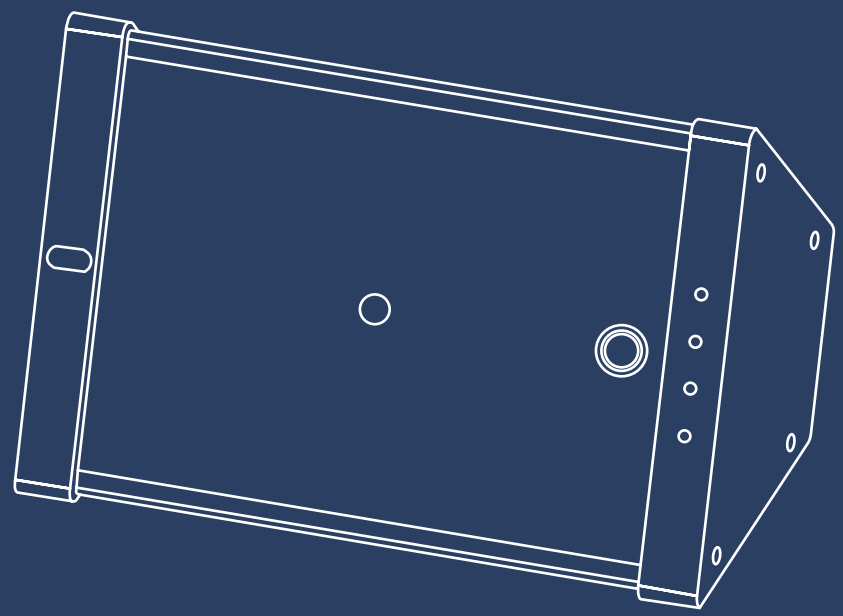


EVY LIGHT[®]

User Manual
EN



OC
OPTOCEUTICS



Read before use

User Manual (revision 2.1)

English

Technical Identifier: Neurostimulation System (NSS) 2.0

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Read this User Manual completely before use of EVY LIGHT®.

⚠ WARNING!

If you experience any epileptic seizure-like events related to the use of EVY LIGHT®, immediately stop its use and seek advice from your physician.

⚠ WARNING!

If you experience a migraine, feel nausea, headaches, or other discomforts, immediately stop the ongoing session. If the situation persists, consult your physician.

PLEASE NOTE:

If any serious incident has occurred with the device, please report this to OptoCeutics and the competent authority within your country. OptoCeutics can be contacted at any time. The contact information can be found on the back of the user manual.

Introduction

Thank you for getting your EVY LIGHT® and becoming a pioneer in brain stimulation for the activation of gamma brainwaves.

*Kind regards,
The OptoCeutics Team*

What is EVY LIGHT® ?

EVY LIGHT® is a non-invasive light-based brain stimulation device for activating gamma brainwaves developed by OptoCeutics ApS. EVY LIGHT is an electronic equipment with LED technology providing its intended performance and safety. EVY LIGHT is made to adhere to the published guidelines by FDA for Low Risk General Wellness Products. EVY LIGHT is made in compliance with the safety regulations of the European Union.

Intended use of EVY LIGHT®

The device is intended for 40 Hz brain stimulation and activation of gamma brainwaves. It is intended to be used in conjunction with a healthy lifestyle to promote mental acuity. The device does not have any medical indication for any specific patient population. It is intended but not limited to residential use.

What is Invisible Spectral Flicker?

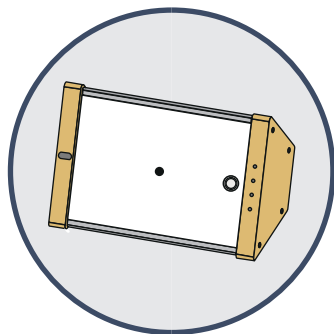
OptoCeutics has invented a way to make 40 Hz flashing lights more comfortable. Traditional 40 Hz flashing lights can be disturbing, highly uncomfortable to use, and may induce side effects such as nausea and headaches, especially if used for extended periods.

Instead of flashing 40 times per second between the light being on and off, EVY LIGHT® alternates between two different combinations of colors that together form a nearly continuous light, we call it Invisible Spectral Flicker.

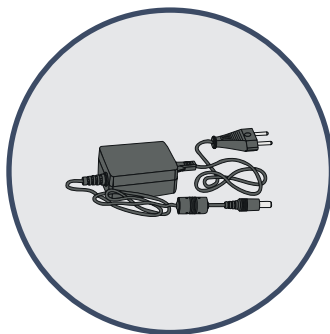
(The effect can be seen if you try to record a video of the light.)

