



CMS Dental
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FlashMax[®] P7

Manual



CE

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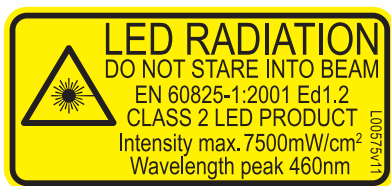
1. Intended purpose

The intended purpose of FlashMax® P7 is curing of dental composite and elimination of bacteria's in the biofilm of the root canals and of soft and hard tissue. The FlashMax P7 is a LED light source producing light with a peak wavelength of 460nm.

- FlashMax® P7 can be used for light curing of dental composites and other dental light cured materials that have an absorption spectrum and react around 460nm.
- FlashMax® P7 can be used as a photosensitizer light for light activated disinfection to eliminate bacterial growth. The photosensitizer light must be used in conjunction with QROXB2 photosensitizer.

WARNINGS

- Do not expose directly into the eyes, or look directly at the emitted light.



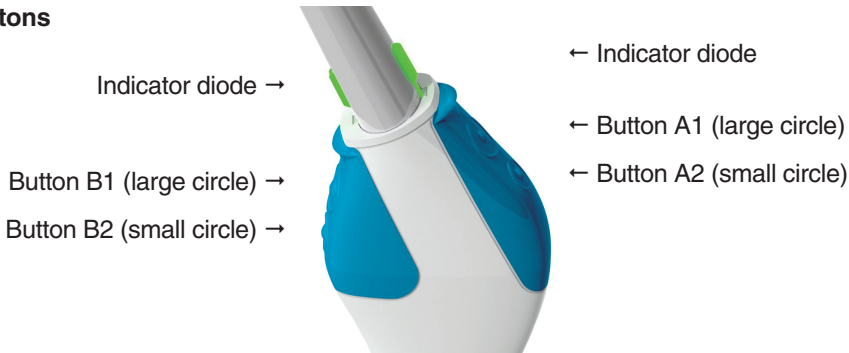
- "Eye protection: The enclosed click-on protection shield is only recommended for short time light exposure intervals as curing of dental composite. For long time exposure such as photosensitizer therapy or orthodontic treatments a protection spectacle or protection google with a light transmittance of 0,01% covering the blue light spectrum is required. Is available as accessories from CMS Dental.
- 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.
- Use of the light without a tip may cause overheating of the tissue if the light is used close to the gingiva.
- Extended use cause tips and cover to be hot and may cause slight burning sensation of mucosa, if touched.
- Do not reuse covers or tips as this may cause cross contamination.
- If the light beeps every 2 seconds when placed in docking station a wrong type of power supply is connected.
- The FlashMax® P7 QROXB2 photosensitizer can stain clothing.

2. Function and Use

Connecting

Connect the power supply under the bottom 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.

Buttons



Button function: A1 = B1

Button function: A2 = B2

Treatment settings - Program modes

The FlashMax[®] P7 light can be used for multiply intended uses. Each type of treatment has its own program. The indicator signal shows the setting of the FlashMax[®] P7 once it is lifted out of the docking station. Programs are Green, Orange and Red. Change program by pressing and holding the two buttons for 3 seconds until a beep sounds. Scroll by pressing either button, stop at the desired program and wait for the beep. The light will stay in the chosen program until manually changed.

Composite Curing – Green program

The green program mode is used for curing composites and other dental materials. In this program the intensity is approx. 5,500 mW/cm².

Small button	Large button
1s ●	3s ●



Use

1. Cure with the light (tip) as close to the composite as possible. Increase curing time according to the distance of the composite.
2. When building up the restauration follow the instructions of the composite manufacturer. Cure 1s or 3s for every 2-3mm layer. Compensate for distance between the tip and the material.
3. If each layer is wider that the tip – move the tip and cure again.
4. Always cure the final layer for 3s.

CAUTION! Never light directly on gingiva without a tip, as the heat may damage the tissue. If the composite is darker than A3, use 3s for each layer as penetration of the light is reduced in darker materials.

Periodontic Biofilm Control – Orange program

The orange program is used for light activated disinfection. A blunt tip is used for surface treatments and one of the perio tips is used for the dental pocket.

Small button	Large button
5s 	15s 

Alternatively, the endo tip may be used for this purpose. In this program the light vibrates when activated to ensure micro movements in the fluid/gel. In this program the intensity is approx. 7,500 mW/cm².

Use - On gingiva/mucosa

1. Apply QROXB2 Perio to gingiva/mucosa.
2. Activate Light for 5s per treatment spot.

CAUTION! Never treat more than 10s at same spot to avoid a burning sensation

Use - On larger mucous areas

1. Apply the QROXB2 Perio over the entire inflamed area using for example a cotton pellet.
2. Activate Light for 5s per treatment spot.

CAUTION! Never treat more than 10s at same spot to avoid a burning sensation.

Use - Periodontal areas



Preparation: Perform conventional scaling and root planning.

1. Fill the pocket with photosensitizer QROXB2 Perio.
2. Cure through gingiva using the 8mm Blunt tip when pocket is deeper than 5mm. Lingual and Facial for 10 seconds each.
3. Treat pocket from inside (perio tip 15mm or 23mm) minimum 15s per surface of tooth, depending of depth. See table.

Situation	Dosage
PD > 5mm	15s per site
PD > 8mm	30s per site
PD > 10mm	45s per site

Endodontic Biofilm Control – Red program

A blunt tip is used for surface treatments and the endo tip is used for root canal.

Small button	Large button
10s 	30s 

In this program the light vibrates when activated to ensure micro movements in the fluid/gel. In this program the intensity is approx. 7,500 mW/cm².

