

# Instructions for use

Operating light

Sim.LED 8000 SC/MC



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PUSHING TECHNOLOGY TO EXCELLENCE

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**Before starting any work please read  
these instructions for use!**

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# Table of Content

1.	General information	5
1.1.	Information on these instructions for use	5
1.2.	Explanation of symbols	6
1.2.1.	Safety information	6
1.2.2.	Explanation of symbols	6
1.2.3.	Abbreviations / explanations	9
1.3.	Spare parts	10
1.4.	Warranty provisions	10
1.5.	Technical service	10
1.6.	CE mark	10
1.7.	Purpose and intended use	11
1.8.	Incoming goods inspection	12
1.9.	Duties of the operator	12
1.10.	Dismantling and disposal	13
2.	Basic safety instructions	14
2.1.	General safety instructions	14
3.	Operation	15
3.1.	Installation and initial start-up	16
3.2.	Variants and accessories	17
3.2.1.	Ceiling variant	17
3.2.2.	Mobile variant	18
3.3.	Visual inspection of the lights	19
3.4.	Replacing the sterilizable handle	21
3.4.1.	Intended use	21
3.4.2.	Replacing the sterilizable handle	21
3.4.3.	Replacing the sterilizable handle on the monitor holder	21
3.4.4.	Handles for sterile disposable covers	22
3.5.	Light controls	23
3.5.1.	Positioning the lights	23
3.5.2.	Sterile operation with the my.GRIP sterilizable handle	24
3.5.3.	Non-sterile operation of the operating light	28
3.5.4.	Switching the light on/off	33
3.5.5.	Setting the illumination intensity	35
3.5.6.	Adjusting the light field	37
3.5.7.	Setting the color temperature (for MC variant only)	38
3.5.8.	my.LED function	39
3.5.9.	Active shadow management	47
3.5.10.	Synchronization	49
3.5.11.	Sim.CAM operation	51
4.	Accessories and other products	52
4.1.	Sterile handle (preparable)	52
4.2.	Sterile handle adapter for disposable cover	52
4.3.	Sim.INTERFACE	53
4.4.	Sim.SCREEN	53
4.5.	Sim.CARRY GTP8	54
4.6.	Sim.CARRY GTP14	55
4.7.	Adapter for central axes / Sim.FLEX	56
5.	Maintenance	57
5.1.	Maintenance plan	58
5.2.	Maintenance work	59
5.2.1.	Setting the spring force: Ceiling variant	59
5.2.2.	Setting the spring force: Mobile variant	59
5.2.3.	Adjusting the vertical stop of the spring arm & LC spring arm	59
5.2.4.	Setting the braking power	60

6.	Preparation	61
6.1.	Clean the device and disinfect the device: Wiping disinfection	61
6.1.1.	Cleaning the unit	61
6.1.2.	Disinfecting the unit: Wiping disinfection	62
6.1.3.	Cleaning procedure	63
6.2.	Preparing the sterile handle	64
7.	Malfunction, display and resulting measures	67
7.1.	Display in the event of a malfunction	67
7.1.1.	Foil control malfunction	67
7.1.2.	Malfunction in touch control	67
7.1.3.	Possible causes of malfunctions	68
7.2.	Error codes	70
7.2.1.	Error codes for foil control	70
7.2.2.	Error codes for touch control	71
8.	Technical data	72
8.1.	Sim.LED 8000 SC technical data	72
8.2.	Technical data Sim.LED 8000 MC	75
8.3.	Permissible additional load for Sim.SCREEN monitor holders	77
8.4.	Permissible additional load for Sim.CARRY device carrier plate	78
8.5.	Type plate	78
8.6.	Dimension sheets	79
8.6.1.	Sim.LED 8000 ceiling variant	79
8.6.2.	Sim.LED 8000 mobile variant	79

# 1. General information

## 1.1. Information on these instructions for use

These instructions for use enable the safe and efficient handling of the Sim.LED 8000 SC/MC.

The instructions for use are an integral part of the lighting and must be stored near the unit, in a manner accessible to personnel, at all times. Persons who handle the light must have carefully read the instructions for use and understood the contents before starting any work.

The basic requirement for a safe work process is the adherence to all safety and handling instructions in this manual. Furthermore, local regulations on the operation of medical equipment apply.

The illustrations in these instructions are intended to provide general understanding and may differ from the device's actual appearance.


### Safety information

Safety indications are identified in these instructions for use through symbols.

#### Symbols

1. Step-by-step sequence

 Indicates handling instructions.

 Indicates a status or an automatic sequence as a result of a handling step.

 "*Reference title*", page XX is a cross-reference to a chapter in this document.

### Copyright protection

These instructions for use are copyright-protected.

Forwarding of the instructions for use to a third party, its reproduction in any type or form - even if only partial - and the exploitation and/or dissemination of its contents are not allowed without written authorization from the manufacturer.

Violations will result in claims for damages. We reserve the right to assert further claims.

### Limitation of liability

All specifications and instructions in these instructions for use have been compiled under consideration of applicable norms and standards, the current state of the art and our many years of knowledge and experience.

Damages resulting from the following will render the warranty and guarantee null and void:






- Non-compliance with these instructions for use
- Non-observance of the designated use / specific function
- Use by non-qualified personnel
- Use of the product by insufficiently trained personnel
- Modifications conducted independently
- Technical modifications
- Use of a defective or improperly repaired unit
- Use of unauthorized spare parts or accessories
- Use of the device if packaging is damaged and/or failure to comply with the transport and storage conditions

The actual scope of delivery may deviate from the explanations or illustrations provided in this manual in the case of special designs, the use of additional order options, or due to the most recent technical changes.

## 1.2. Explanation of symbols

Safety indications are identified in these instructions for use through symbols.

### 1.2.1. Safety information

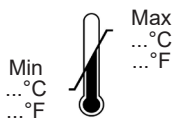
	Indicates a hazardous situation which will result in death or serious injury if not prevented.
	Indicates a hazardous situation which could result in death or serious injury if not prevented.
	Indicates a hazardous situation which could result in <b>minor or moderate</b> injury if not prevented.
	Risk of material damage: Non-observance of the instructions may result in damage to or destruction of the product or other objects, as well as loss of data or loss of working hours.
	Product information, useful tips and <b>additional information</b> regarding operation.

### 1.2.2. Explanation of symbols

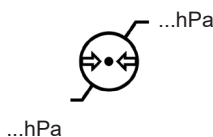
The following symbols can be found on the type plate and/or packaging. Symbols must always be observed.



Follow the instructions for use



Specifications on minimum and maximum ambient temperature for storage and transport



Specifications on minimum and maximum air pressure for storage and transport



Specifications on minimum and maximum air humidity for storage and transport



The arrows indicate the top of the package. They must always point upwards. Otherwise, the contents could be damaged.

## General information



This symbol identifies packages with fragile or sensitive contents. Handle the package with care; do not drop it and do not strike it.



Protect the package from wetness and keep dry.



Date of manufacture and manufacturer's address



Item code:



Serial number



Protective grounding

IP...

Degrees of protection provided by enclosures (IP code) according to IEC 60529



Medical Equipment – General Medical Equipment  
REGARDING ELECTRIC SHOCK, FIRE, AND MECHANICAL DAMAGE: ONLY IN ACCORDANCE WITH STANDARDS ANSI/AAMI ES60601-1 (2012), CAN/CSA-C22.2 No. 60601-1 (2014), IEC 60601-2-41:2009-A1:2013



CE mark of conformity



The crossed-out bin symbol indicates that the product may not be disposed of with household waste at the end of its service life.



Indicates that the object in question is a medical device (DIN EN ISO 15223)



Unique product identification, indicates a medium that contains information for unique product identification (UDI).



Local authorized representative, EC = Authorized representative in the European Union



Distribution partner, indicates the company that distributes the medical device on site.



Importer, indicates the company that is introducing or has introduced the medical device at the location.




**1.2.3. Abbreviations / explanations**

<b>Abbreviation</b>	<b>Explanation</b>
<b>Fig.</b>	Figure
<b>AC</b>	Alternating current
<b>CE</b>	Conformité Européenne (European Conformity) Graphical labeling symbol pursuant to EU product law
<b>DIN</b>	Deutsche Industrie Norm (German Industrial Standard) Independent platform for standardization in Germany and worldwide
<b>EMC</b>	Electromagnetic compatibility
<b>EN</b>	European standard
<b>EEC</b>	European Economic Community
<b>HF</b>	High frequency
<b>IEC</b>	International Electrotechnical Commission International standardization organization for electrical and electronic standards
<b>IP</b>	IP protection class describes a device's housing protection against the ingress of foreign bodies and water, IP protection class according to IEC 60529
<b>Chap.</b>	Chapter
<b>LED</b>	Light-emitting diode
<b>ME device</b>	Medical electrical devices
<b>OP</b>	Operation
<b>Sec</b>	Second
<b>V.</b>	Version
<b>e.g.</b>	For example

### 1.3. Spare parts

Procure spare parts from your authorized dealer or directly from the manufacturer. For the address, see page 2.

 <b>WARNING</b>	<p><b>Risk of injury due to the use of incorrect spare parts!</b></p> <p>The use of incorrect or defective spare parts may place personnel and patients at risk as well as cause damage, malfunctions, or a total breakdown of the unit.</p> <ul style="list-style-type: none"> <li>☞ Only use original manufacturer spare parts or manufacturer-approved spare parts.</li> <li>☞ If uncertain, always contact the manufacturer.</li> </ul>
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### 1.4. Warranty provisions

The warranty provisions are contained in the manufacturer's General Business Terms and Conditions. The manufacturer's warranty will be voided if unauthorized spare parts are used.

### 1.5. Technical service

Software is embedded in the product and does not require any specific minimum requirements for the IT environment. Adjustments to the light can and may only be made by authorized service personnel using service software provided by SIMEON. A service file generated by SIMEON is required for this purpose.

Our Technical Service is available to provide technical information. For contact information, see page 2.

Our staff members are always interested in hearing about new information and experiences related to product usage that may aid us in improving our products.

### 1.6. CE mark

The medical device complies with the requirements of the Medical Device Regulation 2017/745(EU), or MDR. The CE mark can be found on the type plate.

## General information

### 1.7. Purpose and intended use

#### Purpose

The light serves as an individual light in the vicinity of the patient for use in operating rooms for the local illumination of the patient's body to support diagnosis or treatment.

#### Usage restrictions

The light may not be used as an individual light, but only as an OR light system, if a light failure would pose a risk to the patient.

The light is not suitable for operation in explosion-prone or oxygen-rich environments.

The operating light is intended for use in operating rooms.

#### Intended use

The operating light can be mobile, ceiling- or wall-mounted.

The concept of intended use also includes compliance with all specifications in these instructions for use and the separate installation instructions. The light may only be operated by professional users.

Any use that exceeds the intended use, and any other kinds of uses, are considered to be incorrect uses.

#### Indication(s)

Lighting during operations and examinations.

#### Contraindication(s)

Accelerated wound drying by overlapping the light fields of various operating lights.

**⚠ DANGER!**

#### Danger due to incorrect use!

Incorrect use of the unit may lead to dangerous situations. The following are especially considered to be incorrect uses:

- Use of the unit in facilities that have not been built in compliance with applicable standards and guidelines regulating the construction of medical facilities.
- Use of the unit in explosion-prone areas.
- Use of a damaged unit.
- Opening of the unit.
- Use of the unit by unqualified personnel.
- Use of the unit when objects are hanging from its extension arm, spring arm or light head.

Claims of any type due to damages caused by misuse, alteration or modification of the operating lights are excluded.

As a general rule, modifications to medical devices are not allowed. Exceptions are only given to authorized technical specialists appointed by the manufacturer.

### **Electromagnetic compatibility (EMC)**

As electric medical devices, these lights are subject to special precautionary measures with regard to EMC. They must be installed and commissioned in accordance with the EMC specifications.

Mobile HF communication devices may affect the functioning of the lights. The operation of accessories, converters and cables on the lights which the manufacturer has not expressly approved may increase the lights' interference emissions or reduce their interference resistance.

The lights may not be used in the immediate vicinity of other devices. If this cannot be avoided, the affected lights must be observed in order to make sure they are functioning reliably in this environment.

All necessary EMC measures must be conducted and observed during installation.

### **Operational reliability**

The main performance features of the Sim.LED are:

- emission of minimum and adequate illumination of the surgical field
- the reduction of heat radiation in the surgical field

## **1.8. Incoming goods inspection**

Inspect your delivery for completeness and integrity, immediately after receipt. Any transportation damages must be notified immediately.

## **1.9. Duties of the operator**

### **Responsibility to instruct**

The operator must inform himself of all applicable accident prevention and hygiene regulations, and must additionally conduct a risk assessment in order to identify the risks posed by the particular work conditions at the site where the unit will operate. The operator must use this risk assessment as the basis for creating user instructions for operating the device.

During the entire time that the unit is in use, the operator must check whether the operating instructions that he prepared comply with current technical regulations and revise them if necessary.

The operator must clearly regulate and define responsibilities for installation, operation, troubleshooting, maintenance and cleaning.

The operator must ensure that all employees who handle the unit have read and understood these instructions for use. He or she must train personnel at regular intervals and inform them of all dangers. The operator must take measures to ensure that unauthorized persons cannot use the device.

The operator must ensure that all maintenance intervals and technical safety controls described in these instructions for use are adhered to.

The operator must ensure that only permitted, manufacturer-authorized accessories are used in connection with the device.

### **Technical safety inspections**

The operator must have technical safety checks performed every two years.

Technical safety checks may only be conducted by the manufacturer's personnel, or by authorized specialists who have received written approval from the manufacturer.

The protocol prepared by the authorized specialist, detailing the measurement procedures, measurement results, and other evaluations, must be kept until the next check.

## General information

### No liability for failure to observe maintenance intervals!

The manufacturer assumes no liability for personal or material damages if technical safety inspections are not contracted and conducted within the time limits provided.

### Notification of accidents and damages

All serious incidents which occur in connection with the product must be reported to SIMEON Medical and the competent authority of the country in which the incident took place.

The authorities in charge may request that the operator submit the incident being notified to a technical safety evaluation by an authorized expert, at its own expense, and that the evaluation be submitted in writing to such authorities. The authorized expert will be selected in consultation with the authorities in charge.

The technical safety evaluation will include determinations on

- whereupon fault for the incident lies,
- whether the unit was in proper condition,
- whether any further danger exists following rectification of defects,
- whether new knowledge has been gained, calling for different or additional precautionary measures.

## 1.10. Dismantling and disposal



The unit must be dismantled properly and disposed of in an environmentally friendly manner.

Dismantling should only be conducted by trained, skilled personnel.

The devices may be returned to the manufacturer.


May not be disposed of as household waste.


You will find further information on the materials used in the technical data so that they can be disposed of in an environmentally friendly manner.


 **DANGER**

### Risk of death due to improper dismantling!

Errors during dismantling may result in life-threatening situations and cause significant material damages.

 Only allow trained, qualified personnel to conduct dismantling.

 Contact the manufacturer for any subsequent changes of location as well.

 Unauthorized dismantling and relocations are prohibited.




## 2. Basic safety instructions

### 2.1. General safety instructions

 **DANGER!**

**Risk of death due to improper installation or commissioning!**

Errors during the installation or initial start-up may result in life-threatening situations and cause considerable material damages. For that reason, please note the following:







-  Installation and initial start-up may only be conducted by the manufacturer's personnel or by persons authorized by the manufacturer.
-  Contact the manufacturer for any subsequent changes of location as well.
-  Do not install or relocate the device without manufacturer involvement.

 **WARNING**

This product emits possibly hazardous optical radiation. Do not stare at the light emitted from the surgical luminaire. Eye injury may occur.

The optical radiation emitted by this product complies with the exposure limits for reducing the risk of photobiological hazards in IEC 60601-2-41.

### 3. Operation

	<p><b>Read all instructions before operating the device!</b></p>
	<p><b>The device may only be operated by trained and authorized personnel.</b></p>
	<p><b>Do not consume alcohol or drugs before or during operation, and follow the safety instructions carefully.</b></p>
	<p><b>Prevent a direct glare effect: Users, patients and third parties should avoid looking into the operating light for long periods of time!</b></p>
 <p><b>WARNING</b></p>	<p>This product emits optical radiation. Do not stare into the light emitted by the surgical light for a long time. Eye injury can occur.</p>
 <p><b>CAUTION</b></p>	<p><b>Risk of excessive radiation energy in the surgical field! Possible tissue damage due to drying of the wound!</b></p> <p>The superimposed light fields from multiple lamp bodies produce a combination of high illumination intensities and generate an elevated temperature in the illuminated area. This can cause tissue damage.</p> <ul style="list-style-type: none"> <li>☞ Separate the superimposed light fields from multiple lamp bodies.</li> <li>☞ Immediately reduce the illumination intensity of the light heads when the wound begins to dry out, e.g. increase the distance between the light and the wound.</li> </ul>

### 3.1. Installation and initial start-up

The installation and initial start-up should be exclusively conducted by the manufacturer's personnel or by persons authorized by the manufacturer.