Read more at www.optoceutics.com

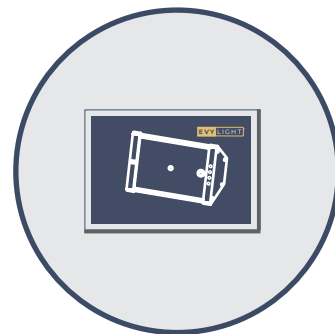
Inside the package:



EVY LIGHT®



Power Supply



User Manual

Safety Information

CONTRAINDICATIONS

No matter your reason for using the device, we recommend not exceeding the intended daily use of 1 hour.

Do not use the device if:

- You suffer from photosensitive epilepsy (PSE)

Consult your physician before use if:

- You are highly sensitive to light (photophobia)
- You have a history of migraines
- You suffer from any neurological conditions
- You have any eye disease (glaucoma, retinitis, retinopathy, or macular degeneration)
- You suffer from bipolar disorder, as it could provoke manic episodes

POSSIBLE REACTIONS



The possible adverse reactions to using EVY LIGHT® are relatively mild and only temporary. They may include but are not limited to the following:

- Irritability
- Headache
- Nausea
- Early wakening / trouble falling asleep
- Dry eyes or eye strain
- Light sensitivity
- Nervousness or anxiety
- Sleepiness or drowsiness
- Numbness
- Dizziness or disorientation
- Temporary change in color and brightness perception, slower vision readjustment

Measures to avoid, minimize or alleviate these adverse reactions:

- Stop using the device for a few days to make the reactions disappear and then try again.
- Always use the device in a normally-lit room.
- Follow the instructions for use with special attention to the user's distance to the device and the time of day.
- Consult a physician if the reaction does not dissipate after a few days.

WARNING!

- If you experience any epileptic seizure-like events related to the use of the equipment, immediately stop its use and seek advice from your physician.
- If you experience a migraine, feel nausea, headaches, or other discomforts, immediately stop the ongoing session. If the situation persists, consult your physician.
- This equipment is not intended for use by children. Children should be supervised to ensure that they do not play with the packaging and equipment to avoid the risk of suffocation, fire, and burns.
- EVY LIGHT® is not intended for use by persons with reduced physical, sensory, or mental capabilities, or lack of experience and knowledge unless they have been given supervision or instruction concerning the use of EVY LIGHT® to avoid the risk of fire or burns.
- If the mains power cord becomes damaged, STOP its use to avoid the risk of electric shock and contact OptoCeutics or qualified personnel for replacing the cord.
-   **KEEP DRY!** Water and electricity are a dangerous combination! To avoid the risk of electrocution:
 - » do not use this equipment in wet surroundings (e.g. in the bathroom, near a shower or a swimming pool);
 - » do not let the water run into the equipment.

- If the wall socket used to power the equipment has poor connections, the plug becomes hot. Make sure you plug the equipment into a properly installed wall socket to avoid the risk of fire and burns.
- Do not leave the equipment unattended when it is switched on to avoid the risk of fire or burns.

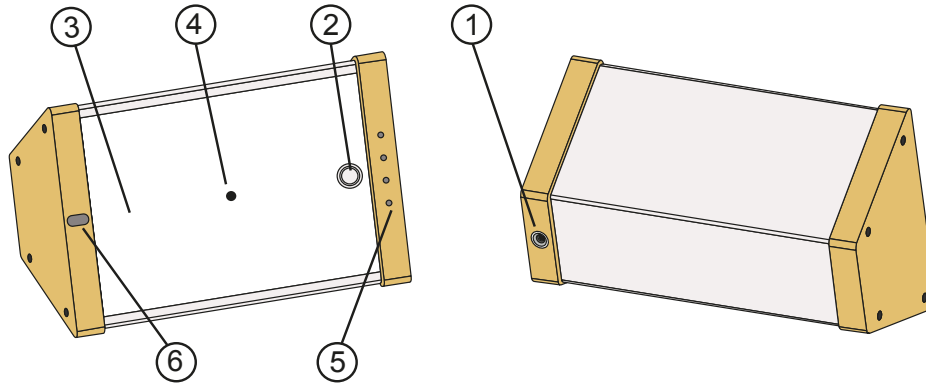
CAUTION!

