

# OPERATING INSTRUCTIONS MANUAL

## BLUEDENT SMART XPRESS

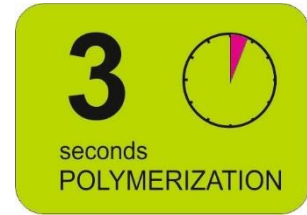
### ORTHO cordless

Dental LED curing light

Ref.#200-006ort



*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 SMART XPRESS ORTHO is an accessory to a medical device - specialized light source for intraoral polymerization of dental materials, sensitive to the blue part of the light spectrum.



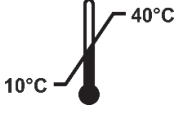
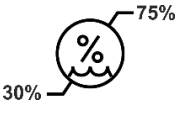



The device is intended for use only by a qualified dental practitioner and in a dental practice.

BLUEDENT SMART XPRESS ORTHO consists of Wireless handpiece with stand and Charging adapter.

BLUEDENT SMART XPRESS ORTO 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

	<p><b>Caution!</b></p> <p>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.</p>
	<p><b>Consult instructions for use</b></p> <p>Indicates the need for the user to consult the instructions for use.</p>
	<p><b>Dangerous voltage</b></p> <p>To indicate hazards arising dangerous voltage.</p>
	<p><b>Hazardous light emission</b></p> <p>To indicate hazards arising from light radiation.</p>
	<p><b>Hazardous thermal effects</b></p> <p>To indicate hazards arising from thermal effects.</p>
	<p><b>Manufacturer</b></p> <p>Indicates the medical device manufacturer.</p>
	<p><b>Date of manufacture</b></p> <p>Indicates the date when the medical device was manufactured</p>
	<p><b>Medical Device</b></p> <p>Indicates the item is a medical device</p>
	<p><b>Unique Device Identifier</b></p> <p>Indicates a carrier that contains Unique Device Identifier information</p>
	<p><b>Catalogue number</b></p> <p>Indicates the manufacturer's catalogue number so that the medical device can be identified.</p>
	<p><b>Serial number</b></p> <p>Indicates the manufacturer's serial number so that a specific medical device can be identified.</p>



	<p><b>Batch code</b></p> <p>Indicates the manufacturer's batch code so that the batch or lot can be identified.</p>
	<p><b>Applied part type B</b> according to electric safety classification</p>
	<p><b>Temperature limit</b></p> <p>Indicates the temperature limits to which the medical device can be safely exposed.</p>
	<p><b>Humidity limitation</b></p> <p>Indicates the range of humidity to which the medical device can be safely exposed.</p>
	<p><b>Waste Electrical and Electronic Equipment (WEEE)</b></p> <p>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.</p>
	<p><b>Fragile</b></p> <p>Indicates a medical device that can be broken or damaged if not handled carefully.</p>
	<p><b>European Conformity</b></p> <p>Indicates conformity with local laws and regulations within the European Economic Area</p>

### III. SAFETY PRECAUTIONS



#### **GENERAL WARNINGS:**

BLUEDENT 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 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!
-  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 use 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 SYS1381N-1209-W2E.

Electrical safety is ensured by class II protection against electric shock according to EN 60601-1.

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!

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 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.

Irradiation of the eyes and skin with intense light carries a risk of damage from light and heat.

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. Contraindications:**

- 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.



#### IV. TECHNICAL DATA

1. Operating voltage:

- Handpiece - 3.7V Li Ion battery type LIR 18650 (2600mAh capacity)
- Adapter – type SYS1381N-1209-W2E, 100-240V AC / 50-60Hz / 9V DC / 1.33A, power consumption - 0.5A max
- Charging station - 9VDC, power consumption - 0.8A max

2. Dimensions (approx.)

- Charging station – length 180mm, width – 130mm, height – 66mm
- Cordless handpiece - diameter - 32mm; length - 235mm

3. Weight (approx.):

- Charging station – 560g
- Cordless handpiece (with lightguide) – 260g

4. Polymerization modes – STANDARD (S), HYPER ORTHO (H), LONG (L)

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

Light intensity - up to 1500 mW/sq.cm (S, L modes), up to 3500 mW/sq.cm (H mode).

