

# Instructions for Use

**Surgical Lighting**  
**Sim.LED 450/500/700 SC/MC**



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CO #003-01671

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**CE**

**Before starting any work please  
read these Instructions for Use!**



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# 1 General

## 1.1 Information on these Instructions for Use

These instructions for use enable the safe and efficient handling of the surgical lighting Sim.LED 450/500/700 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 lights must have carefully read the instructions for use and understood their contents before starting any work. The basic requirement for safe operation is following all safety and handling instructions in this manual.

Furthermore, local regulations on the operation of medical equipment apply.


The illustrations in this manual are provided for basic understanding and could deviate from the actual design.


### Safety information

Safety indications are identified in these Instructions for Use through symbols.

### Symbols

 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.

Transferring these Instructions for Use to a third party, reproducing them in any type or form – even if only partial – and using and/or disseminating their contents are prohibited without written authorization from the manufacturer.

Infringements will incur liability for damage compensation. We reserve the right to assert further claims.

### Limitation of liability

All specifications and instructions in these Instructions for Use have been compiled in observance 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-observance of these Instructions for Use
- Non-adherence to the designated use / specific function.

- Use by non-qualified personnel
- Operation of the surgical lights by insufficiently trained personnel
- Modifications conducted independently
- Technical modifications
- Use of defective or improperly repaired unit
- Use of unauthorized spare parts or accessories
- Use of the device with damaged packaging and/or non-compliance with the transport and storage conditions

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

**Contraindications**





There are no known contraindications.

## 1.2 Explanation of symbols

### Safety information


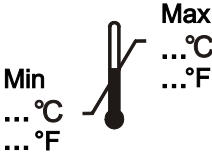
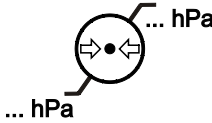



Safety indications are identified in these Instructions for Use through symbols.

### 1.2.1 Safety symbols






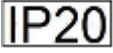







	Indicates a hazardous situation that, if not avoided, <b>will</b> result in death or serious injury.
	Indicates a hazardous situation that, if not avoided, <b>could</b> result in death or serious injury.
	Indicates a hazardous situation that, if not avoided, <b>could</b> result in <b>minor or moderate</b> injury.
	Indicates information considered important, but not hazard-related (e.g. messages relating to property damages).

### 1.2.2 Symbol explanation

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

	Follow the Instructions for Use
 <p>Min ... °C ... °F</p> <p>Max ... °C ... °F</p>	Specifications on minimum and maximum ambient temperature for storage and transportation
 <p>... hPa</p> <p>... hPa</p>	Specifications on minimum and maximum air pressure for storage and transportation
 <p>... %</p> <p>... %</p>	Specifications on minimum and maximum air humidity for storage and transportation
	The arrows point towards the top side of the package. They must always point upwards; otherwise, the contents could be damaged.
	This symbol identifies packages that contain breakable or sensitive contents. Handle the package carefully, do not allow it to drop and do not subject it to any blows.

General

	Protect the package from wetness and keep dry
	Date of manufacture and manufacturer's address
	Article number
	Serial number
	Protective grounding
	Protection type
	<p>Medical Equipment – General Medical Equipment                  AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE                  WITH ANSI/AAMI ES60601-1 (2012), CAN/CSA-C22.2 No. 60601-1 (2014), IEC 60601-2-41:2009-                  A1:2013</p>
	CE mark of conformity
	<p>The symbol of the crossed-out wheeled bin means that the product must not be                  disposed of with household waste at the end of its useful life.</p>
	Indicates that the object in question is a medical device (DIN EN ISO 15223)
	<p>Unique Product Identifier, displays a carrier that contains information about a                  Unique Product Identifier (UDI).</p>
	Local Agent, EC = Agent in the European Union
	Local authorized representative, CH = authorized representative in Switzerland





Distributor indicates the company that sells the medical device locally.



Importer, indicates the company that imports or has imported the medical device locally.

### 1.3 Spare parts

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



#### **Risk of injury due to the use of incorrect spare parts!**

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.

- ☞ Only use original manufacturer spare parts or manufacturer-approved spare parts.
- ☞ If uncertain, always contact the manufacturer.

### 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.

In addition, our personnel is always interested in new information and experience from using the product which may be valuable for the improvement of our products.

## 1.6 Intended purpose / Intended use

<b>Intended purpose</b>	<p>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.</p> <p>For back-up purposes, these lights may only be used in combination with a minimum of 2 lamps.</p> <p>The concept of intended use also includes adherence to all specifications in these Instructions for Use.</p>
<b>Usage restrictions</b>	<p>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.</p> <p>The light is not suitable for operation in explosion-prone or oxygen-rich environments. The surgical light is intended for use in operating rooms.</p>
<b>Intended use</b>	<p>The surgical light can be mobile, ceiling- or wall-mounted.</p> <p>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.</p> <p>Any use that exceeds the intended use, and any other kinds of uses, are considered to be incorrect uses.</p>
<b>Indications</b>	<p>Lighting during operations and examinations.</p>
<b>Contraindications:</b>	<p>Accelerated wound drying by overlapping the illuminated fields of various surgical lights.</p>



### **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 surgical lights are excluded.

Any changes to this medical unit are fundamentally 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 instructions.

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 monitored 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

## **1.7 Incoming inspections**

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

## 1.8 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 regulations must be implemented in the form of instructions for operation of the unit.

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 establish and manage responsibilities in the areas of 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. Furthermore, he must train personnel at regular intervals and inform them of all dangers. He must also place safeguards so that unauthorized persons do not use the unit.

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 approved accessories and accessories released by the manufacturer are used in conjunction with the unit.

### Technical safety controls

The operator must allow technical safety controls to be conducted biennial.

Technical safety controls 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 control.

**No liability in the event of non-compliance with time limits!**

The manufacturer assumes no liability for personal injury or material damages if technical safety controls 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 new precautionary measures.

## 1.9 Dismantling and disposal



The unit must be dismantled and undergo environmentally friendly disposal.

Dismantling should only be conducted by trained, qualified personnel.

The devices may be returned to the manufacturer.



### **Risk of death due to improper dismantling!**

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

- ☞ Dismantling should only be conducted by trained, qualified personnel.
- ☞ The manufacturer must also be involved when conducting unit relocations at a later time.
- ☞ Unauthorized dismantling and relocations are prohibited.

## 1.10 Authorized representatives and importers








## 2 Operation

	<p><b>Read all instructions first before operating!</b></p>
	<p><b>Operating is to be performed by properly trained and authorized personnel only!</b></p>
	<p><b>Do not drink any alcohol or take any drugs before or during the operating and follow the safety instructions carefully.</b></p>
	<p><b>Prevent direct glare! Users, patients and third parties should avoid looking into the surgical light for long periods of time.</b></p>
<div style="border: 1px solid black; padding: 2px; display: inline-block;"><b>⚠ WARNING</b></div>	<p>This product emits potentially hazardous optical radiation. Do not look into the light emitted by the operating light. Eye injury can occur.</p>
<div style="border: 1px solid black; padding: 2px; display: inline-block;"><b>⚠ CAUTION</b></div>	<p><b>Risk of excessive radiation energy in the surgical field! Possible tissue damage due to drying out of the wound!</b></p> <p>Superimposed light fields of several luminaire bodies of a light combination with high illuminance levels generate an increased temperature in the light field area. This can cause tissue damage.</p>

	<p>Separate superimposed light fields of several light bodies.</p> <p>Immediately reduce the illuminance of the light bodies when the wound begins to dry out, e.g. increase the distance between the lamp and the wound.</p>
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## 2.1 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. For service address, see page 2.

	<p><b>Risk of death due to faulty installation or faulty initial start-up!</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>☞ The installation and initial start-up may only be conducted by the manufacturer's personnel or by persons authorized by the manufacturer.</li> <li>☞ The manufacturer must also be involved when conducting unit relocations at a later time.</li> <li>☞ Unauthorized installation and relocations are prohibited.</li> </ul>
	<p><b>Risk of injury due to electric shock!</b></p> <p>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!</p>
	<p><b>Risk of injury due to pinching!</b></p> <p>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!</p>

## 2.2 Variants and accessories

The surgical lighting Sim.LED 450/500/700 SC/MC is available in different variants.

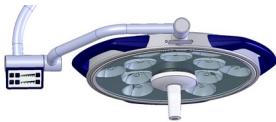
The sterilizable handle (SteC Sim.LED OpL - Art. No. 142-0004330) is available as an accessory for the Surgical Lighting.

The sterilizable handle (SteC Sim.LED ExL - Art. No. 142-0000011) is available as an accessory for the monitor bracket.

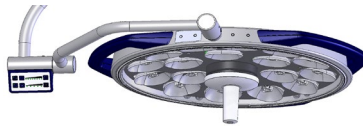
### 2.2.1 Light head

The various type designations generally denote light heads with different numbers and designs of Sim.PODs (reflector/LED unit),

☞ *“Technical data”, page 56:*



Sim.LED 450 (SC)  
12 reflectors



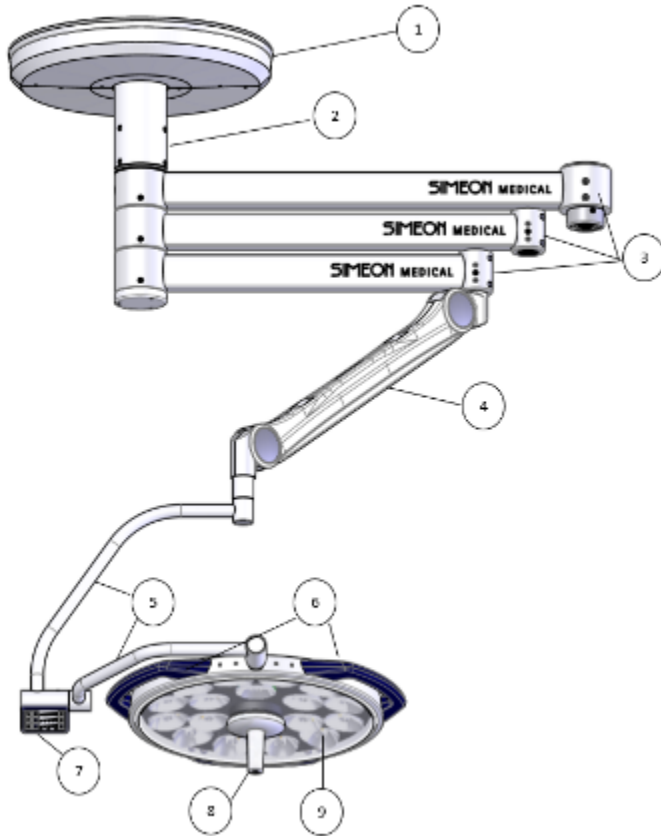
Sim.LED 500 (SC)  
18 reflectors



Sim.LED 700 (MC, with  
Sim.CAM)  
24 reflectors

Multi-color lights (MC) allow you to select the factory-set color temperatures on the control panel.

