# Bluephase® PowerCure

[en]	Instructions for Use LED Polymerization unit	2
[de]	Gebrauchsinformation LED-Polymerisationsgerät	22
[fr]	Mode d'emploi Lampe à photopolymériser LED	42
[it]	Istruzioni d'uso Lampada a LED per polimerizzazione	62
[es]	Instrucciones de uso Lámpara de polimerización LED	82
[pt]	Instruções de Uso Unidade de Polimerização LED	102
Appe	ndix	122

Rx ONLY



Manufacturer: Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan/Liechtenstein www.ivoclar.com

Date information prepared: 2023-03-23/Rev. 1 756422/WE1

### https://stomshop.pro/

# ivoclar

# Introduction

### Dear Customer

Optimum polymerization is an important requirement for all light cured materials in order to consistently produce high quality restorations. The curing light selected also plays a decisive role in this respect. Therefore, we would like to thank you for having purchased Bluephase® PowerCure.

Bluephase PowerCure 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 Team

# Table of Contents

<b>1</b> 1.1 1.2 1.3 1.4	<b>Product Overview</b> List of parts Indicators on the charging base Indicators on the handpiece Operating the curing light	4
2	Intended Use	7
<b>3</b> 3.1 3.2	Application Start-Up Operation	9
4	Maintenance and Cleaning	14
5	What if?	16
6	Safety Information	18
7	Product Specifications	20
8	Additional Information	21

# 1 Product Overview

#### 1.1 List of parts



#### 1.2 Indicators on the charging base



Charging base with integrated radiometer and Click & Cure function:

- Indicator is dark: Battery is charged
- Indicator shows battery symbol: Battery is charging
- Indicator shows light intensity: Measurement has been carried out

#### 1.3 Indicators on the handpiece



#### 1.4 Operating the curing light



Start/Stop button to trigger/abort the curing process

Time selection button to select the desired curing time

Program selection button to select the desired curing program

#### Activating/deactivating polyvision



The polyvision function is activated by long pressing (>2 s) the program or time selection button (see 3.2 Operation). To confirm that polyvision is activated, the handpiece will beep and vibrate for a short time and the polyvision indicator will light up. Renewed long pressing of the program or time selection button results in the polyvision function being deactivated; the handpiece will not vibrate.

With the handpiece switched on, the current charging status is shown on the handpiece as follows:

# No indicators lit up on the handpiece: Battery sufficiently charged

Curing capacity of minimum 20 minutes in the High Power program, approx. 15 minutes in the Turbo program and approx. 8 minutes in the 3sCure program.

#### • Battery symbol on the handpiece is flashing orange: Battery weak

Time/intensity can still be set and a polymerization time of approx. 6 minutes in the High Power program, approx. 4 minutes in the Turbo program, or 30 cycles in the 3sCure program are left. Place the device into the charging base as soon as possible.

# • Battery symbol on the handpiece is flashing orange and a red "x" is shown: Battery completely discharged

The light can no longer be activated and the curing time can no longer be set. However, the handpiece can be used in the Click & Cure corded mode.



# 2 Intended Use

#### Intended purpose

Polymerization of light-curing dental materials

#### Patient Target group

- Patients with permanent teeth
- Patients with deciduous teeth

#### Intended users / Special training

- Dentists (clinical procedure)
- Dental assistants (clinical procedure)
- No special training required

#### Use

For dental use only.

#### Description

Bluephase PowerCure is an LED curing light that produces blue light. It is used for the polymerization of light-curing dental materials directly in the oral cavity of patients.

#### Indications

None

#### Areas of application:

Polymerization of light-curing dental materials in the wavelength range of 385-515 nm, including filling materials, dental adhesives, cavity liners, bases, fissure sealants, temporary restorations, luting materials for brackets and indirect restorations (e.g. ceramic inlays).

