Bluephase N®

CE 0123

For dental use only!
Made in Austria

Manufacturer
Ivoclar Vivadent AG
9494 Schaan/Liechtenstein
www.ivoclarvivadent.com

Rx ONLY
In USA distributed by
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Amherst, NY 14228, USA

ivoclar vivadent® clinical

Dear Customer,

Optimum polymerization is an important requirement for all light cured materials in order to consistently produce high quality restorations.
The polymerization light selected also plays a decisive role in this respect. Therefore, we would like to thank you for having purchased Bluephase N.
Bluephase N is a high-quality medical device which has been designed according to the latest standard of science and technology in compliance with the relevant industry standards.

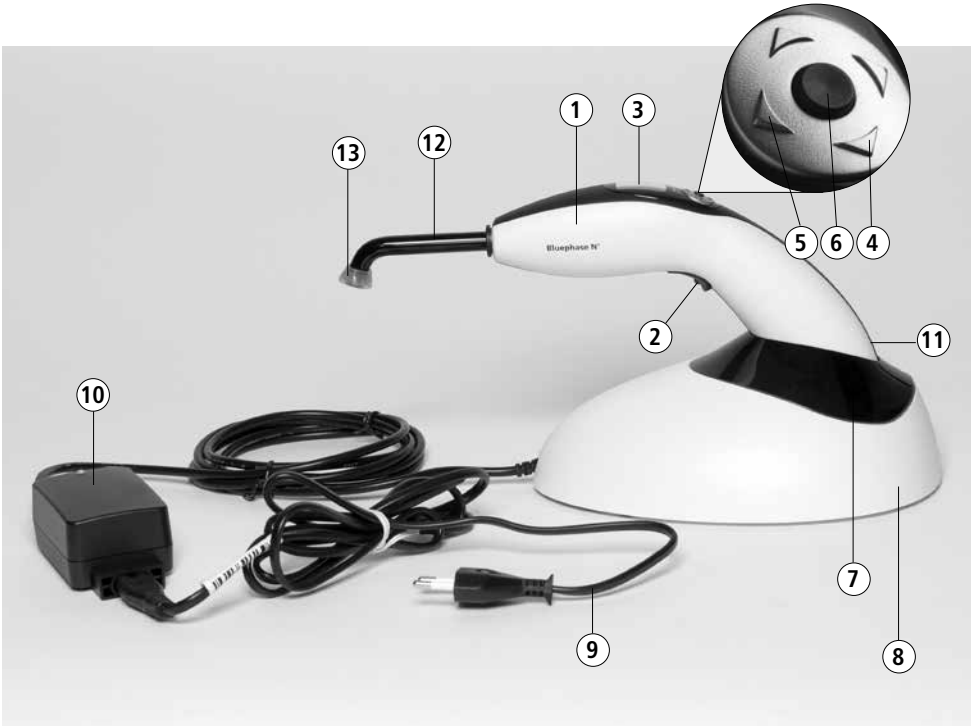
These Instructions for Use will help you safely start-up the device, make full use of its capabilities, and ensure a long service life.

Should you have any further questions, please do not hesitate to contact us (see addresses on the reverse page).

Your Ivoclar Vivadent Team

Table of Contents

List of parts

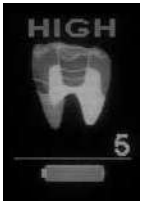


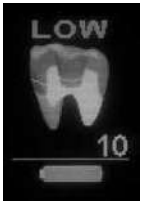
1 Handpiece
2 Start button
3 Display
4 Program selection button
5 Time selection button
6 Volume button
7 Power indicator
8 Charging base
9 Power cord
10 Power pack
11 Battery
12 Light probe 10 mm
13 Anti-glare cone

Indicators on the charging base

Indicator lights up in blue - the charging base is connected to the power supply

Indicators on the handpiece





Curing program and operating state

Selected indications and curing time

Charging status of the battery

Safety

Intended use
Bluephase N is an LED polymerization light that produces energy-rich blue light. It is used for the polymerization of light-curing dental materials immediately at the dental unit. The intended place of application is inthe dental practice, in the medical practice or in the hospital. The intended use also includes the observation of the notes and regulations in these Instructions for Use.

