

FotoSan[®] Blue

Manual



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FotoSan® Blue kit contains:

- **FotoSan® Blue** light
- Docking station
- Power supply: Plugs for mains: EU/US/AUS/UK
- Manual
- Barrier sleeves *open* 10 pcs.
- Barrier sleeves *closed* 10 pcs.
- Click-on protection



WARNINGS

1. Do not expose directly into the eyes, or look directly at the emitted light.
2. Eye 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.
4. In order to maintain proper operation, follow instructions in this manual.
5. Use of the light without a tip may cause overheating of the tissue if the light is used close to the gingiva.
6. Extended use cause tips 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 2s 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.
9. The FotoSan® Blue agent can stain clothing.

1. Technical description

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 1 LED product according to EN 60825-1:2001 Ed 1.2.

1.1 Technical specifications

Power supply	
Manufacturer	Dongguan Shilong Fuhua Electronic Co. Ltd.
Model	UE08WCP-050100SPA
Input power	100–240VAC, 50/60Hz
Output power	5.0VDC, 1.0A
Battery	
Battery type	LiFePO4
Nominal voltage	3.2V
Nominal capacity	1.200mA
Re-charging time	2.5 hours
User capacity	approx. 760 seconds
LED Diode	
Output intensity	3.700-4.000 mW/cm ²
Wavelength	450-470nm (85%), peak 460nm

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

The **FotoSan® Blue** light consists of a hand piece, a docking station and an external power supply. Disposable covers and tips protect against cross contamination.

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 FotoSan® Blue

Connect the power supply under the base of the docking station and 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 **FotoSan® Blue** intended usage is light activation of photosensitive materials in the light spectrum around 460 nm.

Examples are dental composites and other dental light cured materials. Furthermore the **FotoSan® Blue** agent is used for light activated disinfection.

3.1 Three program modes

The **FotoSan® Blue** light has three programs each with different time settings. 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.

The green program mode is typically used for curing composites and other dental materials. Press the large button and the unit will light for 5s. This is effective in full curing a composite in a layer of 2-3 mm in thickness. Press the small button and the unit will light 2s. This is used to cure a layer of composite in 2-3 mm in thickness when building up in multiple layers. When curing the next layer til first layer will receive light again etc. The final layer is cured with 5s.

In the orange program mode the large button will give you 30s of light and the small 10s. 30s is typically used when disinfecting a root canal with **FotoSan® Blue** agent. 10s is typically use in each “corner” of a pocket when disinfecting with **FotoSan® Blue** agent.

In the red program mode the large button will give you 10s of light, 0.5s pause, 10s light, pause etc. until you press the button again. This mode is useful when disinfecting multiple pockets with **FotoSan® Blue** agent. You simply move the light but do not need to activate to get light. The small button will give you 4 x 10s of light interrupted by 0.5s of pause. This mode is useful for the disinfection of one pocket in 4 places.

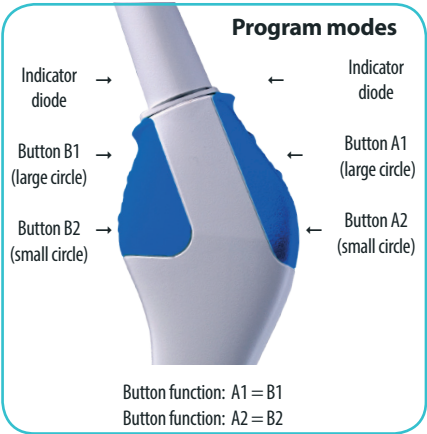
3.2 Temperature safety

The FotoSan® Blue 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. 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 minutes, or placed in the dock, it will go into sleep mode to conserve energy. Press any button to reactivate it.

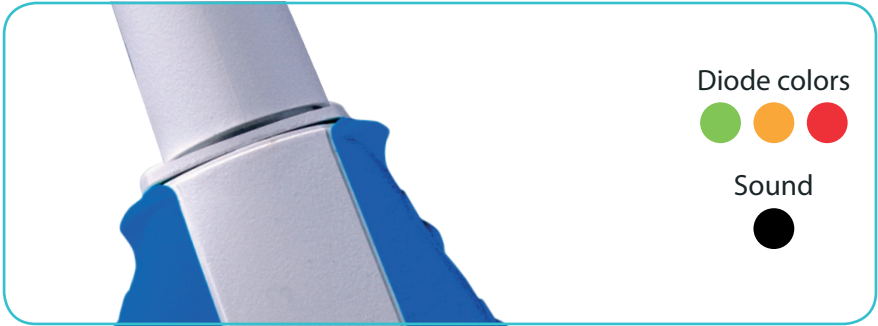
Deep sleep: If not placed in the charging dock or activated for 6 hours the light will go into deep sleep mode. It must be placed in the dock for one second to be reactivated.