#### Contraindications

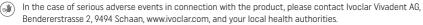
None

#### Limitations of use

- Materials whose polymerization is activated outside the wavelength range of 385–515 nm (no such materials known to date). If you are not sure about certain products, please ask the manufacturer of the corresponding material.
- Do not charge or use the appliance near flammable or combustible substances.
- Never use without light guide.
- $\gg$ ) The use of a light guide other than the one provided in the delivery form is not admissable.
- Using the device stacked on or close to other equipment should be avoided because correct function can be disrupted. If such use is unavoidable, the device needs to be monitored and checked for correct function.
- Portable and mobile high-frequency communication devices may interfere with medical equipment. The use of mobile phones during operation is not allowed.
- Caution The use of control or adjustment devices or performing procedures other than those specified herein may result in hazardous radiation exposure.
- Never use without eye protection for patients and users.
- If the light emission window cannot be optimally placed in relation to the composite restoration, the restoration must be polymerized using a conventional method. If soft tissue exposure to the curing light cannot be avoided, the 3sCure program must not be used, as exposure may result in damage of the soft tissues.
- The 3sCure program (3,000 mW/cm<sup>2</sup>) must only be used for direct restorations in the posterior region (Class I & II) in combination with Tetric PowerFill, Tetric PowerFlow or Adhese Universal. Do not use the 3sCure program in cases of deep cavities (caries profunda).
  - The 3sCure curing mode (3,000 mW/cm²) must not be used for deciduous teeth.

#### Warning





Direct exposure to curing light may cause damage to the eyes.

#### **Clinical benefit**

In combination with restoration materials:

- Reconstruction of chewing function
- Restoration of esthetics

#### **Residual risks**

Users should be aware that any dental intervention in the oral cavity involves certain risks. Some of these risks are listed below:

As 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 damage.

#### Signs and symbols in these Instructions for Use

The signs and symbols in these Instructions for Use facilitate the finding of important points and have the following meanings:

### Warning symbols and mandatory signs on the device

The signs on the device have the following meaning:

Symbol Notor

Symbol	Notes
*	Observe Instructions for Use
$\triangle$	Caution
	Limitations of use and Warning

Symbol	Notes
	Double insulation (device complies with safety class II)
★	Protection against electrical shock (BF type apparatus)
$\sim$	AC voltage
	DC voltage
X	The product must be disposed of according to the corresponding national legal requirements.
	Recyclable
$\triangle$	Caution
8	Observe Instructions for Use (Failure to observe the Instructions for Use may result in a risk to the patient or user.)
	Observe Instructions for Use

# 3 Application

#### 3.1 Start-Up

Check the delivery for completeness and any possible transportation damage (see List of Parts). If parts are damaged or missing, contact your lvoclar representative.

#### Charging base

Before you switch on the device, make sure that the voltage mentioned on the rating plate complies with your local power supply.

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

Connect the power cord with the power supply and the power pack. Make sure that the power cord is easily accessible at all times and and can easily be disconnected from the power supply. The charging base will briefly display "Bluephase PowerCure" as ticker text on the screen.





#### Handpiece

Unpack the handpiece from the packaging and detach the light guide by pulling it out. Then clean the handpiece and light guide (see Maintenance and Cleaning). After cleaning, reinsert the light guide.

For reasons of hygiene, we recommend using a disposable protective sleeve for each patient (see Maintenance and Cleaning). Make sure to fit the protective sleeve snugly to the light guide. Sleeves enclosed in the delivery form may be used or sleeves can be purchased per country specific regulations. Then, attach the anti-glare cone or anti-glare shield to the light guide.





#### Battery

The battery must be fully charged before it is used for the first time! When fully charged, the battery features a curing capacity of at least 20 minutes in the High Power program, approx. 15 minutes in the Turbo program and approx. 8 minutes in the 3-second curing program (3sCure). 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 without using any force. If a hygiene sleeve is used, please remove it before you charge the battery. If possible, always use the light with a fully charged battery. This will prolong the service life. We therefore recommend placing the handpiece into the charging base after each patient. If the battery is fully discharged, the charging time is 2 hours.

The battery is an expendable part that typically needs to be replaced after approximately 2.5 years. See battery label for the age of the battery.

#### Battery: charging status

The current charging status is displayed on the handpiece as described on page  $\boldsymbol{\delta}.$ 







#### Click & Cure corded operation

Bluephase PowerCure can be used in corded operation mode at any time and particularly when the battery is completely empty. For corded operation, release the battery by pressing on the release button on the lower part of the handpiece and then pull the battery out of the handpiece completely.

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, since it is not connected to a power source.

A complete disconnection from the power supply is only ensured when the power cord is disconnected from the power socket.







#### Measuring the light intensity

The integrated radiometer allows the light intensity (mW/cm<sup>2</sup>) to be measured easily and quickly while the charging base is connected.

