

FlashMax P4 Ortho Pro Manual



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FlashMax P4 Ortho Pro accessories

FlashMax P4 Ortho Pro kit contains:

- FlashMax P4 Ortho Pro light
- Docking station
- Power supply: Plugs for mains: EU/US/AUS/UK
- Covers: 2 x 10 pcs
- Tips: 10 pcs each of: BLUNT \varnothing 4 mm, BLUNT \varnothing 8 mm
- Protective shield
- Barrier sleeves: 10 x *closed*
- Manual



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. Extended use cause tip and cover to be hot and may cause slight burning sensation of mucosa, if touched.
6. Do not reuse covers or tips as this may cause cross contamination.
7. If the light beeps every 2s when placed in docking station, it is a warning that the charging voltage is 6V or higher, i.e. a wrong power supply is being used.



1. Technical description

The FlashMax P4 Ortho Pro light is a medical device, class I, in compliance with MDD (Medical Devices Directive) section IX. 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 60601-1:2010. The product is classified as a class 2 LED product according to EN 60825-1:2001 Ed1.2.

The product described in this manual complies with the above mentioned standards.

The FlashMax P4 Ortho Pro light consists of a hand piece, a docking station and an external power supply. Disposable covers and tips protect against cross contamination.

1.1 Technical specifications

Power supply	
Input power	100–240V AC, 50/60Hz
Output power	5.0V DC, 1.0A
Battery	
Battery type	LiFePO4
Nominal voltage	3.2V
Nominal capacity	1.200mA
Charging time	2 hours
User capacity	approx. 500 seconds
LED Diode	
Output intensity	4.000-5.000 mW/cm ²
Wavelength	450-470nm (85%), peak 460nm

1.2 Environmental conditions for intended use

Temperature range	+10°C to +40°C
Humidity range	30% to 75%
Atmospheric pressure range	70kPa to 106kPa (0.7 bar to 1.06 bar)
IP class	2X

2. Preparing to use the FlashMax P4 Ortho Pro light

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

3. Use and program modes

The FlashMax P4 Ortho Pro is only intended for the polymerization of dental materials:

- 1s time cycle is used for a layered build-up and/or bonding agents.
- 3s time cycle is used for the finishing layer and/or darker shades.

Three program modes

The FlashMax P4 Ortho Pro light is used intermittently in one of three programs each with time settings of 1s or 3s.

To see the program selected, press the two buttons at the same time and hold for 3s 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 **green** program mode is the manual mode. Press the large button and the unit will light for 3s. Press the small button and it will light for 1s.

In the **orange** program mode, pressing the large button will give you 3s of light, a 0.5s pause, then again 3s of light. The small button 1s of light, a 0.5s pause, then 1s of light.

In the **red** program mode the large button will give you 3s + 3s + 3s + 3s continuously, with 0,5s pause between each activation, until you press the button again to stop it. The small button gives 1s + 1s + 1s + 1s continuously, with 0,5s pause between each activation, until you press the button again to stop it.

This mode is used for cementing orthodontic brackets or veneers or in any other situation where repetitive activations are required.

3.2 Temperature safety

The FlashMax P4 Ortho Pro 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 45s and 80s. The light can be used for approximately another 15s before it cuts off. Overheating is indicated by 3 short beeps followed by fast red flashing.

3.3 Battery power saving

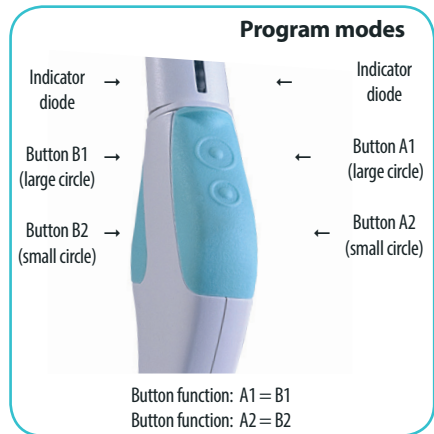
Sleep

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







Press any button to reactivate it.