The FotoSan® Blue has 3 programs:

	Small button	Large button
Manual use Press once	2s 	5s 
Manual use Press once	10s 	30s 
Rapid automated function Press once / Press again to stop	4 x 10s with 0.5s breaks 	10s with 0.5s breaks 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 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.

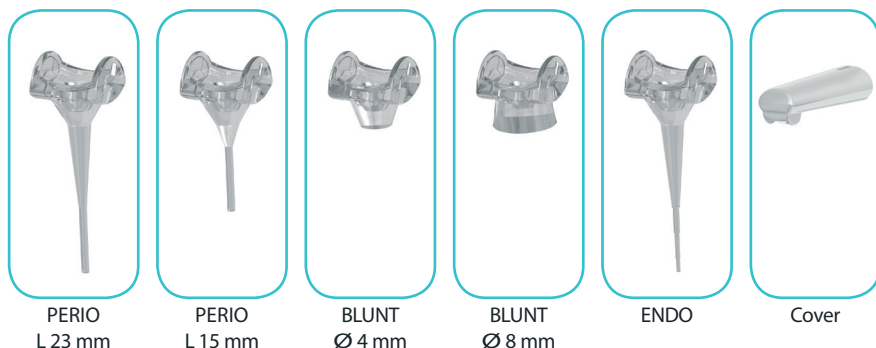
4. Cover and tips

There are five tips for the **FotoSan® Blue**. Use the tip that is best suited for the application. The two perio tips have a diameter of 1 mm. The distal 5 mm have a surface permitting the light to go sideways. The endo tip has a diameter of 0.5 mm.

4.1 Attaching and detaching tips

Tips are snapped onto the cover by pressing the two parts 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.

The blunt tips are used for surface disinfection treatment and when curing composites close to the gingival. This is to avoid too much heating of the gingiva which may happen when the light is used without tips.



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.

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. FotoSan® Blue agent

The **FotoSan® Blue** agent is available in two different viscosities: *Liquid* for use in the root canal and *Gel* for use in pockets and on the surface.

The concentration of active substances is the same, the gel is just easier to use in pockets and surfaces. Both agents is packed as powder in a syringe. Draw up water or 2-3% H₂O₂ and shake until the powder is dissolved and wait 5-10 min for the gel to have the proper viscosity.

The **FotoSan® Blue** agent Gel comes in two sizes: 0.5 ml and 1.5 ml. (1.5 ml is for a full mouth treatment)

Agent type	Application	Fluid to draw up
FotoSan® Blue agent liquid	Root canals	0.5 ml
FotoSan® Blue agent gel 0.5 ml	Pockets, surface	0.5 ml
FotoSan® Blue agent gel 1.5 ml	Pockets, surface	1.5 ml

7. Important treatment principles (Light curing)

1. Cure with the light (tip) as close to the composite as possible, as light intensity is reduced by distance.
2. Use the 2s setting when curing each layer in a composite build up.
3. Always cure the finishing layer 5s.
4. If each layer is wider that the tip – move the tip and light again.
5. Never light directly on gingiva without a tip, as the heat may damage the tissue.
6. If the composite is darker than A3, light longer as penetration of the light is reduced in darker materials.

8. Practical treatment guidelines

8.1 Endodontic treatment

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

1. Fill the canal with **FotoSan® Blue** agent Liquid, stir to avoid bubbles using a small hand file.
2. Insert the endo light tip until resistance is met and light for minimum 30s. See table.
3. Rinse and dry.

Endodontic treatment	
Situation	Dosage
If endo tip goes 2/3 into canal	30s
If endo tip goes 1/2 into canal	2 x 30s
In case of apical clearing	2 x 30s AND 10s with blunt tip on gingiva at level of apex

8.2 Periodontal treatment

Preparation: Perform conventional scaling and root planning.

1. Fill the pocket with **FotoSan® Blue** agent Gel.
2. Treat pocket from inside (perio tip 15 mm or 23 mm) minimum 10s per surface of tooth, depending of depth. See table.
3. You may find it useful to treat from outside using one of the blunt tips, especially if there is gingivitis.
4. Rinse pocket.