To measure the light intensity, place the tip of the light guide, without protective cover, flush into the marked recess on the upper side of the charging base. Then activate the light and read the value displayed on the screen. Measurement accuracy is in the range of +/- 10%. If the light intensity is below 400 mW/cm<sup>2</sup>, the screen will display "LOW". Measure the light intensity of the curing light only with the accompanying charging base supplied in the delivery form.



#### 3.2 Operation

Disinfect contaminated surfaces of the curing light as well as light guides and anti-glare cones before each use. Additionally, the light guide can be sterilized using the autoclaves intended for this purpose (see chapter Maintenance and Cleaning). Furthermore, make sure that the emitted light intensity permits adequate polymerization. For that purpose, inspect the light guide for contamination and damage and check the light intensity at regular intervals (see paragraph Measuring the light intensity).

#### Selecting the curing program and curing time

Bluephase PowerCure is equipped with 5 selectable curing times and 4 curing programs for different indications. Use the Time/Program selection button to set the desired curing time and/or the light intensity.

#### Hộ: (High Power program), 1,200 mW/cm<sup>2</sup>\*:

The following curing times can be selected in the High Power program: 10, 15 or 20 seconds.

#### Tik (Turbo program), 2,000 mW/cm<sup>2</sup>\*:

The curing time is set to 5 seconds in the Turbo program and cannot be changed.

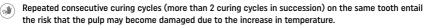
#### 3s \* (3sCure program), 3,000 mW/cm<sup>2</sup> \*:

In the 3sCure program, the curing time is set to 3 seconds and cannot be changed. The 3sCure program can be activated no more than twice in direct succession. After the two curing cycles have been conducted, a 30-second break is necessary for safety reasons before the next curing cycle can be activated.

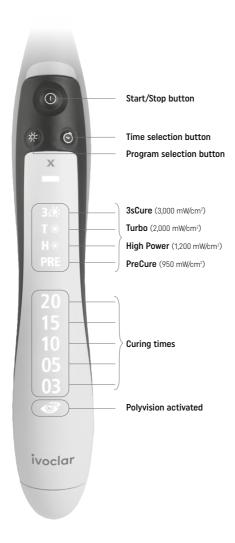
#### PRE (PreCure program) \*:

The PreCure program is used to tack cure light-curing, adhesive luting composites in order to facilitate the removal of excess material. If other luting composites are used, the distance from the light guide to the composite must be increased or several curing cycles must be conducted. The curing time of the PreCure program is preset to 2 seconds and cannot be altered.

\*Rounded values. See Chapter 7 Product Specifications



The PreCure program must not be used for conventional light-curing!



Observe the Instructions for Use of the material applied when selecting the curing time and intensity. The curing recommendations for composite materials apply to all shades and, if not mentioned otherwise in the Instructions for Use, to a maximum layer thickness of 2 mm. Generally, these recommendations apply to situations where the emission window of the light guide 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 approx. 8 mm, the effective light output is reduced by approx. 50%. In this case, the recommended curing time has to be doubled.

1) The information provided herein applies to the 10>9 mm light guide supplied in the delivery form.

2) The information regarding heat development and burn hazards must be taken into consideration (see Safety notes).

#### Polyvision - Automatic assistant with intelligent anti-glare protection



Bluephase PowerCure features a fully automated "polyvision" assistant for safe polymerization. This feature enables the curing light to automatically sense if the handpiece is inadvertently moved from its position during the curing procedure. To prevent any associated reduction in the amount of energy being transferred, the device will start to vibrate to alert the user to the

improper use and will automatically extend the curing time by 10%. If the handpiece is significantly shifted away from its initial position (e.g. out of the oral cavity), the light will automatically switch off so that the curing process can be restarted and carried out correctly.

In addition, polyvision also acts as intelligent anti-glare protection. Polyvision ensures that the curing light cannot be used outside the mouth. The light can only be activated once the light guide is positioned directly over the material to be polymerized. This protects the operator and patient from being blinded by the light.

If a protective sleeve is used, this function is not available. Contamination of the light guide may affect the functionalities of the polyvision assistant. The automatic assistant is there to support the user. It does not obviate the need for monitoring by the user. If you do not want to use the assistant, you can deactivate it at any time by long pressing (> 2 seconds) the Time or Program selection button. The symbol on the handpiece (see 3.1 Indicators on the handpiece) then disappears.