Indication
With its "Polywave®" broadband spectrum, Bluephase N is suitable for the polymerization of all light-curing dental materials curing in the wavelength range of 385–515 nm. These materials include restoratives, bonding agents/ adhesives, bases, liners, fissure sealants, temporaries, as well as luting materials for brackets and dental-lab materials such as ceramic inlays.

Signs and symbols

Non permissible use

Symbols on the curing light


Double insulation
(device complies with safety class II)


Protection against electrical shock
(BF type apparatus)


Observe Instructions for Use


Observe Instructions for Use


Caution


The curing light must not be disposed of in the normal domestic waste. Information regarding disposal of the light can be found on the respective national Ivoclar Vivadent homepage.


Recyclable

Safety notes
The Bluephase N is is an electronic device and a medical product which is subject to IEC 60601-1 (EN 60601-1) and EMC directives IEC 60601-1-2 (EN60601-1-2) Edition 3.0 + Edition 4.0, as well as the 93/42/EEC Medical Device Directive. The appliance complies with the relevant EU regulations and is classified as an LED Class 2 product.

CE 0123

The apparatus has been shipped from the manufacturer in a safe and technically sound condition. In order to maintain this condition and to ensure risk-free operation, the notes and regulations in these Instructions for Use have to be observed. To prevent damage to equipment and risks for patients, users, and third parties, the following safety instructions have to be observed.


Materials, the polymerization of which is activated outside the wavelength range of 385–515 nm (no materials known to date.) If you are not sure about certain products, please ask the manufacturer of the corres-ponding material.


Do not charge or use the appliance near flammable or combustible substances.


Portable and mobile high-frequency communication devices may interfere with medical equipment. The use of mobile phones during operation is not allowed.
Such communication equipment (including auxiliary components such as antenna cables and external antennas) must not be used closer than 30 cm (12 inches) to a Bluephase N component, including cables specified by the manufacturer. Failure to do so may result in reduced performance of the equipment.

The device withstands ESD values up to 8 kV.The device is not designed for higher values. If the device is switched off by ESD, it must be reactivated.

Do not use this unit next to or stacked on top of other units as this may interfere with its proper functioning. If such use is unavoidable, the equipment must be monitored and checked for correct operation.

Usage and liability

- Bluephase N must only be employed for the intended use. Any other uses are contraindicated. Liability cannot be accepted for damage resulting from misuse or failure to observe the Operating Instructions.
- The user is responsible for testing Bluephase N for its use and suitability for the intended purposes. This is particularly important if other equipment is used in the immediate vicinity of Bluephase N at the same time.
- Use only original spare parts and accessories from Ivoclar Vivadent (see Accessories). The manufacturer does not accept any liability for damage resulting from the use of other spare parts or accessories.
- The light probe is an applied part and may warm up to a maximum of 45 °C (113 °F) at the interface to the handpiece during operation.

Operating voltage

Before switching on, make sure that

a) the voltage indicated on the rating plate complies with the local power supply.

b) the unit has acquired the ambient temperature.

If the battery or power pack are used separately, e.g. during start-up or Click & Cure corded operation, contact with patients or third parties must be prevented. Do not touch the exposed contacts of the battery or connection plug (power pack).

Assumption of impaired safety

If it has to be assumed that safe operation is no longer possible, the power must be disconnected and the battery removed to avoid accidental operation. This may be the case, for example, if the apparatus is visibly damaged or no longer works correctly. A complete disconnection from the power supply is only ensured when the power cord is disconnected from the power source.

Eye protection

Direct or indirect exposure of the eyes must be prevented. Prolonged exposure to the light is unpleasant for the eyes and may result in injury. Therefore, using the supplied anti-glare cones is recommended. Individuals who are generally sensitive to light, who take photosensitizing drugs, have undergone eye surgery, or people who work with the apparatus or in its vicinity for long periods of time should not be exposed to the light of this device and wear protective goggles (orange) that absorb light below 515 nm.