- Before use, make sure that all packaging material is removed and that there is no visible damage to the equipment or accessories.
- Using the equipment close to your bedtime may alter or disturb your sleep.
- Do not subject the equipment to heavy shocks to avoid the risk of damage to the equipment.
- Always unplug the equipment after use and in case of a power failure to avoid the risk of damage to the equipment.
- Do not attempt to repair or modify the equipment. The electronics and LEDs are not replaceable.
- Do not use the equipment outdoors or near heated surfaces or heat sources.
- Do not pull the mains cable from the socket by the cord.
- Connect the equipment only to the main voltage listed on the technical data or power adapter.

Device Description

1. Power Socket & Status Light
2. On / Off Button
3. Light Panel

4. Focus Point
5. Time Indicators
6. Usage Tracker



Operation

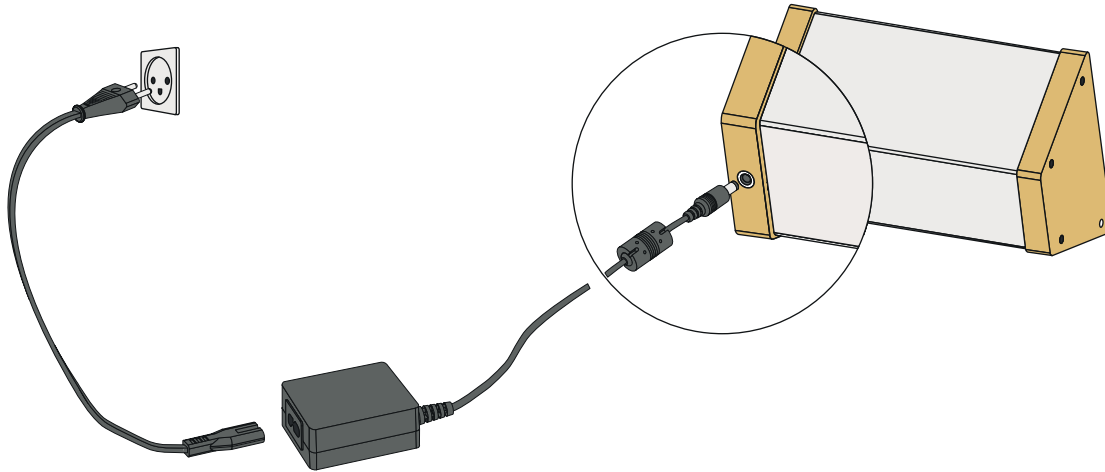
QUICK START GUIDE

1. Connect the device to power.
2. Place yourself comfortably within arm's reach of the device.
3. Press the front button to start a session.
4. Read our guidelines for effective and comfortable use.
5. How to track your usage (optional).

Detailed stepwise description on the following pages.

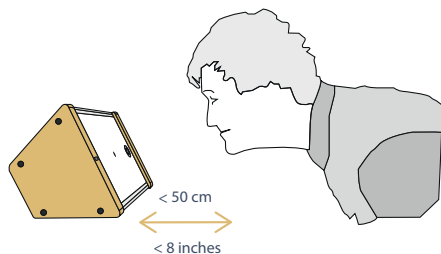
1. Connect the device to power

Connect the power supply to a power outlet and connect the power plug to the device power socket (1). A white status light around the power socket turns on, indicating that the device is plugged in and powered.

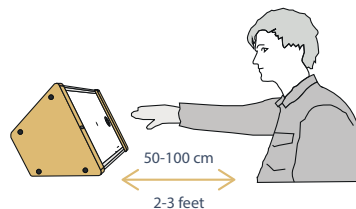


2. Place yourself comfortably within arm's reach of the device

You should place yourself within a distance of 50-100 cm (2-3 feet) of your device, corresponding roughly to an arm's reach. The device should be placed in front of you, so the light has access to your eyes.



Incorrect use



Correct use



Time of the day

It is recommended to use the device in a period between morning and late afternoon. Using the device the last 4 hours before going to bed may alter or disturb your sleep.