#### Measuring the light intensity

We recommend checking the light intensity emitted by the curing light at regular intervals using the integrated radiometer in order to be sure that the materials are adequately cured and the composite fillings are of a high and lasting quality (see 3.1 Start-Up).

#### **Cure Memory function**

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

#### Start/Stop

The light is switched on by means of the Start/Stop button. It is recommended that the emission window of the light guide is placed directly on the material to be polymerized. 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/Stop button again.

#### Acoustic signals

Acoustic signals can be heard for the following functions:

- Start (Stop)
- Every 10 seconds
- Curing time and program change
- Insert battery
- Error message (when anti-glare protection is activated or curing cycle aborted)
- Error message when attempting to activate the 3sCure program during the 30-second waiting time that follows
  after the program has been used twice in succession.

#### Light intensity

The light intensity is maintained at a consistent level during operation. If the supplied 10>9 mm light guide is used, the light intensity has been calibrated to 1,200 mW/cm<sup>2</sup>  $\pm$  10% in the High Power program.

In the Turbo program, the light intensity is calibrated to 2,000 mW/cm<sup>2</sup>  $\pm$  10%. In the 3-second program (3sCure), the light intensity is calibrated to 3,000 mW/cm<sup>2</sup>  $\pm$  10%. If another light guide than the one supplied is used, it directly influences the emitted light intensity.

When focussing light guides (10>9 mm) or Pin-Point light guides (6>2 mm) are used, the diameter of the light entry is larger than the diameter of the light emission window. The incident blue light is therefore concentrated over a smaller area. As a result, the emitted light intensity is increased.

Pin-Point light guides are suitable for spot-on polymerization, e.g. to tack veneers in place before removing excess material. For complete polymerization, the light guide must be changed.

# 4 Maintenance and Cleaning

For reasons of hygiene, we recommend using a disposable protective sleeve for each patient. Make sure to fit the protective sleeve closely to the light guide. Disinfect contaminated surfaces of the device and antiglare cones (FD 366/Dürr Dental, Incidin Liquid/Ecolab, CaviCide/Metrex Research). Sterilize the light guide 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.

#### Cleaning the 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.





#### Pre-treating the light guide

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

- Remove substantial contamination immediately after use or 2 hours after that at the latest. For this purpose, thoroughly rinse the light guide under running water (for at least 10 seconds). Alternatively, use a suitable aldehyde-free disinfecting solution to remove any adherent 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:

Machine cleaning and disinfection in a washer-disinfector unit should be preferred.

#### Mechanical cleaning and disinfection the light guide (Disinfector/CDU (cleaning and disinfection unit))

Machine cleaning and disinfection is possible using e.g. Neodisher® MediClean forte, Dr. Weigert, 0.5 %, according to the cleaning program, e.g. cleaning 55 °C (131 °F) (+5 °C (41 °F)/-0 °C), 5–10 min, disinfection 90 °C (194 °F) (+5 °C (41 °F)/-0 °C), 5–10 min.

#### Manually cleaning and disinfecting the light guide

For manual cleaning, place the light guide in an instrument cleaning solution (e.g. ID 212 forte/Dürr Dental) for the recommended reaction time (15 minutes). Make sure that the light guide is sufficiently immersed in cleaning solution (cleaning bath with sieve insert and lid). Observe the instructions for use of the disinfectant manufacturer when using cleaning and disinfectant solution.

(💓) 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 solutions (the maximum admissible pH value is 11)
- oxidizing agent (e.g. hydrogen peroxide)

After the cleaning process, remove the light guide from the solution and thoroughly rinse it under running water (20 +/- 2 °C / 36 +/- 4 °F ) for at least 10 seconds.

#### Sterilization of the light guide

Thorough cleaning and disinfecting is imperative to ensure that the subsequent sterilization is effective. Use only autoclave sterilization for this purpose: 3x pre-vacuum, sterilization time (exposure time at sterilization temperature) is 4 minutes at 134 °C (273 °F); pressure should be 2 bar (29 psi). Use nationally approved sterilization pouches. Dry the sterilized light guide (10 min) using either the special drying program of your steam autoclave or hot air. The light guide has been tested for up to 200 sterilization cycles.

