FotoSan® 630

Manual

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Content of the FotoSan® 630 introkit:

1. FotoSan® light

2. Docking station

3. Power supply: Plugs for mains: EU/US/AUS/UK

4. Covers: 2 x 10 pcs

5. Tips: 10 pcs each of: BLUNT d 4 mm, BLUNT d 8 mm,
 PERIO L 15 mm, PERIO L 23 mm, ENDO

6. FotoSan® Agent: One box of assorted syringes with application tips

7. Manual

**1. Technical description**

The FotoSan® 630 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 60601-1:2006. The product is classified as a class 1 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 FotoSan® 630 light consists of a hand piece, a docking station and an external power supply. Disposable covers and tips protect against cross contamination.

**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.

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. Do not reuse covers or tips as this
 may cause cross contamination.

7. 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.

8. The FotoSan® agent is a blue dye
 and it stains clothing.

**1.1 Technical specifications**

**Power supply**

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 hours

User capacity approx. 760 seconds

**LED Diode**

Output intensity 2.000-4.000 mW/cm2

Wavelength 620-640nm (85%),
 peak 630nm

**1.2 Environmental conditions for intended use**

Temperature range +10˚C to +40˚C

Humidity range 30% to 75%

Atmospheric 70kPa to 106kPa
 pressure range (0.7 bar to 1.06 bar)

**2. Preparing to use the FotoSan® 630**

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® 630 is intended to be used for the photoactivation of the FotoSan® Agent:

10-30 s is usually sufficient as
activation in one site. See practical treatment guidelines for more details.

**Three program modes**

The FotoSan® 630 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 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 FotoSan® 630 is the first LAD light with this new concept.

The green program mode is the manual mode. Press the large button and the unit will light for 30 s. Press the small button and it will light for 10 s.

In the orange program mode, pressing the large button will give you 20 s of light, a 1 s pause, then again 20 s of light. The small button gives you 20 s of light.

This mode is used for deep pockets where 20 s of activation is needed.

In the red program mode the large
button will give you 4 times 10 s
activations with 1 s pause between each
activation. The small button will give you 2 times 10 s with 1 s pause between each activation. This mode is used for treatments of pockets where 10 s is administered typically for each side of the tooth.

**3.2 Temperature safety**

The FotoSan® 630 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 15 s
before it cuts off. Overheating is
indicated by 3 short beeps followed by fast red flashing.

The light can cool passively or be actively cooled if you need to use it right away.

**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.

**Intelligent Automated Functions: Program modes**

Indicator diode 

Button B1 (large circle) 

Button B2 (small circle) 

 Indicator diode

 Button A1 (large circle)

 Button A2 (small circle)

Button function: A1 = B1

Button function: A2 = B2

Program change:

   : Press A1+A2 at same time 3 s  scroll  wait 3 s for beep

 A1/B1: A2/B2:

 30s 10s

 A1/B1: A2/B2

 20s 20s 20s

 A1/B1: A2/B2

 10s 10s 10s 10s 10s 10s

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

Diode colors

Sound

Ready

Activated light

Charging battery

Low battery

Diode heat warning

Diode overheated

Sleep mode

Deep sleep mode

Error

ready for use

sound to indicate start and stop

may be used

if not used, place in dock

15 s from cut-off

needs to cool before it can be activated

press any button

place in dock

reset by pressing two buttons on same side for 3 s

**4. Cover and tips**

Perio L 23 mm

Perio L 15 mm

BLUNT d 4 mm

BLUNT d 8 mm

ENDO

The light should only be used with a tip and cover attached. There are five tips for the FotoSan® 630. 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.

**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 charging dock may be wiped with a slightly damp cloth using standard cleaning solutions and surface disinfection products, typically based on 70% alcohol.

Do not disperse disinfection fluids into the diode opening. This may damage the diode.

The removable cover is disposable.

The tips are disposable.