Intensity is constant and not dependent on battery charge level.

Light source – 2 band LED module with reflector optics.

6. Emitting time:

- |                              |   |                          |
|------------------------------|---|--------------------------|
| - 10 / 20 / 30 sec (modes S) | - 3 / 6 / 9 / 18 / 30 / 36 sec (mode H) | - 1-9 min (mode L) (±5%) |
|------------------------------|---|--------------------------|

7. Audible signal every 10 sec / 3 sec / 1 min according to the selected mode.

Possibility to turn on / off the sound signal.

8. Working ability after fully charged battery - up to 4000sec.

- up to 400 cycles x 10 sec    - up to 130 cycles x 30 sec    - up to 7 cycles x 9 min
- up to 200 cycles x 20 sec    - up to 66 cycles x 1 min

9. Charge time - 6 hours for full charge and 4 hours to 80% charge.

10. Indication for charging, end of charge and low battery warning.

11. Digital display for the selected mode and countdown timer.

12. Built-in 4-level indicator for checking the light intensity (optional).

13. Micro fan cooling.

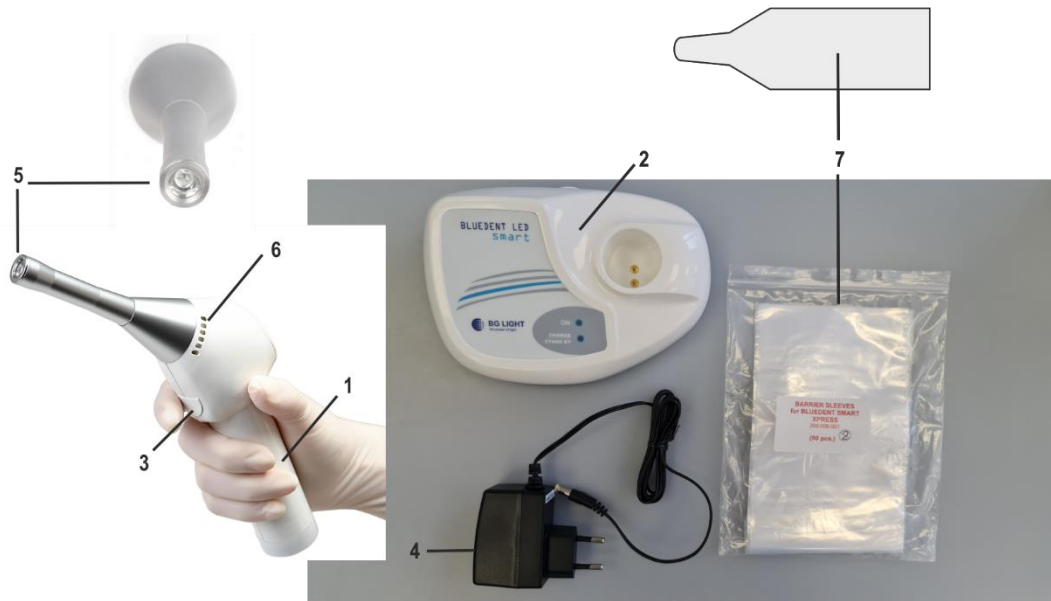
14. Working mode (1 min. work / 10 min. pause)

15. 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. Cordless handpiece – 1 pc.               | 5. Emitting head             |
| 2. Charging station - 1 pc.                 | 6. Cooling fan               |
| 3. Start / Stop button                      | 7. Barrier sleeves - 50 pcs. |
| 4. Charge adapter<br>9V DC / 1.33 A – 1 pc. | 8. Operations guide - 1 pc.  |



**VI. PREPARATION AND SEQUENCE OF OPERATION**

BLUEDENT SMART XPRESS ORTHO is designed for use as a wireless stand-alone device.