Detailed information on installation and initial start-up can be found in the associated installation instructions.

↳ *Sim.LED 8000 installation instructions*



#### **Risk of death due to improper installation or commissioning!**

Errors during the installation or initial start-up may result in life-threatening situations and cause considerable material damages. For that reason, please note the following:

- ↳ Installation and initial start-up may only be conducted by the manufacturer's personnel or by persons authorized by the manufacturer.
- ↳ Contact the manufacturer for any subsequent changes of location as well.
- ↳ Do not install or relocate the device without manufacturer involvement.



#### **Risk of injury due to electric shock!**

In order to avoid the risk of an electric shock, the lighting may only be connected to a power supply system with a ground connection!



#### **Risk of injury due to pinching!**

When moving the extension arm, objects and fingers placed on it may be pinched! When moving the arm system, please make sure to place your grip on the equipment attached to the arm systems, and that the entire range of rotation is unobstructed!



## Operation

### 3.2. Variants and accessories

The Sim.LED 8000 SC/MC operating light is available in different variants.

SC = Single Color with a fixed color temperature of 4,500 K.

MC = Multi Color with the option of color temperature adjustment from 3,500, 4,000, 4,500, 5,000 to 5,500 K.

The sterile handle (SteC Sim.LED OPL – Item code 142–0004330).

The sterile handle (SteC Sim.LED ExL – Item code 141–0000011).

#### 3.2.1. Ceiling variant



- |   |                                    |   |                               |
|---|------------------------------------|---|-------------------------------|
| 1 | Canopy                             | 6 | Handles                       |
| 2 | Ceiling tube                       | 7 | Light controls                |
| 3 | Extension arm (different variants) | 8 | Sterilizable handle / Sim.CAM |
| 4 | Spring arm                         | 9 | Light head                    |
| 5 | Cardanic                           |   |                               |



#### Risk of injury due to falling objects!

👉 Do not hang any objects on the load-bearing system or fasten them to it!

### 3.2.2. Mobile variant

The device is available as a mobile variant or optionally as a mobile variant with a single or double battery stand. Further details on battery variant → [100-0016815 Mobile battery stand instructions for use](#).



- |   |                |    |                                |
|---|----------------|----|--------------------------------|
| 1 | Spring arm     | 6  | Sterilizable handle            |
| 2 | Cardanic       | 7  | Mobile stand, cable length 5 m |
| 3 | Handles        | 8  | Junction box                   |
| 4 | Light head     | 9  | Casters                        |
| 5 | Light controls | 10 | Parking brake                  |



#### Risk of injury due to falling objects!

→ Do not hang any objects on the mobile stand or fasten them to it!



Risk of death due to electric shock!

It must be possible to access the power plug or other disconnection device at all times in order to disconnect the connection in case of emergency.

### 3.3. Visual inspection of the lights

Before switching on the lights, ensure that they are undamaged and correctly plugged in.

There is no danger when intact lights are used as intended, ↪ "1.7. Purpose and intended use" on page 11.

Damages to the lighting, current supply or mounting could cause considerable risks, however:



**Risk of death due to electric shock!**

If live parts are touched, there is an immediate risk of death due to electric shock. Damage to the insulation or individual components could be life-threatening.

☞ In the event of insulation damages or electric cable defects, the lights must immediately be disconnected from the mains through the main switch in the operating room (wall- and ceiling-mounted versions; for mobile lamps, pull the power plug). Perform repairs! Never supply voltage to defective lights!

☞ Repairs may only be conducted by skilled electricians!

☞ Keep moisture away from live parts. Moisture could lead to a short-circuit.

☞ Before conducting any maintenance, cleaning or repairs, switch off the power supply and safeguard against reconnection.

☞ Before starting any work, ensure that:

- a visual inspection for damage or cracks on the unit has been conducted.
- all hygiene regulations have been adhered to
- there are no unauthorized persons in the vicinity of the unit.

**⚠ WARNING**

**Risk of infection due to improper hygiene, disinfection, or sterilization!**

There is a risk of infection upon contact with parts that have not been cleaned, sterilized or disinfected.

- ☞ Clean and disinfect the unit before every use.
- ☞ Observe the instructions on sterilization.
- ☞ Adhere to all standards on hygiene, disinfection and sterilization that are locally in effect.

**⚠ WARNING**

**Risk of injury due to contamination of wounds!**

Damage to the light head or to the sterilizable handle can cause loose or porous parts to fall into wounds and contaminate them.

- ☞ Conduct a visual and functional inspection before each use of the device.
- ☞ Do not operate a damaged unit.
- ☞ Inspect the sterilizable handles for safe positioning before each use of the lighting equipment.

### 3.4. Replacing the sterilizable handle

#### 3.4.1. Intended use

Sterilizable handle 142–0004330 is used for sterile positioning of the light and for sterile operation of the light parameters using the my.GRIP function.

Sterilizable handle 142–0000011 serves for the sterile positioning of the monitor holder.

#### 3.4.2. Replacing the sterilizable handle

##### **Sterilizable handle (Item code 142–0005330)**

☞ Ensure that the sterilizable handle (1) has been properly disinfected and sterilized, ☞ "6.2. Preparing the sterile handle" on page 64.

☞ Insert the sterilizable handle onto the handle unit and turn until the safety (2) audibly snaps into position.

##### **Remove sterilizable handle (Item code 142–0005220)**

☞ Push the release button (1) on the sterilizable handle inwards.

☞ Pull the sterilizable handle off from the handle unit.

☞ Inspect the sterilizable handle for wear and damage, dispose of and replace it if necessary.

#### 3.4.3. Replacing the sterilizable handle on the monitor holder

##### **Sterilizable handle (Item code 141–0000011)**

☞ Ensure that the sterilizable handle (1) has been properly disinfected and sterilized, ☞ "6.2. Preparing the sterile handle" on page 64.

☞ Insert the sterilizable handle onto the handle unit and turn until the safety (2) audibly snaps into position.

##### **Sterilizable handle (Item code 142–0005220)**

☞ Press the safety (2) inwards.

☞ Pull the sterilizable handle (1) off from the handle unit.

☞ Inspect the sterilizable handle for wear and damage, dispose of and replace it if necessary.

### 3.4.4. Handles for sterile disposable covers

#### Using handles for sterile disposable covers

- ✎ Remove sterilizable handle, ↪ *"6.2. Preparing the sterile handle" on page 64.*
- ✎ Detach the handle unit (2) with the two screws (1) from the light head.
- ✎ Adapter (3, SIMEON Item code 142–0015720) to the light head with the screws (1).
- ✎ Insert handle (5, to be ordered from Litex, Item code: 3600-104) for sterile disposable covers into the adapter (3) and turn it slightly until the safety (4) audibly snaps into place.
- ⇒ You can now attach the sterile disposable covers for sterile work onto the handle.

#### Using the handle unit

- ✎ Detach the handle for sterile disposable covers (5) with 2 screws (1) from the light head.
- ✎ Mount handle unit (2) with the 2 screws (1) on the light head.
- ✎ Attach sterilizable handle, ↪ *"6.2. Preparing the sterile handle" on page 64.*

### 3.5. Light controls



**Risk of injury due to electric shock!**

Unreliably grounded lights could cause an electric shock. For that reason, please note the following:

- ☞ Ensure that the lights have been correctly grounded. In the case of mobile lights: a power outlet with protective contact.
- ☞ Never touch the patient and lighting system at the same time.

#### 3.5.1. Positioning the lights



**Risk of injury due to collision!**

- ☞ When positioning the lights, ensure that they do not collide with other objects.

Before each start-up, the lights must be positioned to illuminate the expected area of use.

**Positioning the ceiling variants**

Bring the lamp bodies into the desired position using the handles (1, unsterile) or the sterilizable handle (2).

**Positioning the mobile variants**

- ☞ Make sure that the spring arm is in the lowest possible position when the mobile stand is transported, in order to optimize its balance.
- ☞ Release the stop brake (3).
- ☞ Secure the mobile stand (5) (observe label with marking) and move the light and mobile stand to the desired position. Avoid transporting the device across uneven surfaces and inclines. Ensure that the light stands securely in the new position.
- ☞ Lock the stop brakes (3) for the casters (4).
- ☞ Move the light heads into the desired position using the sterilizable handle(s).

**NOTE**

Carefully pull the stand over thresholds and avoid obstacles in order to prevent the stand from being damaged or tipping over.

### 3.5.2. Sterile operation with the my.GRIP sterilizable handle



#### Control of two operating functions with the my.GRIP sterilizable handle

The my.GRIP sterilizable handle is able to control two different operating functions by turning it to the right and left.

In the **as-delivered state**, operating function 1 is the setting of the light field ↪ "3.5.6. Adjusting the light field" on page 37 and operating function 2 is the setting of the illumination intensity ↪ "3.5.5. Setting the illumination intensity" on page 35

Function 1 (light field, illumination intensity, color temperature) is operated via "Turn and release" to the right (decrease) or left (increase).

Function 2 (illumination intensity, light field, color temperature) is operated via "Turn and hold" (at least 1 second) to the right (decrease) or left (increase). Function 2 is also used to operate the Sim.BIANCE function. This can also be operated by "Turn and hold" (at least 1 second) to the right (switch on) or to the left (switch off).

The handle can be programmed with 12 different operating functions ↪ "3.5.2.3. Programming the sterilizable handle my.GRIP via cardanic foil control" on page 25.



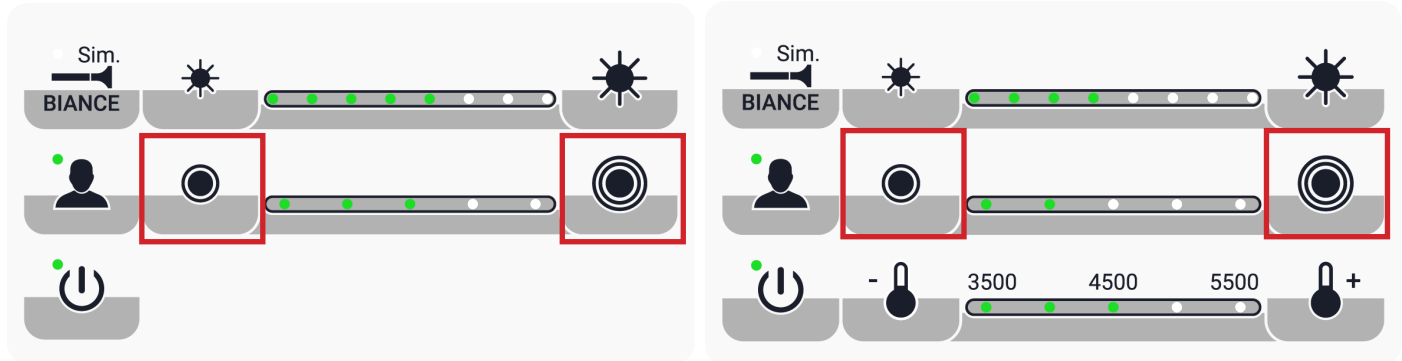
### 3.5.2.1. Function display and programming of the my.GRIP sterilizable handle

The currently stored settings of the my.GRIP control functions 1 and 2 can be accessed and displayed by using the cardanic foil control as well as by using the cardanic touch control. Both product variants also offer the option of user-specific programming of the my.GRIP function (12 different operating functions available for my.GRIP function).

### 3.5.2.2. Function display via cardanic foil control

Function display for single-color lights

Function display for multi-color lights



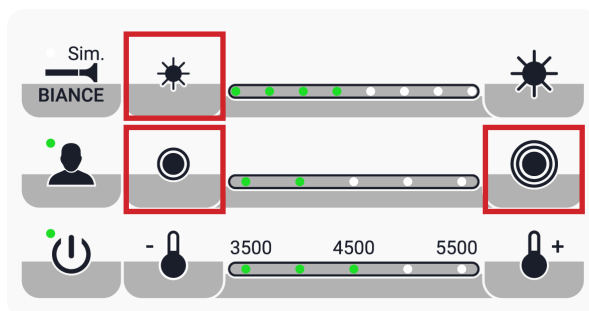
- Hold down the **Reduce light field** and **Enlarge light field** buttons at the same time. The operating functions are depicted by LEDs which light up successively.
  1. Display: Operating function 1
  2. Display: Operating function 2

After the operating functions are displayed, the function display will automatically be exited.

### 3.5.2.3. Programming the sterilizable handle my.GRIP via cardanic foil control

Programming is done via the cardanic foil control panel as follows:

#### Programming of operating function 1:



- Hold down the **Illumination intensity minus**, **Reduce light field** and **Enlarge light field** buttons at the same time until the LEDs for illumination intensity, light field and color temperature (MC only) start flashing.

The light will now be in programming mode for operating function 1 for 5 seconds.

Operating function 1 can be programmed as desired by pushing the following buttons:

#### Illumination intensity setting:

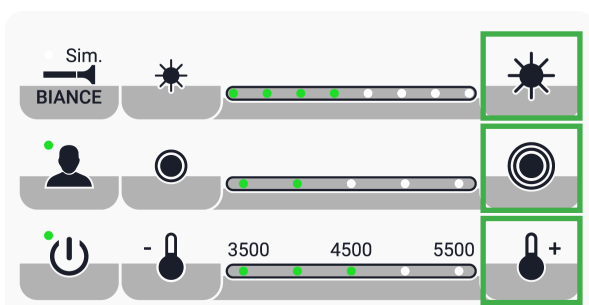
- Push the **Illumination intensity plus** button

#### Adjusting the light field:

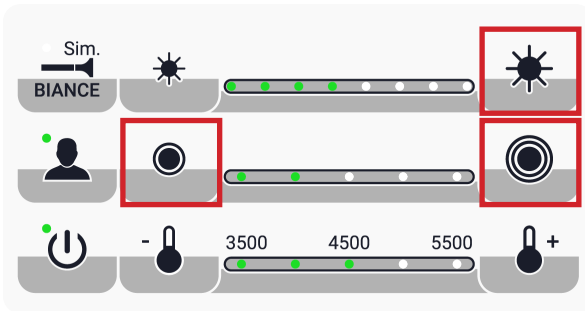
- Push the **Enlarge light field** button

#### Color temperature setting (MC only):

- Push the **Increase color temperature** button
- If no button is pushed within 5 seconds, the programming mode will automatically be exited.



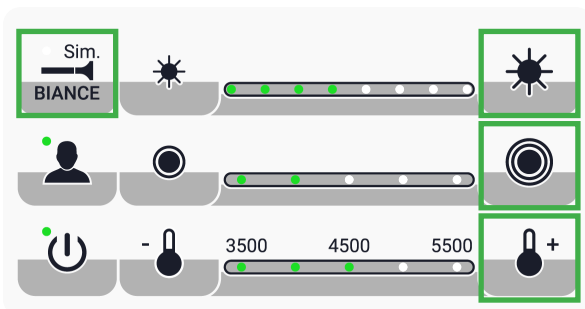
**Programming of operating function 2:**



☞ Hold down the **Illumination intensity plus**, **Reduce light field** and **Enlarge light field** buttons at the same time until the LEDs for illumination intensity, light field and color temperature (MC only) start flashing.

The light will now be in programming mode for operating function 2 for 5 seconds.

Operating function 2 can be programmed as desired by pushing the following buttons:



**Illumination intensity setting:**

☞ Push the **Illumination intensity plus** button

**Adjusting the light field:**

☞ Push the **Enlarge light field** button

**Color temperature setting (MC only):**

☞ Push the **Increase color temperature** button

**Activation of Sim.BIANCE:**

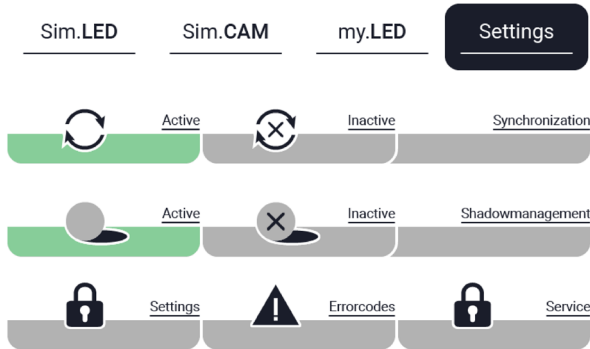
☞ Push the **Sim.BIANCE** button

If no button is pushed within 5 seconds, the programming mode will automatically be exited.

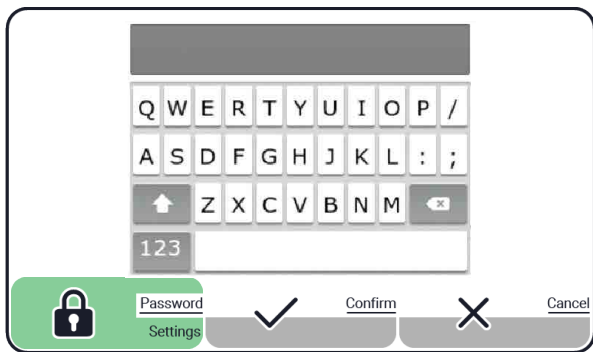
## Operation

### 3.5.2.4. Function display and programming via cardanic touch control

With cardanic touch control, both the function display and the programming of the my.GRIP function can be carried out via the settings menu and the corresponding submenu described below.