#### Checking the light guide

After that, check the light guide for damage. Hold it against the light. If individual segments appear black, glass fibres are broken. If this is the case, replace the light guide with a new one. If you can still see signs of contamination on the light guide, the cleaning and disinfecting procedure must be repeated.

# 5 What if ...?

Indicator	Causes	Error rectification
Red "x" lights up	The device is overheated.	Allow the device to cool down and try again after a certain time. If the error persists, please contact your dealer or your local Service Centre.
* 0	Electronic component of the handpiece is defective.	Remove and reinsert the battery. If the error persits, please contact your dealer or your local Service Centre.
Red "x" and battery symbol light up	Battery empty	Place the device in the charging base and charge it.
* 0	Battery contacts dirty	Remove battery and clean the battery contacts.
3s flashes	shes In the 3sCure program, the curing time is set to 3 seconds and cannot be changed. The 3sCure program can be used no more than twice in direct succession.	After two consecutive curing cycles, an extended waiting time of 30 seconds is necessary for safety reasons before the next curing cycle can be started.
* 0		If for compelling reasons an additional curing cycle is required before the prescribed interval of 30 seconds has elapsed, the 3sCure program can be activated again by selecting it anew with the program selection button.
The charging base is not illuminated during charging	<ul> <li>Power pack not connected or defective</li> <li>Battery fully charged</li> </ul>	Check if the power pack is correctly positioned in the charging base or if the power pack is connected to the power supply by means of the power cord.

#### Repair work

The warranty period for Bluephase PowerCure 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 however does not confer rights to compensation for any material or non-material damage. 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 Product Specifications: 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, drops 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 Centres.

In case of a claim under warranty, the complete apparatus (handpiece, charging base, battery, 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 Centre. In case of a defect that cannot be rectified, please contact your dealer or your local Service Centre (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.

# 6 Safety Information

- In the case of serious adverse events in connection with the product, please contact lvoclar Vivadent AG, Bendererstrasse 2, 9494 Schaan, www.ivoclar.com, and your local health authorities.
- The current Instructions for Use are available in the download section of the Ivoclar Vivadent AG website (www.ivoclar.com).
- Bluephase PowerCure is an electrical appliance and a medical device which is subject to IEC 60601-1 (EN 60601-1) and EMC Standard IEC 60601-1-2 (EN 60601-1-2) as well as the Medical Device Regulation (EU) 2017/745 (MDR). The curing light complies with the relevant EU regulations.
- The curing light 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 must be observed. To prevent damage to equipment and risks for patients, users and third parties, the following safety instructions must be observed.

Safety notes for the "3sCure program" (3,000 mW/cm<sup>2</sup>):

- Avoid direct exposure of the gingiva, oral mucous membrane or skin.

#### Usage and liability

- Bluephase PowerCure must only be employed for its intended use. Any other uses are contraindicated. Do not touch defective, open devices. Liability cannot be accepted for damage resulting from misuse or failure to observe the Instructions for Use.
- The user is responsible for testing Bluephase PowerCure for its use and suitability for the intended purposes.
   This is particularly important if other equipment is used in the immediate vicinity of the curing light at the same time.
- Use only original spare parts and accessories from lvoclar. The manufacturer does not accept any liability for damage resulting from the use of other spare parts or accessories.
- The light guide is an applied part and may warm up to a maximum of 45 °C (113 °F) at the interface to the handpiece during operation.
- Keep out of the reach of children!
- For use in dentistry only!

#### **Operating voltage**

Before switching on, make sure that

- a) the voltage indicated on the rating plate complies with the local power supply and
- b) the unit has acquired the ambient temperature.

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

#### 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 device 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. Ensure that the device can be quickly and easily disconnected at any time.

#### 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. To optimize user safety, the device has been equipped with intelligent anti-glare protection. For this, the "polyvision" function must be activated (see 3.2. Operation). With the polyvision function activated, the Bluephase PowerCure automatically senses if the handpiece is outside of the mouth and automatically switches off the light if it has been activated inadvertently. If a protective sleeve is used, this function is not available.

In addition, we also recommend using the anti-glare protective equipment supplied. Individuals who are sensitive to light, who take photosensitizing drugs, have undergone eye surgery, or work with the apparatus (or in its vicinity) for long periods of time, should not be exposed and should wear protective orange goggles that absorb light below a wavelength of 515 nm. The same applies for patients.