## 2.2.2 Ceiling variants



- 1 Canopy
- 2 Ceiling tube
- 3 Extension arm (different variants)
- 4 Spring arm
- 5 Cardan joint

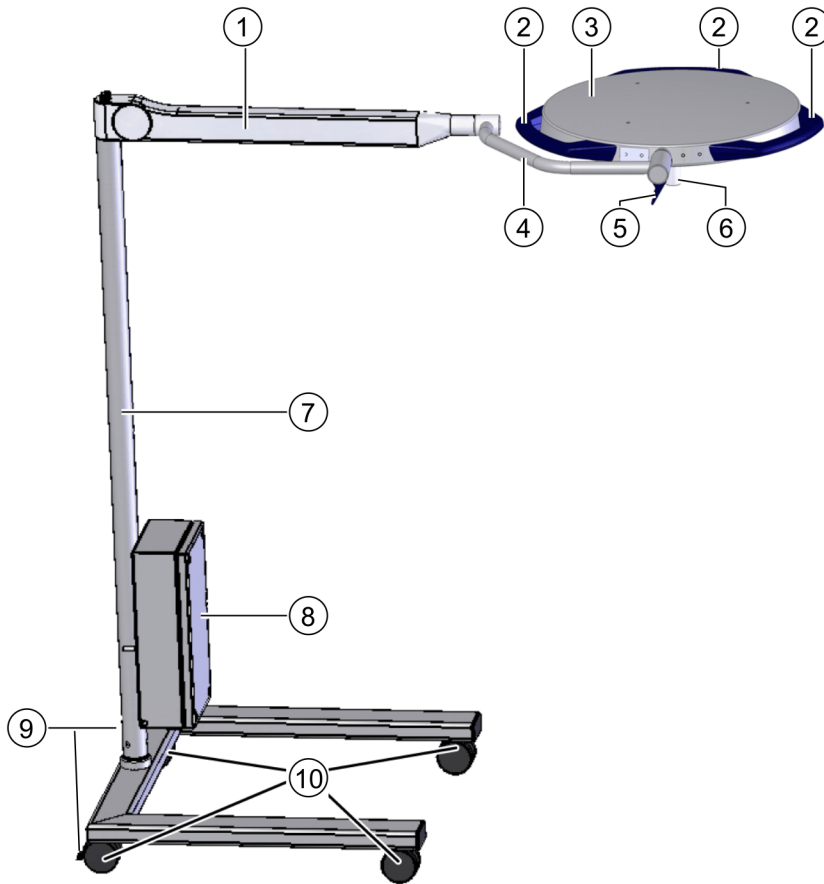
- 6 Handles (non-sterile)
- 7 Light head
- 8 Sterilizable handle / Sim.CAM
- 9 Light controls



### Risk of injury due to falling objects!

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

### 2.2.3 Mobile Variants



- |                         |                       |
|-------------------------|-----------------------|
| 1 Spring arm            | 6 Sterilizable handle |
| 2 Handles (non-sterile) | 7 Mobile stand        |
| 3 Light head            | 8 Junction box        |
| 4 Cardan joint          | 9 Stop brakes         |
| 5 Light controls        | 10 Casters            |



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

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

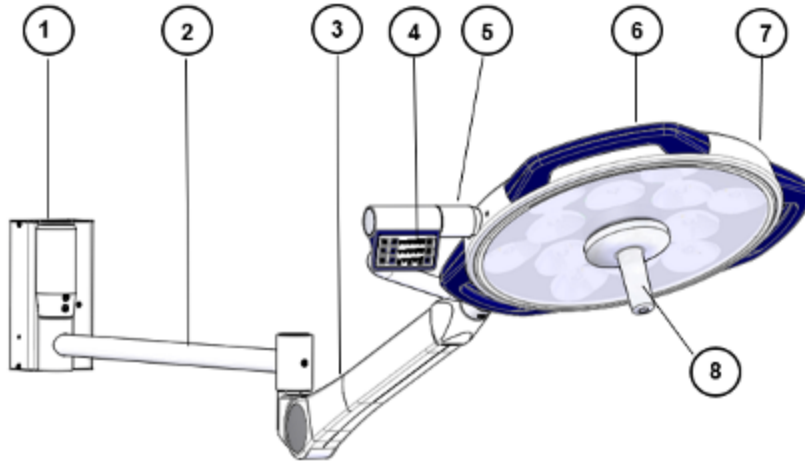


**Risk of death due to electric shock!**

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.

Operation

### 2.2.4 Wall variants



- 1 Wall bearing
- 2 Extension arm
- 3 Spring arm
- 4 Light controls (MC)

- 5 Cardan joint
- 6 Handles (non-sterile)
- 7 Light head
- 8 Sterilizable handle



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

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



## 2.3 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, ↪ *"Intended"*, page 11.

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



### Risk of death due to electric shock!

Touching components under power poses 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 lights, pull the power plug). Conduct repairs! Never supply voltage to defective lights!
- ↪ Repairs may only be conducted by skilled electricians!
- ↪ Keep moisture away from components under power. This 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 damages or cracks on the unit has been conducted,
  - all hygiene regulations have been complied with,
  - there are no unauthorized persons in the vicinity of the unit.



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

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

- ↪ Clean and disinfect the unit before every use.
  - ↪ *"Disinfecting the unit: Wiping disinfection"* page 49
- ↪ Observe the instructions on sterilization.
  - ↪ *"Preparing the sterilisable handle"* page 50
- ↪ 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 lighting unit.
- ☞ Do not operate a damaged unit.
- ☞ Inspect the sterilizable handles for safe positioning before each use of the lighting equipment.

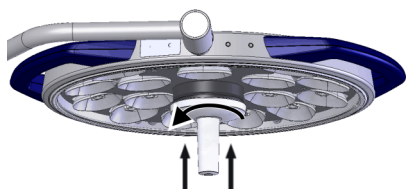
**2.4 Work on the handle unit**

**2.4.1 Intended use**

The sterilizable handle 142-0004330 is used for sterile positioning of the light head and for sterile operation of the illuminated field size.

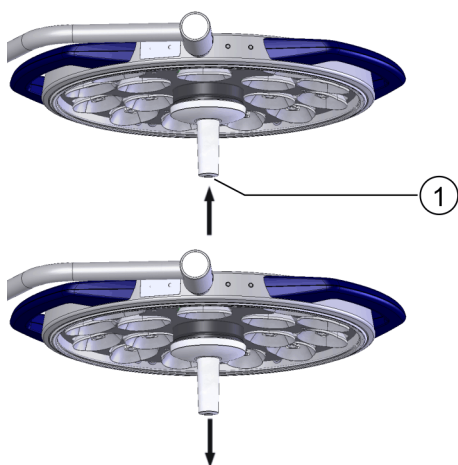
The sterilizable handle 142-0000011 is used for sterile positioning of the monitor bracket.

**2.4.2 Exchanging the sterilizable handle**



**Inserting the sterilizable handle (Art. No. 142-0004330)**

- ☞ In order to enable sterile work, it must be ensured that the sterilizable handle has been properly disinfected and sterilized.
  - ☞ *“Preparing the sterilisable handle”, page 50.*
- ☞ Insert the sterilizable handle onto the handle unit and turn until the safety snaps audibly into position.



**Removing the sterilizable handle (Art. No. 142-0004330)**

- ☞ Press the release button (1) on the sterilizable handle.
- ☞ Pull the sterilizable handle out of the handle unit.
- ☞ Inspect the sterilizable handle for wear and damages, and dispose of or replace it if necessary.

### 2.4.3 Exchanging the sterilizable handle on the monitor bracket



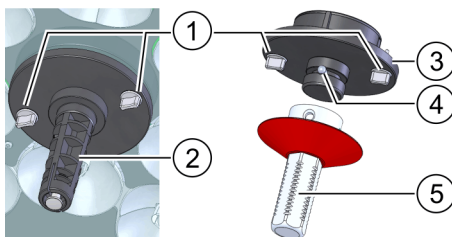
#### Inserting the sterilizable handle (Art. No. 141-000011)

- ☞ In order to enable sterile work, it must be ensured that the sterilizable handle has been properly disinfected and sterilized. ☞ *“Preparing the sterilisable handle”, page 50.*
- ☞ Slide the sterilizable handle onto the handle unit and turn until the safety (2) snaps audibly into position.

#### Removing the sterilizable handle (Art. No. 141-000011)

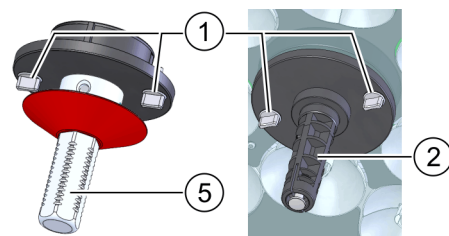
- ☞ Press the safety (2) inwards.
- ☞ Remove the sterilizable handle (1) from the handle unit.
- ☞ Inspect the sterilizable handle for wear and damages, and dispose of or replace it if necessary.

### 2.4.4 Handle for sterile disposable covers



#### Using handle for sterile disposable covers

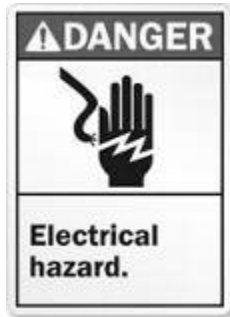
- ☞ Remove the sterilizable handle, ☞ *“Exchanging the sterilizable handle”, page 26.*
- ☞ Detach the handle unit (2) with the 2 screws (1) from the light head.
- ☞ Mount adapter (3, Simeon Art. No.: 142-0015720) onto light head with the 2 screws (1).
- ☞ Insert handle (5, to be ordered from Litex, Art. No.: 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, ☞ *“Exchanging the sterilizable handle”, page 26.*

## 2.5 Light controls



### Risk of injury due to electric shock!

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

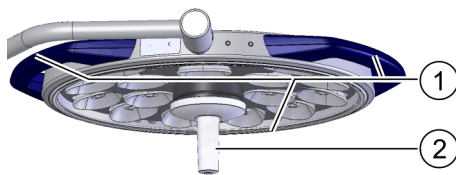
- ☞ Ensure that the lights have been correctly grounded. In the case of mobile lights: a power outlet with protective contact.
- ☞ Never touch the patient and lighting system at the same time.

### 2.5.1 Positioning the lights



### Risk of injury due to collision!

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



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

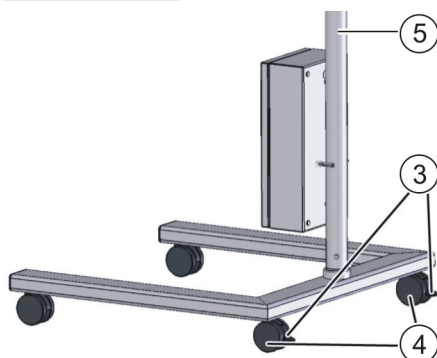
#### Positioning the ceiling variants

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 brakes (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 lamp heads into the desired position using the sterilizable grip or handles.

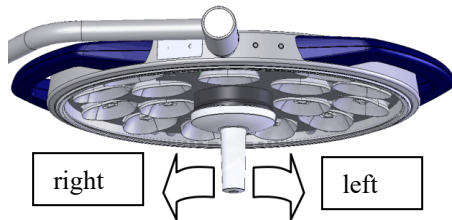


### NOTICE

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

## 2.5.2 Sterile operation via sterilizable handle my.GRIP

### Control of two operating functions via sterilizable handle my.GRIP



The sterilizable handle my.GRIP is able to control two different operating functions by turning it to the right and left. In **default state**, operating function 1 is the setting of the “**illuminated field**”

☞ “Setting the illuminated field,” see page 35

and operating function 2 is the setting of “**illumination intensity**”.

☞ “Setting the illumination intensity” see page 36

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

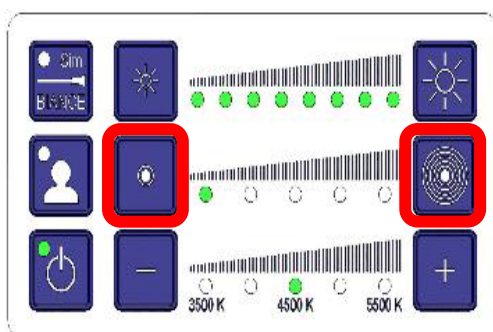
Function 2 (illumination intensity, illuminated field, color temperature) is operated via “Turn and hold” (at least 1 second) to the right (decrease) or left (increase).

Function 2 (Sim.BIANCE) is operated via “Turn and hold” (at least 1 second) to the right (switch on) or left (switch off).

The handle can be programmed with different operating functions.