1. Remove the appliance from its packaging. The charging station is placed on a stable horizontal surface. The device is switched on in standby mode by pressing the Start / Stop button once.

2. Connect the adapter to the mains and the socket - to the charging station.



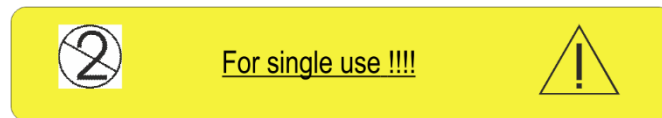
The ON indicator lights up on the charging station. When the cordless handpiece is inserted in the charging socket, the CHARGE indicator also lights up.



The radiating head does not rotate!  
Under no circumstances should an attempt be made to pull, rotate or apply physical force to it.



3. The barrier sleeve is disposable and is placed on the handle of the device before each patient. It is marked with the appropriate sign on the package.



After fully charging the device or at the end of the day, disconnect the charging adapter from the mains.

4. BLUEDENT SMART XPRESS has **3 work modes**, which guarantee fast polymerization and complete hardening of the photocomposite material. The selection of the mode is done by pressing the MODE button located below the left side of the display:

**S - STANDARD**

1500 mW

**H – HYPER ORTHO**

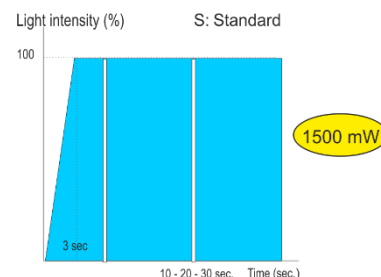
3500 mW

**L - LONG**

1500 mW

**S - STANDARD mode (10 - 20 - 30 sec)**

During the first 3 seconds, the light intensity slowly increases to avoid stress in the photocomposite.



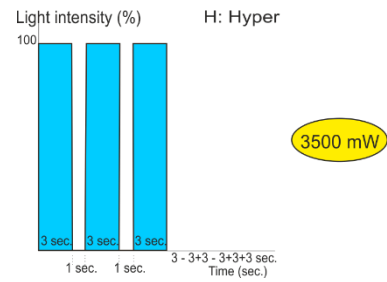
**H – HYPER ORTHO mode - (3 / 3+3 / 3+3+3 / 6 x 3 sec / 10 x 3 sec / 12 x 3 sec) with 1-sec pause between each 3-sec cycle**

The emitted light has the highest intensity to achieve very fast polymerization and complete hardening of the material.

It is suitable for working with nano and liquid composites.

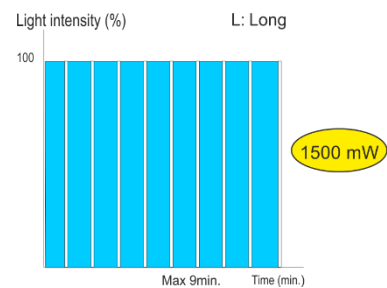
Light intensity - up to 3500 mW / sq.cm

The pause between every 3 seconds. does not allow to damage the dental tissues.



**L - LONG mode (1-9 min)**

The light intensity is at a maximum level of 100%, the mode is suitable for long procedures, e.g. teeth whitening.



- 1.Curing mode display
- 2.Timer display
- 3.Selection of curing mode
- 4.Selection of timer



(In this example, the display shows HYPER ORTHO mode with a timer time of 30 sec (3 x 10 sec)

The timer is selected by pressing the “TIMER” button. The horizontal light line on the right shows the selected time:  
 - S mode - 10, 20, 30 sec  
 - L mode – 1-9 min (display shows min)  
 - H mode – display displays with numbers 3, 6, 9 sec and with horizontal illuminated lines 18, 30, 36 sec.

In HYPER ORTHO mode, the timer is selected as follows:



5. The device is started by pressing Start / Stop probe button - see figure.

After starting, the timer starts counting down.