Battery

Caution: Use only original spare parts, particularly Ivoclar Vivadent batteries and charging bases. Do not short circuit battery. Do not store at temperatures above 40 °C / 104 °F (or 60 °C / 140 °F for a short period). Always store batteries charged. The storage period must not exceed 6 months. May explode if disposed of in fire.

Please note that the lithium polymer battery may react with explosion, fire, and smoke development in case of inappropriate handling and mechanical damage. Damaged lithium polymer batteries must no longer be used.

The electrolytes and electrolyte fumes released during exlosion, fire, and smoke development are toxic and corrosive. In case of contact with the eyes and skin, immediately rinse with copious amounts of water. Avoid the inhalation of the fumes. See a physician immediately in case of indisposition.

Heat development

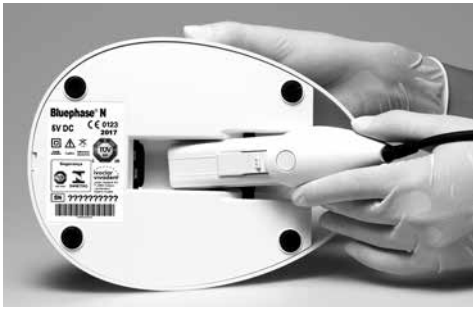
As it is the case with all high-performance lights, the high light intensity results in a certain heat development. Prolonged exposure of areas near the pulp and soft tissues may result in irreversible or reversible damage. Therefore, the recommended curing times have to be observed. Uninterrupted curing times of more than 20 seconds on the same tooth surface, as well as direct contact with the gingiva, oral mucous membrane, or skin, have to be prevented. If required, polymerize indirect restorations at intermitting intervals of 20 seconds each or use external cooling with an air stream.

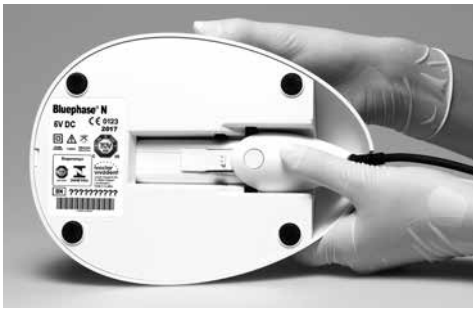
Start-up

Check the delivery for completeness and any possible transportation damage (see delivery form). If components are missing or damaged, immediately contact your dealer or your Service Center.

Charging base

Before you switch on the device, make sure that the voltage mentioned on the rating plate complies with your local power supply. The rating plate is attached to the underside of the charging base.





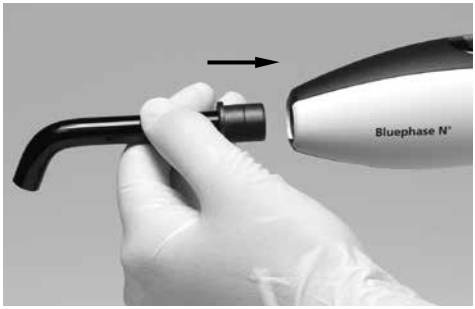
Place the charging base on a suitable, flat table top.

Remove the protective foil from the connection plug of the power pack. Slide the connection plug of the power pack into the socket on the underside of the charging base. Tilt it slightly and apply slight pressure until you hear and feel it snap into place.

Connect the power cord with the power supply and the power pack. The Power ON indicator on the left side of the housing lights up in blue (see Indicators on the charging base).

Handpiece

Before you insert the light probe, remove the protective foil on the corresponding opening of the handpiece.



Slightly turn the light probe while attaching it to the handpiece.

After that, mount anti-glare protection on the light probe.

Battery
We recommend fully charging the battery before the first use.
If the battery is fully charged, it features a curing capacity of approximately 60 minutes.

Slide the battery straight into the handpiece until you hear and feel it click into place.

Gently place the handpiece in the corresponding rest in the charging base. If a sleeve is used, please remove it before you charge the battery.

If possible, use the light always with a fully charged battery. This will prolong the service life. It is therefore recommended to place the handpiece into the charging base after each patient. The charging time for empty batteries is 2 hours.