☞ “Programming the sterilizable handle my.GRIP“, page 30.

## 2.5.3 Function display of the sterilizable handle my.GRIP



☞ Hold down the **Reduce illuminated field** and **Enlarge illuminated 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.

## 2.5.4 Programming the sterilizable handle my.GRIP

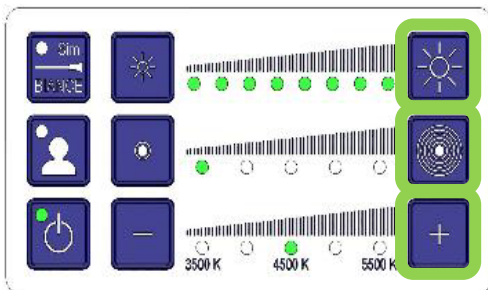
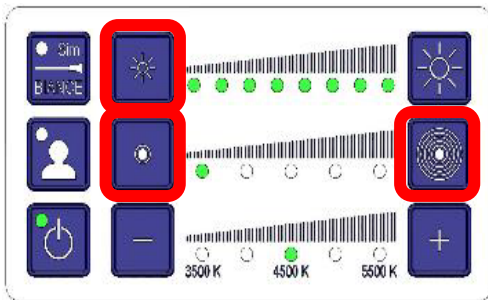
Programming is conducted via cardanic operation or wall control:

### Programming of operating function 1:

- ☞ Hold down the **Illumination intensity minus, Reduce illuminated field** and **Enlarge illuminated field** buttons at the same time until the LEDs for illumination intensity, illuminated field and color temperature 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:

- ☞ Pushing the **Illumination intensity plus** button

#### Illuminated field setting:

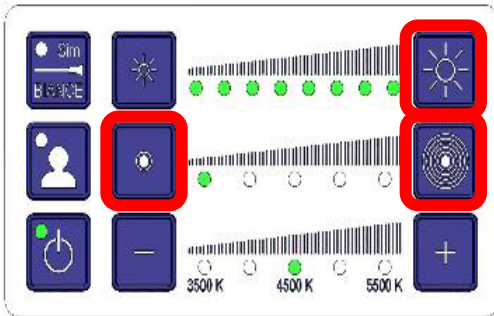
- ☞ Pushing the **Enlarge illuminated field** button

#### Color temperature setting:

- ☞ Pushing the **Plus** button

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

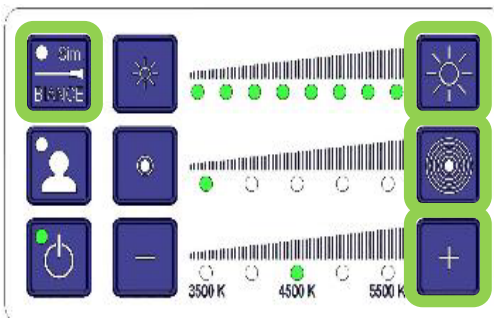
### Programming of operating function 2:



- ☞ Hold down the **Illumination intensity plus**, **Reduce illuminated field** and **Illuminated field** buttons at the same time until the LEDs for illumination intensity, illuminated field and color temperature 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:

- ☞ Pushing the **Illumination intensity plus** button

**Illuminated field** setting:

- ☞ Pushing the **Enlarge illuminated field** button

**Color temperature** setting:

- ☞ Pushing the **Plus** button

Activation of **Sim.BIANCE**:

- ☞ Pushing the **Sim.BIANCE** button

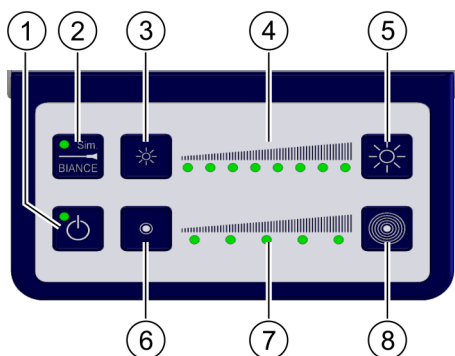
If no button is pushed within 5 seconds, the programming mode will automatically be exited.

## 2.5.5 Non-sterile operation via control panel

### Light controls on the cardanic

The light controls can be found on the cardanic. The unit can be turned on and off using the **On/Off** button (1). The buttons **Illumination intensity minus** (3) and **Illumination intensity plus** (5) are used to set the illumination intensity, which can be read on the illumination scale (4). The **Sim.BIANCE** button (2) switches on the background illumination and can switch back to the last setting.

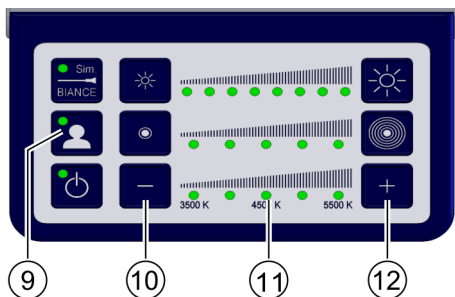
#### SC variant (single color)



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

The buttons **Illuminated field smaller** (6) and **Illuminated field larger** (8) are used to adjust the size of the illuminated field. The current setting is displayed via LED (7).

#### MC variant (multi-color)



Additional elements:

9. **my.LED** button
10. **Color temperature minus** button
11. Color temperature display
12. **Color temperature plus** button

The **my.LED** button restores the values for illumination intensity, illuminated field size and color temperature that were last saved. Pressing the button for a min. of 3 seconds saves the current values.

The buttons **Color temperature minus** (10) and **Color temperature plus** (12) are used to adjust the color temperature. The current setting is displayed via LED (11).





### Wall control panel



The wall control panel contains a light control (1, 2) for each light. These light controls are identical to the light controls found on each cardanic.

## 2.5.6 Switching the lights on/off

	<p><b>Possible eye damage due to glare</b></p> <p>Looking directly into the light can be damaging to the eyes.</p> <ul style="list-style-type: none"> <li>- Protect patients' eyes from the direct light of the lamps.</li> <li>- Do not look directly into the light.</li> </ul>
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	<p><b>Possible tissue damage due to drying of the wound!</b></p> <p>The superimposed illuminated 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 illuminated fields from multiple lamp bodies.</li> <li>☞ In the event of incipient drying of the wound, reduce the illumination intensity of the lamp bodies immediately, e.g. increase the distance from the lights to the wound.</li> </ul>
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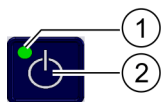
### Disconnect the unit from the mains power supply

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 version is plugged into the power outlet.

### Switching on the unit

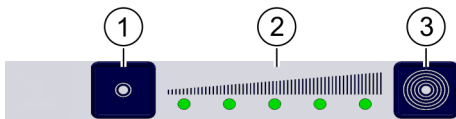
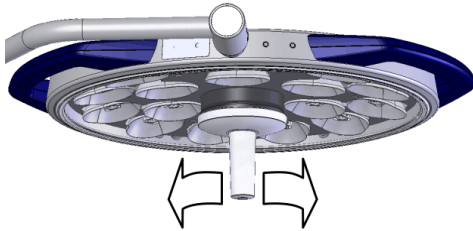
- ☞ Make sure that no one is looking directly into the light reflectors.
- ☞ Press the **On/Off** button (2) on the light or wall control panel.
  - ⇒ The lights are turned on. The LED (1) is lit green.



### Switching off the lighting

- ☞ Ensure that the room is sufficiently illuminated, even without the lights, to be able to move around safely.
- ☞ Press the **On/Off** button on the light or wall controls once again.
  - ⇒ The lights are turned off. The LEDs are turned off.

## 2.5.7 Setting the illuminated field



There are 5 levels available as illuminated field settings. S (small), SM (small – medium), M (medium), L (large) and XL (extra-large).

It is possible to move among the levels by using the sterilizable handle or by pressing the **Illuminated field smaller/larger** buttons on the light or wall controls.

### Enlarging the illuminated field

The lit green LEDs (2) show the current size of the illuminated field.

- ☞ Turn the sterilizable handle clockwise, or alternatively press the **Illuminated field larger** (3) button on the light or wall controls, until the desired illuminated field size is set.

### Downsizing the illuminated field

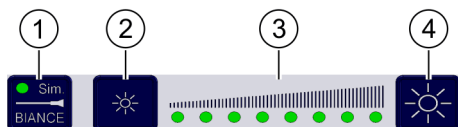
- ☞ Turn the sterilizable handle counterclockwise, or alternatively press the **Illuminated field smaller** (1) button on the light or wall controls, until the desired illuminated field size is set.

## 2.5.8 Setting the illumination intensity



### Warning of excessive heat development in the illuminated field

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



The illumination intensity is increased or reduced gradually using the light or wall controls. The set illumination intensity is displayed by the LED (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

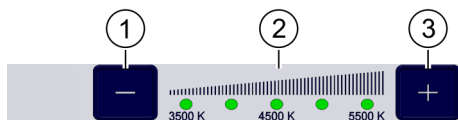
- ☞ Press repeatedly or press and hold the **Illumination intensity minus** (2) key, until the desired illumination intensity is set.

### 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** button (1): The illumination intensity is reduced to background lighting.
- ☞ Press the **Sim.BIANCE** button (1) again: The previously-set illumination intensity is active once again.

## 2.5.9 Setting the color temperature (only for MC variants)



The color temperature's 5 levels are set using the light or wall controls. The set color temperature is displayed via 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.

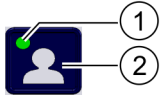
### Increasing the color temperature

- ☞ 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.

## 2.5.10 my.LED function (only for MC variants)



The my.LED function is set at the light or wall controls using the button (2). The LED (1) is illuminated when lighting parameters are saved.


### Saving lighting parameters

- ☞ Press the **my.LED** button (2) for min. 3 seconds: the current settings for illuminated field, illumination intensity and color temperature will be saved as a result.

### Restoring lighting parameters

- ☞ Briefly press the **my.LED** button (2): the previously saved lighting parameters will be restored.


### 3 Accessories

	<p><b>Risk of injury due to heavy objects!</b></p> <p>Persons beneath the carrier plate may bump into carriers and devices and severely injure themselves.</p> <p>☞ It is critical to ensure that there are no persons positioned below the GTP8 and GTP14 unit carrier plates!</p>
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#### 3.1 Carrier system

**Intended use**

The carrier systems serve as a connection to fulfill the intended use of the attached medical device. Within in this medical electrical system they become an accessory according to Regulation (EU) 2017/745.

	<p><b>Risk of death due to incorrect mounting!</b></p> <p>Incorrect or unsafe mounting of the assembled unit may lead to life-threatening situations and cause significant material damages.</p>
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#### 3.2 Sim.INTERFACE

The correct product version of Sim.INTERFACE is required in order to be able to synchronize light functions and integrate Sim.LED surgical lights into OR integration systems.

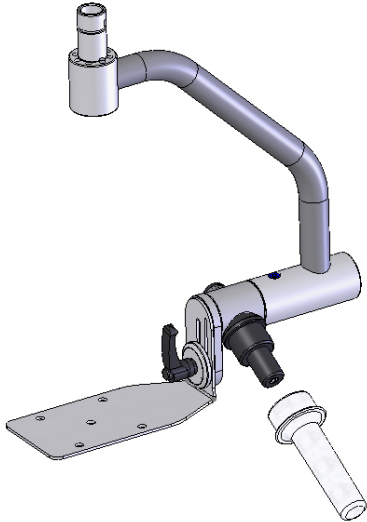
- Art. Nr. 191-0013925 Sim.INTERFACE for MC synchronization and integration in “open” OR integration systems
- Art. Nr. 191-0015008 Sim.INTERFACE for MC synchronization and integration in Storz OR1
- Art. Nr. 191-0019264 Sim.INTERFACE for MC synchronization and integration in Olympus Endo Alpha

#### 3.3 Sim.CARRY GTP8

**Intended use**

The Sim.CARRY GTP8 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 mount, ☞ “Exchanging the

*sterilizable handle on the monitor bracket”, page 27. For accessories, see Accessory list 100-001.*



**⚠ DANGER**

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

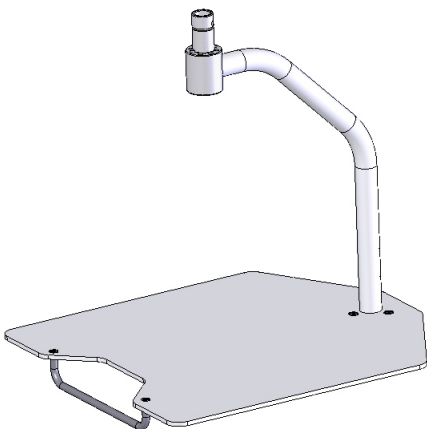
Incorrect or unsafe mounting of the assembled unit may lead to life-threatening situations and cause significant material damages. For that reason, please note:

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

### 3.4 Sim.CARRY GTP14

**Intended use**

The Sim.CARRY GTP14 accessory is intended for the accommodation of ME devices or other medical products.