An audible signal is heard.



6. The handpiece is aimed at the place designated for irradiation, the emitting tip is brought as close as possible to the object of irradiation (4 - 7 mm) and after a few seconds when the surface layer has hardened enough, it can be irradiated contact.

7. After pressing the Start / Stop button again or after the selected time has elapsed, the device stops. If a next irradiation cycle is required, it can be restarted without waiting. During prolonged operation, it is possible that the fan cooling switches on.

8. In HYPER ORTHO mode, after each cycle 3/3 + 3 / ... sec, there is a pause of 5 sec, During which the display flashes and the device cannot be activated. This indication is designed to protect the patient from overheating of the dental pulp.

9. After the procedure, return the handpiece to the charging station.

10. The adapter is connected to the mains when the device needs to be charged. The dental curing light is switched off at the end of the day by disconnecting the charging adapter from the mains.

#### 11. "SLEEP" function

The wireless handpiece has a "sleep" function, which helps reduce energy consumption. The handpiece goes into sleep mode:

- when it is placed on the charging base and is fully charged;
- when it does not emit light and is not started for more than 30 sec. outside the charging base;

Pressing the Start / Stop button once wakes up the device. The display shows the last selected time and operating mode.

#### 12. Light intensity indicator (option)

The light intensity can be checked with the indicator built into the BLUEDENT SMART XPRESS ORTHO charging base. Carry the probe so that the light guide is centered in the sensor and start the device.

The number of illuminating points indicates the measured light intensity:

- 4 - 100%; - 3 - 80%; - 2 - 60%; - 1 - 40%;

The different modes must be:

H – HYPER ORTHO - 4 light points.

S- STANDARD - 2 light points.

L - LONG - 2 light points.



We recommend that the light intensity be measured in HYPER ORTHO mode. If the light intensity is below 80% (less than 3 LEDs are lit), it is necessary to check the emitting tip for stuck photographic material or mechanical defects.

### 13. "SOUND SIGNAL OFF" function

This function allows you to turn the sound of the device on and off. The MODE button is held for 5-6 seconds, the sound signal indication is heard and the sound ON / OFF setting is changed automatically:

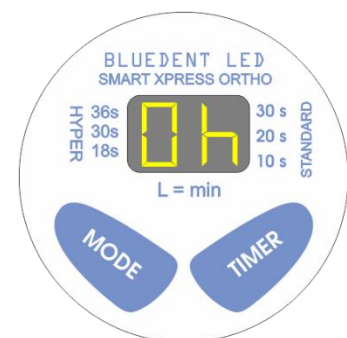
If the sound signal is ON, after holding down the MODE button, OFF is displayed and the sound is turned off.

If the sound signal is OFF, after holding down the MODE button, ON is displayed and the sound is turned on.

### 14. Thermal protection

It can be switched on during prolonged operation fan cooling.

In the event of an extreme temperature rise, the light will stop, the display will show "Oh" (Overheating), and the fan will continue to run until the unit cools down. It takes a few minutes.



## VII. ROUTINE CARE AND MAINTENANCE

### 1. Cleaning the emitting tip

Clean the emitter glass daily with an alcohol swab dipped in alcohol. Adhesive photocomposite is not allowed - if there is one, it should be carefully removed with a blunt, non-metallic object.