Charging status of the battery
With the handpiece switched on, the current charging status is shown on the display as follows:

Battery fully charged (curing capacity of approximately 60 minutes)

Battery half full

Reserve (The last bar in the battery indicator is red in the reserve mode. The battery has to be charged as soon as possible.)

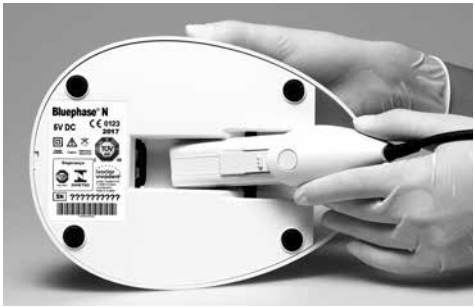
When the battery is being charged, „Charging Battery" briefly appears in the display before the display returns to the stand-by mode.

If the battery is completely empty, the handpiece automatically switches to the stand-by mode. The light can no longer be called up and the curing program and curing time can no longer be set. However, the handpiece can be used in the Click & Cure corded operation.

Since the battery is a consumable, it has to be replaced after its typical life cycle has expired after 2½ years.
See battery label for the age of the battery.

Operation

Click & Cure corded operation
Bluephase N can be used in corded operation at any time, but particularly when the battery is completely empty.



For this purpose, remove the battery from the handpiece. Then remove the power pack from the underside of the charging base. Do not pull on the power cord.

Insert the connection plug straight into the handpiece until you hear and feel it click into place.

During corded operation, the charging base cannot charge the battery.

The apparatus is only completely disconnected from the power supply if the power cord has been pulled out of the plug-in socket.

Disinfect or autoclave contaminated surfaces of the curing light, as well as light probes, and anti-glare cones before each use. Furthermore, make sure that the stipulated light intensity permits adequate polymerization. For that purpose, check the light probe for contamination and damage, as well as the light intensity at regular intervals (e.g. with the Ivoclar Vivadent radiometer "Bluephase Meter").

Selecting the curing program and time
The curing program and the curing time can be individually set. Bluephase N is equipped with the following 3 curing programs for the different indications. The desired curing program is selected with the program selection buttons. The display changes accordingly (see Indicators on the handpiece).
Upon the first start-up, the following settings have been preset:

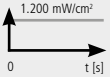
- HIGH (High Power): 10 seconds
- LOW (Low Power): 10 seconds
- SOFT (Soft start): 15 seconds

The intended curing time is selected using the time selection buttons. Users may choose between 5, 10, 15, 20 and 30 seconds.

Observe the Instructions for Use of the material applied when selecting the curing time.
The curing recommendations for composite materials apply to all shades and, if not mentioned otherwise in the Instructions for Use of the relevant material, to a maximum layer thickness of 2 mm. Generally, these recommendations apply to situations where the emission window of the light probe is placed directly over the material to be polymerized. Increasing the distance between the light source and the material will require the curing time to be extended accordingly. For instance, if the distance to the material is 9 mm, the effective light output is reduced by approx. 50%. In this case, the recommended curing time has to be doubled.

Curing programs

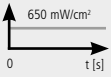
Light intensity	1,200 mW/cm²
Exposure time for composites	15 s
Exposure time for Tetric EvoCeram / IPS Empress Direct	10 s



HIGH POWER Program

Consistently high light intensity for the polymerization of restorative and cementation materials for direct and indirect restorations.

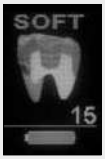
Filling materials	Curing time
Composite	
• 2 mm [1]	
IPS Empress Direct / IPS Empress Direct Flow / Tetric EvoCeram / Tetric EvoFlow / Tetric / Tetric Basic White / Tetric N-Ceram / Tetric N-Flow	10 s
Heliomolar / Heliomolar HB / Heliomolar Flow All conventional composites	15 s
• 4 mm [2]	
Tetric EvoCeram Bulk Fill / Tetric Basic White	10 s
Compomer [3]	
Compoglass F / Compoglass Flow	20 s
Indirect restorations / Luting materials	
Variolink II Base [4] / Variolink Veneer / Variolink N Base [4] / Variolink N Clear Veneer / Variolink Ultra [5] / Dual Cement [5] / Variolink II [5]	per mm ceramic: 10 s per segment
Miscellaneous	
Helioseal / Helioseal F / Helioseal Clear	10 s
Monopaque	20 s
MultiCore Flow / Multicore HB	20 s
Heliosit Orthodontic	10 s
Telio Add-On Flow	15 s
Telio Stains	10 s
IPS Empress Direct Color	10 s
IPS Empress Direct Opaque	20 s