**⚠ WARNING**

**Risk of injury due to incorrect mounting!**

Incorrect or unsafe mounting of the assembled unit may lead to life-threatening situations and cause significant material damages. For that reason, please note the following:

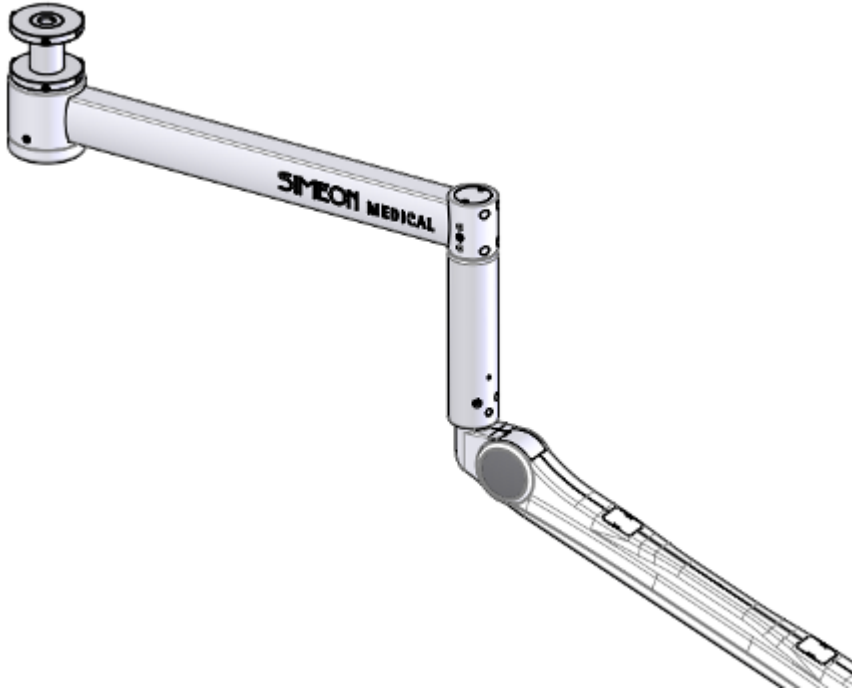
- The size of the device that is positioned on the plate may not exceed the plate's surface area.
- Placement of monitors on this plate is strictly prohibited!
- It is important to ensure that all devices placed on this plate have rubber feet so that the devices cannot slide or fall off.



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

**Intended use**

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



☞ „Setting the braking power,, Page 47






**Risk of injury due to incorrect mounting!**

Incorrect or unsafe mounting of the assembled unit may lead to life-threatening situations and cause significant material damages. For that reason, please note the following:

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

## 4 Maintenance

	<p><b>Read all instructions first before maintenance!</b></p>
	<p><b>Maintenance is to be performed by properly trained and authorized personnel only!</b></p>
	<p><b>Do not drink any alcohol or take any drugs before or during the maintenance and follow the safety instructions carefully.</b></p>
<div style="border: 1px solid black; padding: 5px; display: inline-block;"><b>NOTICE</b></div>	<p>Do not conduct maintenance or service work while the devices are being used.</p>
<div style="background-color: black; color: white; padding: 5px; display: inline-block;"><b>⚠ DANGER</b></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 damages. For that reason, please note 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>

## 4.1 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 questions regarding maintenance work and intervals, contact information is found on page 2.

Interval	Maintenance work	Personnel
Biennial	Conduct technical safety controls of the unit in accordance with the Service manual.	Manufacturer
Monthly	Inspect the braking power of the extension arm and adjust if necessary ↳ „Setting the braking power“, page 47	Operator's medical technicians
	Inspect the spring force setting ↳ „Setting the spring force: Ceiling and wall variants“, page 46 ↳ „Setting the spring force: Mobile variants“, page 46	Operator's medical technicians
	Inspect the vertical stop ↳ „Setting the height limit: Spring arm & LC spring arm“, page 46	Operator's medical technicians

**Maintenance**

Interval	Maintenance work	Personnel
After every operation	Exchange the sterilizable handle for a clean and steam-sterilized handle ↳ <i>“Exchanging the sterilizable handle”, page 26</i>	Qualified medical personnel
	Clean and disinfect the unit ↳ <i>“Cleaning the unit”, page 46</i> ↳ <i>“Disinfecting the unit: Wiping disinfection”, page 49</i>	Qualified medical personnel
	Inspect the unit for exterior damages	Qualified medical personnel
	Test the unit for faultless function	Qualified medical personnel
	Inspect the sterilizable handle for wear and damages	Qualified medical personnel

## 4.2 Maintenance work



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

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

- ☞ Only allow trained, qualified personnel to conduct maintenance.
- ☞ Dismantling and relocations may not be conducted by independent parties.

#### **4.2.1 Setting the spring force: Ceiling and wall variants**

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 the spring force can be adjusted could be read in capture 5 from the current operating instructions from OASYS Healthcare.

#### **4.2.2 Setting the spring force: Mobile variants**

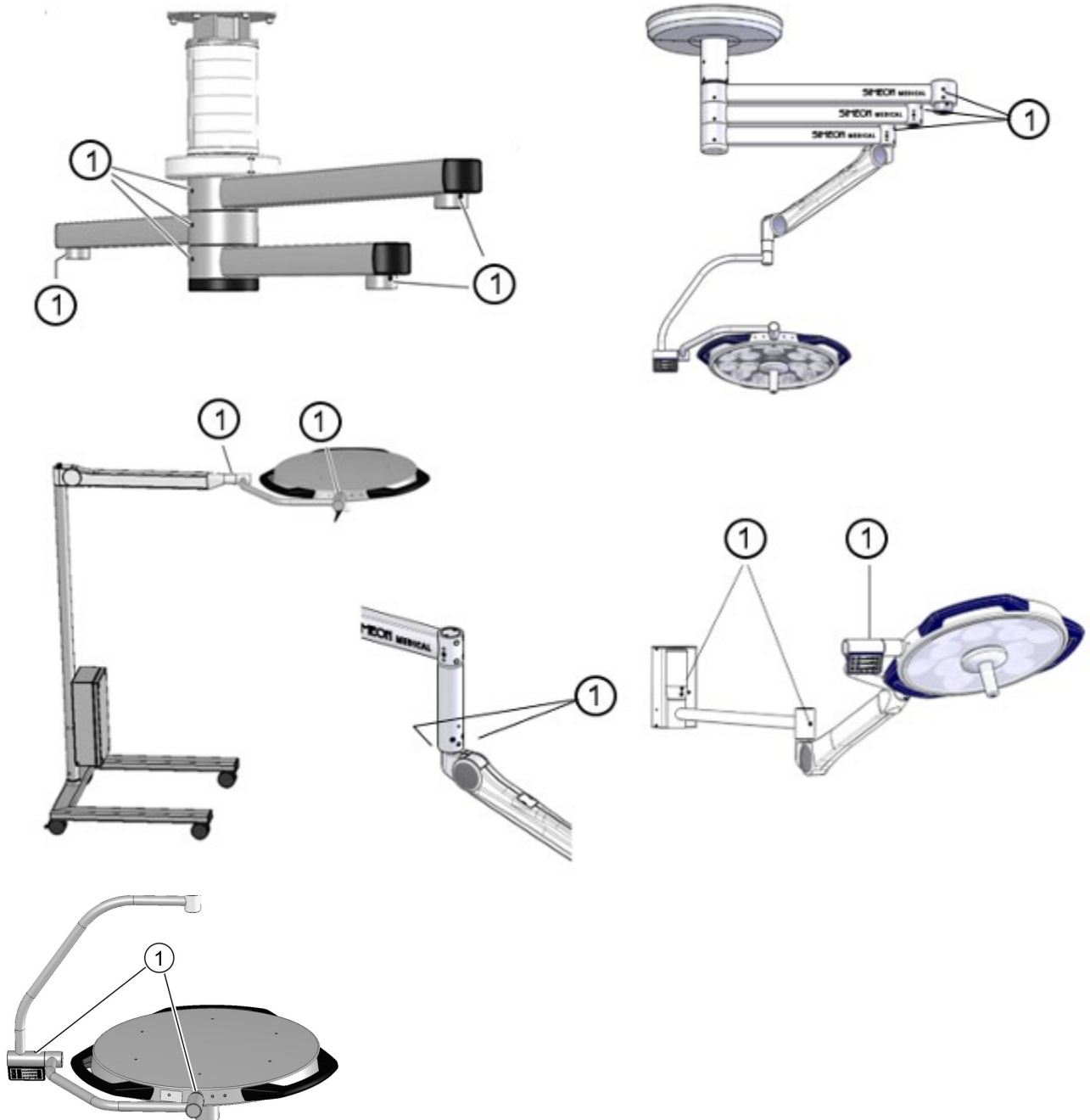
A different type of spring arm is used for the mobile variants. Here, the adjustment opening (1) for the spring force is found on the top. The adjustment steps are the same as for the ceiling variants. How the spring force can be adjusted could be read in capture 5 from the current operating instructions from MZ Liberec.

#### **4.2.3 Setting the height limit: 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 the height limit can be adjusted could be read in capture 5 from the current operating instructions from OASYS Healthcare.

#### 4.2.4 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 the braking power limit can be adjusted could be read in capture 5 from the current operating instructions from OASYS Healthcare and MZ Liberec.



## 5 Preparation

### 5.1 Cleaning the unit


<div data-bbox="422 499 659 562" data-label="Section-Header"> <p><b>NOTICE</b></p> </div>	<div data-bbox="683 499 1382 566" data-label="Section-Header"> <p><b>Material damages due to the use of improper cleaning agents!</b></p> </div> <div data-bbox="683 582 1385 649" data-label="Text"> <p>Abrasive, corrosive, or paint-thinning cleaning agents may damage the surface of the unit.</p> </div> <div data-bbox="683 667 1441 940" data-label="List-Group"> <ul style="list-style-type: none"> <li>☞ Do not use any abrasive, corrosive or paint-thinning cleaning agents containing benzine or aldehyde.</li> <li>☞ Always apply the cleaning agent in such a manner that no liquid is able to penetrate the unit.</li> <li>☞ Only clean accessible parts using neutral, tenside-based cleaning agents (manual dishwashing liquid, neutral cleansers).</li> </ul> </div>
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<div data-bbox="437 987 651 1279" data-label="Image">  </div>	<div data-bbox="683 983 1142 1014" data-label="Section-Header"> <p><b>Risk of death due to electric shock!</b></p> </div> <div data-bbox="683 1032 1431 1099" data-label="Text"> <p>There is an immediate risk of death due to electric shock from contact with components under power.</p> </div> <div data-bbox="683 1120 1466 1514" data-label="List-Group"> <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>☞ Safeguard the main switch or power plug from unintended switching-on/plugging-in.</li> <li>☞ Always protect the unit from splash water and never wet clean or wet disinfect it.</li> <li>☞ Always ensure that no liquid or moisture is able to penetrate into the unit through openings.</li> </ul> </div>
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- ☞ Disconnect the power supply.
- ☞ Wipe the unit using a moist – not wet – cloth.



