

Model 3

# FlashMax P3 460 4W

Manual



English

CE

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## 1. Technical description

The FlashMax P3 light is a medical device, class I, in compliance with the European Medical Device Regulation 2017/745. The light must only be used in dental clinics by dental personnel, and only for designated purposes. The product is classified as an electronic medical device electric class II according to DS/EN 60601-1:1998. The product is classified as a class 2 LED product according to EN 60825-1:2001 Ed1.2.

CMS Dental declares that the product described in this manual complies with the above mentioned standards.

The FlashMax P3 light consists of a hand piece, a docking station and an external power supply. Disposable covers and tips protect against cross contamination.

The main device is configurable. The accessory light guide tip corresponding to the planned treatment must be attached to the main product prior to usage.

## WARNINGS



1. Do not expose directly into the eyes, or look directly at the emitted light.
2. Eyewear protection should be used.
3. Medical electronic equipment is sensitive to electromagnetic fields. Portable and mobile high frequency communication devices may interfere with medical devices. In order to maintain proper operation, follow instructions in this manual.

4. Use of the light without a tip may cause overheating of the tissue if the light is used close to the gingiva.
5. In the unlikely situation that a serious incident should occur in relation to use of the product, the incident should be reported to the dentist, dealer or manufacturer and the competent authority of medical devices in your home country.
6. Extended use cause tip and cover to be hot and may cause slight burning sensation of mucosa, if touched.
7. Do not reuse covers or tips as this may cause cross contamination.
8. If the light beeps every 2 s when placed in docking station, it is a warning that the charging voltage is 6 V or higher, i.e. a wrong power supply is being used.

## 1.1 Technical specifications

Power supply	
Input power	100–240VAC, 50/60Hz
Output power	5.0VDC, 1.0A
Battery	
Battery type	LiFePO <sub>4</sub>
Nominal voltage	3.2V
Nominal capacity	1.200mA
Re-charging time	2 hours
User capacity	approx. 500 seconds
LED diode	
Output intensity	5.000-6.000 mW/cm <sup>2</sup>
Wavelength	450-470nm (85%), peak 460nm
Other	
Operation mode	Intermittent. No continuous use over 1 minute to prevent overheating

## 1.2 Environmental conditions

Transport	
Temperature	+5 to + 40 C
Moisture	10% to 75%
Altitude	70kPa to 106kPa (0.7 bar to 1.06 bar) Keep away from sunlight
Storage	
Temperature	+5 to + 40 C
Moisture	10% to 75%
Altitude	70kPa to 106kPa (0.7 bar to 1.06 bar) Keep away from sunlight
Use	
Temperature	+10 to + 40 C
Moisture	30% to 75%
Altitude	70kPa to 106kPa (0.7 bar to 1.06 bar)

## 2. Preparing to use the FlashMax P3

Connect the power supply under the base of the docking station to a main electrical outlet. Place the light in the dock and the battery will begin charging. This is indicated by a green light flashing.

## 3. Use and program modes

The FlashMax P3 is only intended for the polymerization of dental materials: The 1 s time cycle is used for a layered build-up and/or bonding agents. The 3 s time cycle is used for the finishing layer and/or darker shades.

### Three program modes

The FlashMax P3 light is used intermittently in one of three programs each with time settings of 1 or 3 seconds.

To see the program selected, press the two buttons at the same time and hold for 3 s until a beep is heard. The diode will flash the color of the program, green, orange or red.

To change the program, scroll using any button. Stop at the chosen program and wait for the beep. The light will stay in the chosen mode until changed manually.

### 3.1 Intelligent Automated Functions

The FlashMax P3 is the first light with this new concept.

**The green program** mode is the manual mode. Press the large button and the unit will light for 3 s. Press the small button and it will light for 1 s.

**In the orange program** mode, pressing the large button will give you 3 s of light, a 0.5 s pause, then again 3 s of light. The small button 1 s of light, a 0.5 s pause, then 1 s of light. This mode is used for layered build-ups when the composite restoration is wide enough to require two side by side activations.

**In the red program** mode the large button will give you 3s + 3s + 3s + 3s continuously, with 0,5 s pause between each activation, until you press the button again to stop it. The small button gives 1s + 1s + 1s + 1s continuously, with 0,5 s pause between each activation, until you press the button again to stop it. This mode is used for cementing brackets or veneers or in any other situation where repetitive activations are required.

### 3.2 Temperature safety

The FlashMax P3 light has a safety cut off to preserve the lifetime of the diode should overheating occur.

When the light gets close to the cut off temperature, you will be warned by intermittent beeping. User time before the warning varies between 45 and 80 seconds. The light can be used for approximately another 15 s before it cuts off. Overheating is indicated by 3 short beeps followed by fast red flashing.