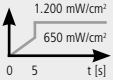


LOW POWER Program

Reduced light intensity with reduced heat development for the polymerization of adhesives, liners, and restorative materials in areas near the pulp when restoring Class V cavities.

Adhesive	Curing time
AdheSE / AdheSE One F ExciTE / ExciTE DSC Tetric N-Bond / Tetric N-Bond Self-Etch Heliobond (Syntac)	10 s
Temporary materials	
Telio CS Inlay/Onlay	10 s
Systemp.inlay/onlay	10 s
Fermit / Fermit N	10 s
Telio CS Link / Systemp.link	20 s per segment
Miscellaneous	
Heliosit Orthodontic	20 s
Vivaglass Liner	20 s





SOFT START Program

Step-by-step increase of the light intensity with reduced shrinkage stress and reduced heat development for the polymerization of restorative materials.

Filling materials	Curing time
Composite	
• 2 mm [1]	
IPS Empress Direct / IPS Empress Direct Flow / Tetric EvoCeram / Tetric EvoFlow / Tetric / Tetric Basic White / Tetric N-Ceram / Tetric N-Flow	15 s
Heliomolar / Heliomolar HB / Heliomolar Flow All conventional composites	20 s
• 4 mm [2]	
Tetric EvoCeram Bulk Fill / Tetric Basic White	15 s
Compomer [3]	
Compoglass F / Compoglass Flow	20 s

1) Applies to a maximum layer thickness of 2 mm and provided that the Instructions for Use of the respective material do not state any other recommendation (might be the case, e.g. with dentin shades)
2) Applies to a maximum layer thickness of 4 mm and provided that the Instructions for Use of the respective material do not state any other recommendation (might be the case, e.g. with dentin shades)
3) Applies to a maximum layer thickness of 3 mm
4) Applies to light-curing (use of the base past only)
5) Applies to dual-curing

Cure Memory function
The last settings used, together with the combination of curing program and curing time, are automatically saved.

Start
The light is switched on by means of the start button. Once the selected curing time has elapsed, the curing program is automatically terminated. If desired, the light can be switched off before the set curing time has elapsed by pressing the start button again. The fan is activated simultaneously to the light. Once the curing time has elapsed, the fan continues to run for a certain time to cool the apparatus. The battery must not be removed as long as the fan is still running.

Acoustic signals
Acoustic signals can be heard for the following functions:
- Start (Stop)
- Every 10 seconds
- Program change
- Curing time change
- Connecting the battery to the charging base
- Inserting battery
- Error message


If desired, the volume of the acoustic signals can be adjusted. For that purpose, press the blue volume button while the light is off and reduce the volume or turn the acoustic signals off with the left program selection button. If you want to turn the acoustic signals back on or increase the volume, press the blue volume button and then the right program selection button.

Light intensity
The light intensity is maintained at a consistent level during operation. If the supplied 10 mm light probe is used, the light intensity has been calibrated to 1200 mW/cm² ± 10%.

The use of a light probe other than the one provided has a direct influence on the light intensity emitted.

In parallel-walled light probes (10 mm), the diameter is equal at both ends. In focussing light probes (10>8 mm light probe, Pin-Point light probe 6>2 mm), the diameter of the rear end is larger than that of the light emission window. The incident blue light is thus bundled to a smaller surface, which increases the light intensity emitted.

Pin-Point light probes are suitable for the polymerization of confined areas, such as the attachment of veneers prior to excess removal. For thorough curing, it is necessary to change the light probe.