In the “Settings” menu tab, the settings menu can be accessed via the “**Settings**” button (bottom left).



A pop-up window appears with a password prompt, in which the password “0000” is entered via the QWERTZ keyboard displayed in the pop-up window. Confirm the entry with **Confirm**. In the settings menu and by selecting the



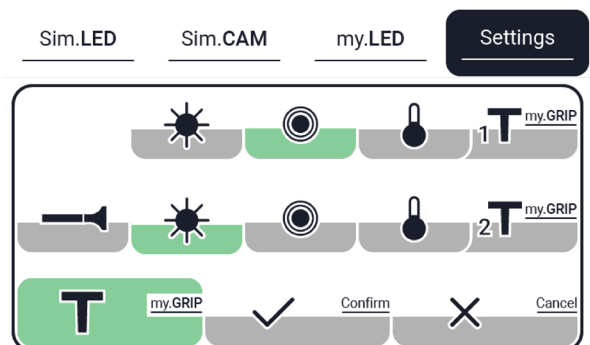
“**my.GRIP**” button, you can access the my.GRIP submenu.



The menu provides an overview of which settings are currently saved for operating functions 1 and 2.

The operating functions can be programmed by clicking on the respective button. This means that the desired setting can be saved for each operating function.

The selected function is displayed in green.



Select the **Confirm** button to accept and save the new settings.

### 3.5.3. Non-sterile operation of the operating light

#### 3.5.3.1. Non-sterile operation via foil control

##### Light controls on the cardanic

The light controls can be found on the cardanic. The operating light can be turned on and off using the **On/Off** keys (1).

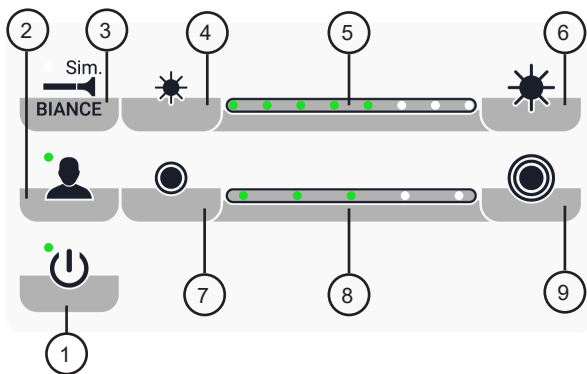
The **my.LED** (2) key restores the values for illumination intensity, light field size and color temperature (MC only) that were last saved. → "3.5.8. my.LED function" on page 39.

The **Sim.BIANCE** key (3) switches on the background illumination and can switch back to the last setting when pushed again.

The keys **Illumination intensity minus** (4) and **Illumination intensity plus** (6) are used to set the illumination intensity, which can be read on the illumination scale (5).

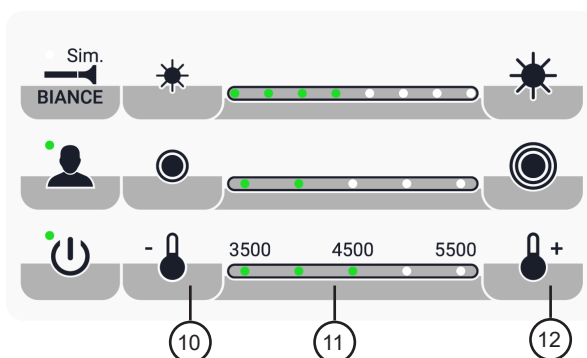
The keys **Light field smaller** (7) and **Light field larger** (9) are used to adjust the size of the light field. The current setting can be read on the illumination scale (8).

##### SC (single color) variant



1. **On/Off** key with LED
2. **my.LED** key
3. **Sim.BIANCE** key (background illumination for endoscopic procedures)
4. **Illumination intensity minus** key
5. Illumination intensity display
6. **Illumination intensity plus** key
7. **Light field smaller** key
8. Light field size display
9. **Light field larger** key

##### MC variant (Multi Color)



Additional elements:

10. **Color temperature minus** key
11. Color temperature display
12. **Color temperature plus** key

The keys **Color temperature minus** (10) and **Color temperature plus** (12) are used to adjust the color temperature. The current setting is indicated by the color temperature scale (11).

3.5.3.2. Non-sterile operation via touch control



**Risk of freezing touch display**

There is a risk that the display of the touch control will freeze. Please call your responsible service partner.

Cardanic touch control

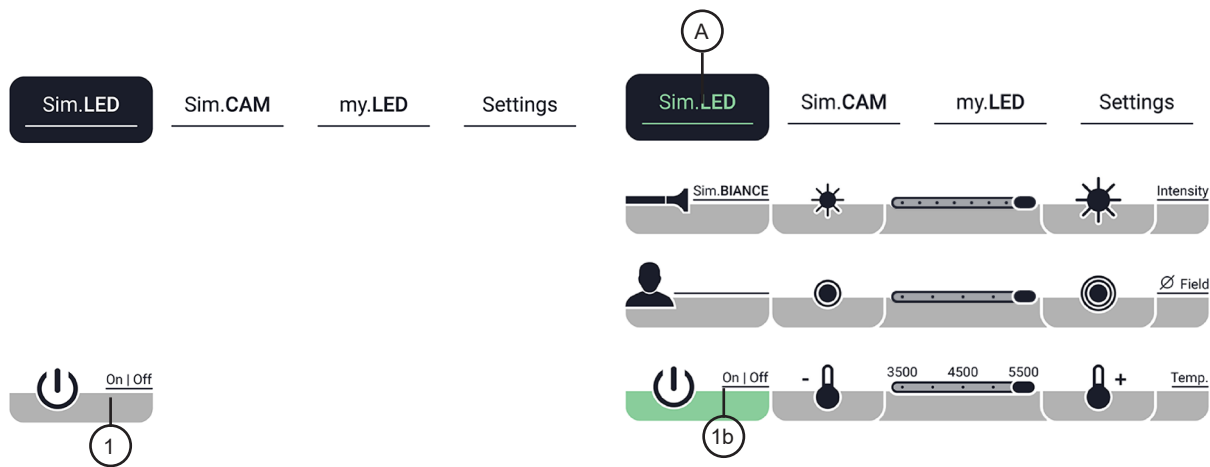


The light controls can be found on the cardanic. It can be activated by touching the black screen.



If the screen does not react when touched, it could be a failure in which the light is still being operated in the background. Please inform a service technician.

You can access the Sim.LED light menu and switch on the operating light via the “On/Off” button (1). The button (1b) now marked in green and the green text “Sim.LED” (A) in the menu tab indicate that the operating light is switched on.



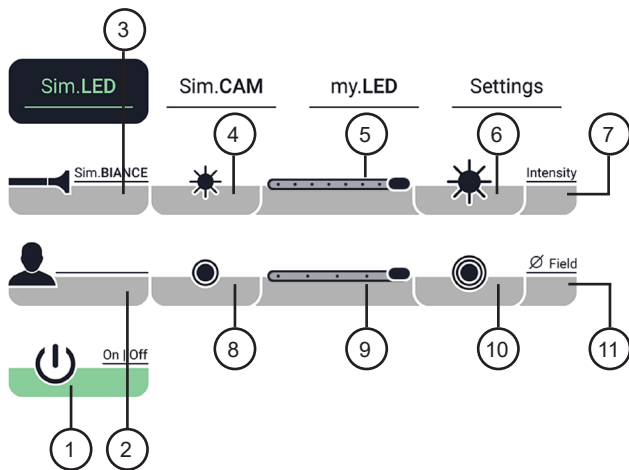
The **my.LED** (2) button restores the saved values of the stored and selected user profile. ↪ "3.5.8. my.LED function" on page 39.

The **Sim.BIANCE** button (3) switches to backlighting and returns to the last.

The **Illumination intensity minus** (4) and **Illumination intensity plus** (6) buttons are used to set the illumination intensity. The illumination intensity can also be adjusted and read using the **illumination intensity slider** (5).

The **Light field smaller** (8) and **Light field larger** (10) buttons are used to set the light field size. The illumination intensity can also be adjusted and read using the **light field slider** (9).

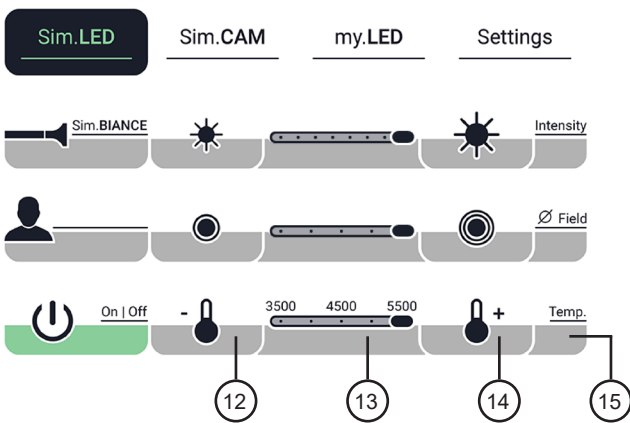
The **Color temperature minus** (12) and **Color temperature plus** (14) buttons are used to adjust the color temperature. The current color temperature can also be adjusted and read using the **color temperature slider** (13)



**SC (single color) variant**

1. **On/Off**
2. **my.LED**
3. **Sim.BIANCE**
4. **Illumination intensity minus**
5. Illumination intensity slider
6. **Illumination intensity plus**
7. "Intensity" Description of the Illumination intensity function (no button)
8. **Light field smaller**
9. Light field slider
10. **Light field larger**
11. "Ø field" Description of the function Light field diameter (no button)

**MC (Multi Color) variant**



Additional elements:

12. **Color temperature minus**
13. Color temperature slider
14. **Color temperature plus**
15. "Temp" description of the color temperature function (no button)

**Touch wall control**

The light can optionally be operated via the touch wall control. All lights in the system can be controlled centrally here.

If the system consists of an operating light, operation is identical to that of the cardanic touch control → "Cardanic touch control" on page 29.

If the system consists of two or three operating lights, an overview of the lights and their status is displayed on the main screen.

**The buttons and their functions**



## Operation



The **All Lights On** button provides the ability to turn on all of the system's operating lights simultaneously by pressing this button. The parameters that were set when the lights were switched off are automatically set for all lights.



The **Sim.LED 1** button relates to the system's first operating light mounted on the lowest arm position. Pressing this button once takes you to the light menu itself, where you can configure the light settings and (if connected) the Sim. CAM camera.



The **Sim.LED 2** button relates to the system's second operating light. In the case of a double combination, this is used to operate the light at the upper arm position. In the case of a triple combination, the button relates to the operating light in the middle position. Pressing this button once takes you to the light menu itself, where you can configure the light settings and (if connected) the Sim.CAM camera.



The **Sim.LED 3** button relates to the operating light installed in the uppermost arm position in a triple combination. Pressing this button once takes you to the light menu itself, where you can configure the light settings and (if connected) the Sim.CAM camera.

### The buttons and their status display

The buttons provide further information on whether the lights are switched on or off, whether and in which light a camera is installed and also on whether this camera is switched on or off.

As a result, the touch wall control provides a comprehensive overview of all of the system's products.



All operating lights or at least one of the operating lights are switched off.



All operating lights are switched on.



The operating light (example Sim.LED 1) is switched off, no Sim.CAM camera system is connected.



The operating light (example Sim.LED 1) is switched on, no Sim.CAM camera system is connected.



The operating light (example Sim.LED 1) is switched off. A Sim.CAM camera system is connected in Sim.LED 1, which is switched off.



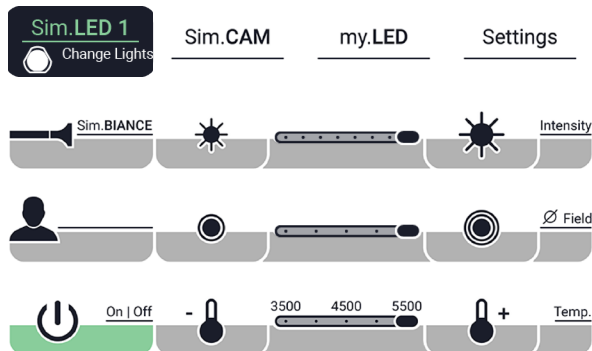
The operating light (example Sim.LED 1) is switched off. A Sim.CAM camera system is connected in Sim.LED 1, which is switched on.



The operating light (example Sim.LED 1) is switched on. A Sim.CAM camera system is connected in Sim.LED 1, which is switched on.

### Operation of the operating lights via the touch wall control

As already described, pressing the “Sim.LED” button takes you to the light menu of the selected operating light. This is identical to the cardanic touch control menu. All details on buttons and operation → *“3.5. Light controls” on page 23.*

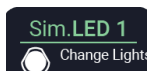


In order to return to the overview of the touch wall control via the menu, the **Change lights** button must be selected in the **Sim.LED** menu tab.

As with the cardanic touch control, this shows the status of the Sim.LED operating light.



Sim.LED 1 (here in the example) operating light switched off



Sim.LED 1 (here in the example) operating light switched on

To return to the overview of the touch wall control from the **Sim.CAM**, **my.LED** or **Settings** menu tabs, you must always switch to the **Sim.LED** menu tab first. The Change Lights function is then available there in the Sim.LED menu tab.



### 3.5.4. Switching the light on/off

#### Disconnecting the unit from the mains power supply

In the case of wall- and ceiling-mounted versions, always use the main switch (part of the building installation) to disconnect the unit from the mains power supply. In the case of mobile lamps, pull the power plug.

Requirement for switching on the lights: The main switch in the operating room is switched on or the power plug for the mobile variant is plugged into the power outlet.

#### Switching on the unit

☞ Make sure that no one is looking directly into the light reflectors.

##### Foil control variant:

☞ Press the **On/Off** button on the cardanic foil control panel



##### Touch control variant:

☞ Turn off the screensaver by pressing the black screen once

☞ Then click the **On/Off** button on the cardanic touch control or touch wall control.



⇒ The lights are turned on.

**Foil control variant:** The LED on the **On/Off** button lights up.



**Touch control variant:** The **On/Off** button turns green. The **Sim.LED** text in the menu tab turns green.



## Switching off the unit

☞ Ensure that the room is sufficiently illuminated, even without the operating light on, to be able to move around safely.

### Foil control variant:

☞ Press the **On/Off** button on the cardanic foil control panel.

### Touch control variant:

☞ Click the **On/Off** button on the cardanic touch control or touch wall control.

☞ Pop-up window with query "Are you sure you want to switch off 'Sim.LED'?" confirm with the **Confirm** button.

⇒ The lamp is switched off.

**Foil control variant:** The LED is turned off.



**Touch control variant:** The **On/Off** button turns grey again. The **Sim.LED** text in the menu tab turns white again.



If both the Sim.LED operating light and the Sim.CAM camera system (if connected) are switched off, the display of the cardanic touch control automatically switches to the black screen saver.

### 3.5.5. Setting the illumination intensity



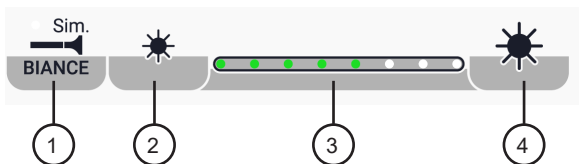
#### Warning of excessive heat build-up in the light field

The light fields of several Sim.LED 8000 operating lights of a lighting system should not be superimposed in order to avoid exceeding the normative total illumination strength of 1,000 W/m<sup>2</sup> and thus to avoid excessive heat development in the light field.

#### 3.5.5.1. Setting the illumination intensity using the foil control

The illumination intensity is gradually increased or decreased on the cardanic foil control panel. Eight different levels of illumination intensity are available. It is possible to switch between the levels by pressing the decrease/increase **illumination intensity buttons** (2, 4) on the cardanic control.

The set illumination intensity is indicated by the green LEDs (3).



#### Increasing the illumination intensity

☞ Press repeatedly or press and hold the **illumination intensity plus** (4) key, until the desired illumination intensity is set.

#### Decreasing the illumination intensity

☞ Press repeatedly or press and hold the **illumination intensity minus** (2) key, until the desired illumination intensity is set.

#### Sim.BIANCE

Sim.BIANCE is a function that can be used during endoscopic procedures. It involves diffuse background illumination that is required for orientation purposes during endoscopic procedures. If the Sim.INTERFACE option is installed, Sim.BIANCE will be switched on/off together with the system lights.

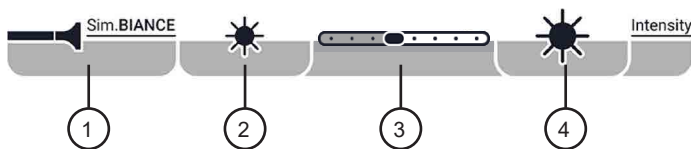
☞ Press the **Sim.BIANCE** key (1): The illumination intensity is reduced to background lighting.

☞ Press the **Sim.BIANCE** key (1) again: The previously-set illumination intensity is active once again.

