OPERATING INSTRUCTIONS MANUAL

BLUEDENT SMART XPRESS
ORTHO cordless

Dental LED curing light

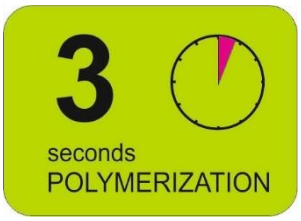
Ref.#200-006ort



BG LIGHT PRO
the power of light

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 ORHO is 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 ORTHO 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

European Conformity
Indicates conformity with local laws and regulations within the European Economic Area.



Caution
To indicate that caution is necessary when operating the device or control close to where the symbol is placed.



Refer to instruction manual/booklet
To signify that the instruction manual/booklet must be read.



Electronic instructions for use
To indicate on product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed paper form.



Dangerous voltage
To indicate hazards arising from dangerous voltage.



Hazardous light emission
To indicate hazards arising from light radiation.



Hazardous thermal effects
To indicate hazards arising from thermal effects.



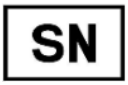
Manufacturer
Indicates the device manufacturer.



Date of manufacture
Indicates the date when the device was manufactured.



Catalogue number
Indicates the manufacturer's catalogue number so that the device can be identified.



Serial number
Indicates the manufacturer's serial number so that a specific device can be identified.



Batch code
Indicates the manufacturer's batch code so that the batch or lot can be identified.



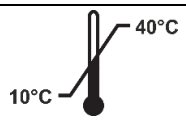
Applied part type B according to electric safety classification.

IP20
IEC - IP rating

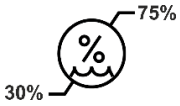
For indoor use in dry conditions.
Protection against solid objects larger than 12.5mm; no protection against water.
(Ingress Protection rating)



For indoor use only
To identify electrical equipment designed primarily for indoor use.



Temperature limit
Indicates the temperature limits to which the device can be safely exposed.



Humidity limitation
Indicates the range of humidity to which the device can be safely exposed.



Keep away from sunlight
To indicate that transport package shall not be exposed to sunlight.



Keep away from rain
To indicate that the transport package shall be kept away from rain and in dry conditions.



Fragile; handle with care
To indicate that the contents of the transport package are fragile and the package shall be handled with care.



This way up
To indicate the correct upright position of the transport package.



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. It must be sent to separate collection facilities for recovery and recycling.

III. SAFETY PRECAUTIONS



GENERAL WARNINGS:

BLUEDENT is a Class I medical device and it meets the 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.
- The device should be disconnected from the power supply at the end of the working day.
- 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 wiping with a swab soaked in disinfectant is acceptable.
- Do not get it wet and store it in a dry place to avoid electric shock or damage to the device.
- The device should not be used if any of its parameters are not within the norm.
- 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 outlet or another room, even in another building.
- Opening and repairing the device may only be carried out by service technicians authorized by the manufacturer.
- When replacing defective parts, only original parts must be used. The device or any of its parts must not be disassembled while it is connected to the power supply!

-  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 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 device, 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!

If there is a problem with the power adapter or its cable, replace the adapter with a new one.
During thunderstorms, the device should not be charged from the power supply.

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 intense light in the blue range, to which the human eye is highly sensitive. Irradiation of the eyes and skin with intense light carries a risk of damage. This leads to the serious measures that must be taken to protect patients and medical staff.

The light should never be directed at the eyes! Irradiation should be limited to the work area. Do not irradiate soft tissues.
It is mandatory to use special filters or protective glasses that meet the requirements:
- Glasses should tightly cover the eyes and temples, even if the person is wearing optical glasses.
- be made of volumetric colored impact-resistant plastic.
- block light with a wavelength of 410 - 490 nm at least 100 times.
- have a stable mechanical structure, have no scratches, cracks or damage to its surface.

The device can only be used after medical consultation on or by persons suffering from photo-biological reactions; persons taking photosensitive medications; persons operated on for cataracts, persons with retinal diseases, etc.

The risk of unlawful exposure is severe eye irritation, temporary spots in the visual field, severe vision damage in case of direct exposure, including loss of vision.



3. Thermal radiation

The thermal effect is a consequence of the absorption of the energy of the blue light in the tissues, in which the energy is converted into heat. Irradiate only the dental tissue without the surrounding soft tissues. Take breaks in case of sensitivity. The risk of overheating and burning occurs only with prolonged continuous overdose of irradiation.

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 cleaning agents to enter the device, as this may cause damage or fire.
- 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 and burns.