Measuring the light intensity
The light intensity of the Bluephase N and the enclosed 10 mm light probe can be checked by means of the Bluephase Meter.

If the measured value does not correspond with the expected light intensity, proceed as follows:
- Check the selected curing program.
- Clean possibly dirty light sensor (radiometer).
- Remove the light probe and clean the light emission window of the handpiece with a cotton swab dipped in alcohol.
- Clean possibly dirty light probe (see Maintenance and cleaning).
- Replace a damaged light probe with a new one.

If these measures do not improve the results, please contact your dealer or your local Service Center.

Maintenance and cleaning

For reasons of hygiene, we recommend using a disposable protective sleeve for each pa-tient. Make sure to fit the protective sleeve closely to the light probe. Disinfect contaminated surfaces of the device and anti-glare cones (FD 366/Dürr Dental, Incidin Liquid/Ecolab) and sterilize the light probe before each use if disposable protective sleeves are not used. Make sure that no liquids or other foreign substances enter the handpiece, charging base and particularly the power pack during cleaning (risk of electrical shock). Disconnect the charging base from the power source when cleaning it.

Housing
Wipe the handpiece and handpiece holder with a customary aldehyde-free disinfecting solution. Do not clean with highly aggressive disinfecting solutions (e.g. solutions based on orange oil or with an ethanol content of more than 40%), solvents (e.g. acetone), or pointed instruments, which may damage or scratch the plastic. Clean dirty plastic parts with a soapy solution.

Light probe
Before cleaning and/or disinfecting the light probe, pretreat it. This applies to both automated and manual cleaning and disinfection.

Pretreatment
- Remove gross contamination immediately after use or within 2 hours. For this purpose, thoroughly rinse the light probe under running water (for at least 10 seconds). Alternatively, use a suitable aldehyde-free disinfecting solution to prevent the fixation of blood.
- To remove contamination manually, use a soft brush or soft cloth. Partially polymerized composite can be removed with alcohol and a plastic spatula, if necessary. Do not use sharp or pointed objects, as they may scratch the surface.

Cleaning and disinfection
For cleaning, immerse the light probe in a cleaning solution and ensure that it is sufficiently covered with liquid (ultrasound or careful brushing with a soft brush may support the effect). A neutral-enzymatic cleaning agent is recommended. When cleaning and disinfecting, please make sure that the agents used are free of:
- organic, mineral and oxidizing acids (the minimum admissible pH value is 5.5)
- alkaline solution (the maximum admissible pH value is 8.5)
- oxidizing agent (e.g. hydrogen peroxide)

Afterwards, remove the light probe from the solution and thoroughly rinse it under running water (for at least 10 seconds). Cleaning in a thermal disinfector is an effective alternative.

Sterilization
Thorough cleaning and disinfecting is imperative to ensure that the subsequent sterilization is effective. Use only autoclave sterilization for this purpose. The sterilization time (exposure time at sterilization temperature) is 4 minutes at 134 °C (273 °F); pressure should be 2 bar (29 psi). Dry the sterilized light probe using either the special drying program of your steam autoclave or hot air. The light probe has been tested for up to 200 sterilization cycles.

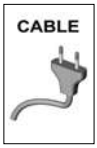
After that, check the light probe for damage. Hold it against light. If individual segments appear black, glass fibres are broken. If this is the case, replace the light probe with a new one.

Battery contacts
To ensure reliable conductivity at all times, keep the battery contacts free from possible contamination (e.g. composite residue). For this purpose, clean the affected contacts regularly in the course of the usual wipe disinfection (after each patient).

Disposal

The curing light must not be disposed of as urban waste. Dispose unserviceable batteries and polymerization lights according to the corresponding legal requirements in your country. Batteries must not be incinerated.

What if....?