## 5.2 Disinfecting the unit: Wiping disinfection

 <b>WARNING</b>	<p><b>Health risk due to disinfectant!</b></p> <p>Disinfectants may contain agents hazardous to health.</p> <ul style="list-style-type: none"> <li>☞ Always select and use disinfectants that comply with local hygienic and operating regulations.</li> <li>☞ You can find recommendations and information on selecting and using disinfectants in the most current standards and guidelines on disinfection and explosion protection.</li> </ul>
<b>NOTICE</b>	<p><b>Risk of material damages due to spray disinfectants!</b></p> <p>Spray mist may cause short-circuits in the electrical installations and corrosion of the mechanical components.</p> <ul style="list-style-type: none"> <li>☞ Do not use spray disinfectants.</li> <li>☞ All components, including accessories and connecting cables, may only be disinfected by wiping using a surface disinfectant.</li> <li>☞ You can find recommendations and information on selecting and using disinfectants in the most current standards and guidelines on disinfection and explosion protection.</li> </ul>
<b>NOTICE</b>	<p><b>Risk of material damages when using unsuitable disinfectants!</b></p> <p>Disinfectants containing chloride, peroxide or halide may corrode the unit's surfaces or plastic parts.</p> <ul style="list-style-type: none"> <li>☞ Do not use any disinfectants containing chloride, peroxide or halide.</li> <li>☞ Apply the disinfectant in such a manner that no moisture or liquid is able to penetrate the unit.</li> <li>☞ You can find recommendations and information on selecting and using disinfectants in the most current standards and guidelines on disinfection and explosion protection.</li> </ul>

- ☞ Disconnect the power supply
- ☞ All of the unit's components, including connecting cables, must be wiped to disinfect them.

Preparation

### 5.3 Preparing the sterilisable handle

**Products:** 141-0000011 SteC Sim.LED ExL (GTIN: 04250613810824)  
 142-0004330 SteC Sim.LED OpL (GTIN: 04250613807299)

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

<b>Pretreatment at the site of Use:</b>	Remove heavy dirt 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 prior to cleaning</b>	No special requirements. No disassembly necessary.
<b>Automated cleaning</b>	<p><b>Furnishings</b>                  Cleaner/disinfector: Miele PG8535 with standard furnishings with floor grilles, mesh basket and bottle rack  <i>(It is recommended to use a cleaner/disinfector in accordance with ISO 15883.)</i></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/disinfector 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: Do not exceed a temperature of 120°C</li> </ul>
<b>Manual cleaning:</b> <i>(if automated cleaning is not possible)</i>	<p><b>Furnishings</b>                  Ultrasound bath: Bandelin RK510H</p> <p><b>Cleaning products and material</b>                  Tooth brush (medium) Dr. Best</p>

	<p>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>
<b>Manual disinfection:</b>	<p>The disinfectant solution should be used in accordance with the instructions on the label!</p> <p><b>Manual disinfection</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>
<b>Maintenance, inspection and testing:</b>	<p>Visually inspect all handles for damage, discoloration and wear.</p>
<b>Packaging:</b>	<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>
<b>Sterilization:</b>	<p>It is recommended to use damp heat (steam) for sterilization!</p> <p><b>Furnishings</b>          Steam autoclave: Systec HX-320  <i>(It is recommended to use a sterilizer in accordance with EN 285.)</i>          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.</p>

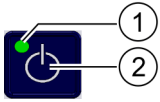
Preparation

	Do not exceed the maximum temperature of 134 °C.
<b>Storage:</b>	No special requirements.
<b>Additional information:</b>	When sterilizing reusable handles in an autoclave cycle, it must be ensured that the maximum load for the sterilizer is not exceeded.
<b>Contact to manufacturer:</b>	<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: <a href="mailto:service@simeonmedical.com">service@simeonmedical.com</a>

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.

## 6 Troubleshooting

### 6.1 Malfunctions



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

The following table 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.

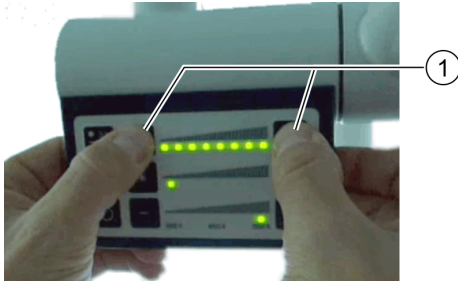
In the case of faults that cannot be rectified using the following instructions, contact the manufacturer. The Technical Service address can be found on page 2.

Description of fault	Cause	Remedial action	Personnel
Light head rises or sinks uncontrollably	The spring force of the spring arm is too low or too high	↪ <i>“Setting the spring force: Ceiling and wall variants”, page 46</i>  If the spring force cannot be properly adjusted, replace the spring arm	<b>Setting the spring force:</b> Operator's medical technicians  <b>Replacing the 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 low/high.	↪ <i>“Setting the braking power”, page 47</i>  If the braking power cannot be adjusted, exchange the brake screws	Operator's medical technicians
The illumination intensity is too weak or too strong	The illumination intensity has been improperly set	↪ <i>“Setting the illumination intensity”, page 36</i>	Qualified medical personnel
The illuminated field is too large or too small	The illuminated field has been improperly set	↪ <i>“Setting the illuminated field”, page 35</i>	Qualified medical personnel

Troubleshooting

Description of fault	Cause	Remedial action	Personnel
The sterilizable handles show cracks and are porous	Sterilization/disinfection were conducted improperly	Dispose of and replace the cracked and porous sterilizable handles. In the future, conduct sterilizing/disinfecting procedures only in accordance with the instruction manual. ☞ <i>“Preparing the sterilisable handle”, page 50</i>	Qualified medical personnel
	End of lifespan reached	Dispose of and replace sterilizable handle	Qualified medical personnel
Unit does not light up	Power supply to the room is turned off	Turn on power supply to the room	Qualified medical personnel
	Unit turned off at the power switch	Switch on unit ☞ <i>“Switching the lights on/off”, page 34</i>	Qualified medical personnel
	Power supply is interrupted	Inspect power and fuses	Electrical experts qualified for the medical field
	Electronics are defective	Replace electronics	Manufacturer
	Lamps are defective	Replace lamps	Manufacturer
Lights cannot be controlled from the wall controls	CAN communication is not working	Inspect CAN communication	Manufacturer

## 6.2 Error codes



### Displaying error code

Your control panel may display the last error code for a light. If a wall control unit exists, it may also show this display. The wall control unit also displays error resulting from the wall control unit itself.

☞ 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.

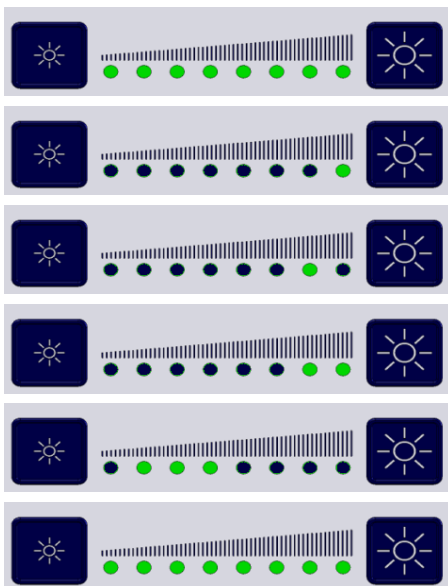
⇒ Error code display: Light

⇒ 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](#).

Technical data

## 7 Technical data

### 7.1 Technical data Sim.LED 450 SC

Data 450 SC	Description	Values	
<b>General information</b>	Weight of the light head	13 kg	28.7 lbs.
	Lamp lifespan	> 60,000 h	
	Expected operating life (light head incl. mounting)	8 years	
	Protection class acc. to IEC 60529-1 (light head)	IP 52	
	<b>Connection values</b>		
	Power supply unit, ceiling variants/mobile variants		
	Supply voltage AC	100 – 240 V	
	Mains frequency	50 / 60 Hz	
	Power consumption	140 VA	
	<b>Light head</b>		
	Voltage DC	24 V	
	Rated power	45 W	
	Protection class acc. to IEC 60601	I	
<b>Technical light values</b>			
	Illumination intensity EC at distance of 1 meter/39.4 in	140 klx	
	Electronic brightness regulation	30 – 100 %	
	d10: Light field diameter at 10% of max. illumination intensity at a distance of 1 meter/39.4 in	140 – 250 mm	5.5 – 9.8 in
	d50: Light field diameter at 50% of max. illumination intensity at a distance of 1 meter/39.4 in	80 mm	3.1 in
	Field adjustment	yes	
	Residual illumination with 1 shadow-mask	32 %	
	Residual illumination with 2 shadow-masks	42 %	
	Residual illumination with 1 tube	100 %	
	Residual illumination with 1 tube and 1 shadow-mask	33 %	
	Residual illumination with 1 tube and 2 shadow-masks	42 %	
	Color rendering index R <sub>a</sub>	96	
	Red rendering index	96	
	Illumination depth (L1/L2) at 20 % intensity	975 mm	38.4 in



Data 450 SC	Description	Values	
	Illumination depth (L1/L2) at 60 % intensity	470 mm	18.5 in
	Total irradiance	468 W/m <sup>2</sup>	
	Color temperature	4,500 K	
	Illumination strength/illumination intensity	274 lm/W	
<b>Operating conditions</b>			
	Temperature range	5 – 40 °C	41 – 104 °F
	Relative air humidity, maximum	95 %	
	Air pressure	700–1,060 hPa	
	Usage	Indoor Use	
	Pollution Degree	2	
	Overvoltage Category	II	

Technical specifications are subject to change: Tolerance ±10%

## 7.2 Technical data Sim.LED 500 SC

Data 500 SC	Description	Values	
<b>General information</b>			
	Weight of the light head	15 kg	33.1 lbs.
	Lamp lifespan	> 60,000 h	
	Expected operating life (light head incl. mounting)	8 years	
	Protection class acc. to IEC 60529-1 (light head)	IP 52	
<b>Connection values</b>			
	Power supply unit, ceiling variants/mobile variants		
	Supply voltage AC	100 – 240 V	
	Mains frequency	50 / 60 Hz	
	Power consumption	140 VA	
	Light head		
	Voltage DC	24 V	
	Rated power	53 W	
	Protection class acc. to IEC 60601	I	

Technical data

Data 500 SC	Description	Values	
<b>Technical light values</b>			
	Illumination intensity EC at distance of 1 meter/39.4 in	160 klx	
	Electronic brightness regulation	30 – 100 %	
	d10: Light field diameter at 10% of max. illumination intensity at a distance of 1 meter/39.4 in	170 – 290 mm	6.7 – 11.4 in
	d50: Light field diameter at 50% of max. illumination intensity at a distance of 1 meter/39.4 in	98 mm	3.9 in
	Field adjustment	yes	
	Residual illumination with 1 shadow-mask	69 %	
	Residual illumination with 2 shadow-masks	42 %	
	Residual illumination with 1 tube	100 %	
	Residual illumination with 1 tube and 1 shadow-mask	68 %	
	Residual illumination with 1 tube and 2 shadow-masks	42 %	
	Color rendering index R <sub>a</sub>	96	
	Red rendering index	96	
	Illumination depth (L1/L2) at 20 % intensity	930 mm	36.6 in
	Illumination depth (L1/L2) at 60 % intensity	460 mm	18.1 in
	Total irradiance	534 W/m <sup>2</sup>	
	Color temperature	4,500 K	
Illumination strength/illumination intensity	270 lm/W		
<b>Operating conditions</b>			
	Temperature range	5 – 40 °C	41 – 104 °F
	Relative air humidity, maximum	95 %	
	Air pressure	700–1,060 hPa	
	Usage	Indoor Use	
	Pollution Degree	2	
	Overvoltage Category	II	