5. Prohibitions for using the device:

The device can only be used after medical consultation on or by: persons suffering from photobiological reactions; persons taking photosensitizing medications; persons having cataract surgery; persons with retinal diseases; persons with allergies; people who have recently undergone surgical or cosmetic operations on the face or lips, including hyaluronic acid or Botox injections; persons with very sensitive skin or dermatitis, etc. If photosensitizing agents or medications are being taken, check the package insert of the medicine.

IV. TECHNICAL DATA

1. Operating voltage:
- Handpiece - 3.7V Li Ion battery type 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 – 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 – wideband 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.

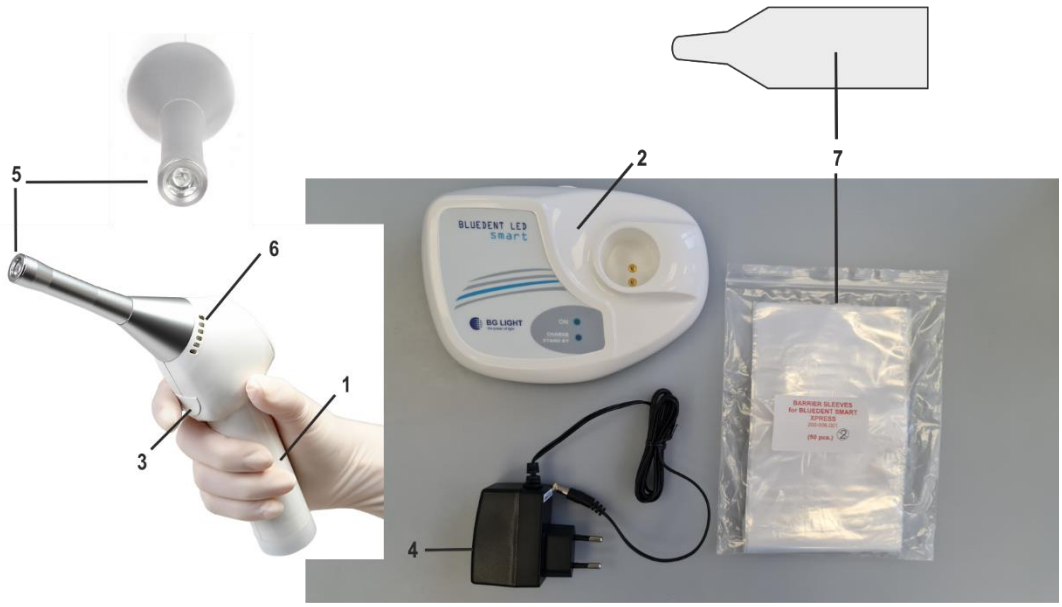
The manufacturer of this unit declares to provide on request all additional necessary technical documentation / information which will help the user's technical staff to service the parts of the unit which the manufacturer has claimed to be a subject for repair.

V. COMPLETE SET

1. Cordless handpiece – 1 pc.
2. Charging station - 1 pc.
3. Start / Stop button
4. Charge adapter

9V DC / 1.33 A – 1 pc.

5. Emitting head
6. Cooling fan
7. Barrier sleeves - 50 pcs.
8. Operations guide - 1 pc.



VI. PREPARATION AND SEQUENCE OF OPERATION

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

1. The device is removed from its packaging. The charging station is placed on a stable horizontal surface. The adapter is plugged into the network, and the cable is inserted into the socket to the charging station - the ON indication lights up. If the handpiece is inserted into the charging socket, the CHARGE indication will also light up.







2. After the device is fully charged or at the end of the working day, unplug the charging adapter from the mains.

3.The handpiece is switched to standby mode by pressing the Start/Stop button once. The display shows the last selected mode and the timer time.

4. The emitting head does not rotate!

Under no circumstances should you attempt to pull, rotate or apply physical force to it.



5. Before each patient, a new protective plastic barrier sleeve is placed on the front of the handpiece. It is for single use and is marked with the appropriate symbol.