Deep sleep

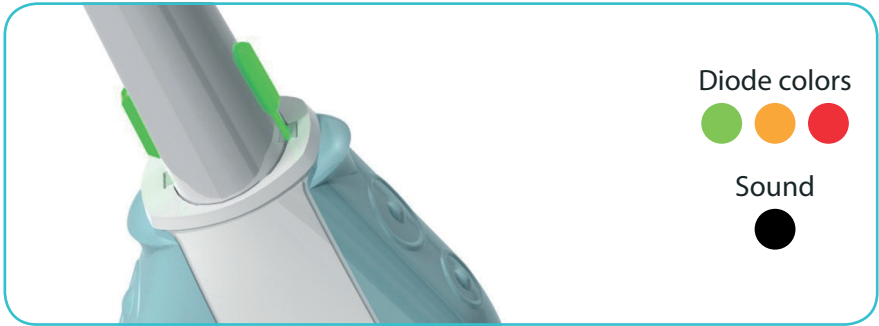
If not used or placed in the docking station for 6 hours the light will go into deep sleep mode. It must be placed in the docking station for one second to be reactivated.



The FlashMax P4 Ortho Pro has 3 programs:

	Small button	Large button
Manual use Press once	1s 	3s 
Manual use Press once	2 x 1s with 0.5s pause 	2 x 3s with 0.5s pause 
Rapid automated function Press once / Press again to stop	1s with 0.5s pauses cont. 	3s with 0.5s pauses cont. 

3.4 Indications: Three-colored diode and sound



Ready		Ready for use
Activated light		Sound to indicate start and stop. DANGER! Do not stare into light. It may cause eye damage.
Charging battery		May be used
Low battery		If not used, place in docking station
Diode heat warning		15s from cut-off
Diode overheated		Needs to cool before it can be activated. DANGER! Tip is hot and may cause light burning to mucosa.
Sleep mode		Press any button
Deep sleep mode		Place in docking station
Error		Reset by pressing two buttons on same side for 3s. DANGER! No effect of treatment.

4. Cover and tips

The light should only be used with a tip and cover attached. There are two standard tips for the FlashMax P4 Ortho Pro - BLUNT \varnothing 4 mm and BLUNT \varnothing 8 mm tip.

4.1 Attaching and detaching tips

Tips are snapped onto the cover by pressing the two items together.

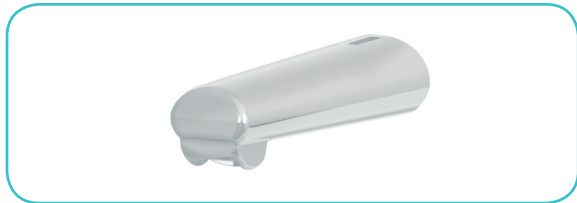
The tips can be moved \pm 15 degrees in the longitudinal direction of the cover. To detach the tip, rotate the tip away from the cover and it will pop out.



BLUNT
 \varnothing 4 mm



BLUNT
 \varnothing 8 mm



Cover

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 removeable cover is disposable. The tips are disposable.

We highly recommend the use of the barrier sleeves to protect the light from contamination. They generally increase the lifetime of the unit. Use the open barrier sleeve when you use the light with tips, and the closed barrier sleeve if you light cure without using a tip.

6. Labelling

	Operating Instructions
	Product Serial Number
	Manufacture identification number
	Expiry date
	Medical Electrical Equipment Directive, DS/EN 60601-1:2010, Electrical shock protection, Type B
	Medical Electrical Equipment Directive, DS/EN 60601-1:2006, Electrical double insulation, Class II
	Medical Devices Directive, MDD Directive 93/42/EEC, Medical device, Class I
	Canadian Standards Association, CSA, Approved for use in Canada and USA
	Waste Electrical and Electronic Equipment Directive, WEEE, Directive 2002/96/EC. Dispose product to a recycling central
	Safety of laser products, EN 60825-1:2001 Ed1.2 Class 2 LED product

7. Service and warranty

The FlashMax P4 Ortho Pro light is covered by a 2 year warranty.

CAUTION!

The FlashMax P4 Ortho Pro light must only be serviced and repaired by RMO, 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 center.

9. FlashMax P4 Ortho accessories



Barrier sleeves *open*
250 pcs.



Barrier sleeves *closed*
250 pcs.



Hand held paddle
protection



Click-on
protection



Single-use disposable
covers
10 pcs.



Ø4 mm adjustable
disposable BLUNT tip
50 pcs.



Ø8 mm adjustable
disposable BLUNT tip
50 pcs.



CQ LIT
Light intensity tester for
curing lights