Technical specifications are subject to change: Tolerance ±10%

### 7.3 Technical Data Sim.LED 700 SC

Data 700 SC	Description	Values	
<b>General information</b>	Weight of the light head	18 kg	39.7 lbs.
	Lamp lifespan	> 60,000 h	
	Expected operating life (light head incl. mounting)	8 years	
	Protection class acc. to IEC 60529-1 (light head)	IP 52	
	<b>Connection values</b>		
	Power supply unit, ceiling variants/mobile variants		
	Supply voltage AC	100 – 240 V	
	Mains frequency	50 / 60 Hz	
	Power consumption	140 VA	
	<b>Light head</b>		
	Voltage DC	24 V	
	Rated power	62 W	
	Protection class acc. to IEC 60601	I	
<b>Technical light values</b>			
	Illumination intensity EC at distance of 1 meter/39.4 in	160 klx	
	Electronic brightness regulation	30 – 100 %	
	d10: Light field diameter at 10% of max. Illumination intensity at a distance of 1 meter/39.4 in	170 – 300 mm	6.7 – 11.8 in
	d50: Light field diameter at 50% of max. Illumination intensity at a distance of 1 meter/39.4 in	101 mm	4.0 in
	Field adjustment	yes	
	Residual illumination with 1 shadow-mask	67 %	
	Residual illumination with 2 shadow-masks	47 %	
	Residual illumination with 1 tube	97 %	
	Residual illumination with 1 tube and 1 shadow-mask	64 %	
	Residual illumination with 1 tube and 2 shadow-masks	45 %	
	Color rendering index R <sub>a</sub>	96	
	Red rendering index	96	
	Illumination depth (L1/L2) at 20 % intensity	875 mm	34.5 in
	Illumination depth (L1/L2) at 60 % intensity	420 mm	16.5 in
Total irradiance	629 W/m <sup>2</sup>		

Technical data

Data 700 SC	Description	Values	
	Color temperature	4,500 K	
	Illumination strength/illumination intensity	264 lm/W	
Operating conditions	Temperature range	5 – 40 °C	41 – 104 °F
	Relative air humidity, maximum	95 %	
	Air pressure	700–1,060 hPa	
	Usage	Indoor Use	
	Pollution Degree	2	
	Overvoltage Category	II	

Technical specifications are subject to change: Tolerance ±10%

### 7.4 Technical data Sim.LED 450 MC

Data 450 MC	Description	Values	
General information	Weight of the light head [kg]	13 kg	28.7 lbs.
	Lamp lifespan	> 60,000 h	
	Expected operating life (light head incl. mounting)	8 years	
	Protection class acc. to IEC 60529-1 (light head)	IP 52	
	Connection values	Power supply unit, ceiling variants/mobile variants	
Supply voltage AC		100 – 240 V	
Mains frequency		50 / 60 Hz	
Power consumption		140 VA	
Light head			
Voltage DC		24 V	
Rated power		51 W	
Protection class acc. to IEC 60601		I	
Technical light values	Illumination intensity EC at distance of 1 meter/39.4 in	140 klx	
	Electronic brightness regulation	30 – 100 %	
	d10: Light field diameter at 10% of max. Illumination intensity at a distance of 1 meter/39.4 in	140 – 230 mm	5.5-9.1 in
	d50: Light field diameter at 50% of max. Illumination	88 mm	3.5 in

Data 450 MC	Description	Values	
	intensity at a distance of 1 meter/39.4 in		
	Field adjustment	yes	
	Residual illumination with 1 shadow-mask	36 %	
	Residual illumination with 2 shadow-masks	37 %	
	Residual illumination with 1 tube	100 %	
	Residual illumination with 1 tube and 1 shadow-mask	35 %	
	Residual illumination with 1 tube and 2 shadow-masks	44 %	
	Color rendering index R <sub>a</sub>	96	
	Red rendering index	96	
	Illumination depth (L1/L2) at 20 % intensity	925 mm	36.4 in
	Illumination depth (L1/L2) at 60 % intensity	510 mm	20.1 in
	Total irradiance	484 W/m <sup>2</sup>	
	Color temperature	3,500, 4,000, 4,500, 5,000, 5,500 K	
	Illumination strength/illumination intensity	266 lm/W	
<b>Operating conditions</b>	Temperature range	5 – 40 °C	41 – 104 °F
	Relative air humidity, maximum	95 %	
	Air pressure	700–1,060 hPa	
	Usage	Indoor Use	
	Pollution Degree	2	
	Overvoltage Category	II	

Technical specifications are subject to change: Tolerance  $\pm 10\%$

## 7.5 Technical data Sim.LED 500 MC

Data 500 MC	Description	Values	
<b>General information</b>	Weight of the light head	15 kg	33.1 lbs.
	Lamp lifespan	> 60,000 h	
	Expected operating life (light head incl. mounting)	8 years	
	Protection class acc. to IEC 60529-1 (light head)	IP 52	
	<b>Connection values</b>	Power supply unit, ceiling variants/mobile variants	

Technical data

Data 500 MC	Description	Values	
	Supply voltage AC	100 – 240 V	
	Mains frequency	50 / 60 Hz	
	Power consumption	140 VA	
	Light head		
	Voltage DC	24 V	
	Rated power	62 W	
	Protection class acc. to IEC 60601	I	
<b>Technical light values</b>			
	Illumination intensity EC at distance of 1 meter/39.4 in	160 klx	
	Electronic brightness regulation	30 – 100 %	
	d10: Light field diameter at 10% of max. Illumination intensity at a distance of 1 meter/39.4 in	170 – 290 mm	6.7 – 11.4 in
	d50: Light field diameter at 50% of max. Illumination intensity at a distance of 1 meter/39.4 in	105 mm	4.1 in
	Field adjustment	yes	
	Residual illumination with 1 shadow-mask	65 %	
	Residual illumination with 2 shadow-masks	44 %	
	Residual illumination with 1 tube	100 %	
	Residual illumination with 1 tube and 1 shadow-mask	65 %	
	Residual illumination with 1 tube and 2 shadow-masks	44 %	
	Color rendering index R <sub>a</sub>	96	
	Red rendering index	96	
	Illumination depth (L1/L2) at 20 % intensity	945 mm	37.2 in
	Illumination depth (L1/L2) at 60 % intensity	495 mm	19.5 in
	Total irradiance	516 W/m <sup>2</sup>	
	Color temperature	3,500, 4,000, 4,500, 5,000, 5,500 K	
	Illumination strength/illumination intensity	273 lm/W	
<b>Operating conditions</b>			
	Temperature range	5 – 40 °C	41 – 104 °F
	Relative air humidity, maximum	95 %	
	Air pressure	700–1,060 hPa	
	Usage	Indoor Use	

Data 500 MC	Description	Values
	Pollution Degree	2
	Oversvoltage Category	II

Technical specifications are subject to change: Tolerance  $\pm 10\%$

## 7.6 Technical data Sim.LED 700 MC

Data 700 MC	Description	Values
<b>General information</b>	Weight of the light head	18 kg   39.7 lbs.
	Lamp lifespan	> 60,000 h
	Expected operating life (light head incl. mounting)	8 years
	Protection class acc. to IEC 60529-1 (light head)	IP 52
	<b>Connection values</b>	Power supply unit, ceiling variants/mobile variants
Supply voltage AC		100 – 240 V
Mains frequency		50 / 60 Hz
Power consumption		140 VA
Light head		
Voltage DC		24 V
Rated power		66 W
Protection class acc. to IEC 60601		I
<b>Technical light values</b>	Illumination intensity EC at distance of 1 meter/39.4 in	160 klx
	Electronic brightness regulation	30 – 100 %
	d10: Light field diameter at 10% of max. Illumination intensity at a distance of 1 meter/39.4 in	170 – 300 mm   6.7 – 11.8 in
	d50: Light field diameter at 50% of max. Illumination intensity at a distance of 1 meter/39.4 in	106 mm   4.2 in
	Field adjustment	yes
	Residual illumination with 1 shadow-mask	65 %
	Residual illumination with 2 shadow-masks	47 %
	Residual illumination with 1 tube	97 %
	Residual illumination with 1 tube and 1 shadow-mask	62 %
	Residual illumination with 1 tube and 2 shadow-masks	45 %

Technical data

Data 700 MC	Description	Values	
	Color rendering index R <sub>a</sub>	96	
	Red rendering index	96	
	Illumination depth (L1/L2) at 20 % intensity	915 mm	36.0 in
	Illumination depth (L1/L2) at 60 % intensity	450 mm	17.7 in
	Total irradiance	600 W/m <sup>2</sup>	
	Color temperature	3,500, 4,000, 4,500, 5,000, 5,500 K	
	Illumination strength/illumination intensity	264 lm/W	
<b>Operating conditions</b>			
	Temperature range	5 – 40 °C	41 – 104 °F
	Relative air humidity, maximum	95 %	
	Air pressure	700–1,060 hPa	
	Usage	Indoor Use	
	Pollution Degree	2	
	Overvoltage Category	II	

Technical specifications are subject to change: Tolerance ±10%

### 7.7 Permissible load for Sim.SCREEN monitor mounts

Monitor mount	Max. monitor weight incl. power supply	
Sim.SCREEN Single up to 24" with SA 2075 3,5 - 13kg	7 kg	15.4 lbs.
Sim.SCREEN Single up to 24" with SA 2075 10 – 20 kg	14 kg	30.9 lbs.
Sim.SCREEN Single up to 26" with SA 2075 10 – 20 kg	13 kg	28.7 lbs.
Sim.SCREEN Single up to 26" with SA 3075 20 – 30 kg	23 kg	50.8 lbs.
Sim.SCREEN Single up to 32" with SA 2075 10 – 20kg	7 kg	15.4 lbs.
Sim.SCREEN Single up to 32" with SA 3075 20 – 30kg	17kg	37.5 lbs
Sim.SCREEN Double up to 24" with OndaSpace spring arm 20–40 kg	12 kg per side	26.5 lbs. per side
Sim.SCREEN Double up to 26" with OndaSpace spring arm 20–40 kg	10 kg per side	22.0 lbs. per side

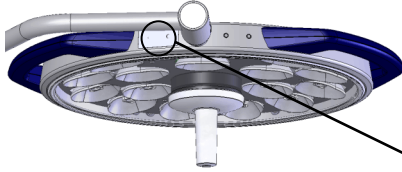


## 7.8 Permissible load for Sim.CARRY carrier plate

Sim.CARRY carrier plate for unit	Max. load	
Sim.CARRY GTP8 with SA 2075 3,5 – 13kg	10 kg	22.0 lbs.
Sim.CARRY GTP14 with SA 2075 10–20 kg	15 kg	33.1 lbs.
Sim.CARRY GTP14 with SA 3075 20–30 kg	25 kg	55.1 lbs.