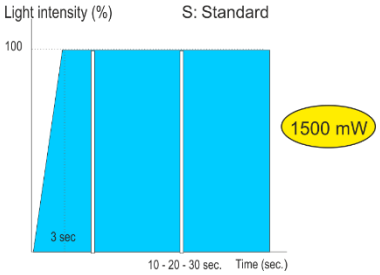


6. WORK MODES

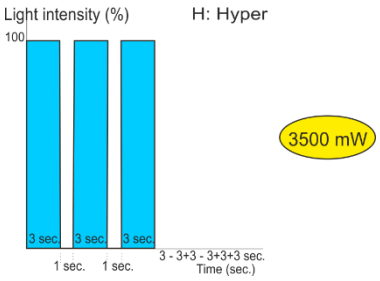
BLUEDENT SMART XPRESS ORTHO has **3 work modes**, which guarantee fast polymerization and complete hardening of the photocomposite material. The selection of the mode is done by pressing the MODE button located below the left side of the display:

S - STANDARD	H – HYPER ORTHO	L - LONG
1500 mW	3500 mW	1500 mW

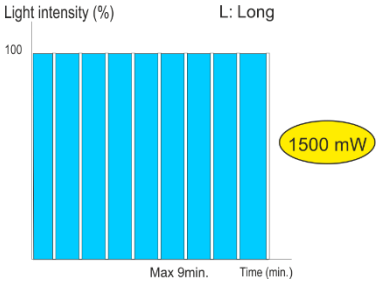
S - STANDARD mode (10 - 20 - 30 sec)
During the first 3 seconds, the light intensity slowly increases to avoid stress in the photocomposite.



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.

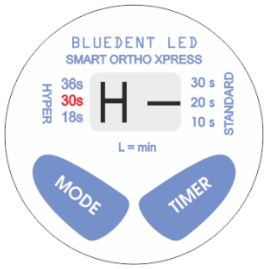


L - LONG mode (1-9 min)
The light intensity is at a maximum level of 100%, the mode is suitable for long procedures, e.g. teeth whitening.



7. Display

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

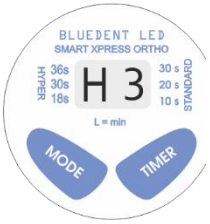


(In this example, the display shows HYPER ORTHO mode with a timer time of 30 sec (3 x 10 sec)

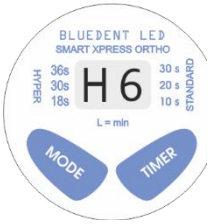
The timer is selected by pressing the "TIMER" button. The horizontal light line on the right shows the selected time:

- 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:



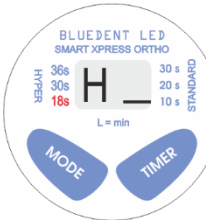
Timer – 3 sec



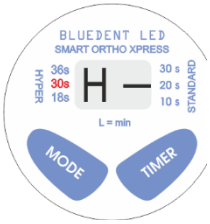
Timer – 6 sec
(3+3 sec)



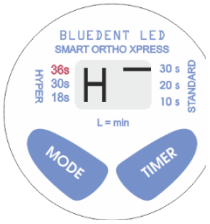
Timer – 9 sec
(3+3+3 sec)



Timer – 18 sec
(6 x 3 sec)



Timer – 30 sec
(10 x 3 sec)



Timer – 36 sec
(12 x 3 sec)

8. The device is started by pressing Start / Stop handpiece button - see figure.
After starting, the timer starts counting down.
An audible signal is heard.



9. The handpiece is directed to the designated area for irradiation and started, maintaining a minimum distance of 1 mm to the obturation.

10. If during irradiation Start/Stop button is pressed or after the selected time has elapsed, the device stops. In case of prolonged operation, it is possible that the fan cooling is activated.

11. In HYPER ORTHO mode, after each cycle 3/3 + 3 / … sec, there is a pause of 3 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.

12. “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 and has not been started for more than 30 seconds outside the charging base;

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

13. Light intensity indicator (option)

The light intensity can be checked with the indicator built into the BLUEDENT SMART charging base. Bring the handpiece close so that the emitting tip 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 should be:

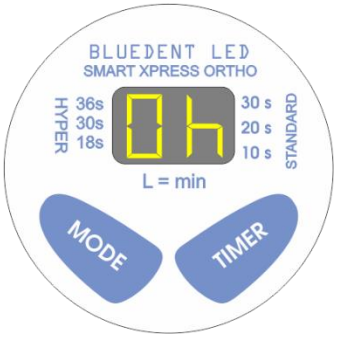
H - HYPER - 4 light points.
S- STANDARD - 2 light points.
P - PULSE - 1 and 2 alternating illumination points
L - LONG - 2 light points.

We recommend that the light intensity be measured in HYPER 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.

14. "SOUND SIGNAL OFF" function

This function allows you to turn the sound signal of the device on and off. Hold down the MODE button for 5-6 seconds, the sound signal indication appears and the sound ON/OFF setting changes automatically:
If the sound signal is on (ON) - after holding down the MODE button, OFF is displayed and the sound is turned off.