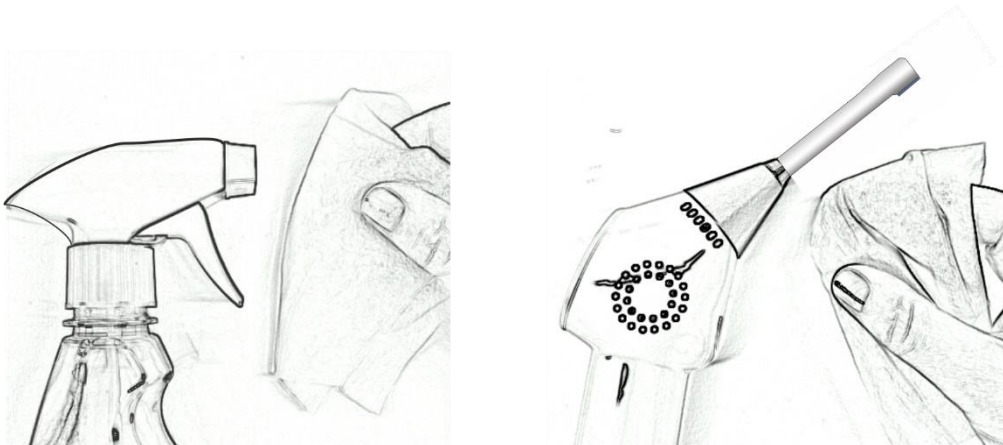


### 2. Cleaning of the unit.

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!

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



To avoid cross-contamination, it is mandatory to use disposable barrier sleeve on the handpiece, new one for each patient.

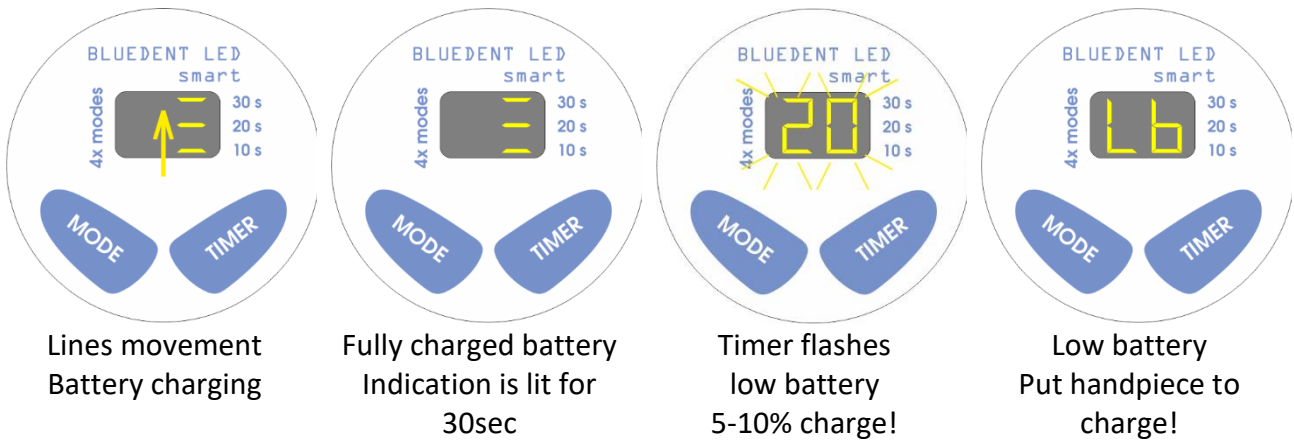
### 3. MAINTENANCE, CHARGING AND REPLACING THE BATTERY

The device uses Li-Ion battery type LIR 18650 / 3,7V / 2600 mAh.

The charging station can be used as a stand and only when the battery is discharged, the charging adapter can be switched on.