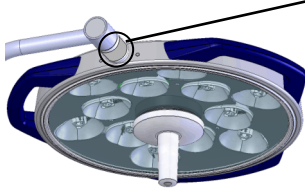
## 7.9 Type plate





Sim.LED 500/700



The type plate can be found on the light head (Sim.LED 500/700) or directly next to the light head on the cardan joint (Sim.LED 450):

Sim.LED 450



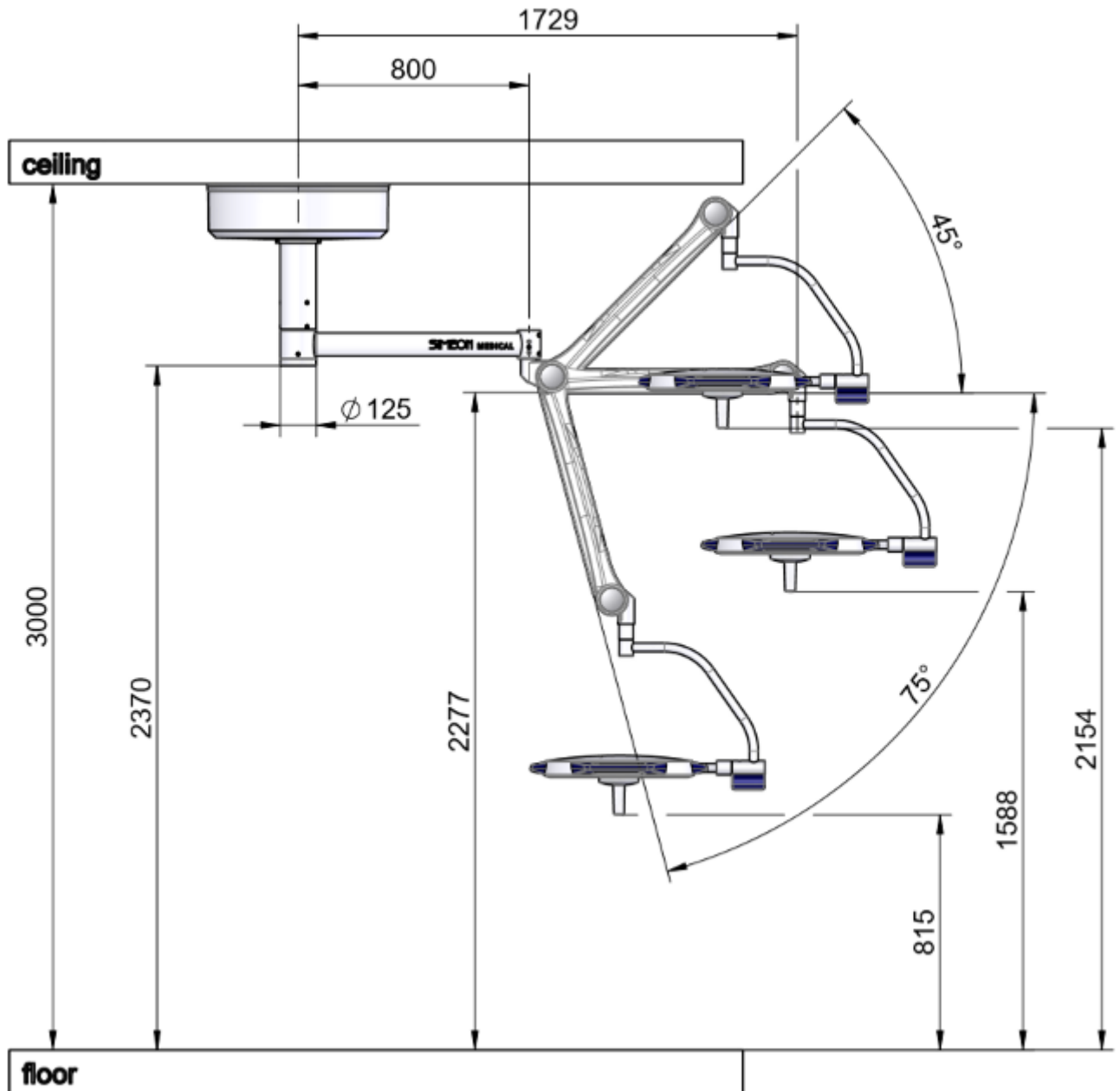
2022-03-14 S.I.M.E.O.N. Medical GmbH & Co. KG In Grubenäcker 18 78532 Tuttlingen, Germany www.simeonmedical.com	Sim.LED 500 MC 3p		(01) 04250613840258 (21) 123456789101112
	REF <b>141-0015635</b>	IP52	UDI 
SN <b>123456789101112</b> 24VDC, 62W		(93) 141-0015635	
			 Made in Germany
		700-00004 V1.3	

It includes the following information:

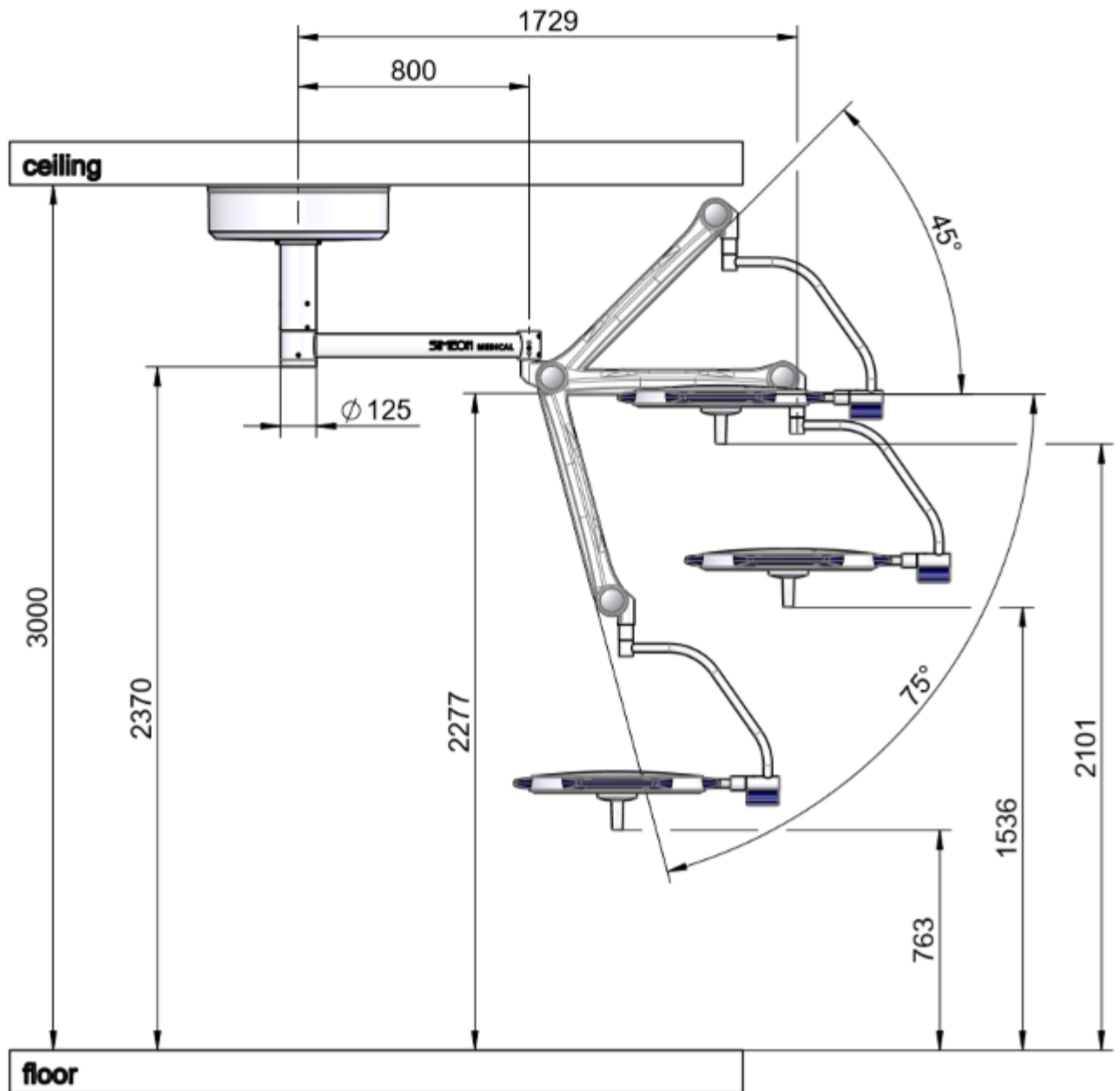
Manufacturer address, article number (REF), product name, serial number (SN), electrical power data, manufacturing month and year

