

SurgiMedia Interface

Operating light control



Instructions for use


CAUTION

An operating light is a Class I medical device; this MD can be controlled by the SurgiMedia “operating light control” application. To use this medical device correctly, read and follow the instructions for use below and more specifically the one provided by the manufacturer of the operating light you are using.

1. Operating light control

1.1 Depending on your operating room's configuration, it may be possible to control the surgical light through an interface on the SurgiMedia.

Please contact ISIS or its representative for a list of compatible lights.

Control is performed through a graphical interface launched by the icon  in the toolbar.

1.2 Generic graphical interface (OR Light Manager)



The graphical interface replicates the representation of control panels on lamps or wall displays.

The functions between the panels and the SurgiMedia interface are identical.




Click  to exit the function and close the command window.

Figure 1 – Operating light control



To turn off the operating field lighting, press and hold the button  on the control interface for a long time (>2s), then release when the window outline turns white to complete the switching off.



To activate the ambient lighting, you must hold down a long press (>2s) on the button  on the control interface, then release the button when the window outline turns white to complete the extinction.



The operating lights can be controlled directly via their own control unit or command unit with an "ON/OFF" push button. In the event of a communication failure between the SurgiMedia and the operating light, control is still provided by the light itself.

2 Information about this document

2.1 Electronic user manual



- The SurgiMedia Operating Lighting Control user manual can be downloaded electronically by following the link: [Instructions for use SurgiMedia Interface – Operating light control](#)

Complete user instructions specific to the models you use can be downloaded from the manufacturers' websites; for any other information, please contact your operating light dealer.

3 Safety Information

3.1 Scope of application

3.1.1 Operating lighting system

The lighting system is defined as an operating lighting system in accordance with IEC 60601-2-41 and designed for local illumination of operating and patient treatment areas in operating theatres, emergency rooms and treatment rooms.

3.1.2 Individual operating lamp

An individual lamp is classified as an individual operating lamp according to IEC 60601-2-41. The individual operating lamp is used for local illumination of operating and treatment areas for diagnostic and treatment purposes, which can be switched off without risk to the patient in the event of lamp failure.

3.2 Application environment

The lamps are intended for use in medical areas, including operating rooms and treatment rooms.

3.3 Essential features

Proper implementation of the essential product features ensures that the product can be used in accordance with its intended use. The product has the following essential features:

Operating lighting system

- Illumination of the operating field
- Reduction of thermal radiation in the operating field

3.4 User Group Requirements

The term "User Group" describes the responsible personnel assigned by the operator to perform a specific task on the product.

3.4.1 Obligations of the operational organization

The operational organization must ensure the following:

- Each user group has the required qualifications (e.g., has completed specialized training or acquired specialized knowledge in the performance of their work).
- Each user group has been trained to perform the task.
- Each user group has read and understood the relevant chapters of this document.

3.4.2 User groups

Clinician users

This user group uses the product in accordance with its intended application.

Users have specialized medical knowledge in the product's application.

Hygienist

This user group performs the activities necessary to reprocess the product.

Hygienists have specialized knowledge in medical device reprocessing.

Maintenance staff

This user group installs the product and performs maintenance operations.

The maintenance personnel have specialized knowledge in electrical and mechanical engineering and experience in maintaining medical devices.

When product-specific knowledge or tools are required, maintenance operations must be performed by specialized maintenance personnel. Specialized maintenance personnel have been trained by your supplier to perform maintenance operations on this product.

3.4.3 Product training

The operational organization must ensure that all product users and hygienists have been trained before using the product.

3.5 Information relating to safety instructions and warnings

Safety instructions and warnings warn the user of risks and dangers and provide instructions to ensure safe use of the product. Failure to comply may result in personal injury or property damage. All users must ensure they have received comprehensive training, particularly regarding safety precautions related to the use of surgical lighting.

These safety precautions are not described in this manual and are covered in the manufacturer's specific surgical lighting manual.