### 3.5.5.2. Setting the illumination intensity via touch control

The illumination intensity is gradually increased or decreased in the **Sim.LED** menu tab on the cardanic touch control or alternatively on the touch wall control. Eight different levels of illumination intensity are available. You can switch between the levels by pressing the **decrease/increase illumination intensity buttons** (2, 4) on the cardanic control or wall control.

The illumination intensity setting is indicated by the **illumination intensity slider** (3).



#### Increasing the illumination intensity

☞ Press repeatedly or press and hold the **illumination intensity plus** (4) button, until the desired illumination intensity is set.

☞ Alternatively, the illumination intensity can be adjusted using the **illumination intensity slider** (3).

#### Decreasing the illumination intensity

☞ Press repeatedly or press and hold the **illumination intensity minus** (2) button, until the desired illumination intensity is set.

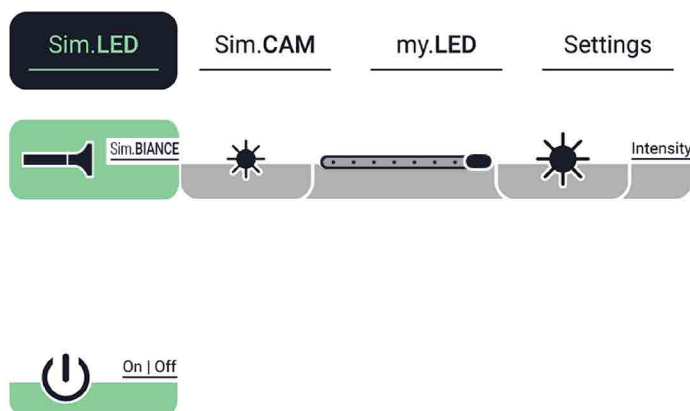
☞ Alternatively, the illumination intensity can be adjusted using the **illumination intensity slider** (3).

#### Sim.BIANCE

Sim.BIANCE is a function that can be used during endoscopic procedures. It involves diffuse background illumination that is required for orientation purposes during endoscopic procedures. If the Sim.INTERFACE option is installed, Sim.BIANCE will be switched on/off together with the system lights.

☞ Push the **Sim.BIANCE** button (1): The illumination intensity is reduced to background lighting.

A pop-up window opens in which the illumination intensity of the backlighting can be fine-tuned again using eight different levels of illumination intensity:

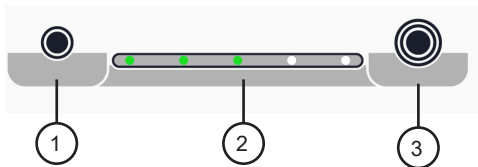


☞ Push the **Sim.BIANCE** button (1) again: Sim.BIANCE mode will be deactivated and the previously set illumination intensity will be active again.

### 3.5.6. Adjusting the light field

#### 3.5.6.1. Adjusting the light field using the foil control

The illumination intensity is gradually increased or decreased on the cardanic foil control panel. There are 5 levels available as light field settings. S (small), SM (small – medium), M (medium), L (large) and XL (extra large). It is possible to switch between the levels by pressing the buttons **Light field smaller/larger (1, 3)** on the cardanic control. The lit green LEDs (2) show the current size of the light field.



**Enlarge light field:**

☞ Press and hold the **Light field larger** key (3) repeatedly until the desired size of the light field is set.

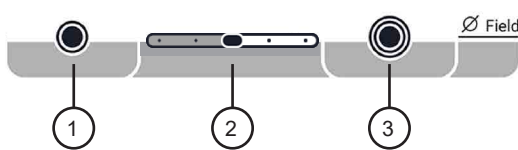
**Reduce light field:**

☞ Press and hold the **Light field smaller** key (1) repeatedly until the desired size of the light field is set.

#### 3.5.6.2. Adjusting the light field via touch control

The size of the light field is gradually increased or decreased in the **Sim.LED** menu tab on the cardanic touch control or alternatively on the touch wall control. Five different levels are available: S (small), SM (small – medium), M (medium), L (large) and XL (extra large). It is possible to switch between the levels by pressing the buttons **Light field smaller/larger (1, 3)** on the cardanic control or wall control.

The set size of the light field is indicated by the **light field slider (2)**.



**Enlarge light field:**

☞ Press and hold the **Light field larger** button (3) repeatedly until the desired size of the light field is set.

☞ Alternatively, the size of the light field can be adjusted using the **light field slider (2)**.

**Reduce light field:**

☞ Press and hold the **Light field smaller** button (1) repeatedly until the desired size of the light field is set.

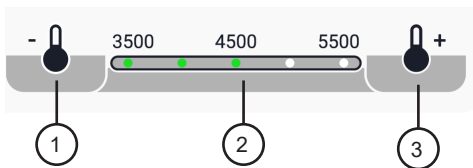
☞ Alternatively, the size of the light field can be adjusted using the **light field slider (2)**.

### 3.5.7. Setting the color temperature (for MC variant only)

#### 3.5.7.1. Set color temperature via foil control

The illumination intensity is gradually increased or decreased on the cardanic foil control panel. Five levels are available for setting the color temperature. It is possible to switch between the levels by pressing the **color temperature minus/plus** buttons (1, 3) on the cardanic control. The set color temperature is displayed by the green LEDs (2).

If the Sim.INTERFACE option is installed, the color temperature for all of the system lighting will be set at the same time (synchronized).



#### Increasing the color temperature:

☞ Press repeatedly or press and hold the **Color temperature plus** (3) key, until the desired color temperature is set.

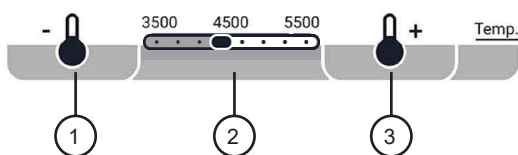
#### Reducing the color temperature:

☞ Press repeatedly or press and hold the **Color temperature minus** (1) key, until the desired color temperature is set.

#### 3.5.7.2. Setting the color temperature via touch control

The color temperature is gradually increased or decreased in the **Sim.LED** menu tab on the cardanic touch control or alternatively on the touch wall control. Five different levels are available. It is possible to switch between the levels by pressing the **color temperature minus/plus** buttons (1, 3) on the cardanic control or wall control.

The set size of the light field is displayed by the **color temperature slider** (2).



#### Increasing the color temperature:

☞ Press repeatedly or press and hold the **Color temperature plus** (3) key, until the desired light field size is set.

☞ Alternatively, the size of the light field can be set using the **color temperature slider** (2).

#### Reducing the color temperature:

☞ Press repeatedly or press and hold the **Color temperature minus** (1) key, until the desired light field size is set.

☞ Alternatively, the size of the light field can be set using the **color temperature slider** (2).

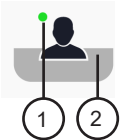
## Operation

### 3.5.8. my.LED function

my.LED is a function that allows you to save user profiles with specific light settings. The my.LED function is available for single-color and multi-color as well as for all lights with cardanic foil and touch control.

#### 3.5.8.1. Set my.LED via foil control

The my.LED function is set on the cardanic foil control via the my.LED button (2). The LED (1) is illuminated when lighting parameters are saved and set.



##### Saving lighting parameters:

☞ Press the **my.LED** key (2) for min. 3 seconds: This saves the current settings for the light field, illumination intensity, color temperature (MC variants only) and the settings for the my.GRIP sterilizable handle control functions 1 and 2.

##### Restoring lighting parameters:

☞ Briefly press the **my.LED** button (2): The previously saved light parameters are restored.

#### 3.5.8.2. Set my.LED via touch control

If the Sim.LED 8000 has cardanic touch control or touch wall control, the my.LED function can be set in several ways.

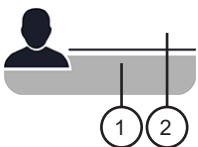
#### NOTE

Do not enter personal data when creating my.LED profiles. Access by third parties is possible in case of service. Responsibility lies with the operator.

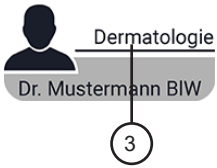
#### my.LED button display in Sim.LED menu

In the **Sim.LED** menu tab, the my.LED button (1) shows whether a my.LED user profile is currently activated or not. In addition, the my.LED button (1) indicates whether (2) or which (3) user profile is currently stored. When displaying the user profile (3), a distinction is made between discipline (here: dermatology) and user name (here: Dr. Mustermann BIW).

A) my.LED button inactive without stored user profile:



B) my.LED button inactive with stored user profile:



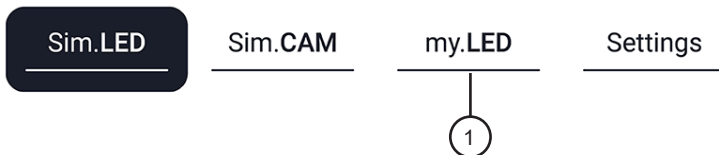
C) my.LED button active with stored user profile



### Saving a new my.LED user profile

You are in the **Sim.LED** menu tab. If the my.LED button is in status A described above (no user profile stored), pressing the my.LED button once will automatically take you to the my.LED menu.

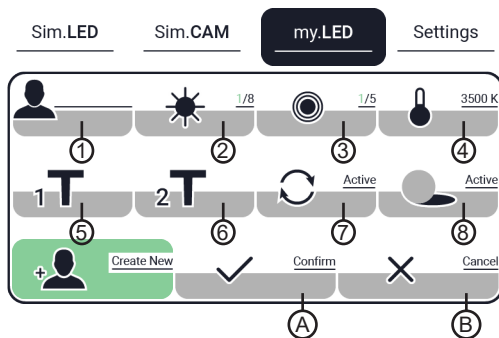
Alternatively, the my.LED menu can be accessed directly by selecting the menu tab **my.LED** (1).



Once you have reached the my.LED menu, you can create a new user profile using the **Create new** (2) button.



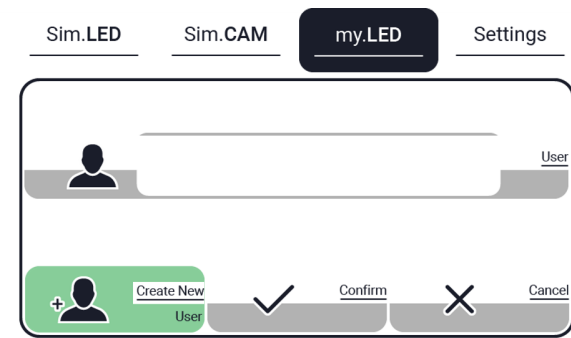
A pop-up window opens in which all desired settings can be made. By default, the light settings currently set in the Sim.LED menu are always displayed.



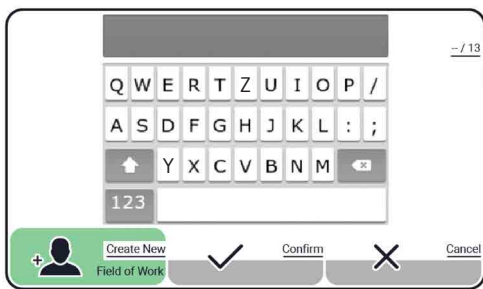
1. Discipline / Username
2. Intensity
3. Illumination field diameter
4. Color temperature
5. my.GRIP function 1
6. my.GRIP function 2
7. Synchronization
8. Shadow management



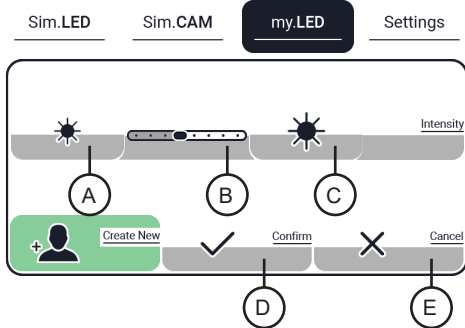
**Entry of discipline and username (1):**



Clicking on the input field opens an input window with a QWERTZ keyboard. The user name (**user**) can be entered here first. Confirming the **Confirm** button automatically takes you to the entry screen for the discipline (**Field of Work**). The input window is exited by confirming again with the **Confirm** button. The entry can be canceled at any time with **Cancel**, which takes you back to the previous **Create-new** overview.

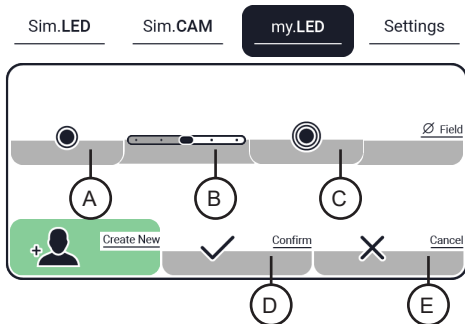


At the bottom left (W), the green field shows whether the discipline (**Field of Work**) or the user name ("User") is currently being entered. At the top right (X) you can see how many characters are still available for input.



**Setting the intensity (2):**

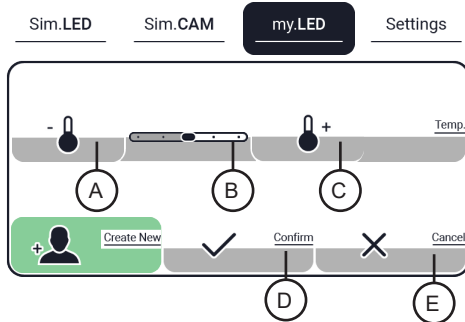
Clicking once on the **Intensity** button (2) takes you to the corresponding pop-up window. Here, as in the Sim.LED menu, the intensity can be reduced or increased using the **Illumination intensity minus** (A) and **Illumination intensity plus** (C) buttons, and optionally also via the **slider** (B). To save the settings made, confirm the intensity with **Confirm** (D). To cancel the setting and return to the previous **Create-new** overview, select **Cancel** (E).



**Setting the field diameter (3):**

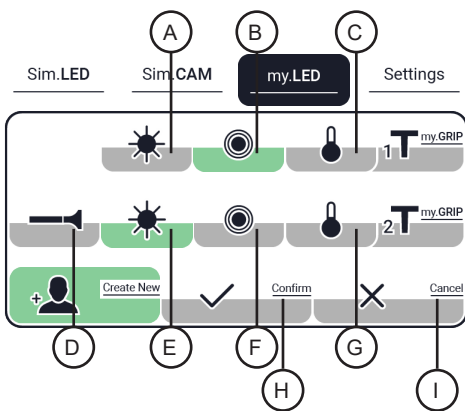
Clicking once on the **field diameter** button (3) takes you to the corresponding pop-up window. As in the Sim.LED menu, the light field diameter can be reduced or enlarged using the buttons **Light field smaller** (A) and **Light field larger** (C) and optionally also adjusted using the **slider** (B). To save the settings made, confirm the light field diameter with **Confirm** (D). To cancel the setting and return to the previous **Create-new** overview, select **Cancel** (E).

**Setting the color temperature (4):**



Clicking once on the color temperature button (4) takes you to the corresponding pop-up window. Here, as in the Sim.LED menu, the intensity can be reduced or increased using the **Color temperature minus** (A) and **Color temperature plus** (C) buttons, and optionally also via the **slider** (B). To save the settings made, confirm the color temperature with **Confirm** (D). To cancel the setting and return to the previous **Create-new** overview, select **Cancel** (E).

**Setting my.GRIP functions 1 and 2 (5 and 6):**



Clicking the my.GRIP 1 (5) or my.GRIP 2 (6) buttons once takes you to the corresponding pop-up window. Here you can set the settings you want to use with my.GRIP function 1 (click) and my.GRIP function 2 (click and hold). This can be done by simply selecting the desired button, which is highlighted in green for the activation display.

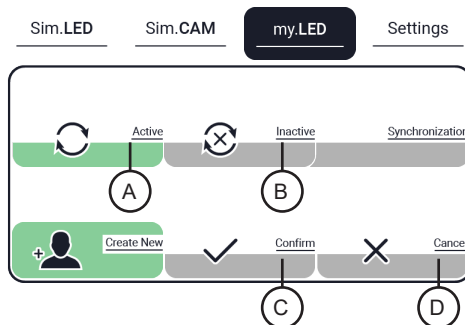
my.GRIP function 1 (click) operates the adjustment of the **light field size** (B) in factory state and can also be set to **intensity** (A) or **color temperature adjustment** (C) depending on requirements.

my.GRIP function 2 (click and hold) operates the adjustment of the illumination intensity (E) in the as-delivered state and can also be set to **Sim.BIANCE** (D), **light field size** (F) and **color temperature adjustment** (G) depending on requirements.

To save the settings you have made, confirm with **Confirm** (H). To cancel the setting and return to the previous **Create-new** overview, **Cancel** (I) for recommendations.

↳ "3.5.2. Sterile operation with the my.GRIP sterilizable handle" on page 24.

**Activation or deactivation of synchronization (7):**



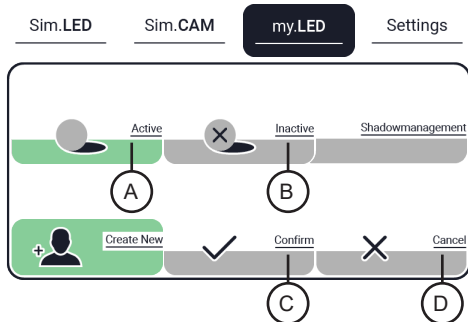
Synchronization can be **activated** (A) or **deactivated** (B) by pressing the Synchronization button (7) once. This can be done by simply selecting the desired button, which is highlighted in green for the activation display.