## 7.10 Dimension sheets

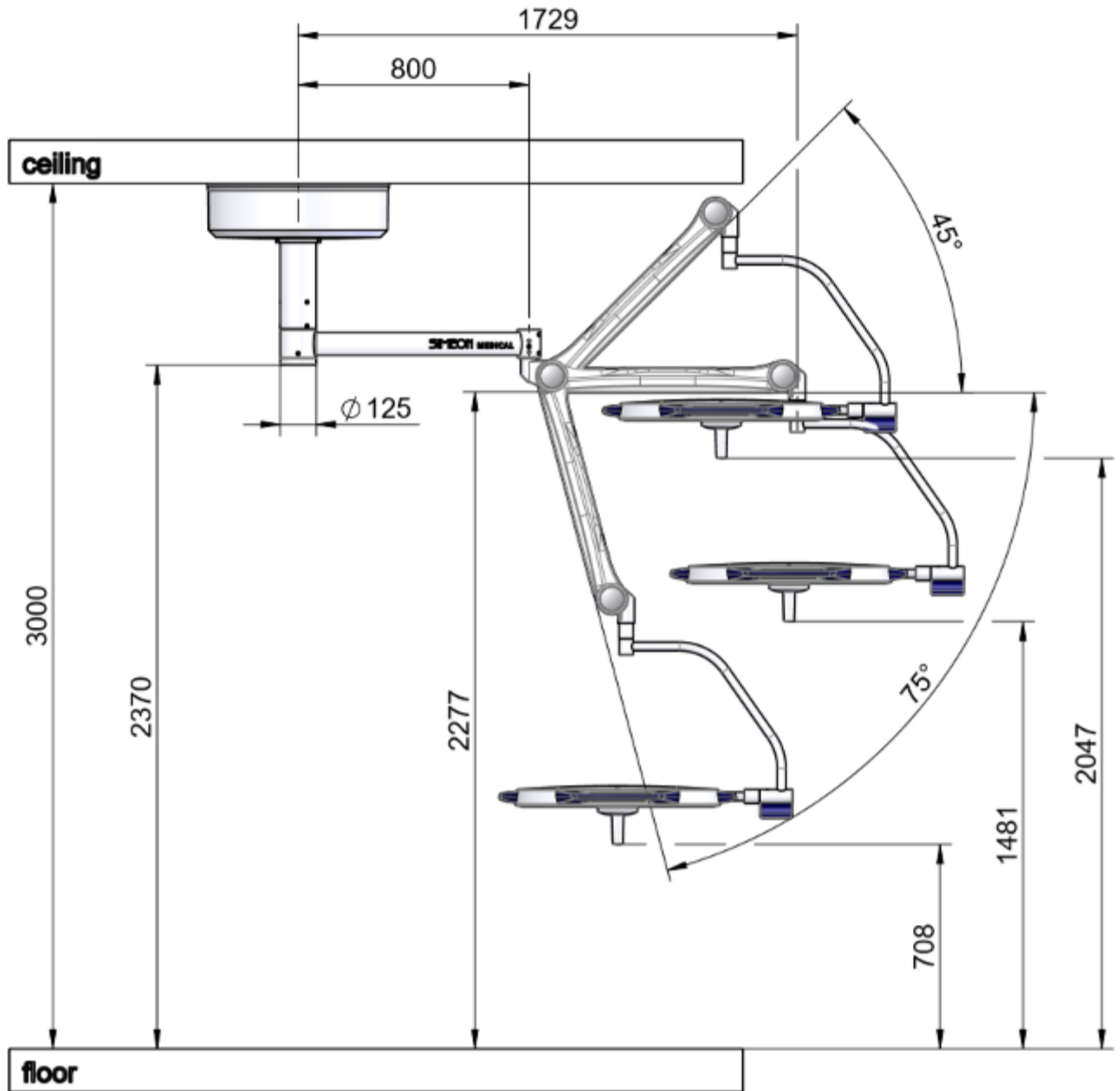
### 7.10.1 Sim.LED 450 ceiling variant



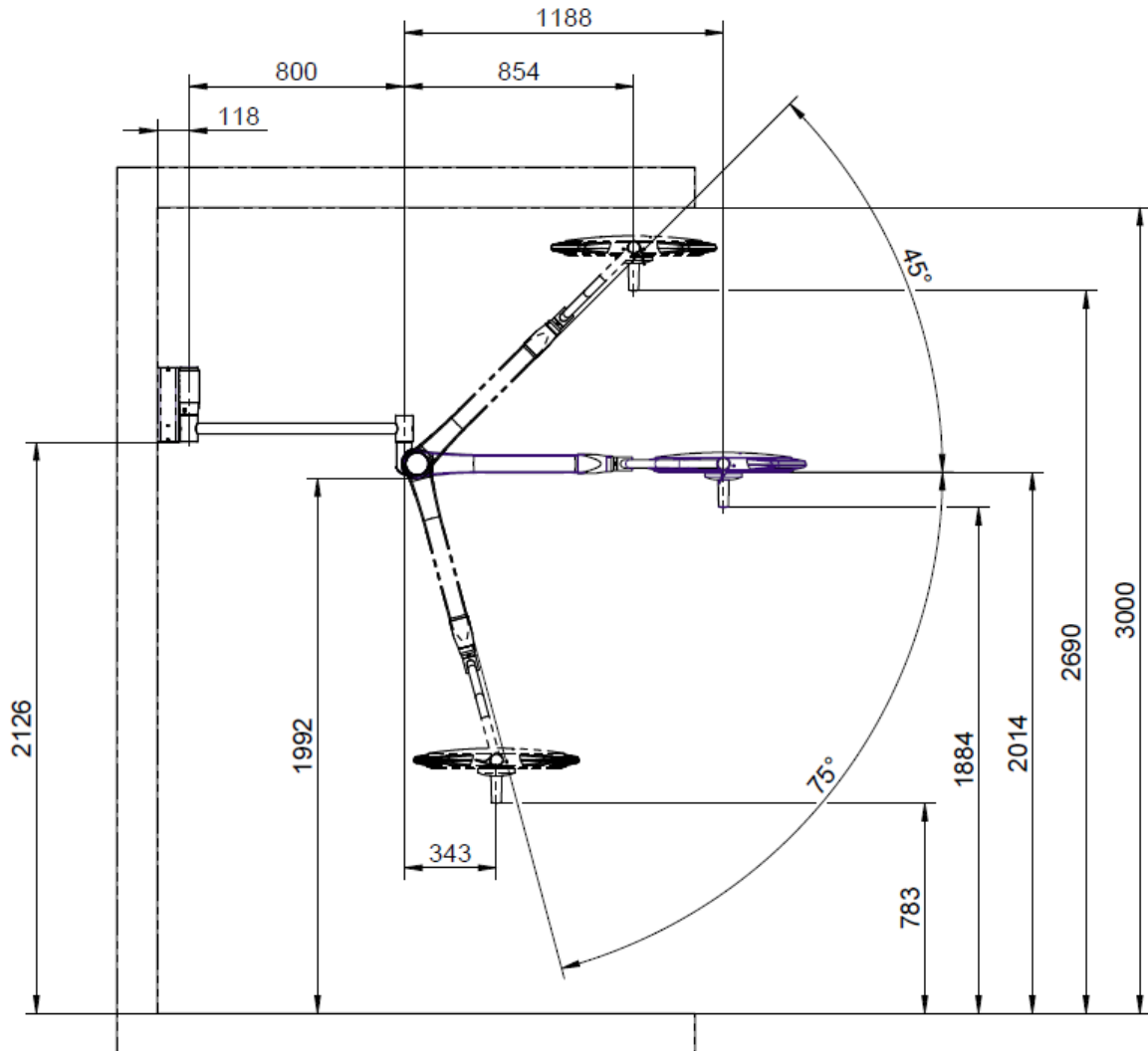
7.10.2 Sim.LED 500 ceiling variant



**7.10.3 Sim.LED 700 ceiling variant**



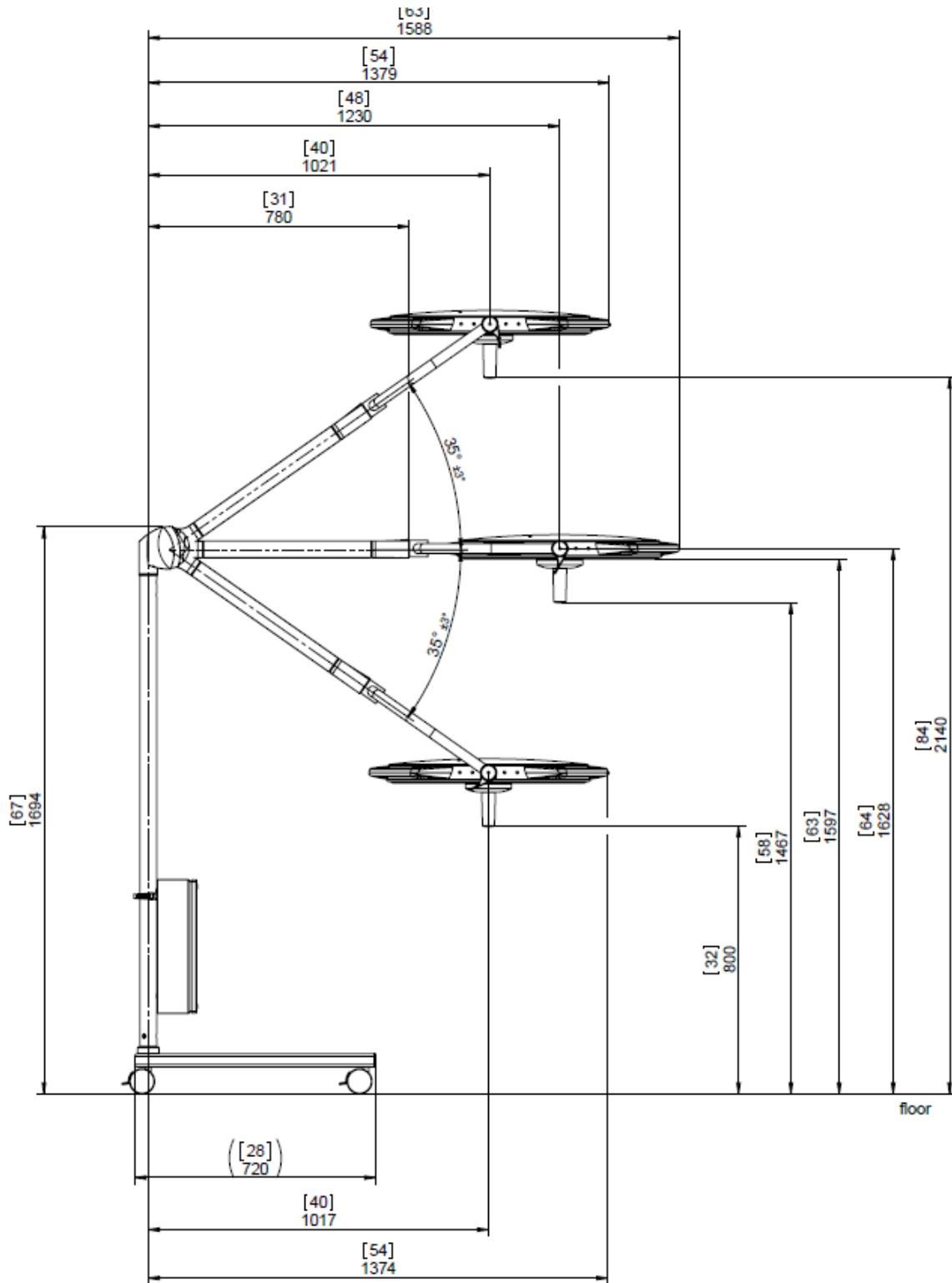
**7.10.4 Sim.LED 450 wall variant**



mm [inch]



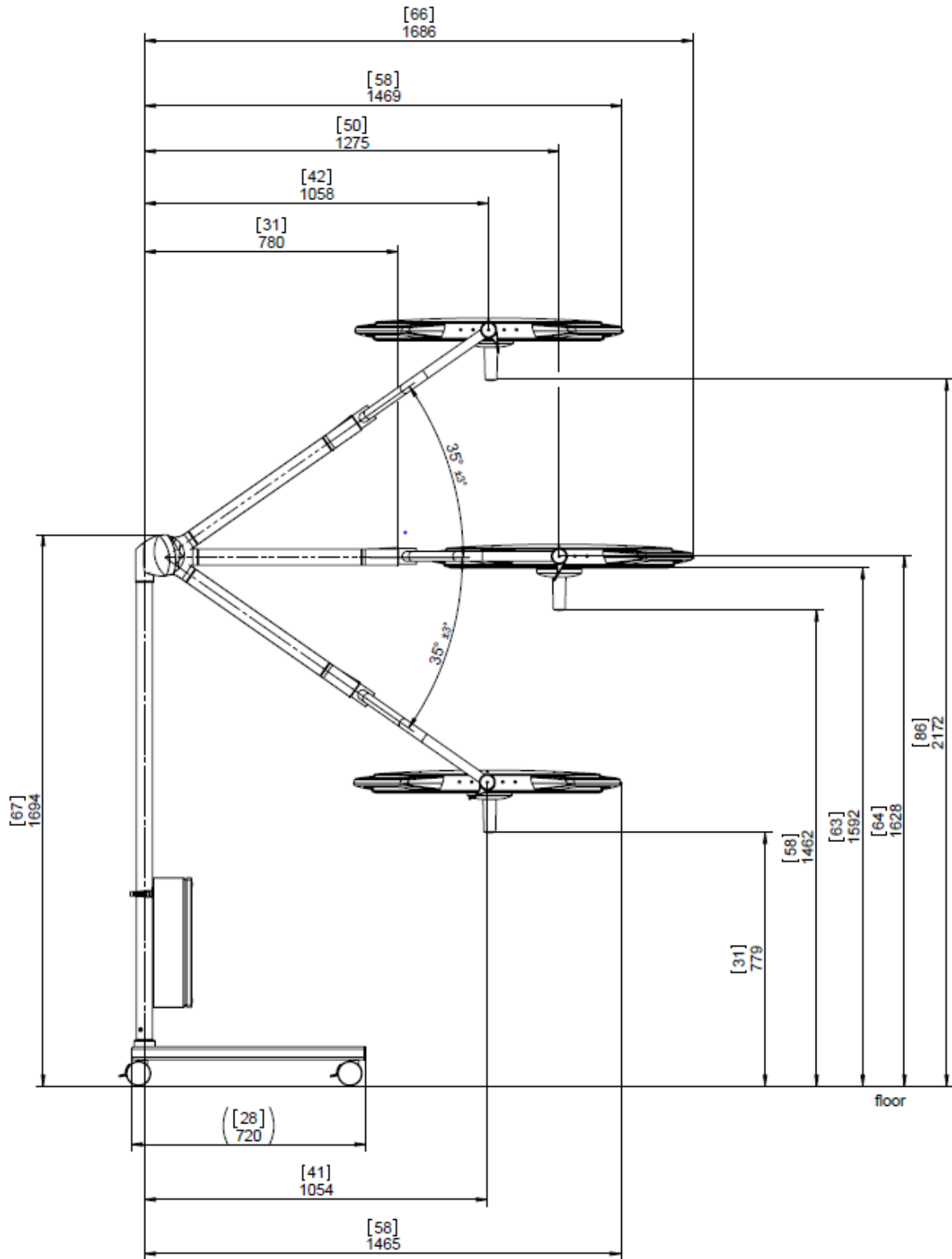
7.10.6 Sim.LED 500 mobile variant



mm [inch]



### 7.10.7 Sim.LED 700 mobile variant



mm [inch]