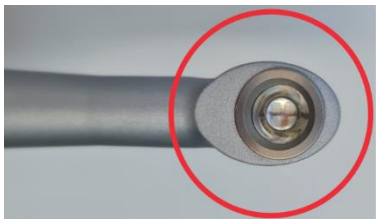
If the sound signal is off (OFF) - after holding down the MODE button, ON is displayed and the sound is turned on.



15. **Thermal protection**
Thermal protection is activated if the temperature of the LED module rises to 50 ° C. Then the light will stop, the display will show “Oh” (Overheating), and the fan will continue to operate until the device cools down.

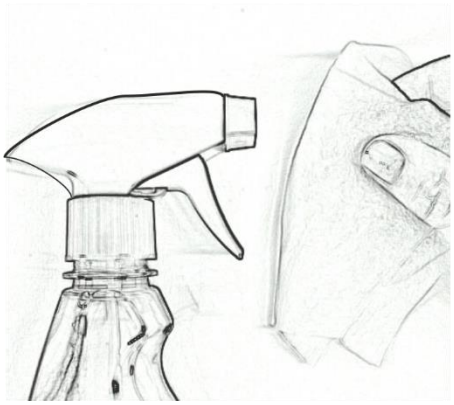
VII. ROUTINE CARE AND MAINTENANCE

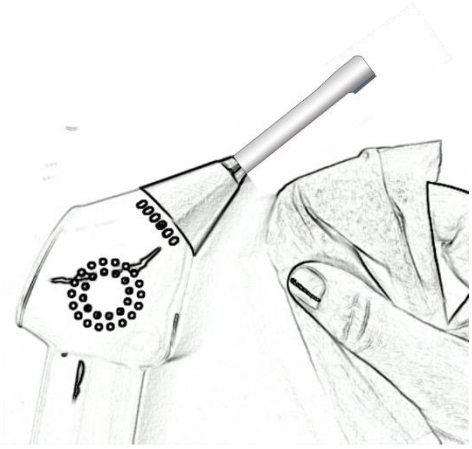
1. **Cleaning the emitting tip**
Clean the emitter glass daily with a swab dipped in alcohol / disinfectant. Adhesive photocomposite is not allowed - if there is one, it should be carefully removed with a blunt, non-metallic object.



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 on the handpiece, the button, on contact plates or charging socket!





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

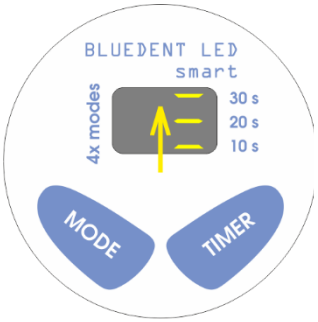
3. Maintenance, charging and replacing the battery

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

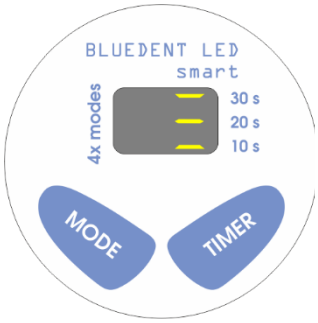
The charging station can be used as a stand and only when the battery is discharged, the charging adapter can be switched on.

- After polymerization - place the handpiece on the charging base.

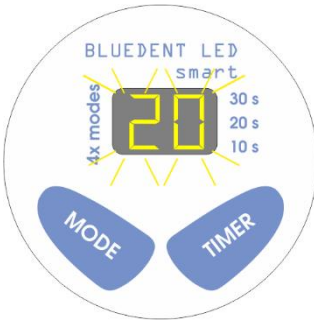
- If the battery is discharged to 5-10%, the display starts flashing, which means the battery is almost discharged. If operation continues, the battery is completely depleted after a few cycles - “Lb” (Low Battery) appears on the display. In this case, place the handpiece on the charging station - The 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.



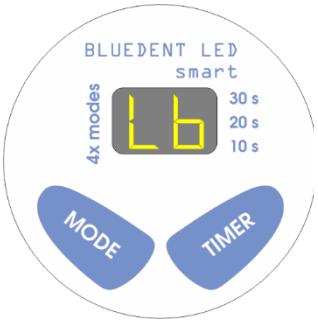
Lines movement
Battery charging



Fully charged battery
Indication is lit for
30sec



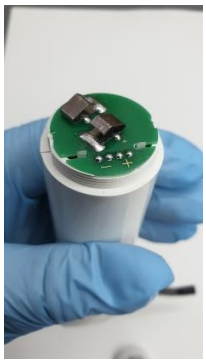
Timer flashes
low battery
5-10% charge!