Synchronization is **activated** in as-delivered state (A).

To save the settings you have made, confirm with **Confirm** (C). To cancel the setting and return to the previous **Create-new** overview, **Cancel** (D) for recommendations.

↳ "3.5.10. Synchronization" on page 49.

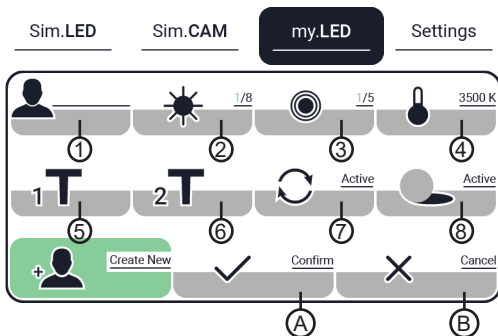
**Activation or deactivation of shadow management (8):**



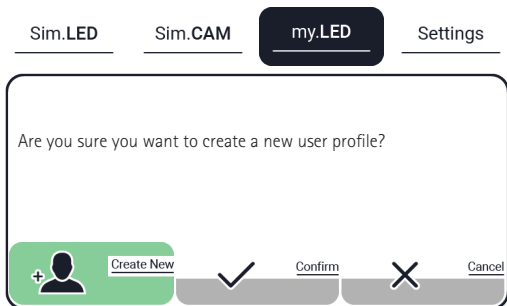
Active shadow management can be **activated** (A) or **deactivated** (B) by pressing the Shadow management button (8) once. This can be done by simply selecting the desired button, which is highlighted in green for the activation display.

Active shadow management is **activated** (A) in as-delivered state. To save the settings you have made, confirm with **Confirm** (C). To cancel the setting and return to the previous my.LED overview, **Cancel** (D) for recommendations.

↳ "3.5.10. Synchronization" on page 49.



As soon as all settings have been made, the new my.LED user profile can be confirmed with **Confirm** (A). **Cancel** (B) can be used at any time.



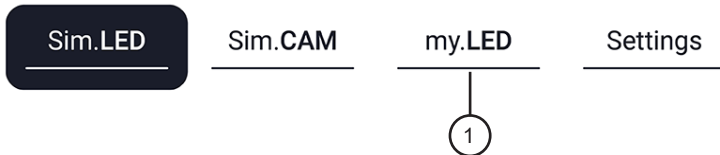
The following query "Are you sure you want to create a new user profile" can also be confirmed with **Confirm** or alternatively cancelled with **Cancel**.

The desired user profile is now saved and can be accessed.

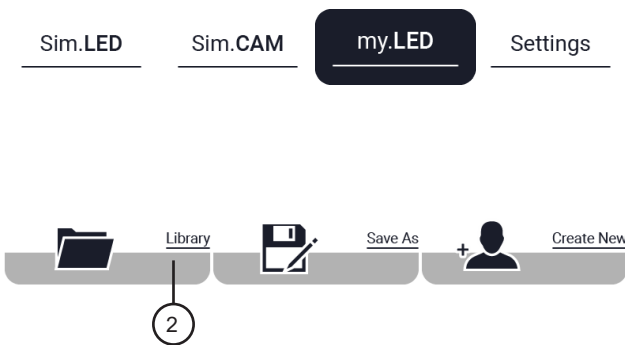
### Accessing saved settings from a my.LED user profile

You are in the **Sim.LED** menu tab. If the my.LED button is in status A described above (no user profile stored), pressing the my.LED button once will automatically take you to the my.LED menu.

Alternatively, the my.LED menu can be accessed directly by selecting the menu tab **my.LED** (1).

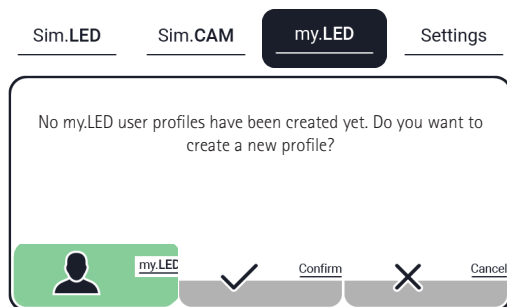


To call up an already saved user profile, the **Library** button (2) in the my.LED menu must be selected.



If no my.LED user profile has been saved yet, the query "No my.LED user profiles have been created yet. Would you like to create a new profile?" will be displayed. If the query is confirmed with "Confirm", the user is automatically forwarded to the submenu for saving a new my.LED user profile.

↳ "Saving a new my.LED user profile" on page 40.

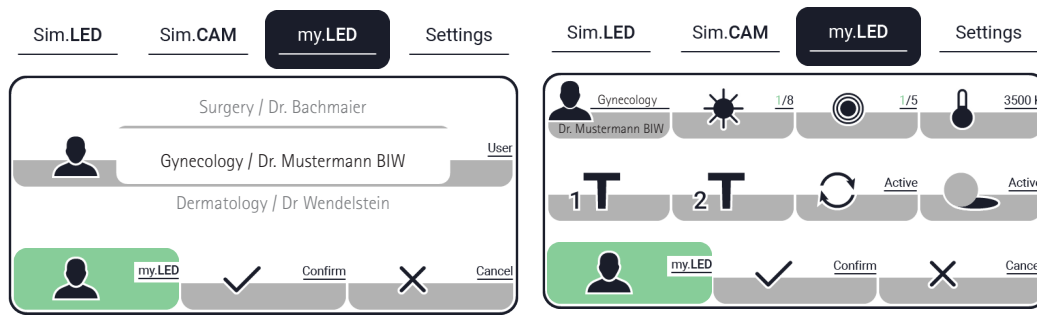


If my.LED user profiles have already been created, you can access the overview of stored profiles by selecting the "Library" button. These are arranged clearly and alphabetically in a scroll menu.

By moving the Surface scroll menu up or down, you can switch between the stored profiles. The profile with black lettering in the middle is the profile that is currently selected.

Pressing the **Confirm** button takes you to the profile overview, in which the key data of the set light parameters stored for the profile are displayed.

## Operation



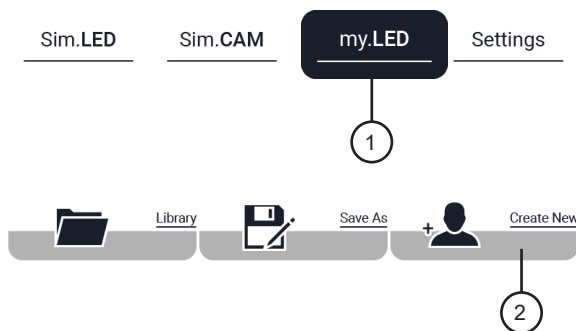
**Confirm** again to accept the selected profile and its settings. You are automatically returned to the Sim.LED menu, in which the selected user profile settings are activated. The my.LED button also shows the selected user.

Selecting the **Cancel** button takes you back to the my.LED menu.

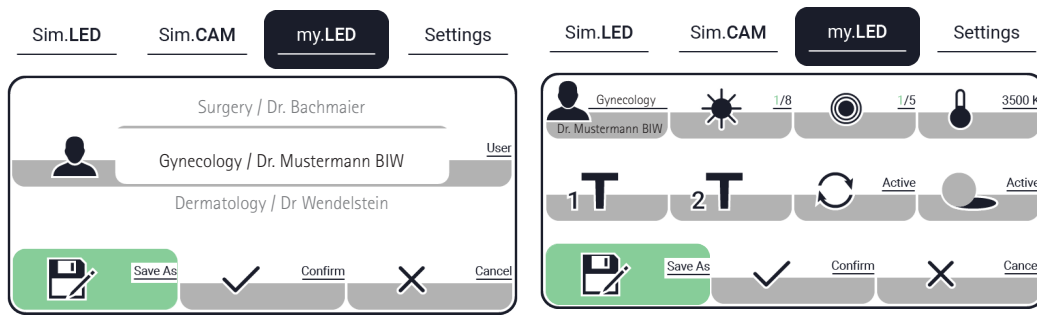
### Overwriting a my.LED user profile

To overwrite an existing my.LED user profile, all desired light parameters should first be set in the Sim.LED menu. This also offers the option of saving the intraoperatively changed light settings in a new my.LED user profile after the operation or alternatively under an existing my.LED user profile

Once the settings have been made, go directly to the my.LED menu via the menu tab **my.LED** (1) and select the **Save as** (2) button.

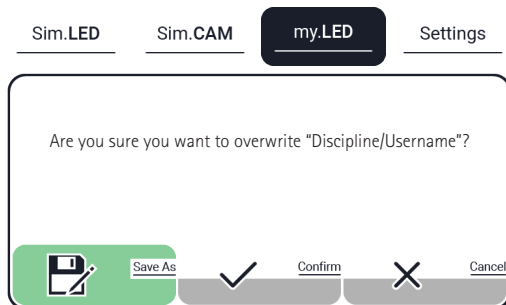


In the displayed scroll menu, the user profile to be overwritten can now be selected by sliding the display up or down. The profile with black lettering in the middle is the profile that is currently selected. Pressing the **Confirm** button takes you to the overview of the user profile settings. The light settings (illumination intensity, light patch diameter and color temperature) are adopted from the current settings of the Sim.LED menu. The settings for my.GRIP functions 1 and 2, synchronization and shadow management correspond to the settings currently stored in the profile. All settings can be changed again manually.



By selecting the **Confirm** button, the query “Are you sure you want to overwrite the ‘Discipline/user name’?”. To confirm, press the **Confirm** button again and you will automatically return to the Sim.LED menu. The now overwritten my.LED user profile is activated.

Alternatively, **Cancel** can be used to return to the overview of parameters.



### Deleting a my.LED user profile (separate authorization required)

A separate authorization is required to delete saved my.LED user profiles. All further information on deleting my.LED user profiles can be found in the service manual.

↳ *Sim.LED 8000 service manual*

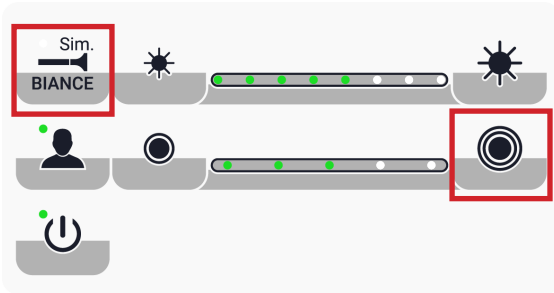
### 3.5.9. Active shadow management

The Sim.LED 8000 series of operating lights offers active shadow management to optimize shadow illumination. This can be optionally activated or deactivated.

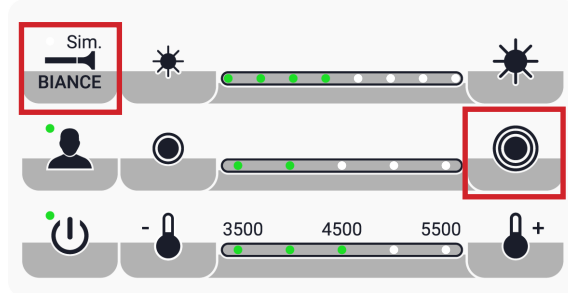
#### 3.5.9.1. Function display via foil control

The status of the active shadow management can be queried via the cardanic foil control using the clamp handle.

Status display for single-color lights



Status display for multi-color lights



Press and hold the **Sim.BIANCE** and **Color temperature plus** buttons simultaneously.

Active = All LEDs at “illumination intensity” light up

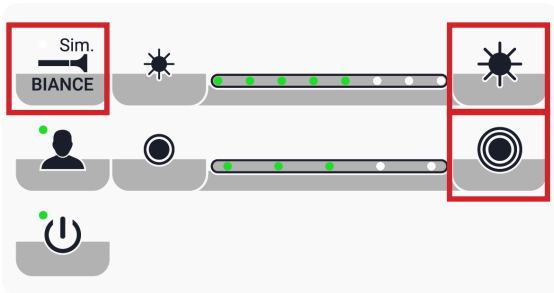
Inactive = Only the leftmost and rightmost LEDs at “illumination intensity” light up

After the status display, the function display is exited automatically.

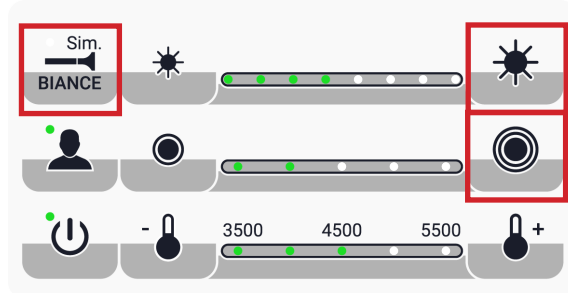
#### 3.5.9.2. Activation or deactivation via foil control

##### Activation of active shadow management

Activation for single color lights



Activation for multi color lights

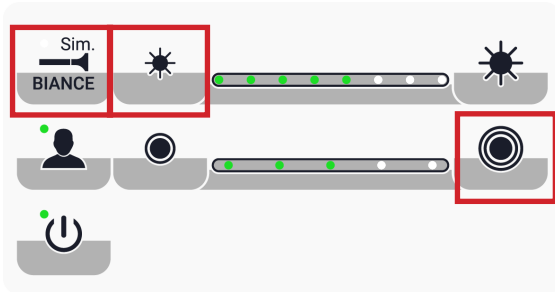


Press and hold the **Sim.BIANCE**, **Illumination intensity plus** and **Color temperature plus** buttons simultaneously.

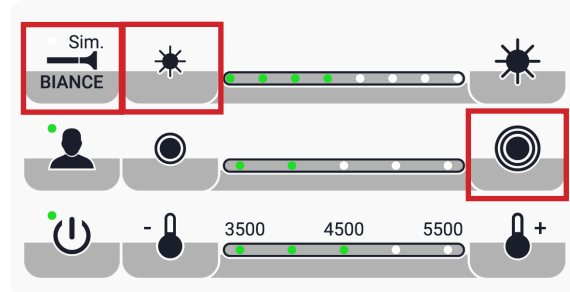
Confirmation: All LEDs at “illumination intensity” light up

### Deactivation of active shadow management

Deactivation for single-color lights



Deactivation for multi-color lights



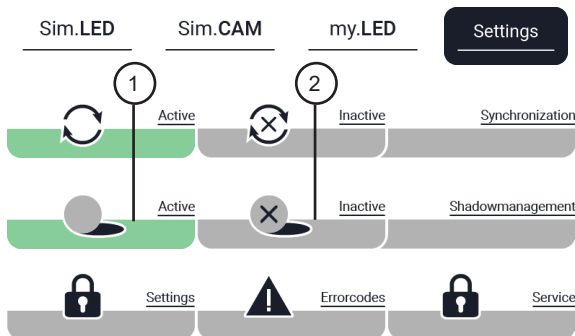
Press and hold the **Sim.BIANCE**, **illumination intensity minus** and **Color temperature plus** buttons simultaneously.

Confirmation: LEDs on the far left and far right at "Illumination intensity" light up

#### 3.5.9.3. Function display via touch control

The settings menu tab takes you to the settings menu of the cardanic / wall touch control.

The stored **Active** (1) and **Inactive** (2) buttons show the current status of shadow management.

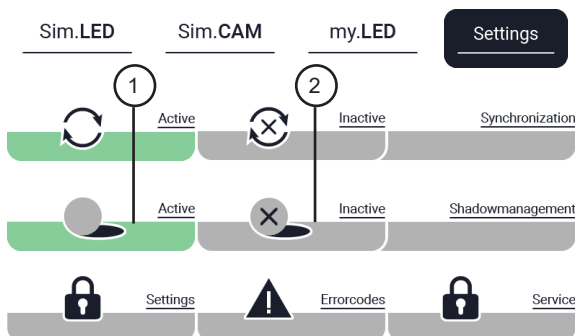


**Active** indicates that active shadow management is activated and thus functional.

**Inactive** indicates that active shadow management is deactivated.

#### 3.5.9.4. Activation or deactivation via touch control

The active shadow management of the Sim.LED 8000 operating light can be activated or deactivated by touching the **Active** (3) or **Inactive** (4) buttons once. The green backlight button shows the current shadow management status.





### 3.5.10. Synchronization

The Sim.LED 8000 operating light offers a synchronization function.