### 3.3 Battery power saving

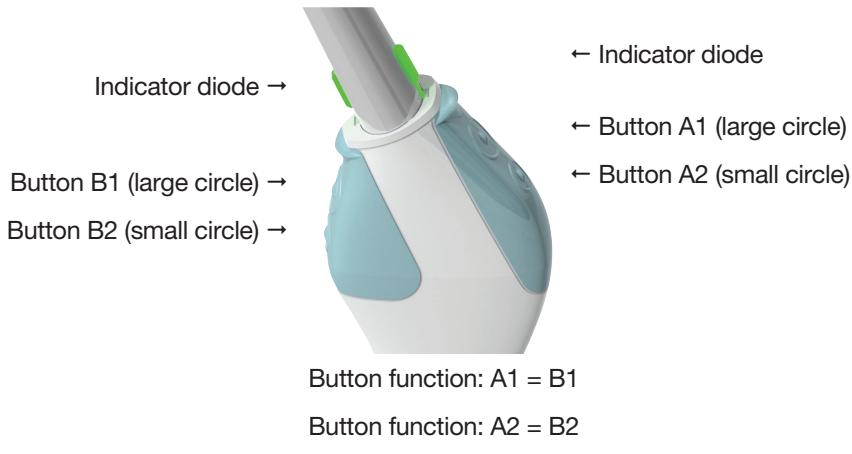
#### Sleep

If the light has not been activated for 5 minutes, or placed in the dock, it will go into sleep mode to conserve energy. Press any button to reactivate it.

#### Deep sleep

If not used or placed in the docking station for 6 hours the light will go into deep sleep mode. It must be placed in the dock for one second to be reactivated.

## Intelligent Automated Functions: Program modes

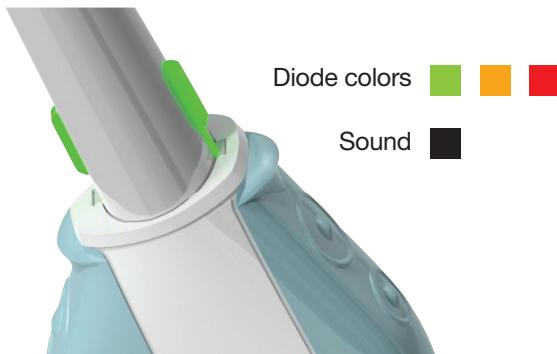


Program change:

● → ○ → ● : Press A1+A2 at same time 3 s → scroll → wait 3 s for beep



### 3.4 Indications: Three-colored diode and sound



Ready		ready for use
Activated light		sound to indicate start and stop. <b>DANGER!</b> Do not stare into light. It may cause eye damage.
Charging battery		may be used
Low battery		if not used, place in dock
Diode heat warning		15 s from cut-off
Diode overheated		needs to cool before it can be activated. <b>DANGER!</b> Tip is hot and may cause light burning to mucosa.
Sleep mode		press any button
Deep sleep mode		place in dock
Error		reset by pressing two buttons on same side for 3 s. <b>DANGER!</b> No curing of materials.

## 4. Cover and tips



BLUNT  
d 4 mm



BLUNT  
d 8 mm



The main device is configurable. The accessory light guide tip corresponding to the planned treatment must be attached to the main product prior to usage.

The light should only be used with a tip and cover attached.

There are two standard tips for the FlashMax P3 - a d 4 mm and a d 8 mm tip.

### Attaching and detaching tips

Tips are snapped onto the cover by pressing the two items together. The tips can be moved +/-15 degrees in the longitudinal direction of the cover. To detach the tip, rotate the tip away from the cover and it will pop out.

## 5. Cleaning

The hand piece and docking station may be wiped with a slightly damp cloth.

**CAUTION!** Use only 70% alcohol when cleaning the light and docking station.

Make sure NOT to leave fluid in the charger socket, remove excess fluid with a dry clean cloth or tissue. Fluid in the docking socket may cause electrolytic corrosion of the charger.

Make sure NOT to disperse disinfection fluids into the diode. This may damage the diode.

The removable cover is disposable. The tips are disposable.

## 6. Labelling

	Observe Operating Instructions
	Product Serial Number
	Medical Electrical Equipment Directive, DS/EN 60601-1:1998 Electrical shock protection, Type B
	Safety of laser products, EN 60825-1:2001 Ed1.2 Class 2 LED product
	Medical Electrical Equipment Directive, DS/EN 60601-1:2006 Electrical double insulation, Class II
	Medical Device Regulation , MDR (EU) 2017/745 Medical device, Class I
	Waste Electrical and Electronic Equipment Directive, WEEE Directive 2002/96/EC. Dispose product to a recycling central

## 7. Service and warranty

The FlashMax P3 light is covered by a 2 year warranty.

### CAUTION

The FlashMax P3 light must only be serviced and repaired by CMS Dental, otherwise the warranty will be void.

## 8. Disposal of waste products

The tips and covers should be disposed as regular waste. The hand piece, docking station and power supply shall be disposed to a recycling central.

## 9. FlashMax P3 accessories

FlashMax P3 tips	
	
50 disposable BLUNT tip d 4 mm <b>Item No. 100501</b>	50 disposable BLUNT tip d 8 mm <b>Item No. 100502</b>
FlashMax P3 Cover	FlashMax P3 protection
	
10 disposable cover <b>Item No. 100510</b>	1 protective shield <b>Item No. 100500</b>
FlashMax P3 protection	FlashMax P3 sleeves
	
1 click-on protective shield <b>Item No. 100511</b>	250 pcs. disposable dental sleeves <b>Item No. 100513</b>

## Notes



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