Use - Inside the root canal





Preparation: Clean and shape the root canal using copious amounts of sodium hypochlorite, citric acid or similar. Dry with paper points.

1. Fill the canal with photosensitizer QROXB2 Endo.
2. Insert the endo light tip until resistance is met and activate light 30s.
3. Rinse and dry.

3. Accessories

Cover and tips

There are five tips available for the FlashMax® P7 light. Use the tip that suits the desired treatment best. Tips do not fit the light without the Cover. Tips snap onto the Cover by pressing the two parts together. Tips can be positioned in an +/-15 degrees angle in the longitudinal direction of the cover. To detach the tip, rotate the tip away from the cover and it will pop out.

 <p>Cover REF 100510</p>	<p>Covers protects the light from contamination and the treatment tips connect to the cover.</p> <p>Covers are single-use and disposable.</p>
 <p>BLUNT Ø 4 mm REF 100501</p> <p>BLUNT Ø 8 mm REF 100502</p>	<p>The blunt tips is used for surface disinfection treatment and when curing composites close to the gingiva. This is to avoid too much heating of the gingiva, which may happen when the light is used without tips.</p> <p>Tips are single-use and disposable.</p>
 <p>PERIO L 23 mm REF 100503</p> <p>PERIO L 15 mm REF 100504</p>	<p>The perio tips is used for periodontal treatment.</p> <p>The perio tips have a diameter of 1 mm. The distal 5 mm have a surface permitting the light to go sideways.</p> <p>Tips are single-use and disposable.</p>
 <p>ENDO REF 100505</p>	<p>The endo tip is used for endodontic treatment.</p> <p>The endo tip has a diameter of 0.5 mm.</p> <p>Tips are single-use and disposable.</p>

QROXB2 – Photosensitizer Agent

To use the FlashMax® P7 light for disinfection purposes it requires the QROXB2 Perio or QROXB2 Endo photosensitizer agent.

QROXB2 is available in two different viscosities:

QROXB2 Perio - REF 100430

Is when ready to use a gel formulation for use in pockets and on the tissue surface

QROXB2 Endo - REF 100432

Is when ready to use a liquid formulation for use in the root canal

The concentration of active substances are the same, the gel is just easier to use in pockets and on surfaces. Both photosensitizer agents comes as a powder in a syringe. To prepare the photosensitizer agent draw up of the amount of water as indicated on product label of QROXB2 and shake until the powder is dissolved. For the gel formulation, wait 3min for the gel to have the proper viscosity.

4. Maintenance

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.
- Make sure NOT to disperse disinfection fluids into the diode. This may damage the diode.
- The removeable cover is disposable. The tips are disposable.

Barrier Sleeves

It is recommended to use barrier sleeves to protect the light from contamination. They generally increase the lifetime of the unit. Use the open barrier sleeve when light is used with tips, and the closed barrier sleeve when the light is used without a tip.

Barrier Sleeves Open -  100512

For use with cover and tips

Barrier Sleeves Closed -  100513

For use without cover and tips

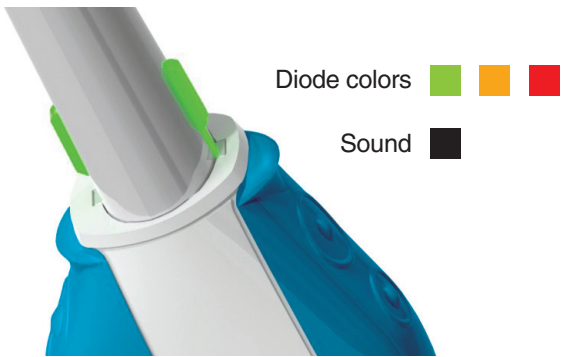
5. Technical description











The product is classified as an electronic medical device electric class II according to DS/EN 60601-1: 2006.

The product is classified as a class 2 LED product according to EN 60825-1:2001 Ed 1.2.

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

Light indication signals and sounds



Placed in dock		Fully charged
Out of dock Composite Curing		Green program settings active
Out of dock Periodontic Biofilm Control		Orange program settings active
Out of dock Endodontic Biofilm Control		Red program settings active
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 dock
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 dock
Error		Reset by pressing two buttons on same side for 3s. DANGER! No effect of treatment.

Temperature safety

The FlashMax® P7 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, an intermittent beep warning occur. 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.

Battery power saving

Sleep mode:

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 mode:

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

Technical specifications

The FlashMax® P7 light consists of a hand piece, a docking station and an external power supply.











Disposable covers and tips protect against cross contamination.

Power supply	
Manufacturer	Dongguan Shilong Fuhua Electronic Co. Ltd.
Model	UEO8WCP-050100SPA
Input power	100–240VAC, 50/60Hz
Output power	5.0VDC, 1.0A
Or equivalent medical approved power supply supplied by CMS Dental	
Battery	
Battery type	LiFePO4
Nominal voltage	3.2V
Nominal capacity	1450 mA
Re-charging time	2,5 hours
User capacity	approx. 760 seconds
LED diode	
Output intensity	5.500-7.500 mW/cm ²
Wavelength	450-470nm (85%), peak 460nm

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

6. Labelling

	Consult Instructions for Use
	Product Serial Number
	Catalogue number identification
	Manufacture identification number
	Expiry date
	Medical Electrical Equipment Directive, DS/EN 60601-1:2006 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

7. Service and warranty

The FlashMax® P7 light, battery inclusive, is covered by a 2 year warranty.

CAUTION! The FlashMax® P7 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.

Your FlashMax® P7 distributor:



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Our Innovation Your Success

Manufactured in Denmark by:

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