Synchronization includes the following parameters:

- Color temperature (MC only)
- Sim.BIANCE (SC/MC)
- Transfer of the saved my.LED user profiles and my.GRIP settings to all system operation lights

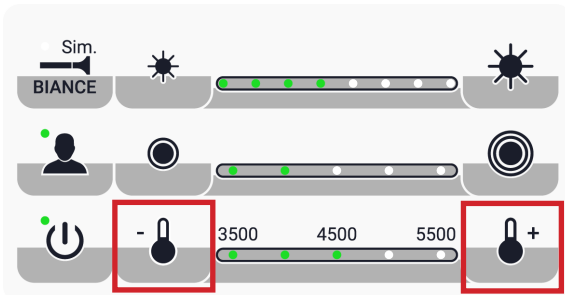
The following parameters can be added to the synchronization on request via the service menu (only for touch control) or the service software (for foil control):

- Illumination intensity (SC/MC)
- Field diameter (SC/MC)

#### 3.5.10.1. Function display via foil control

The status of the synchronization can be queried via the cardanic foil control using the clamp handle. The status query is only possible with the Multi Color lights directly via the cardanic foil control. In the case of single-color lamps, the status and the synchronization setting can be carried out via the service software.

##### Status display for multi-color lights



☞ Press and hold the **Color temperature minus** and **Color temperature plus** buttons simultaneously.

Active = All LEDs at “color temperature” light up

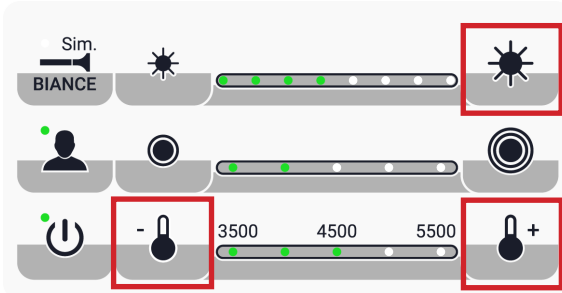
Inactive = Only the leftmost and rightmost LEDs light up at “color temperature”

After the status display, the function display is exited automatically.

### 3.5.10.2. Activation or deactivation via foil control

Activation or deactivation is only possible with the Multi Color lights directly via the cardanic foil control. In the case of single-color lamps, the synchronization can be set via the service software.

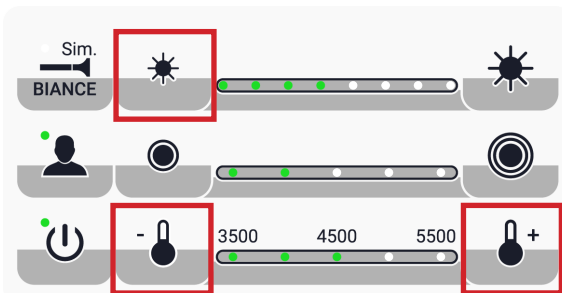
#### Activation of synchronization for multi-color lights



☞ Press and hold the **Illumination intensity plus**, **Color temperature minus** and **Color temperature plus** buttons at the same time.

Confirmation: All LEDs at “Color Temperature” light up

#### Deactivation of synchronization for multi-color lights

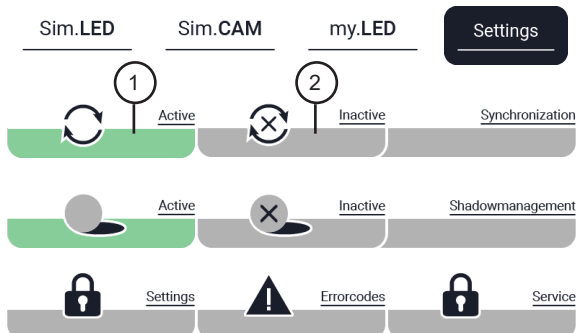


☞ Press and hold the **Illumination intensity minus**, **Color temperature minus** and **Color temperature plus** buttons at the same time.

Confirmation: LED on the far left and far right at “color temperature” light up

### 3.5.10.3. Function display via touch control

The settings menu tab takes you to the settings menu of the cardanic / wall touch control. The stored **Active** (1) or **Inactive** (2) buttons show the current synchronization status.

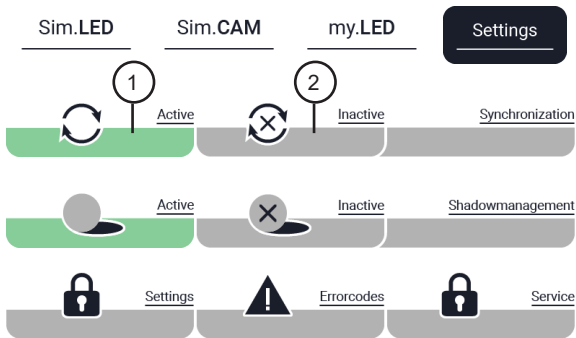


**Active** indicates that synchronization is activated.

**Inactive** indicates that synchronization is deactivated.

### 3.5.10.4. Activation or deactivation via touch control

Automatic synchronization between the light heads can be activated or deactivated by pressing the **Active** (1) or **Inactive** (2) buttons once. The stored button shows the current status of the synchronization.



### 3.5.11. Sim.CAM operation

In addition to the supplied infrared remote control, the Sim.CAM camera system can also be operated via the cardanic and wall-mounted touch control.

All further details on the operation of the Sim.CAM camera systems can be found in the corresponding instructions for use.

↳ 100-0016900 Instructions for use Sim.CAM

## 4. Accessories and other products



### Risk of injury due to heavy objects!

Persons under the carrier plate may bump into carriers and devices and severely injure themselves.

- ☞ Always make sure that there are no persons under the GTP8 and GTP14 mounting plates!

### 4.1. Sterile handle (preparable)

For sterile positioning and operation via the my.GRIP function, the preparable sterile handle with sterile sleeve must be attached.

Item code: 141-0000011 SteC Sim.LED ExL for examination lights and Sim.SCREEN monitor holders



The following must be observed:

- ☞ Proper changing of the sterilizable handle ↪ "3.4.2. Replacing the sterilizable handle" on page 21
- ☞ Proper operation ↪ "3.5.2. Sterile operation with the my.GRIP sterilizable handle" on page 24
- ☞ Proper cleaning and preparation ↪ "6.2. Preparing the sterile handle" on page 64

### 4.2. Sterile handle adapter for disposable cover

As an alternative to the preparable, reusable sterile handles, SIMEON offers an adapter for mounting disposable covers.

Item code: 142-0015720 Adp SteC disposable/SteC ExL Sim.LED

The following must be observed:

- ☞ Proper assembly of the sterile handle adapter ↪ "3.4.4. Handles for sterile disposable covers" on page 22
- ☞ The provisions of the selected disposable covers according to the manufacturer's specifications must be observed.

### 4.3. Sim.INTERFACE

In order to synchronize light functions and integrate Sim.LED operating lights into OR integration systems, the correct product version of Sim.INTERFACE is required.

- Item code No. 191-0013925 Sim.INTERFACE for MC synchronization and integration into "open" OR integration systems
- Item code No. 191-0015008 Sim.INTERFACE for MC synchronization and integration in Storz OR1
- Item code No. 191-0019264 Sim.INTERFACE for MC synchronization and integration in Olympus Endo Alpha

### 4.4. Sim.SCREEN

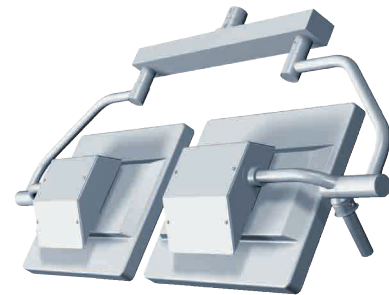
SIMEON offers Sim.SCREEN monitor holders in various sizes for attaching monitors to the lighting system. These offer the option of attaching 24" to 32" monitors. The maximum load capacity of the selected spring arm must be observed.



Sim.SCREEN Single  
for 19 to 24" monitors  
for 26/27" monitors



Sim.SCREEN Single  
for 32" monitors



Sim.SCREEN dual monitor holder  
for 19-24" monitors  
for 26/27" monitors

The sterile positioning of the Sim.SCREEN monitor holder is possible via the sterile handle (item code 141-0000011 SteC Sim.LED ExL for examination lights and Sim.SCREEN monitor holders).

The following must be observed:

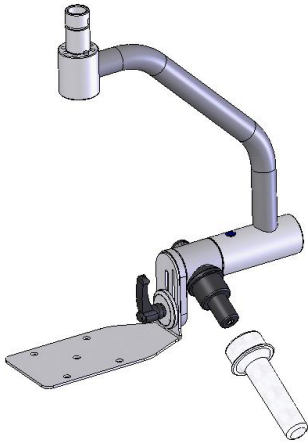
- ☞ Proper changing of the sterilizable handle → "3.4.2. Replacing the sterilizable handle" on page 21
- ☞ Proper cleaning and preparation → "6.2. Preparing the sterile handle" on page 64

## 4.5. Sim.CARRY GTP8

### Purpose

The Sim.CARRY GTP 8 accessory is intended for the accommodation of camcorders or digital cameras that possess a suitable stand fastening thread (1/4" UNC). Sterile positioning can be performed with the sterilizable handle. The sterilizable handle is changed the same way as the monitor holder,

↳ "6.2. Preparing the sterile handle" on page 64



**⚠ DANGER!**

#### **Risk of death due to incorrect mounting!**

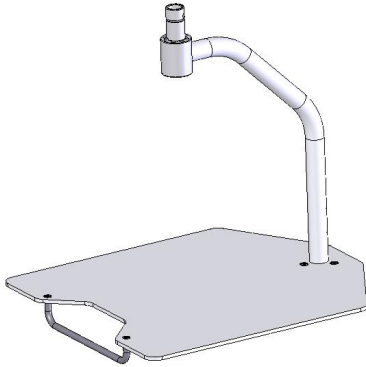
Incorrect or unsafe mounting of the assembled device may lead to life-threatening situations and cause significant material damage.

↳ When placing devices on the Sim.CARRY GTP8, ensure secure fastening by using the mounting screw included in the scope of delivery!

## 4.6. Sim.CARRY GTP14

### Purpose

The Sim.CARRY GTP 14 accessory is intended for the accommodation of ME devices or other medical products. Positioning is non-sterile.



**! DANGER!**

### Risk of death due to incorrect mounting!

Incorrect or unsafe mounting of the assembled device may lead to life-threatening situations and cause significant material damage.

- The size of the device that is positioned on the plate may not exceed the plate's surface area.
- Placement of monitors on this plate is strictly prohibited!
- It is important to ensure that all devices that are placed on this plate possess rubber feet so that the devices cannot slide or fall off.

## 4.7. Adapter for central axes / Sim.FLEX

### Purpose

The adapters serve to put the parts connected to the central axis system on an even level.



↳ "5.2.4. Setting the braking power" on page 60.

**! DANGER!**




### Risk of death due to incorrect mounting!

Incorrect or unsafe mounting of the assembled device may lead to life-threatening situations and cause significant material damage.

- The adapters are not meant to be attached to one another; instead, only one is to be attached to each central axis extension arm.



**5. Maintenance**

	<p><b>Read all instructions before operating the device!</b></p>
	<p><b>The device may only be operated by trained and authorized personnel.</b></p>
	<p><b>Do not consume alcohol or drugs before or during operation, and follow the safety instructions carefully.</b></p>
<div style="border: 1px solid black; padding: 5px; text-align: center;"> <p><i>NOTE</i></p> </div>	<p>Do not conduct maintenance or service work while the device is being used.</p>
<div style="background-color: black; color: white; padding: 5px; text-align: center;"> <p><b>! DANGER!</b></p> </div>	<p><b>Risk of death due to incorrect maintenance!</b></p> <p>Errors during maintenance may result in life-threatening situations and cause significant material damage. For that reason, observe the following:</p> <ul style="list-style-type: none"> <li>☞ Maintenance may only be conducted by employees of the manufacturer or by persons authorized by the manufacturer.</li> </ul>

## 5.1. Maintenance plan

The following sections describe the work that is required for the optimal and fault-free operation of the unit. If increased wear is observed during regular inspections, shorten the required maintenance intervals in accordance with the actual signs of wear and tear. Contact the manufacturer if you have any questions regarding maintenance work and intervals, contact information is found on page 2.

Interval	Maintenance work	Personnel
Twice a year	Conduct technical safety controls of the unit in accordance with the Service manual.	Manufacturer
Monthly	Check the braking power for the extension arm and adjust if required. ↪ "5.2.4. Setting the braking power" on page 60	Operator's medical technicians
	Check spring force setting ↪ "5.2.1. Setting the spring force: Ceiling variant" on page 59 ↪ "5.2.2. Setting the spring force: Mobile variant" on page 59	Operator's medical technicians
	Checking the vertical stop ↪ "5.2.3. Adjusting the vertical stop of the spring arm & LC spring arm" on page 59	Operator's medical technicians
After every operation	Replace the sterilizable handle with a cleaned and steam-sterilized handle. ↪ "6.2. Preparing the sterile handle" on page 64	Medical Qualified personnel
	Cleaning and disinfecting the unit ↪ "6.1.1. Cleaning the unit" on page 61 ↪ "6.1.2. Disinfecting the unit: Wiping disinfection" on page 62	Medical Qualified personnel
	Inspect the unit for exterior damage	Medical Qualified personnel
	Test the unit for faultless function	Medical Qualified personnel
	Inspect the sterile handle for wear and damage	Medical Qualified personnel
	Check the cardanic stop on joint 1 (light head to cardanic) and on joint 2 (cardanic bracket 1 to cardanic bracket 2 (only for double cardanic) by turning the joint as far as it will go	Medical Qualified personnel

## 5.2. Maintenance work

**⚠ DANGER!**

### **Risk of death due to incorrect maintenance!**

Errors during maintenance may result in life-threatening situations and cause significant material damage.

For that reason, observe the following:

- 👉 Only allow trained, qualified personnel to conduct maintenance.
- 👉 Do not allow unauthorized disassembly or relocation.

### 5.2.1. Setting the spring force: Ceiling variant

The spring arm is equipped with an adjustable spring in order to balance the weight of the light head. If the spring arm moves out of its set position after positioning, the spring force must be readjusted. How to adjust the spring force can be found in chapter 5 of the most recent OASYS Healthcare instructions for use; see [👉 instructions for use for Oasys spring arms](#).

### 5.2.2. Setting the spring force: Mobile variant

A different type of spring arm is used for the mobile variants. Here, the adjustment opening for the spring force is found on the top. The adjustment work can be found in the latest instructions for use of the mobile battery stand [👉 100-0016815 instructions for use of the mobile battery stand](#).

### 5.2.3. Adjusting the vertical stop of the spring arm & LC spring arm

The spring arm is equipped with a vertical stop. During installation it must be positioned in such a manner that it prevents collision with other components or with the ceiling. How to set the vertical stop can be found in chapter 5 of the most recent OASYS Healthcare instructions for use; see [👉 instructions for use for Oasys spring arms](#).

### 5.2.4. Setting the braking power

The component's joints possess brake screws (1) for setting the braking force. If the unit is too tight or too loose when moved into different positions, the braking power needs to be readjusted. Readjustment is also necessary if the extension arm needs to be extended from a resting position.

How to set the braking force can be found in Chapter 5 of the latest Oasys instructions for use as well as the associated SIMEON installation instructions.



## 6. Preparation

### 6.1. Clean the device and disinfect the device: Wiping disinfection

#### 6.1.1. Cleaning the unit

The device should be cleaned after each use.

- ☞ The power supply must be switched off for cleaning.
- ☞ To clean the device, wipe it with a damp, not wet, cloth (water or detergent). If cleaning is carried out with a cleaning agent, it must be wiped off with a damp cloth (water) to remove cleaning agent residue.
- ☞ For detailed cleaning instructions, see ☞ "6.1.3. Cleaning procedure" on page 63

<b>NOTE</b>	<p><b>Using improper cleaning agents can cause damage!</b></p> <p>Abrasive, corrosive, or paint-thinning cleaning agents may damage the surface of the unit.</p> <ul style="list-style-type: none"> <li>☞ Do not use any abrasive, corrosive or paint-thinning cleaning agents containing benzene or aldehyde.</li> <li>☞ Always apply the cleaning agent in such a manner that no liquid is able to penetrate the device.</li> <li>☞ Only clean accessible parts using neutral, tenside-based cleaning agents (manual dish washing liquid, neutral cleansers).</li> </ul>
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	<p><b>Risk of death due to electric shock!</b></p> <p>There is an immediate risk of death due to electric shock when coming into contact with live parts.</p> <ul style="list-style-type: none"> <li>☞ Switch off the power supply to the unit from the main switch in the operating room before cleaning, disinfecting or sterilizing. With mobile variants, also pull the power plug from the power outlet.</li> <li>☞ Secure the main switch or mains plug against inadvertent switching on/plugging in.</li> <li>☞ Always protect the unit from splash water and never wet-clean or wet-disinfect the unit.</li> <li>☞ Always ensure that no liquid or moisture is able to penetrate into the unit through openings.</li> </ul>
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### 6.1.2. Disinfecting the unit: Wiping disinfection

The device must be disinfected after each use. For this purpose, wipe disinfection with surface disinfectant must be carried out in accordance with the requirements described below.

- ☞ The power supply must be switched off for disinfection.
- ☞ All of the unit's components, including connecting cables, must undergo wipe disinfection.
- ☞ For detailed disinfection instructions, see ☞ "6.1.3. Cleaning procedure" on page 63



#### Health risk due to disinfectant!

Disinfectants may contain agents hazardous to health.