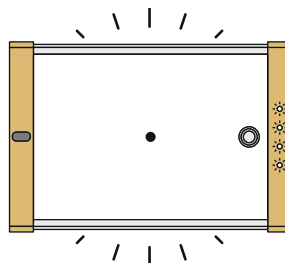
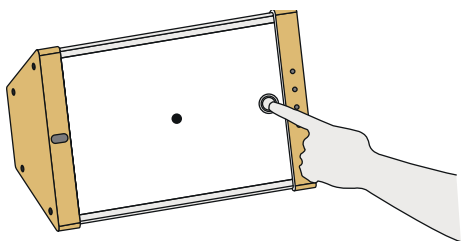
3. Press the front button to turn the light ON and OFF

The front button (2) can be used to turn the device on and off. A full stimulation session is 60 min, and the device will automatically turn off afterward. At any time, you can press the front button again to stop the session and press it again to resume it.

There is no risk if the session is not completed, other than that the full effect may not be gained.

If the session is not resumed within 4 hours, the device starts counting from the beginning again.

Likewise, the device counts from the beginning again if the power is removed.



PLEASE NOTE:

Sunglasses or special lenses can affect your intended stimulation session.

In these instances, you may experience that the light flickers more than usual.

4. Follow these guidelines for use

You receive gamma brain stimulation the moment the light from EVY LIGHT® reaches your eyes. The amount of brain stimulation can vary depending on how it is used but, generally, the following applies:

- The device should be used 1 hour a day, but it can be split up into shorter intervals, for example. 2 x 30 minutes.
- The device should be within 2-3 ft (50-100 cm) and the light should be within your field of view.
- You don't have to stare directly at the light, and you can use the device in connection with other activities (see examples below).



Try using EVY LIGHT® while eating, working, reading, listening to music, or watching TV.

Please visit optoceutics.com to get more suggestions on how to form good and lasting habits.

Disclaimer

The highest brain response is seen when looking directly into the light. If you wish to look directly into the light, the focus point (4) can be used to rest your eyes. However, the above methods can be used to prevent eye strain and achieve consistent use. It's better to find a comfortable use, where you will use it consistently.

Front Indicators

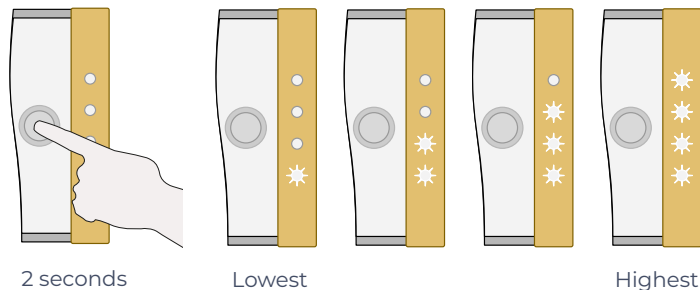
There are four indicators on the front of the device (5).

For each 15 min the light has been turned on, one indicator will light up. After 60 min all four indicators will light up for about 1 min before the light turns off completely.

Brightness Control

You can change the brightness of the device by pressing and holding the front button for 2 seconds. The front indicators will start blinking and indicate which of the four different brightness settings you have chosen.

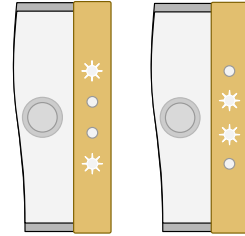
One indicator blinks for the lowest brightness, and four indicators blink for the highest brightness.



PLEASE NOTE:

If you press the front button for about 6 seconds or more, it will go into pairing mode (for connecting to the INSIGHT App), and the two outer front indicators will light up.

Completion of pairing is signified by the two inner indicators pulsing briefly.



5. How to track your usage (optional):

You can enable usage tracking on EVY LIGHT®, by connecting the device to the INSIGHT app. Track your progress and build habits by seeing how long and on which days you use EVY LIGHT.

OptoCeutics is continuously working on building more features for supporting your goals and the INSIGHT App ensures you have access to the latest features.

In the future you will be able to track your presence in front of EVY LIGHT using enhanced usage tracking and feedback. The camera sensor is not activity by default and will not store image data. Enhanced usage tracking will be part of a future update to the INSIGHT App.

Maintenance

Reuse

The expected service life for the device is 5 000 hours of normal use.
The daily expected operating time is 60 minutes (1 hour).





Repairs

Do not attempt to open or repair the device. This can result in serious injuries and will void the warranty. If defects or malfunctions are observed, contact OptoCeutics. The contact information can be found on the back of the user manual.

Storage

Please store your device at room temperature in a dry place.
If you stored the device at the minimal or maximal storage temperatures, please wait 15 minutes before you use it to allow it to reach normal operating temperature.