Symbol	Causes	Error Rectification
	Electronic defect in the handpiece or battery	Remove and reinsert the battery. If the error remains, replace the battery with the power pack (Click & Cure). If the error remains, please contact your dealer or your local Service Center.
	Apparatus is overheated or undercooled	Allow the apparatus to cool down (or assume room temperature if it is undercooled) and try again after a certain time. If the error remains, please contact your dealer or your local Service Center.
	Electronic defect in the battery	Remove and reinsert the battery. If the error remains, place the apparatus into the charging base. If the error remains nonetheless, replace the battery with the power pack (Click & Cure). Please contact your dealer or your local Service Center.
	Battery empty	Position the handpiece in the charging base. „Charging Battery" briefly appears in the display before the display returns to the stand-by mode. If the battery is not charged, the contacts have to be cleaned. If the error remains, please contact your dealer or your local Service Center.
No display during charging	Charging contacts contaminated Battery in safety mode (integrated protective circuit)	Check if the handpiece has been correctly placed into the charging base. Clean battery contacts. Information: "Charging Battery" briefly appears in the display before the display returns to the stand-by mode. If cleaning the battery contacts does not improve the results, remove the battery from the apparatus. Charge the battery separately from the handpiece in the charging base for approx. 10 minutes. If the error remains, please contact your dealer or your local Service Center.
LED of the charging base is not illuminated	Power pack not connected or defective	Check if the power pack is correctly positioned in the charging base (also check the charging contacts) or if the power pack is connected to the power supply by means of the power cord (display on the power pack lights up in green if it works correctly). If the error remains, please contact your dealer or your local Service Center.

Warranty / Procedure in case of repair

The warranty period for Bluephase N is 3 years from the date of purchase (battery 1 year).
Malfunctions resulting from faulty material or manufacturing errors are repaired free of charge during the warranty period. The warranty does not provide the right to recover any material or non-material damage other than the ones mentioned. The apparatus must only be used for the intended purposes. Any other uses are contraindicated. The manufacturer does not accept any liability resulting from misuse and warranty claims cannot be accepted in such cases. This is particularly valid for:

- damage resulting from improper handling, especially incorrectly stored batteries (see Technical data: Transportation and storage conditions).
- damage to components resulting from wear under standard operating conditions (e.g. battery).
- damage resulting from external influences, e.g. blows, drop to the floor.
- damage resulting from incorrect set-up or installation.
- damage resulting from connecting the unit to a power supply, the voltage and frequency of which do not comply with the ones stated on the rating plate.
- damage resulting from improper repairs or modifications that have not been carried out by certified Service Centers.

In case of a claim under warranty, the complete apparatus (handpiece, charging base, power cord, and power pack) must be returned, carriage paid, to the dealer or directly to Ivoclar Vivadent, together with the purchase document. Use the original packaging with the corresponding cardboard inserts for transportation.

Repair work may only be carried out by a certified Ivoclar Vivadent Service Center. In case of a defect that cannot be rectified, please contact your dealer or your local Service Center (see addresses on the reverse side). A clear description of the defect or the conditions under which the defect occurred will facilitate locating the problem. Please enclose this description when returning the apparatus.

Product specifications

Delivery form

1 Charging base, 1 Power cord, 1 Power pack, 1 Handpiece, 1 Battery (Li-Po), 1 10 mm light probe, 3 Anti-glare cones, 1 Set of Instructions for Use

Accessories

The following accessories are available for Bluephase N:

REF	Description
656196	Light probe 10 mm, black (N)
608538	Pin-point light probe 6>2 mm, black
551756	Anti-glare cones
592496	Anti-glare shield
659956	Bluephase N battery
659681	Bluephase N handpiece
607922	Bluephase Meter
608554	Bluephase sleeves

Technical data

Operating voltage charging base	5 VDC
Operating voltage handpiece	3.7 VDC with battery 5 VDC with power pack
Power supply	Input: 100–240 VAC / 50–60 Hz / 400–200 mA Output: 5 VDC / 3 A Manufacturer: Friwo Type: FW8001M/05