#### Battery

Caution: Use only original spare parts for Bluephase PowerCure, particularly lvoclar Vivadent batteries and charging bases. Do not short circuit battery. Do not touch the battery contacts. 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 lithium-ion batteries may react with explosion, fire and smoke development if handled improperly or mechanically damaged. Damaged lithium-ion batteries must no longer be used.

The electrolytes and electrolyte fumes released during explosion, fire and smoke development are toxic and corrosive. Do not touch leaking batteries with bare hands. In case of contact with the eyes or skin, immediately wash with copious amounts of water.

Avoid inhalation of fumes. In case of indisposition, see a physician immediately. Remove electrolyte residue from surfaces by washing/wiping with a moist cloth. Wash contaminated pieces of clothing immediately.

#### Heat development

Generally, the recommended curing times, particularly in areas near the pulp, must be observed. Using more than two 3sCure cycles on the same tooth within a period of 30 seconds and direct contact with the gingiva, oral mucous membrane or skin must be strictly avoided. In addition, the light emission window must remain positioned exactly on the material to be cured during the entire duration of the curing cycle (e.g. by holding it in place using a finger). If soft tissue exposure cannot be avoided, work with reduced light intensity. Polymerize indirect restorations at intermittent intervals of 10 seconds in the High Power program and 1 x 5 seconds each in the Turbo program or use external cooling with an air stream. The instructions regarding curing programs and curing times must be observed (see Selecting the curing program).

After several curing cycles on the same tooth, there is a risk that the pulp suffers damage caused by the increased temperature!

#### Disposal



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

# 7 Product Specifications

Technical data	
Light source	Ivoclar Vivadent Polywave® LED
Wavelength range	385–515 nm Peak 1: 400–410 nm Peak 2: 450–465 nm
Light intensity	3sCure program: 3,050 mW/cm <sup>2</sup> ± 10 % Turbo program: 2,100 mW/cm <sup>2</sup> ± 10 % High Power program: 1,200 mW/cm <sup>2</sup> ± 10 % PreCure program: 950 mW/cm <sup>2</sup> ± 10 %
Operation	3 min on / 7 min off (intermittent)
Light guide	10>9 mm, autoclavable (active surface 0.5 cm <sup>2</sup> )
Signal transmitter	Beeps every 10 seconds and every time the Start/Stop button or the Time/Program selection button is activated or the anti-glare protection is enabled or the curing process is aborted and 30-second waiting time after the 3sCure program has been used twice in succession
Dimensions of the handpiece (without light guide)	L = 170 mm, B = 30 mm, H = 30 mm
Weight of the handpiece	135 g (including battery and light guide)
Operating voltage of the handpiece	3.7 VDC with battery 5 VDC with power pack
Operating voltage of the charging base	5 VDC
Power supply	Input: 100–240 VAC, 50–60 Hz max. 1 A Output: 5 VDC / 3 A Manufacturer: EDAC POWER ELEC. Type: EM1024B2
Operating conditions	Temperature +10 °C bis +35 °C Relative humidity 30 % to 75 % Ambient pressure 700 hPa to 1060 hPa
Dimensions of the charging base	D = 110 mm, H = 55 mm
Weight of the charging base	145 g
Charging time	Approx. 2 hours (with the battery empty)
Power supply of the handpiece	Li-ion battery
Transportation and storage conditions	Temperature -20 °C to +60 °C Relative humidity 5 % to 90 %, non-condensing Ambient pressure 500 hPa to 1060 hPa The curing light has to be stored in closed, roofed rooms and must not be exposed to 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 - Keep the battery charged and store no longer than 6 months.
Delivery form	1 Charging base with power cord and power pack 1 Handpiece 1 Handpiece support 1 Light guide 10>9 mm 1 Anti-glare shield 3 Anti-glare cones 1 Pack of sleeves 1 Instructions for Use

# 8 Additional information

#### Keep material out of the reach of children! Not all products are available in all countries.

The product has been developed solely for use in dentistry. Processing should be carried out strictly according to the Instructions for Use. Liability cannot be accepted for damages resulting from failure to observe the Instructions or the stipulated area of use. The user is responsible for testing the products for their suitability and use for any purpose not explicitly stated in the Instructions.