

Instructions for use
Delight Wireless



Instructions for use - DELIGHT WIRELESS LIGHTING SYSTEM

Thank you for your trust in us and congratulations on your choice.

Read the following information before using the device.

DESCRIPTION OF THE COMPONENTS

The list of components and spare parts are indicated in the documents provided along with the device.

SYMBOLS

Below are the symbols present on the device label (when applicable):

 In accordance with Regulation (EU) 2017/745 on medical devices

This product cannot be disposed of in unsorted municipal waste

 Date of manufacture  Manufacturer  Country of manufacture  Distributor

 Batch number  Serial number  Medical device  Catalogue number

 Instructions for use  Humidity limitation  Atmospheric pressure limitation  Temperature limitation

INTENDED USE

The DELIGHT WIRELESS LED (Light Emitting Diode) system is a portable lighting device that, when worn by the operator, illuminates the visual field during work activities.

The lighting system is an accessory intended to be used, in combination with a “magnifying system” medical device, to illuminate the area viewed by the user.

Intended users: medical professionals.

Intended patients: no limitation except as stated in the “contraindications” section.

DEVICES THAT CAN BE USED TOGETHER

The device can be comfortably attached to all Optergo magnifying system models, thus providing an integrated vision system.

CONTRAINDICATIONS

The device is contraindicated in the event of:

- Patients highly sensitive to light;
- Applications requiring lighting stability that cannot be achieved with devices mounted on the user's head.

WARNINGS

 **Read the following warnings carefully before using the device.**

Failure to follow these safety instructions could result in fire, electric shock, injury or damage to the LED lighting system or to other property. Do not use the device if it has been damaged. Contact your authorised dealer. Do not tamper with or disassemble any component of the system. Do not attempt any repairs unless expressly indicated. The DELIGHT WIRELESS device has a built-in rechargeable lithium battery, which cannot be replaced or disassembled by the user or by unauthorized personnel. The battery must be replaced and disassembled exclusively by personnel authorized by Optergo. Do not try to change the battery by yourself: improper substitution or the use of wrong spare part can cause risk of explosion. Do not expose the device to conditions that could ignite the battery. Avoid contact with heat sources or open flames. Do not use in spaces with flammable anesthetic mixtures. Do not immerse any component in liquid substances. Prevent liquid substances from entering the slots or the connection port. Do not look directly at the light emitted by the LED or direct the light to the patient's eyes.

Use the supplied components only: do not combine the components of the system with other lighting systems or electronic equipment. Use only the power supply if supplied or compliant with technical specifications indicated in this information note. Avoid sudden movements with your head when using the device. Avoid walking with the device worn. In the event of a malfunction, stop using the device. If mounted correctly, the device must not come into contact with the user's skin. Clean the device before use. When charging with adaptor, the socket-outlet shall be installed near the equipment and shall be easily accessible as the power supply plug allows you to disconnect the device from the mains supply.

PRECAUTIONS

Before operating the device it is recommended to fully charge it, waiting for all green LEDs on the Battery/Control Unit to light indicating that it is fully charged. When not in use, store the device in its container. Pay attention to your posture during prolonged use of the device in combination with Optergo loupes.

ADVERSE EFFECTS

No adverse effects detected.

SUPPLY MODE

This device is not supplied sterile. This is not a single use device.

STORAGE AND/OR HANDLING

Store the device at the temperatures and humidity indicated in the "Technical Specifications" section. When not in use, store the cleaned device in its original packaging, disconnecting the Battery/Control Unit from LED.

MAINTENANCE

Clean the device as described in the "cleaning instructions" section. Keep the original packaging required for return/maintenance shipment and contact your authorised dealer. Any eventual activity / maintenance operation of the device must be carried out only and exclusively by Optergo authorized personnel. The device does not need preventive maintenance activities.

TRAINING AND QUALIFICATIONS FOR USE

None.

CLEANING INSTRUCTIONS

Disconnect the LED from all components of the system (magnifying system, Battery/Control Unit) before cleaning. Use a microfiber cloth to clean the lens. The LED can be cleaned with a soft cloth soaked with a gentle detergent solution. Do not immerse or spray any components into or with detergents and other liquids. This device cannot be sterilised. Make sure the device is completely dry before use.



DISPOSAL INSTRUCTIONS

In the event of disposal/demolishing, do not dispose of the device in the environment.

Comply with the relevant national regulations on electronic devices.

HEALTH RISKS

No health risk detected.

WARRANTY


Disconnect the LED from all components of the system (magnifying system, Battery/Control Unit) before cleaning. Use a microfiber cloth to clean the lens. The LED can be cleaned with a soft cloth soaked with a gentle detergent solution. Do not immerse or spray any components into or with detergents and other liquids. This device cannot be sterilised. Make sure the device is completely dry before use.

REGULATIONS / DIRECTIVES / STANDARDS

Compliance: IEC EN 60601-1; IEC EN 60601-1-2; IEC EN 62471.

Unless otherwise indicated, the standards are to be considered in the latest applicable revisions.

Manufacturer's recommendations and declarations Electromagnetic emissions		
Emissions test	Compliance	Electromagnetic environment - Guidelines
RF emissions according to CISPR 16-2-3 CISPR 11	Group 1	This device uses RF energy only for its internal operation. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions according to CISPR 16-2-3 CISPR 11	Class B	This device is suitable for use in all environments, including domestic environments and environments directly connected to low voltage public power supply mains supplying buildings used for residential purposes.

Manufacturer's recommendations and declarations Electromagnetic immunity		
Immunity test	Compliance level	Electromagnetic environment - Guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	±15 kV air ±8 kV contact	The floor should be made of wood, concrete or tile. If floor is covered with synthetic material, the relative humidity should be at least equal to 30%.
Radiated RF according to IEC 61000-4-3	3 V/m from 80MHz to 2,7GHz	Interference may occur in the vicinity of equipment containing a transmitter: 
Fields near Wireless transmitters IEC 61000-4-3	9 V/m to 28 V/m from 385MHz to 5,785GHz	

TECHNICAL SPECIFICATIONS

Recommended Power supply

Power supply approved in accordance with IEC 60950-1 standard (SELV approved) or in accordance with IEC IEC 62368-1 standard (ES1 approved) or in accordance with IEC 60601-1 standard (MOOP approved).

Input power supply.....100-240V~ ; 50-60Hz ; 350mA ;

Output Power Supply.....5V 2A

Battery/Control Unit

Battery type..... Li-Ion / 3,7 V 500 mAh

Charging time (each battery)..... 90 min

Run time (each battery)..... 120 min

LED

Colour temperature..... 5700K

Maximum brightness..... 38000lux

Operating conditions

Room temperature..... from +10°C to +40°C

Relative humidity..... 10% to 90%;

Atmospheric pressure..... 10% to 90%;

Storage and transportation conditions

Room temperature..... from -10°C to +50°C

Relative humidity..... 10% to 90%

Atmospheric pressure..... from 50 kPa to 106 kPa



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