repair the device.

9. Only original BlancOne 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 electricity

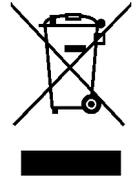
10. Before each patient the PVC window should disinfected (by disinfecting agent sprayed on soft cloth to prevent surface scratching).

11.  **FRAGILE!** Be extremely careful during transportation, storage and handling of the unit!

12. Before the patient is subjected to tooth whitening, must sign the informed consent, where they will be described in detail all the side effects of treatment.

Please note: we recommend the dentist to take a course on the subject: "dental whitening in office techniques"!

13. In accordance with Directive 2002/96/EC, this symbol shows that the product must not be disposed of as solid urban waste at the end of its working life, but we must take it in specialized centers for recycling of electrical and electronic equipment. Proper disposal of the equipment no longer used avoids negative consequences to the environment and human health!!



V. PREPARATION AND SEQUENCE OF OPERATION

BlancOne is designed for use as a build in bleaching unit. The unit must be fixed to vertical pipe of dental unit, to lighting / operation light of the unit

ASSEMBLING / INSTALLATION

1. Unpack the transport box, take out the component parts and first mount the fixing bracket to dental unit - vertical pipe - it necessary that bracket diameter matches vertical pipe diameter (for tightening, put the provided soft PVC strips inside the bracket). Screw the 2 screws using 4 mm hex key.

2. Tighten the securing screw (to prevent up/down movement of arm) using 3 mm hex key.

3. Run cable and coupling through the small hole of fixing bracket and mount the angle arm.



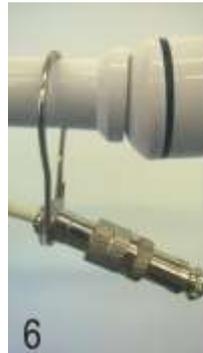
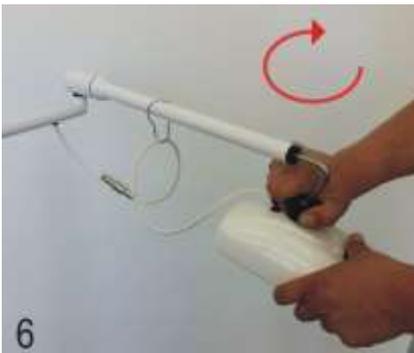
4. Mount the straight arm and cable holder. Tighten the securing screw with 3 mm hex key. Straight arm can be moved up and down for better positioning of bleaching head to patient.

5. If you need to regulate the effort of balancing the bleaching head, on straight arm must be tightened the security screw using 5 mm hex key



6. Mounting of bleaching head - by rotating of positioning assembly.
Connection of cables by couplings. Put the soft transparent PVC ring at the end of coupling to secure the cable holder in it.

7. By moving the telescopic arm can be adjusted suitable position of bleaching unit to patient.
Different positions of arms (extended and folded position)
The device is ready for use.



8. Attention! The unit should be placed at least 1 meter away from any heat source.

After the final preparation of patient, the head is fine adjusted so that a minimum distance 1-3 cm is left between patient and bleaching head.

9. Press the **START/STOP** button to enter in standby mode

10. Before starting to work with bleaching unit BlancOne soft dental tissues must be isolated, 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.



11. Timer is set by pressing buttons **TIMER+** (increase of time) è **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 min. to 99 min. timer has 1-min. step adjustment (example: 13 min.)

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

13. 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** button. If **START/STOP** button is not pressed again, the device will stop after expiring of chosen time.

14. Switching off of bleaching unit in the end of the day shall be done by pressing for 3 sec **START/STOP** button or by turning off power of dental unit.

OVERHEATING PROTECTION

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 the unit is deactivated, audible signal is heard, indicator displays "Oh" and cooling fan works continuously for 1 min.

After cooling work can be resumed.

BlancOne has built-in cooling fan 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 PVC window on bleaching head**

For each patient the polycarbonate window must be disinfected by soft cloth soaked in alcohol / disinfecting 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 bleaching head. Do not use abrasives or solvents as these may damage the plastic parts of the unit!

OPERATIVE PROTOCOL (BLEACHING CYCLES)

Before proceeding to bleaching, consult the Protocol for use within BlancOne packaging or in the professional area of the site www.blancone.eu

GEL ACTIVATION BY 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.

WARRANTY TERMS

1. Warranty period of the BlancOne bleaching unit 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 the 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 is invalid and manufacturer is not responsible for caused harms and damages.
4. If during the guarantee period the unit is damaged, due to incorrect mounting and/or operation (mechanical, chemical, thermal or electrical damages), damage caused by improper use, storage or any other reasons in user's fault, the repair is paid by the user.

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 solvents, aggressive or flammable substances and their vapors, also pouring or wiping the device with the same, insects 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 outer persons towards 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 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 transportation, unpacking, moving, work and preservation of device. Warranty becomes null and void if any of the above mentioned happens.

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 BlancOne spare parts are used therefore.

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. SERVICE DATA

Accepting date	Service date	Service	Signature

IX. BlancOne DATA

SN:
LOT:
QC:

Date of production:
Date of purchase:



X. SYMBOLS

	Manufacturer BG LIGHT LTD, 9-B, Luben Karavelov Str., 4002 Plovdiv, Bulgaria
	Pursuant to Directive 2002/96/EC, this symbol 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.
	The device is equipped with double electric insulation (Class II)
Ω	Ohm (electric resistance unit)
s	Second (time unit)
W	Watt (power unit)
Hz	Hertz (frequency unit)
mm	Milimeter (length 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
QC	Quality control
	Consult Instructions for use!

DECLARATION OF CONFORMITYACCORDING 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: **BLUEDENT 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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