- ☞ Always select and use disinfectants that comply with local hygienic and operating regulations.
- ☞ You can find recommendations and information on the selection and use of disinfecting agents, in the most current standards and guidelines on disinfection and explosion protection.



#### Risk of material damages due to spray disinfectants!

Spray mist may cause short-circuits in the electrical installations and corrosion of the mechanical components.

- ☞ Do not use spray disinfectants.
- ☞ All components, including accessories and connecting cables, may only be disinfected by wiping with a surface disinfectant.
- ☞ You can find recommendations and information on the selection and use of disinfecting agents in the most current standards and guidelines on disinfection and explosion protection.



#### Risk of material damages when using unsuitable disinfectants!

Disinfectants containing chloride, peroxide and halogenide may corrode the unit's surfaces or plastic parts.

- ☞ Do not use any disinfectants containing chloride, peroxide or halogenide.
- ☞ Apply the disinfectant in such a manner that no moisture or liquid is able to penetrate the unit.
- ☞ You can find recommendations and information on the selection and use of disinfecting agents in the most current standards and guidelines on disinfection and explosion protection.

**Preparation**

**6.1.3. Cleaning procedure**

<b>WARNINGS</b>	Only allow suitably trained medical personnel to conduct work.
<b>Restriction on preparation</b>	There is no restriction on preparation. The expected service life must be observed.

<b>Pre-treatment at the site of use</b>	Remove heavy fouling with a disposable cloth/paper towel with low particulate release.
<b>Storage and transport</b>	No special requirements.
<b>Preparation before manual cleaning</b>	No special requirements. No disassembly necessary.
<b>Manual cleaning</b>	<p><b>Furnishings</b> Moist, not wet, cloth (water or detergent). If cleaning is carried out with a cleaning agent, it must be wiped off with a damp cloth (water) to remove cleaning agent residue.</p> <p><b>Cleaning instructions</b> Wipe the device completely with a cloth to remove coarse dirt.</p>
<b>Manual disinfection</b>	<p>The disinfectant solution should be used in accordance with the instructions on the label! Attention must be paid to the risk of material damage if unsuitable disinfectants are used.</p> <p><b>Disinfectants</b> Surface disinfectant according to specifications. (Process has been validated with Meliseptol® surface disinfectant, B.Braun Deutschland GmbH &amp; Co. KG)</p> <p><b>Disinfection instructions</b> Carry out wipe disinfection. The exposure time of the disinfectant is 5 minutes. Wipe disinfect all components of the device, including the connecting cable.</p>
<b>Maintenance, inspection and checking</b>	Visually inspection for damage, discoloration and wear.
<b>Packaging</b>	No packaging required
<b>Storage</b>	No special requirements.
<b>Manufacturer contact information</b>	<p><b>S.I.M.E.O.N. Medical GmbH &amp; Co. KG</b> In Grubenäcker 18 78532 Tuttlingen GERMANY Telephone: +49 (0) 7461 90068-888 E-mail: Service@simeonmedical.com</p>

## 6.2. Preparing the sterile handle

**Products:** 141-0000011 SteC Sim.LED ExL for examination lights and Sim.SCREEN monitor holders  
(GTIN: 04250613810824)  
141-0004330 SteC Sim.LED OPL for operating lights  
(GTIN: 04250613807299)

<b>WARNINGS</b>	Only allow suitably trained medical personnel to conduct work.
<b>Restriction on preparation</b>	The sterilizable handles can undergo approx. 100 steam sterilization cycles if properly steam sterilized.

<b>Pre-treatment at the site of use</b>	Remove heavy fouling with a disposable cloth/paper towel with low particulate release.
<b>Storage and transport</b>	No special requirements. It is recommended to prepare the handles as soon as possible after use.
<b>Preparation before manual cleaning</b>	No special requirements. No disassembly necessary.
<b>Automated cleaning</b>	<p><b>Furnishings</b> Cleaner/disinfectant: Miele PG8535 in standard furnishing with bottom grate, mesh basket and bottle rack (It is recommended to use a washer-disinfectant as per ISO15883).</p> <p><b>Cleaning products</b> neodisher® MediClean Dr. Weigert # 510643/1114</p> <p><b>Cleaning instructions</b> For automatic cleaning, place the product into the cleaner/disinfectant upright with the opening facing downwards. The small sterile handle 141-0000011 SteC Sim.LED ExL is placed into a bottle rack. The large sterile handle 142-0004330 SteC Sim.LED OpL is placed into a mesh basket. The automatic cleaning process is conducted with the following steps (based on the DES-VAR-TD program from Miele):</p> <ul style="list-style-type: none"> <li>• Rinsing 1 min (cold water)</li> <li>• Cleaning at 55°C (± 2 °C) for 5 min with neodisher® MediClean (0.3 % v/v) cleaning product</li> <li>• Neutralization with 1/3 cold water and 2/3 warm water for 1 min</li> <li>• Rinsing with 1/3 cold water and 2/3 warm water for 1 min</li> <li>• Thermal disinfection with A0 value &gt; 3,000</li> <li>• Drying: A temperature of 120°C is not to be exceeded during drying</li> </ul>



**Preparation**

<p><b>Manual cleaning</b> (if automated cleaning is not possible)</p>	<p><b>Furnishings</b> Ultrasound bath: Bandelin RK510H</p> <p><b>Cleaning products and material</b> Toothbrush (medium) Dr. Best neodisher® MediClean Dr. Weigert; # 534621/1115</p> <p><b>Cleaning instructions</b> Completely submerge the products in the ultrasound bath (filled with 0.5 % (v/v) neodisher® MediClean in demineralized water). Ultrasound treatment at 35 kHz for 10 min. Do not exceed the maximum temperature of 40 °C in the process!</p> <p>After the ultrasound treatment, remove any visible residue with the cleaning product and the toothbrush.</p> <p>Then rinse the product for 1 min in demineralized water (temperature 20°C - 25°C).</p>
<p><b>Manual disinfection</b></p>	<p>The disinfectant solution should be used in accordance with the instructions on the label!</p> <p><b>Disinfectants</b> Sekusept® active Ecolab; # 4254FM6908, 4305FM5509</p> <p><b>Disinfection instructions</b> Completely submerge the product in the disinfectant solution Sekusept® active 3 % (w/v) (prepare the solution according to the manufacturer's instructions). Temperature: 20 °C ± 2 °C Time: 15 min Avoid air bubbles on the surface during the immersion bath!</p> <p>Then rinse the product completely for at least 3 min. in cold demineralized water.</p>
<p><b>Maintenance, inspection and checking</b></p>	<p>On all handles: Visually inspection for damage, discoloration and wear.</p>
<p><b>Packaging</b></p>	<p>A standardized, sterilizable system can be used. The bag must be large enough for the handle, so that the seal is not under tension.</p>

<p><b>Sterilization:</b></p>	<p>It is recommended to use damp heat (steam) for sterilization!</p> <p><b>Furnishings</b>            Steam autoclave: Systec HX-320            (It is recommended to use a sterilizer in accordance with EN 285.)            Sterilization packaging: Brömeda, REF 68170912</p> <p><b>Sterilization instructions</b>            Individually package the products            Temperature of saturated steam: 134°C            3x fractionated pre-vacuum            Sterilization time: 4 min            Resulting half-cycle exposure time: 2 min            Drying time: 10 min</p> <p>Improper steam sterilization may damage the sterilizable handles and make their surfaces porous and prone to cracks.            Do not exceed the maximum temperature of 134 °C.</p>
<p><b>Storage</b></p>	<p>No special requirements.</p>
<p><b>Additional information</b></p>	<p>When sterilizing reusable handles in an autoclave cycle, it must be ensured that the maximum load for the sterilizer is not exceeded.</p>
<p><b>Manufacturer contact information</b></p>	<p><b>S.I.M.E.O.N. Medical GmbH &amp; Co. KG</b>            In Grubenäcker 18            78532 Tuttlingen            GERMANY            Telephone: +49 (0) 7461 90068-888            E-mail: Service@simeonmedical.com</p>

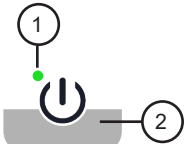
The instructions above were validated by S.I.M.E.O.N. Medical GmbH & Co. KG as being suitable for the preparation of a medical device for use in accordance with ISO 17664. The preparer assumes the responsibility for making sure that the preparation conducted achieves the desired results with the equipment, materials and personnel used in the preparation facility.

This requires the validation and routine monitoring of the procedure.

## 7. Malfunction, display and resulting measures

### 7.1. Display in the event of a malfunction

#### 7.1.1. Foil control malfunction



The LED (1) on the **On/Off** key (2) found on the light serves as a fault indicator. A fault or error condition is indicated by a blinking LED. In this case, contact your Service partner or Customer Service.

The table in chapter ↪ "7.1.3. Possible causes of malfunctions" on page 68 describes possible causes of malfunctions and the actions required to rectify them.

If multiple malfunctions occur, shorten the maintenance intervals in accordance with the actual faults. In the case of faults that cannot be rectified using the instructions below, contact the manufacturer. The Technical Service address can be found on page 2.

#### 7.1.2. Malfunction in touch control

With touch control, a distinction is made between two levels of malfunctions.

The table in chapter ↪ "7.1.3. Possible causes of malfunctions" on page 68 describes possible causes of malfunctions and the actions required to rectify them.

If multiple malfunctions occur, shorten the maintenance intervals in accordance with the actual faults. In the case of faults that cannot be rectified using the instructions below, contact the manufacturer. The Technical Service address can be found on page 2.

#### **Level 1 Malfunction: No direct user intervention required**

If there is a Level 1 malfunction, this is displayed in the **On/Off** button as follows:



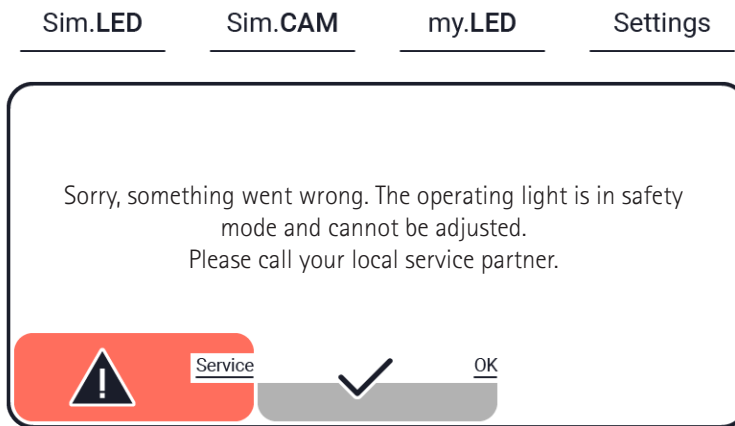
In this case, contact your Service partner or Customer Service. The device can continue to be operated.

#### **Level 2 Malfunction: User intervention required after completion of the operation**

If there is a Level 2 malfunction, this is displayed in the **On/Off** button as follows:



A pop-up window also appears. This provides the following information:



As described in the pop-up, the light can no longer be adjusted in safety mode. The operation can be completed with the set parameters; a service partner or customer service must be contacted immediately afterwards.

When you confirm the **OK** button in the pop-up window, it closes, but opens again immediately if the error has not yet been rectified.

### 7.1.3. Possible causes of malfunctions

Description of fault	Cause	Remedial action	Personnel
Black screensaver is not reacting when being touched	Light is not connected to power supply	Connect light to power supply	Qualified medical technician
Black screensaver is not reacting when being touched, although the light is properly connected to the power supply	Failure of the touch panel	Inform the service technician	
Black screensaver but light is reacting when being touched	Faulty touch panel	Inform the service technician	
Light head rises or sinks uncontrollably	The spring force of the spring arm is too low or too high	↳ "5.2.1. Setting the spring force: Ceiling variant" on page 59 If the spring force cannot be properly adjusted, replace the spring arm	<b>Setting the spring force:</b> Operator's medical technicians  <b>Replace spring arm:</b> Manufacturer
The light head, spring arm or extension arm are too tight or too loose.	The braking power has been set too high/low.	↳ "5.2.4. Setting the braking power" on page 60 If the braking power cannot be adjusted, exchange the brake screws	Qualified medical personnel
The illumination intensity is too weak or too strong	The illumination intensity has been improperly set	↳ "3.5.5. Setting the illumination intensity" on page 35	Medical Qualified personnel

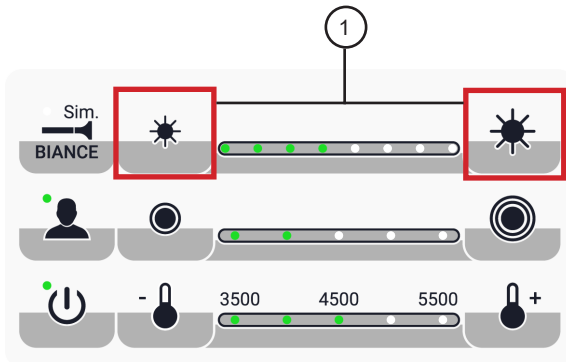
**Malfunction, display and resulting measures**

Description of fault	Cause	Remedial action	Personnel
The light field is too large or too small	The light field has been improperly set	↳ "3.5.6. Adjusting the light field" on page 37	Medical Qualified personnel
The sterilizable handles exhibit cracks and are porous	Sterilization/disinfection was conducted improperly	Dispose of and replace cracked and porous sterilizable handles, perform future sterilization/disinfection procedures strictly according to the instructions for use, ↳ "6.2. Preparing the sterile handle" on page 64	Medical Qualified personnel
	End of lifespan reached	Dispose of and replace sterilizable handle	Medical Qualified personnel
Unit does not light up	Power supply to the room is turned off	Turn on room power supply	Medical Qualified personnel
	Unit turned off at the power switch	Switch on the unit ↳ "3.5.4. Switching the light on/off" on page 33	Medical Qualified personnel
	Power supply is interrupted	Inspect voltage and fuses	Electrical experts qualified for the medical field
	Electronics are defective	Replace electronics	Manufacturer
	Lamp is defective	Replace lamp	Manufacturer
Lights cannot be controlled from the wall controls	CAN communication is not working	Check CAN communication	Manufacturer

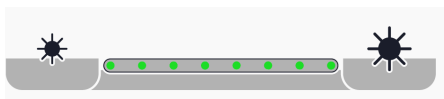
## 7.2. Error codes

### 7.2.1. Error codes for foil control

The last error code of a light can be displayed on the cardanic control panel.



☞ Press the brightness control keys (1) for a minimum of 3 seconds.



☞ The error indication starts with a display of all LEDs (full display) as a function control.



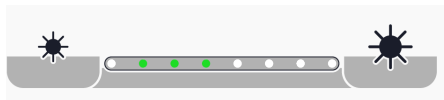
☞ Error code display: Light



☞ Error code display: Wall control unit



☞ Error code display: Sim.CAM wall control unit



☞ The sequence of full display - source - error code is automatically repeated.

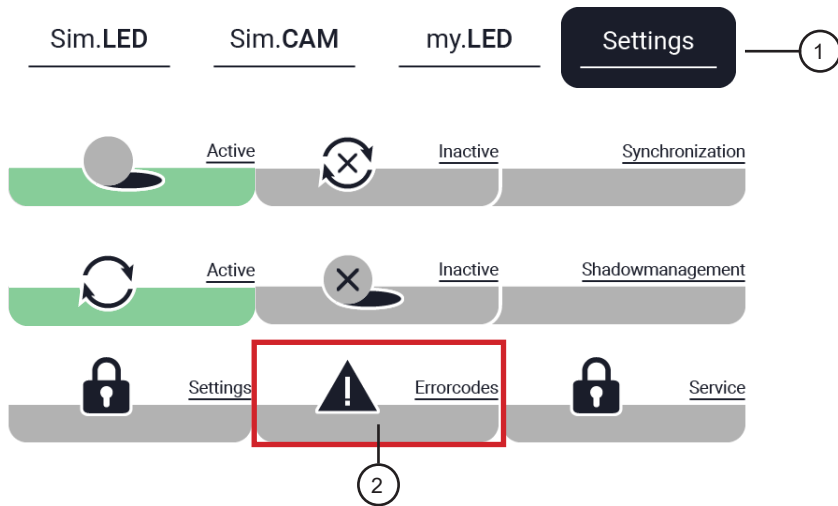


☞ After approx. 30 seconds, the display returns to normal mode.

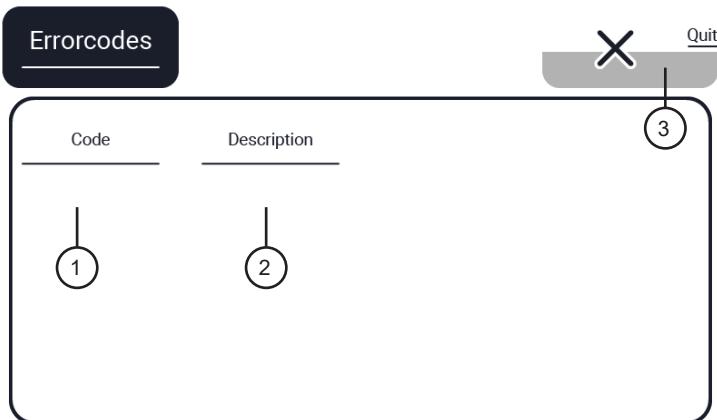
Multiple LED codes for warnings could be present. Navigation is conducted with the keys (1). You can find more information on error codes in the ↗ *Sim.LED service manual*.