Operating conditions

Temperature	+10 °C to +35 °C (+50 to +95 °F)
Relative humidity	30% to 75%
Ambient pressure	700 hPa to 1060 hPa
Dimensions of the charging base	L=205mm W=150mm H=85mm
Weight of the charging base	250 g
Charging time	approx. 2 h (with the battery empty)
Power supply of the handpiece	Li-Po battery
Max. battery time	approx. 60 min. (with a new, fully charged battery)
Light source	Polywave® LED
Wavelength range	385 – 515 nm
Light intensity	max. 1,200 mW/cm² ± 10 %
Operating	5 min. on / 6 min. off (intermittently)
Dimensions of the handpiece:	L=260mm W=42mm H=120 mm
Weight of the handpiece	(incl. battery) 225 g

Transportation and storage conditions:

Temperature	–20 °C to +60 °C (–4 to 140 °F)
Relative humidity	10% to 75%
Ambient pressure	500 hPa to 1060 hPa

Bluephase N has to be stored in closed, roofed rooms.
Protect the device from severe jarring.

Battery

- Do not store at temperatures above 40 °C / 104 °F (or 60 °C / 140 °F for a short period).
  Recommended storage temperature 15–30 °C (59–86 °F).
- Always store the battery charged
- and not for longer than 6 months.

Appendix

Bluephase N is tested according to IEC60601-1-2, Edition 3.0.
Medical electrical devices are subject to particular preventive actions according to EMC rules and must be installed and operated according to the EMC guidelines in the accompanying documents.

Guidance and manufacturer's declaration - electromagnetic emission

The "Bluephase N" is intended for use in the electromagnetic environment specified below. The customer or the user of the "Bluephase N" should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The "Bluephase N" uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The "Bluephase N" is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	P < 75W (pass without test)
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	P < 75W (pass without test)

Table: According to IEC 60601-1-2, Edition 3.0

Guidance and manufacturer's declaration - electromagnetic immunity

The "Bluephase N" is intended for use in the electromagnetic environment specified below. The customer or the user of the "Bluephase N" should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	**± 6 kV contact** **± 8 kV air**	Floors should be concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	**± 2 kV for power supply lines** **± 1 kV for input/output lines**	Mains power quality should be that of typical commercial or dental environment.
Surge IEC 61000-4-5	± 1 kV line - line ± 2 kV line - earth	**± 1 kV line - line** **no prot. earth**	Mains power quality should be that of typical commercial or dental environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	**<5 % U_T** **(>95 % dip in U_T) for 0.5 cycle** **40 % U_T** **(60 % dip in U_T) for 5 cycles** **70 % U_T** **(30 % dip in U_T) for 25 cycles** **<5 % U_T** **(>95 % dip in U_T) for 5 sec**	Mains power quality should be that of typical commercial or dental environment. If the user of the „Bluephase N" requires continued operation during power mains interruptions, it is recommended that the „Bluephase N" be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	**30 A/m**	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or dental environment.

Table: According to IEC60601-1-2, Edition 3.0

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

The "Bluephase N" is intended for use in the electromagnetic environment specified below. The customer or the user of the "Bluephase N" should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should not be used closer to any part of the „Bluephase N", including cables, than the recommended separation distance caculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	**10 V**	$d = 0.35 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	**10 V/m**	$d = 0.35$ P 80 MHz to 800 MHz $d = 0.70$P 800 MHz to 2.5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Table: According to IEC60601-1-2, Edition 3.0

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the „Bluephase N" is used exceeds the applicable RF compliance level above, the „Bluephase N" should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the „Bluephase N".

[b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the "Bluephase N"

The "Bluephase N" is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled.
The customer or the user of the "Bluephase N" can help prevent electromagnetic interference by maintaining a miminum distance between portable and mobile RF communications equipment (transmitters) and the „Bluephase N" as recommended below,
according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 0.4 \sqrt{P}$	80 MHz to 800 MHz $d = 0.4 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$
0.01	0.04	0.04	0.07
0.1	0.13	0.13	0.22
1	0.40	0.40	0.70
10	1.3	1.3	2.2
100	4.0	4.0	7.0

Table: According to IEC60601-1-2, Edition 3.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Verification according to IEC60601-1-2; Edition 4.0:
The Bluephase N is tested according to IEC60601-1-2; Edition 4.0 and complies the requirements to clause 8.9 for Professional Health Care and Home Health Care Environment.

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