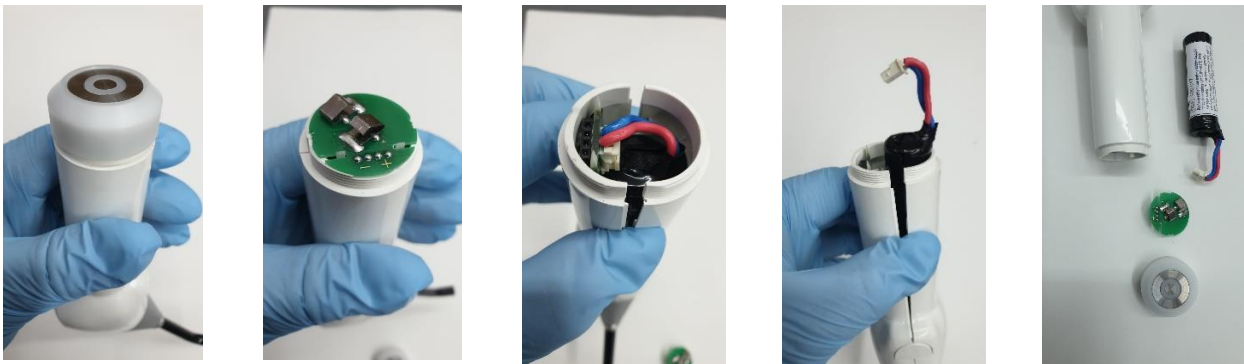
- After polymerization - place the handpiece on the charging base.
- If the battery is discharged to 5-10%, the display starts flashing, which means the battery is almost discharged. If operation continues, the battery is completely depleted after a few cycles - "Lb" (Low Battery) appears on the display. In this case, place the handpiece on the charging station - The CHARGE indicator lights up. While charging, the display of the handpiece shows 3 consecutive illuminated lines. When

the battery is fully charged, a long beep sounds for 30 seconds. The three lines are lit. The handpiece then enters “sleep” mode.



**Use only original BLUEDENT SMART XPRESS ORTHO Li-Ion batteries with factory label (h 65 mm, dia.18 mm), 3.7 V, TYPE 18650 - 2600 mAh.**

- To replace the Li-Ion battery: Unscrew the bottom cover of the handpiece and carefully remove the contact board, remove the plug and pull out the battery, slightly taking apart the plastic shells of the probe. The installation of a new battery is done in the reverse order.



The contact surfaces for charging the wireless probe and the charging station should be cleaned periodically with a cotton cloth soaked in alcohol.





No chargers other than the supplied adapter - SYS1381N-1209-W2E - must be used to charge the BLUEDENT SMART XPRESS battery.

- The battery must not be: electrically shortened or mechanically damaged, become wet, immersed in water or other liquids, heated or thrown into a fire.
- If there is a leak, odour or smoke from the battery - remove it from the appliance using gloves and a mask and dispose of it according to local legislation.
- When disposing of an old battery, observe the rules of environmental protection!

## **VIII. WARRANTY CONDITIONS**

1. Warranty period of BLUEDENT dental curing light 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 is done free of charge by manufacturer's service. Lightguide is not covered by warranty. LED module and battery have 6 months warranty.
3. If during the guarantee period the unit is damaged, due to incorrect 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.
  - 3.1 If liquids, aggressive and flammable substances and their vapors have entered the device, the battery must be removed immediately and sent to the manufacturer's service where the damages are established. In case of such damage, the warranty is lost.
  - 3.2 No damages or complaints are accepted as a result of electric shocks, thunderstorms, non-compliance with electrical safety measures or insufficient protection of patients, personnel and other persons from light radiation.
  - 3.3 Claims due to improper or insufficient security and care, protection and security during transport, unpacking, relocation, operation and storage of the device are not accepted. The warranty is void for the above events.
  - 3.4 The device must only be transported to manufacturer's service only in original packaging in order to avoid unwanted damage. The light guide must be packed

separately from the cordless handpiece. The warranty card must be presented (this Guide, with completed Chapter XII BLUEDENT data) or a copy of the sales invoice showing the serial number of the device.

3.5 When carrying out repairs by unauthorized persons outside the company service or if non-original elements / parts are used, the user loses the right to free service.

4. The manufacturer provides its customers once a year (and in case of a situation - immediately) to check in the company service whether the performance of the devices is within the acceptable limits.

5. The manufacturer does not owe compensation for lost profits in case of damage or incompleteness operation of the device, whatever the cause.

6. In case of disputes in connection with the application and interpretation of this Operating instruction manual, they will be decided by the court in Plovdiv, by virtue of the current Bulgarian legislation.