### 7.2.2. Error codes for touch control

The current error code, including the error description, can be viewed in the **Settings** menu tab (1) and the **Error codes** submenu (2).



The pop-up window provides details on the error code (1) and error description (2). Press **Quit** (3) to exit the pop-up window and return to the previous settings menu.



You can find further information on error codes in the [Sim.LED service manual](#).

## 8. Technical data

### 8.1. Sim.LED 8000 SC technical data

8000 SC data	Description	Values
<b>General specifications</b>	Weight of the light head [kg]	18
	LED life time [h]	> 60,000
	Expected service life (light head incl. mounting bracket)	10 years
	IP protection class of support arm system	IP 30
	IP protection class light head	IP 54
	Laminar flow index (turbulence level measurement) [%]	33
	Laminar flow index (protection class measurement) [protection class]	4.1
	Temperature increase in the head area [°C]	<1
	Temperature increase in the surgical field [°C]	<10
<b>Connection values</b>	Power supply ceiling variant/mobile variant	
	Power supply incl. mounting plate (LxWxH) [mm]	322 x 145 x 90
	Supply voltage AC [V]	100 - 240
	Mains frequency [Hz]	50 – 60
	Light head	
	LED light sources [units]	30 x 3 = 90
	Voltage DC [V]	24
	Voltage range DC [V]	20 - 33
	Current consumption, maximum [A]	5.4
	Current consumption, average [A]	3.6
	Rated power [W]	100



## Technical data

8000 SC data	Description	Values
Technical light values	$D_{REF}$ [mm]	1,000
	Illumination intensity $E_{C,REF}$ at distance of 1 meter [lx]	160,000
	Electronic brightness regulation [%]	2 - 100
	Electronic brightness regulation [lx]	48,000 - 160,000
	Sim.BIANCE electronic brightness control [lx]	3,000 - 48,000
	$d_{10}$ light field, $\emptyset$ at 10% of max. illumination intensity at distance of 1 m [mm]	170 - 320
	$d_{50}$ light field, $\emptyset$ at 50% of max. illumination intensity at distance of 1 m [mm]	98 - 179
	$d_{50} / d_{10}$ Level	0.57
	Field adjustment	Yes
	Residual illumination intensity with shading from 1 masks, Reference to EC [%], (with active shadow management)	92
	Residual illumination intensity with shading from 2 masks, Reference to EC [%], (with active shadow management)	75
	Residual illumination intensity in standardized simulated cavity, reference to EC [%], (with active shadow management)	100
	Residual illumination intensity in 1 simulated cavity and 1 screen [%], (with active shadow management)	92
	Residual illumination intensity in 1 simulated cavity and 2 screens [%], (with active shadow management)	75
	Color temperature [K]	4.500
	Color rendering index $R_a$ (1-8)	98
	Red rendering index $R_g$	99
	Illumination depth 20% (L1/L2) [mm]	2,308
	Illumination depth 60% (L1/L2) [mm]	979
	Working range from/to [mm]	760 - 1,739
	Total irradiance $E_{total}$ [ $W/m^2$ ]	570
	Illumination strength / illumination intensity [lm/W]	295

8000 SC data	Description	Values
<b>Light field safety information</b>	Maximum Illumination Distance, $D_{MI}$ [mm]	1,000
	Maximum Irradiance Settings	(4,500K, Field 2, Maximum Illumination Intensity)
<b>Operating conditions</b>	Temperature range [°C]	5 – 40
	Relative air humidity, maximum [%]	95
	Air pressure [hPa]	700 – 1,060
	Usage	Indoor use
	Pollution degree	2
	Overvoltage category	II

Tolerance +/- 10%, subject to technical changes.

## 8.2. Technical data Sim.LED 8000 MC

8000 MC data	Description	Values
<b>General specifications</b>	Weight of the light head [kg]	15
	LED life time [h]	> 60,000
	Expected service life (light head incl. mounting bracket)	10 years
	IP protection class of support arm system	IP 30
	IP protection class light head	IP 54
	Laminar flow index (turbulence level measurement) [%]	33
	Laminar flow index (protection class measurement) [protection class]	4.1
	Temperature increase in the head area [°C]	<1
	Temperature increase in the surgical field [°C]	<10
<b>Connection values</b>	Power supply ceiling variant/mobile variant	
	Power supply incl. mounting plate (LxWxH) [mm]	322 x 145 x 90
	Supply voltage AC [V]	100 - 240
	Mains frequency [Hz]	50 – 60
	Light head	
	LED light sources [units]	30 x 3 = 90
	Voltage DC [V]	24
	Voltage range DC [V]	20 - 33
	Current consumption, maximum [A]	5.4
	Current consumption, average [A]	3.7
	Rated power [W]	100

8000 MC data	Description	Values
<b>Technical light values</b>	$D_{REF}$ [mm]	1,000
	Illumination intensity $E_{C,REF}$ at distance of 1 meter [lx]	160,000
	Electronic brightness regulation [%]	2 - 100
	Electronic brightness regulation [lx]	48,000 - 160,000
	Sim.BIANCE electronic brightness control [lx]	3,000 - 48,000
	$d_{10}$ light field, $\emptyset$ at 10% of max. illumination intensity at distance of 1 m [mm]	170 - 320
	$d_{50}$ light field, $\emptyset$ at 50% of max. illumination intensity at distance of 1 m [mm]	99 - 178
	$d_{50} / d_{10}$ Level	0.57
	Field adjustment	Yes
	Residual illumination intensity with shading from masks, Reference to EC [%], (with active shadow management)	92
	Residual illumination intensity with shading from 2 masks, Reference to EC [%], (with active shadow management)	75
	Residual illumination intensity in standardized simulated cavity, reference to EC [%], (with active shadow management)	100
	Residual illumination intensity in 1 simulated cavity and 1 screen [%], (with active shadow management)	92
	Residual illumination intensity in 1 simulated cavity and 2 screens [%], (with active shadow management)	75
	Color temperature [K]	3,500 / 4,000 / 4,500 / 5,000 / 5,500
	Color rendering index $R_a$ (1-8)	98
	Red rendering index $R_g$	99
	Illumination depth 20% (L1/L2) [mm]	2,100
	Illumination depth 60% (L1/L2) [mm]	920
	Working range from/to [mm]	760 - 1,680
Total irradiance $E_{total}$ [ $W/m^2$ ]	600	
Illumination strength / illumination intensity [lm/W]	295	

**Technical data**

8000 MC data	Description	Values
<b>Light field safety information</b>	Maximum Illumination Distance, $D_{MI}$ [m]	1,000
	Maximum Irradiance Settings	(5,500K, Field 2, Maximum Illumination Intensity)
<b>Operating conditions</b>	Temperature range [°C]	5 – 40
	Relative air humidity, maximum [%]	95
	Air pressure [hPa]	700 – 1,060
	Usage	Indoor use
	Pollution degree	2
	Overvoltage category	II

Tolerance +/- 10%, subject to technical changes.

### 8.3. Permissible additional load for Sim.SCREEN monitor holders

Monitor holder	Max. Monitor weight incl. network cable [kg]
Sim.SCREEN Single up to 24" with spring arm SA 2075 3.5 - 13 kg	7
Sim.SCREEN Single up to 24" with spring arm SA 2075 10 - 20 kg	14
Sim.SCREEN Single up to 26" with spring arm SA 2075 10 - 20 kg	13
Sim.SCREEN Single up to 26" with spring arm SA 2075 20 - 30 kg	23
Sim.SCREEN Single up to 32" with spring arm SA 2075 10 - 20 kg	7
Sim.SCREEN Single up to 32" with spring arm SA 2075 20 - 30 kg	17
Sim.SCREEN Double up to 24" with OndaSpace spring arm 20 - 40 kg	12 per side
Sim.SCREEN Double up to 26" with OndaSpace spring arm 20 - 40 kg	10 per side

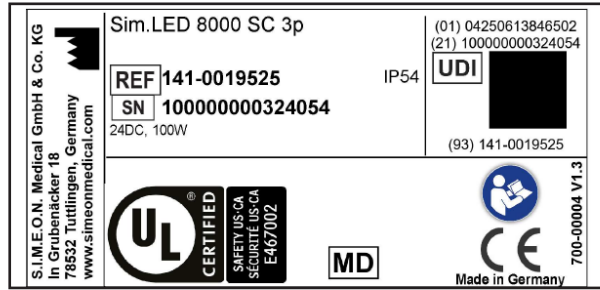
### 8.4. Permissible additional load for Sim.CARRY device carrier plate

Monitor holder	Max. Additional load [kg]
Sim.CARRY GTP8 with spring arm SA 2075 3.5 - 13 kg	10
Sim.CARRY GTP14 with spring arm SA 2075, 10 - 20 kg	15
Sim.CARRY GTP14 with spring arm SA 3075 20 - 30 kg	25

**Technical data**

**8.5. Type plate**

The type plate can be found on the light head:

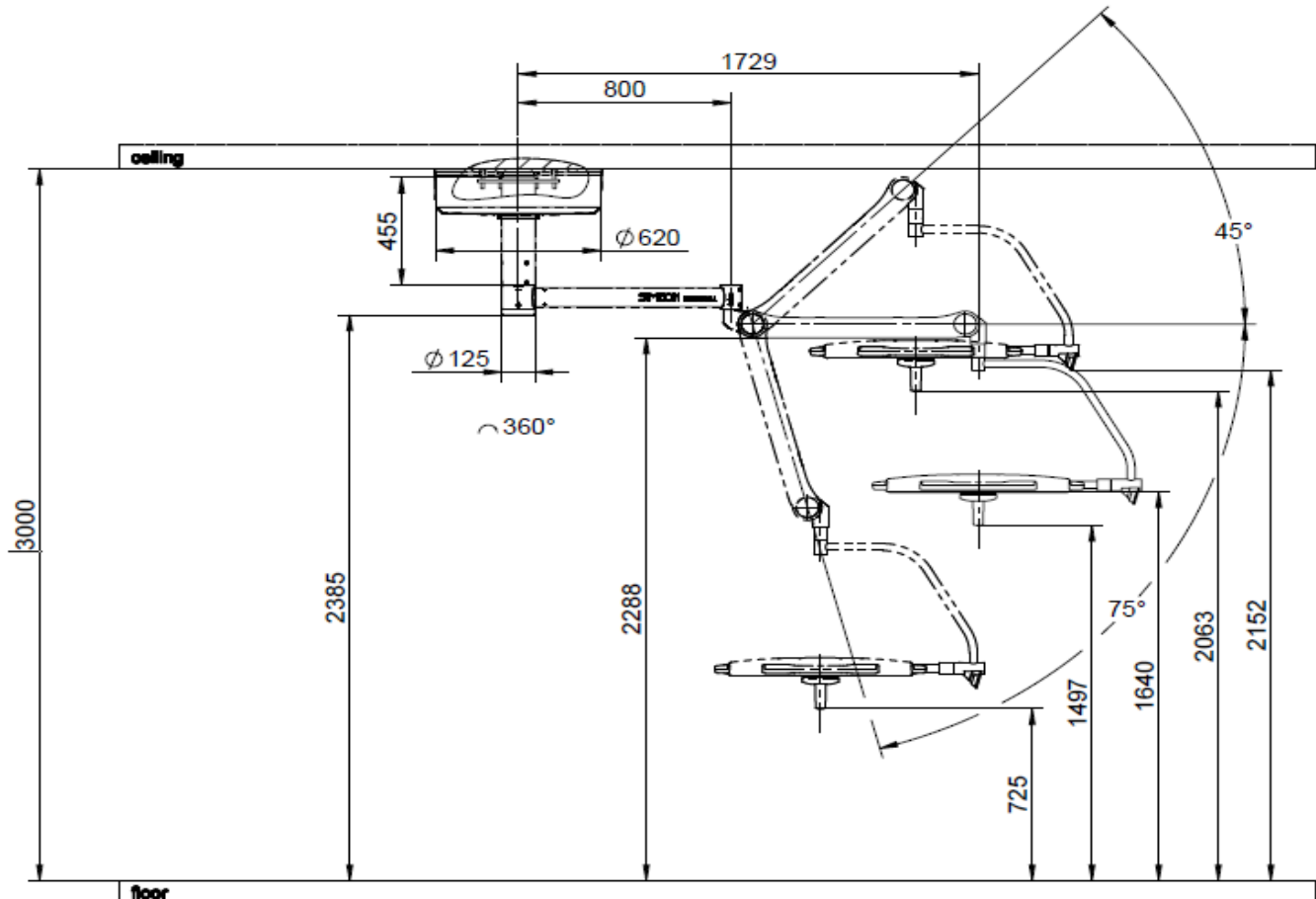


It includes the following information:

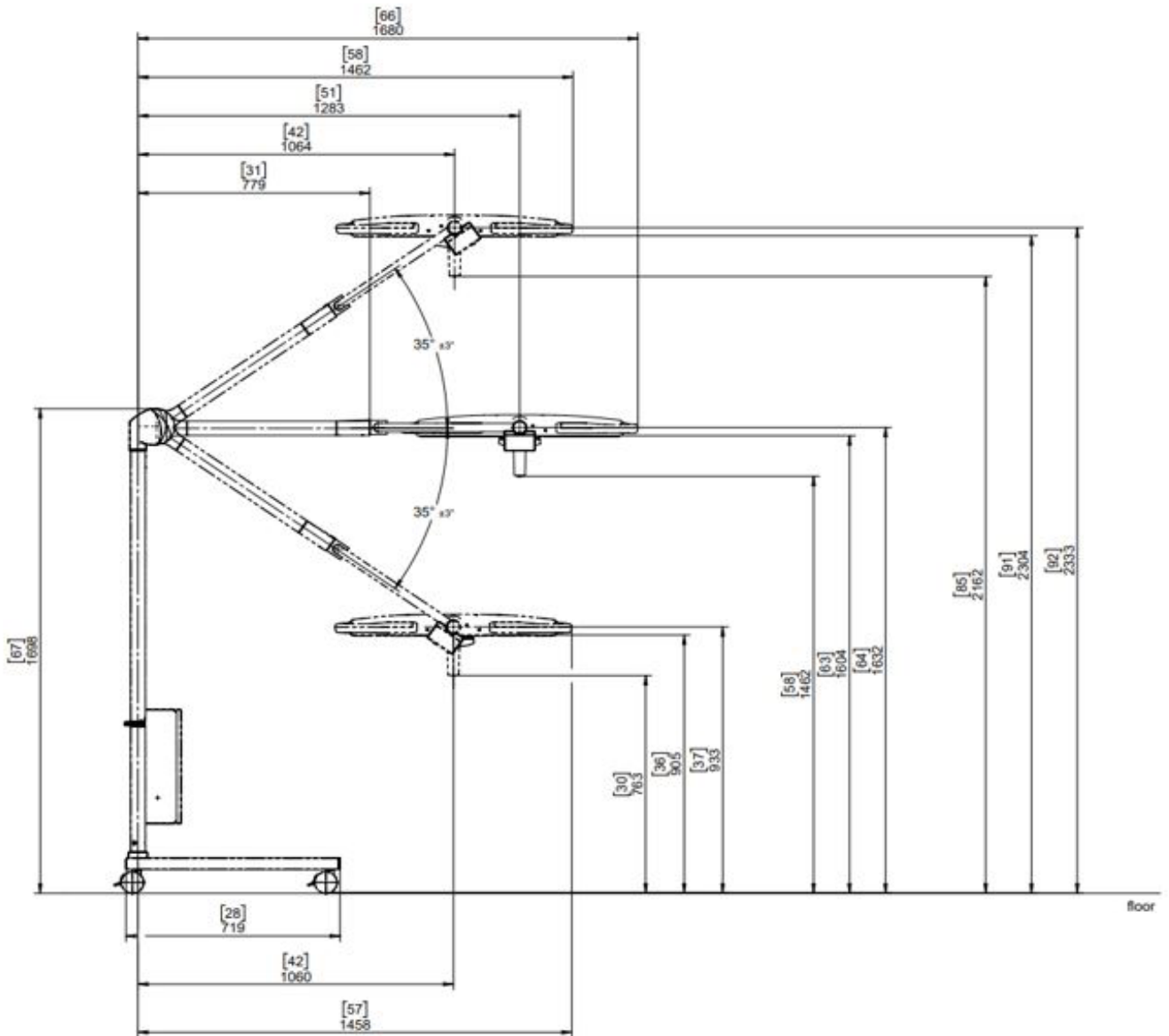
- Manufacturer address
- Item code (REF)
- Product name
- Serial number (SN)
- Electrical rating data
- Year, month and day of manufacture

**8.6. Dimension sheets**

**8.6.1. Sim.LED 8000 ceiling variant**



**8.6.2. Sim.LED 8000 mobile variant**





Technical data