Periodontic treatment	
Situation	Dosage
PD < 5 mm	10s per surface
PD < 8 mm	20s per surface
PD > 8 mm	30s per surface
Apical periodontitis	Extra 10s on gingiva at apex position
Gingivitis	10s per cm ²

TIPS: If the pocket is tight, you may use the endo tip instead.

9. Labelling

	Operating Instructions
	Product Serial Number
	Manufacture identification number
	Expiry date
	Medical Electrical Equipment Directive, DS/EN 60601-1:1998, 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

10. Service and warranty

The FotoSan® Blue light is covered by a 2 year warranty.

CAUTION

The FotoSan® Blue light must only be serviced and repaired by CMS Dental, otherwise the warranty will be void.

11. 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.

12. FotoSan® Blue accessories



Barrier sleeves *open*
250 pcs.
Item no. 100512



Single-use disposable
covers
10 pcs.
Item no. 100510



Barrier sleeves *closed*
250 pcs.
Item no. 100513



Ø 4 mm adjustable
disposable BLUNT tip
50 pcs.
Item no. 100501



Hand held paddle
protection
Item no. 100500



Ø 8 mm adjustable
disposable BLUNT tip
50 pcs.
Item no. 100502



Click-on
protection
Item no. 100511



L 23 mm adjustable
disposable PERIO tip (Long)
50 pcs.
Item no. 100503



FotoSan® Blue agent
Liquid 0.5 ml.
10 syringes in a box.
Item no. 228401



L 15 mm adjustable
disposable PERIO tip (Short)
50 pcs.
Item no. 100504



FotoSan® Blue agent
Gel 0.5 ml.
10 syringes in a box.
Item no. 228411



Adjustable disposable
ENDO tip
50 pcs.
Item no. 100505



FotoSan® Blue agent
Gel 1.5 ml.
10 syringes in a box.
Item no. 228415

FotoSan® Blue Single Use Perio Kit

FotoSan® Blue Single Use Perio Kit DIAMOND

- CLEANING 1 root n' screw **brush™** rotary periodontal brush (2 mm)
- DISINFECTION 1 syringe of **FotoSan®** agent Gel 1.5 ml ●
 - + 4 disposable tips
 - + 2 disposable covers for the **FotoSan® Blue** light
- BACTERIAL REPLACEMENT 1 **ProlacSan®** Gel syringe for sub gingival application
- PROBIOTIC (home use) 3 boxes of **ProlacSan®** lozenges

Item no. 228451

FotoSan® Blue Single Use Perio Kit GOLD 0.5

- CLEANING 1 root n' screw **brush™** rotary periodontal brush (2 mm)
- DISINFECTION 1 syringe of **FotoSan®** agent Gel 0.5 ml ●
 - + 4 disposable tips
 - + 2 disposable covers for the **FotoSan® Blue** light
- BACTERIAL REPLACEMENT 1 **ProlacSan®** Gel syringe for sub gingival application

Item no. 100731

FotoSan® Blue Single Use Perio Kit GOLD 1.5

- CLEANING 1 root n' screw **brush™** rotary periodontal brush (2 mm)
- DISINFECTION 1 syringe of **FotoSan®** agent Gel 1.5 ml ●
 - + 4 disposable tips
 - + 2 disposable covers for the **FotoSan® Blue** light
- BACTERIAL REPLACEMENT 1 **ProlacSan®** Gel syringe for sub gingival application

Item no. 100734

FotoSan® Blue Single Use Perio Kit SILVER 0.5

- CLEANING 1 root n' screw **brush™** rotary periodontal brush (2 mm)
- DISINFECTION 1 syringe of **FotoSan®** agent Gel 0.5 ml ●
 - + 4 disposable tips
 - + 2 disposable covers for the **FotoSan® Blue** light

Item no. 100730

FotoSan® Blue Single Use Perio Kit SILVER 1.5

- CLEANING 1 root n' screw **brush™** rotary periodontal brush (2 mm)
- DISINFECTION 1 syringe of **FotoSan®** agent Gel 1.5 ml ●
 - + 4 disposable tips
 - + 2 disposable covers for the **FotoSan® Blue** light

Item no. 100733

FotoSan® Blue Single Use Endo Kit

FotoSan® Blue Single Use Kit ENDO

- CLEANING 1 sterile rinsing needle with side opening (30 G)
- DISINFECTION 1 syringe **FotoSan® Blue** agent **Liquid 0.3 ml** ●
 - + 1 disposable Endo tip and 1 disposable Blunt tip
 - + 2 disposable covers for the **FotoSan® Blue** light

Item no. 100735