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



155, Vasil Aprilov blvd

4027 Plovdiv

Bulgaria

tel: +359 32 644089, +359 888 809256

email: [office@bglight.com](mailto:office@bglight.com)

[www.bglight.com](http://www.bglight.com)

**IX. SERVICE DATA**

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**X. FAQ**

<b>Problem</b>	<b>Solution</b>
<b>There is no indication "ON" on the charging station</b>	Check the adapter, cable and whether it is plugged into the charging station. Use only the original adapter type SYS1381N-1209-W2E. Check for metal objects on the contact system of the charging station.
<b>Rapid battery drain</b>	The battery needs to be replaced.
<b>There is no charge indication of the handpiece</b>	If there is an "ON" indication on the charging station - clean all contact surfaces of the station and the handle. If "CHARGE" does not appear - replace the battery or send for service.
<b>Weak polymerization effect</b>	It is necessary to clean the emitting tip with a non-metallic object and to clean the adhered composite or other with alcohol. If the result is poor - send the device to the service.
<b>There is no sound signal</b>	Hold down the left MODE button for 5-6 seconds until a sound is heard and ON appears on the display.
<b>The display shows Oh, the fan is running and the blue light cannot be started</b>	The appliance is overheated. Wait for it to cool for 3-5 minutes.
<b>The patient experiences discomfort during the polymerization process, especially during a long polymerization time of 20-30sec</b>	It is necessary to polymerize with short cycles - 10sec or less, with short breaks of 1-3sec. The sensitivity is higher if the light is close to the dental pulp and decreases with each layer. PULSE mode can be used.

<b>The power cord or AC adapter is damaged</b>	Send to the service.
<b>Liquid entering the device</b>	Send to the service.
<b>After falling to the floor, the device does not work properly</b>	Send to the service.

## XI. DECLARATION OF CONFORMITY

 <b>TECHNICAL FILE</b> <b>BLUEDENT</b> <b>LED curing light</b>	<b>EU Declaration of conformity</b> <i>Developed in conformity with MDR (EU) 2017/745</i>	<b>TD 7.2</b>
		<i>Revision 02</i>

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



Product:	Product code:	Name:
<b>Dental LED curing light</b>	<b>200-006ort</b>	<b>BLUEDENT SMART XPRESS ORTHO – cordless</b>

Basic UDI: 3800501374200000VX  
 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 is designed for photopolymerization of composites and materials used in dental practice (irradiation of blue light 410-490 nm). BLUEDENT is accessory for a medical device as described in Article 2, p.(2) as it performs its intended purpose together with dental composite (material).

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
<b>Regulation (EU) 2017/745</b>	<b>REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL</b> <i>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</i>	<b>05.05.2017</b>  <b>(last change 24.04.2020)</b>

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

<b>EN ISO 13485:2016 +/AC:2017/ /AC:2018/ A11:2022 +/AC:2017/ /AC:2018/ A11:2022</b>	Medical devices - Quality management systems - Requirements for regulatory purposes
<b>EN ISO 9001:2015</b>	Quality management systems - Requirements
<b>EN ISO 60601-1:2006 /A1:2013/AC:2014/A2:2022</b>	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
<b>EN 60601-1-2:2015/A1:2021</b>	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
<b>EN 60601-1-6:2010+ /A1:2015 / /A2:2021</b>	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
<b>EN 60601-1-8:2007+ /A1:2013 /A11:2017 /A2:2021</b>	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
<b>EN ISO 10650:2018</b>	Dentistry - Powered polymerization activators
<b>EN 62304:2006/A1:2015</b>	Medical device software. Software life cycle processes.
<b>EN 62353:2014</b>	Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment

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



**XII. BLUEDENT DATA**

<b>SN:</b>	
<b>LOT:</b>	
<b>DATE OF PRODUCTION:</b>	
<b>QC:</b>	
<b>DATE OF PURCHASE:</b>	

Last revision: 01.01.2023

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