**6. FotoSan® Agent**

The FotoSan® Agent is available in
three different viscosities, all with a
concentration of active ingredient
(toluidine blue O (TBO)) of 0.1 mg/ml. Use the viscosity best suited for the practical application.

The agent is best applied using a blunt (bendable) tip to be attached to the syringe. A 22G or 25G tip is
recommended (10 pcs is delivered
with syringe box).

**Agent**

LOW

MEDIUM

HIGH

**Typical applications**

Endo

Periodontal pockets

Periodontal pockets, surface

**7. Important treatment principles**

1. You need the Agent AND the light
 to reach the microorganisms for it to
 be effective.

2. All microorganisms are sensitive to
 the treatment BUT some more than
 others - i.e. there is a dose
 dependency. See literature for details.

3. You cannot treat too much ONLY too
 little.

4. Difficult accessible infections require
 longer time than surface infections.

5. You may repeat treatment as needed.

6. You may choose to treat before AND
 after SRP to reduce bacterial
 spreading in risk patients.

**8. Practical treatment guidelines**

**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 Agent LOW, stir
 to avoid bubbles using a small hand
 file.

2. Insert the endo light tip until
 resistance is met and light for
 minimum 30 s (se table).

3. Rinse and dry.

**ENDODONTIC TREATMENT**

**Situation**

If endo tip goes 2/3 into canal

If endo tip goes 1/2 into canal

In case of apical clearing

**Dosage**

30 s

2 x 30 s

2 x 30 s AND10 s with blunt tip on gingiva at level of apex

**Periodontal treatment**

Preparation:

Perform conventional scaling and root planning.

1. Fill pocket with Agent
 (MEDIUM or HIGH)

2. Treat pocket from inside
 (perio tip 15 mm or 23 mm)
 minimum 10 s 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.

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

**PERIODONTAL TREATMENT**

**Situation**

PD < 5 mm

PD < 8 mm

PD > 8 mm

Apical periodontitis

Gingivitis

**Dosage**

10 s per surface

20 s per surface

30 s per surface

Extra 10 s on ginigiva at apex position

10 s per cm²

**9. Labelling**

Observe Operating Instructions

Product Serial Number

See instructions

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

**10. Service and warranty**

The FotoSan® 630 light is covered by a 2 year warranty.

**CAUTION**

The FotoSan® 630 light must only be serviced and repaired by your CMS Dental
distributor, otherwise the warranty will be void.

**11. FotoSan® accessories**

**FotoSan® Agent in syringes**

5 x 1.2 ml Agent LOW
with 10 bendable
tips 25G.

**Item No. 13603**

5 x 1.2 ml Agent
MEDIUM with 10
bendable tips 22G.

**Item No. 13703**

5 x 1.2 ml Agent HIGH with 10 bendable
tips 22G.

**Item No. 13803**

5 x 1.2 ml Agent Assorted with 7 bendable tips 22G + 3 bendable tips 25G. **Item No. 13855**

**FotoSan® Agent in vials**

6 ml Agent LOW.

**Item No. 13601**

6 ml Agent MEDIUM.

**Item No. 13701**

6 ml Agent HIGH.

**Item No. 13801**

**FotoSan® Agent application tips**

100 x Appli-Vac blunt needle 25G.

 **Item No. 315125**

100 x Appli-Vac blunt needle 22G.

 **Item No. 315122**

**FotoSan® cover**

10 disposable

cover.

**Item No. 100510**

**FotoSan® tips**

50 disposable

BLUNT tip d 4 mm.

**tem No. 100501**

50 disposable BLUNT tip d 8 mm. **Item No. 100502**

50 disposable PERIO tip L 23 mm. **Item No. 100503**

50 disposable PERIO tip L 15 mm. **Item No. 100504**

50 disposable ENDO tip. **Item No. 100505**

**FotoSan® protective glasses**

Protection glasses.
**Item No. 13900**

Flip-on protection glasses. **Item No. 13901**