Environmental conditions

 Storage temperature:	-5°C to +45°C (+23 to +113°F)
 Storage relative humidity:	<90%, without water vapor condensation
 Operation temperature:	5°C to +35°C (+41 to +95°F)
 Operating relative humidity:	15% to 90%, without water vapor condensation

Cleaning of the device

Keep the light panel free of occlusions, heavy dust, stains, etc. Remove dust with a dry cloth or brush. If dirt persists on the surface, use a slightly damp cloth and finish using a dry cloth.

- Prevent the device from getting wet or soaked in water or any other liquid.
- Use only water with mild soap for cleaning the panel and other surfaces.
- Do not use alcohol-containing solutions on the panel.
- Do not use solvents such as acetone on the panel.
- Do not use abrasive cleaners or harsh sponges and fabrics.

Troubleshooting

The light does not turn on

Ensure the power cable is connected correctly by pushing firmly. The ring around the connector (1) should be fully lit.

There is a light in the status light, but the device is not turning on

Try plugging the power cable out and plugging it back in. Ensure that there is light in the status light.

If any problem with the device is persistent, please contact OptoCeutics for a possible repair/replacement. The contact information can be found on the back of the user manual.

Technical Data

Technical Data***	EVY LIGHT®	Power Adapter AC/DC
Dimension**	300 x 198 x 130 mm (12 x 8 x 5 in)	79 x 54 x 33 mm (3.1 x 2.1 x 1.3 in)
Space Clearance During Use** (W x H x D)	350 x 250 x 200 mm (14 x 10 x 8 in)	N/A
Weight**	1.1 kg (2.3 lb) / 1.4 kg (3 lb) including AC/DC power adapter	0.3 kg (0.7 lb)
Product Classification	Home Light Therapy Equipment * Externally powered	Class II Power unit
Electrical Ratings	External AC/DC power adapter (Use only the supplied adapter) 12 VDC input Min. 3 A, Max. 3.3 A Class II (2 x MOPP)	Output: 12 VDC 3 A (3.3 A max) 36 W to 40 W max Input Voltage AC: 120/240 Vac 50 / 60 Hz









Lighting Elements	LED	N/A
Light Wavelengths	Only visible light from 410 nm to 710 nm. No ultra-violet. No infra-red.	N/A
Lighting Brightness	Nominal 1 800-2 200 cd/m ² (<10 000 cd/m ² in all use cases) 220 lux at setting 1 (at 50 cm) 280 lux at setting 2 (at 50 cm) 340 lux at setting 3 (at 50 cm) 380 lux at setting 4 (at 50 cm)	N/A
Radio Frequency Bands	2 402 to 2 480 MHz (Wi-Fi) 5 180 to 5 775 MHz (Wi-Fi)	N/A
Operation Conditions	+5 to +35°C (+41 to +95°F) 15 to 90% relative humidity, without water vapor condensation. Atmospheric Pressure of 700 to 1 060 hPa	-30 to +40°C (-22 to +104°F) 15 to 90% relative humidity, without water vapor condensation
Storage Conditions	-5 to +45°C (+23 to +113°F) < 90% relative humidity, without water vapor condensation	-30 to +85°C (-22 to +185°F) < 90% relative humidity, without water vapor condensation
Ingress Protection Class	IP 20 (keep dry)	IP 22












*EVY LIGHT is not a medical device, however, it is verified against the Home Light Therapy Equipment standard specified for medical devices

**Dimensions and weight are approximate

***Subject to changes

Symbols Explained

Symbol	Meaning	Symbol	Meaning
	Read the manual before using the device		Device emits radio-frequency electromagnetic energy
 Warning	Warning notice indicating a risk of severe injury or damage to health		Keep dry (IP20)
 Caution	Caution notice indicating a risk of minor injury or damage to the device		General warning sign
	Only for indoor use		Protection against electrical shock, class II

	Serial number		Lot number
	Name and address of manufacturer (solid icon)		Manufacturing date (outline icon)
	CE mark		QR device Unique Device Identifier - Production Identifier
	Electronics, do not throw away, must not be disposed of with unsorted household waste but must be collected separately		Polarity indication
	Temperature range specifications for storage (on package) or use (on device)		Relative humidity range specifications for storage (on package) or use (on device)
	Manufacturer's logo		

General Notes

This document is related to and applies to EVY LIGHT[®], which is manufactured by OptoCeutics ApS.