Low battery
Put handpiece to
charge!

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 handpiece. The installation of a new battery is done in the reverse order.




The contact surfaces for charging the wireless handpiece 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 XPRRESS ORTHO 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. The warranty period for the BLUEDENT dental photopolymerization device is 24 (twenty-four) months from the date of purchase. If the date of purchase is not filled in and warranty documents are missing, the warranty begins to run from the date of manufacture.

2. During the warranty period, the replacement of defective elements is carried out free of charge by the manufacturer. The battery has a 6-month warranty period.

3. If during the warranty period the device is defective due to improper operation (mechanical, chemical, thermal, electrical damage, use not for its intended purpose), improper storage and other reasons due to the user's fault, the repair is not covered by warranty.

4. Damage and complaints due to electric shocks, thunderstorms, failure to comply with electrical safety measures are not accepted.

5. The device must be transported to the service center only in the original packaging to avoid unwanted damage. The warranty card (this Manual, with chapter XII BLUEDENT Data completed) or a copy of the sales invoice showing the serial number of the device must be presented.

6. If repairs are carried out by unauthorized persons outside the company service center or if non-original elements and assemblies are used, the user loses the right to warranty service.

7. Disclaimer: The manufacturer is not liable for compensation and lost profits in the event of damage or incomplete functioning of the device, regardless of the cause or in the event of problems arising from failure to comply with safety measures in the event of risks (chapter III, Risks)

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

BG LIGHT PRO Ltd
155, Vasil Aprilov blvd
4027 Plovdiv
Bulgaria

tel: +359 32 644089
office@bglight.com
www.bglight.com

9. The device's service life is set at 5 years from the date of purchase. After the end of its life cycle, the user must discontinue use of the device.
At the user's request, the life cycle can be extended. For this purpose, the device must be returned to the manufacturer BG LIGHT PRO LTD, where its characteristics must be checked and all main elements (emitters, adapter, electronic boards) tested and replaced.

10. In the event of disputes arising in connection with the application and interpretation of these Operating Instructions, they will be resolved by the Plovdiv District Court, in accordance with the current Bulgarian legislation.

IX. SERVICE DATA

X. FAQ

Problem	Solution
There is no indication “ON” on the charging station	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.
Rapid battery drain	The battery needs to be replaced.
There is no charge indication of the handpiece	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.
Weak polymerization effect	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.
There is no sound signal	Hold down the left MODE button for 5-6 seconds until a sound is heard and ON appears on the display.
The display shows Oh, the fan is working and the blue light cannot be started	The device is overheated. Wait for it to cool down.
The patient experiences discomfort during the polymerization process, especially during a long polymerization time of 20-30sec	It is necessary to polymerize with short cycles - 10sec or less, with short breaks of 1-3sec. Sensitivity decreases as the light moves away from the dental tissues. PULSE mode can be used.

The power cord or AC adapter is damaged	Replace with new.
Liquid entering the device	Send to the service.
After falling to the floor, the device does not work properly	Send to the service.

XI. DECLARATION OF CONFORMITY

BG LIGHT PRO **TECHNICAL FILE** **BLUEDENT** **LED curing light**	**EU Declaration of conformity** *Developed in conformity with MDR (EU) 2017/745*	**TD 7.2** *Revision* ***03***

Manufacturer: **BG LIGHT PRO LTD**
SRN:
Address: 155, Vasil Aprilov blvd., 4027 Plovdiv, Bulgaria
Tel.: +359 32 644089, +359 888 809256, email: office@bglight.com
BULSTAT UIC 208000520, VAT N: BG208000520

CE

Product:	Product code:	Name:
Dental LED curing light	**200-006ort**	**BLUEDENT SMART XPRESS ORTHO – cordless**

Basic UDI: 38001748200000G8
EMDN code: Q0190

Classification: Active invasive 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).

The manufacturer declares that the medical devices covered by the Declaration are in compliance with the provisions of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.

The applicable GENERAL REQUIREMENTS FOR SAFETY AND PERFORMANCE, defined in Appendix I of the normative act described below and of normative technical documents, are met when the medical device is 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 - ISO 9001:2015 certificate – No AC090 100/2409/6029/2025, ISO 13485:2016 – No AC090 MD/0008/6029/2025 from TUV NORD Polska Sp. z o.o. (NB 2274).

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

BG LIGHT PRO 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
08.05.2025

Dipl. Eng. Plamen Karaivanov
Manager
BG LIGHT PRO LTD

XII. BLUEDENT DATA

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

Last revision: 22.07.2025
Follow www.bglight.com for updated revision of this Operating instructions manual.