Intended user

In the European Union and the United States of America, EVY LIGHT[®] carries the general wellness device designation, following the FDA guidelines. The device does not have a medical purpose and, hence, no intended medical indication. The device is therefore applicable to all individuals who deem that the intended use applies to them and for whom the device is not contraindicated.

Preservation of user manual

The intention is for the user to keep the instructions for use for a period corresponding to the expected service life of the device. If the User Manual is lost, you can download a PDF version from our website at www.optoceutics.com or request a copy via email at info@optoceutics.com.

Customer service

Feel free to contact OptoCeutics if you have any questions. The contact information can be found on the back of the user manual.

Warranty

A 2-year right to make a complaint is granted following the Danish Sale of Goods Act. The right of complaint applies to defects in material and / or fabrication.

The complaint does not apply to errors or damage committed by incorrect operation of the product. Do not attempt to open the device or attempt to repair the device yourself. This could result in serious injuries.

If you need to have the device repaired, contact OptoCeutics Customer Service. The contact information can be located on the back of the user manual.

Declaration of conformity

OptoCeutics ApS hereby declares that this product complies with the European regulation for placing a safe product on the market. The formal DoC letter can be requested at any time by a request to info@optoceutics.com. Even though EVY LIGHT is not a medical device, this device meets the high safety standards that are applied to medical grade equipment. In this way we can deliver the best assurances to our customers.

Notes on general safety

The device complies with the following European harmonized standards EN 60601-1, EN 60601-1-6, EN 60601-1-11, and the particular standard EN 60601-2-83.

Notes on electromagnetic compatibility

The device complies with the European standard EN 60601-1-2 (following CISPR 11 Group 1 Class B, IEC 61000-3-2, IEC 61000-3-3, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8, IEC 61000-4-11) and is subject to particular precautions about electromagnetic compatibility.

- The device is suitable for use in all the environments listed in this information for use, including domestic environments.
- The use of accessories other than those specified or provided by the manufacturer of the device can lead to an increase in electromagnetic emissions or a decrease in the device's electromagnetic immunity. This can result in faulty operation.
- Failure to comply with the above can impair the performance of the device.

FCC legal notice

Class B digital device for use in a residential environment notwithstanding use in commercial, business, and industrial environments. Examples of such devices include, but are not limited to, personal computers, calculators, and similar electronic devices that are marketed for use by the general public.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used according to the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help.

IMPORTANT NOTE:

FCC Radiation Exposure Statement; This equipment and its antenna must not be co-located or operated in conjunction with any other antenna or transmitter. A minimum separation distance of 20 cm (8 inches) must be maintained between the antenna and the person for this equipment to satisfy the RF exposure requirements.

Following these instructions satisfies the FCC radio-frequency exposure guidelines for an uncontrolled environment.

CAUTION!

Any changes or modifications to the equipment not expressly approved by OptoCeutics could void the user's authority to operate the equipment.

Notes on photobiological safety

The luminance and illuminance values, which refer to the brightness of light, are provided for informational purposes related to the photobiological safety standards DS/EN 62471:2008 and IEC 60601-2-83:2020.

Guidelines for home light equipment recommend using the equipment between 33 cm and 1 m distance as the users should be able to reach out and turn on/off the equipment by themselves.

You can request the full text of the EU Declaration of Conformity by contacting OptoCeutics ApS via email at info@optoceutics.com.

Notes on software licences

Please visit www.optoceutics.com/software-licenses for a complete list of licenses.

Disposal



Electrical and electronic equipment (EEE) contains materials, components, and substances that can be dangerous and harmful to human health and the environment when the waste of electrical and electronic equipment (WEEE) is not disposed of properly.

Products marked with the crossed-out wheeled bin below are electrical and electronic equipment. The crossed-out wheeled bin symbolizes that waste electrical and electronic equipment must not be disposed of with unsorted household waste but must be collected separately.

Users of electrical and electronic equipment must not dispose of waste electrical and electronic equipment together with household waste. Users must use their local or municipal collection schemes to reduce the environmental impact associated with the disposal of waste electrical and electronic equipment and increase the opportunities for recycling and recovery of waste electrical and electronic equipment.



OPTOCEUTICS

OptoCeutics ApS

Gl. Kongevej 1, 4. tv.
1610 Copenhagen
Denmark



CVR nr: 39769689

www.optoceutics.com

info@optoceutics.com

EU +45 50 20 60 71

USA +1 (209) 213-2250