# Instructions for Use

## Examination Lighting
## Sim.LED 3500+

PUSHING TECHNOLOGY TO EXCELLENCE

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CO #003-01671

CE



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

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PUSHING TECHNOLOGY TO EXCELLENCE

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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 Examination Lighting Sim.LED 3500+. 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 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 this manual are provided for basic understanding and could deviate from the actual design.

**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**



**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.

We will accept no liability, and the warranty and guarantee will become inapplicable in the event of damages resulting from:

- Non-observance of these Instructions for Use
- Non-adherence to the designated use / specific function.
- Use by non-qualified 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 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 in this manual 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.

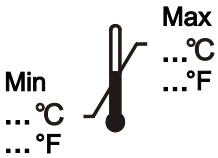
### 1.2.1 Safety symbols

| | |
|---|---|
| ⚠ DANGER | Indicates a hazardous situation that, if not avoided, **will** result in death or serious injury. |
| ⚠ WARNING | Indicates a hazardous situation that, if not avoided, **could** result in death or serious injury. |
| ⚠ CAUTION | Indicates a hazardous situation that, if not avoided, **could** result in **minor or moderate** injury. |
| *NOTICE* | Indicates information considered important, but not hazard-related (e.g. messages relating to property damages). |

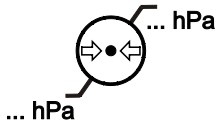
### 1.2.2 Information symbols

The following symbols can be found on Type plate and/or packaging. The symbols must always be taken into account.

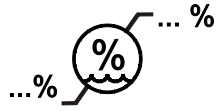
Follow the Instructions for Use




Specifications on minimum and maximum ambient temperature for storage and transportation




Specifications on minimum and maximum air pressure for storage and transportation




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.

| | |
|---|---|
|  | Protect the package from wetness and keep dry |
|  | Date of manufacture and manufacturer's address |
| REF | Article number |
| SN | Serial number |
|  | Protective grounding |
| IP20 | Protection type |
|  | Medical Equipment – General Medical Equipment<br>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 |
| CE | CE mark of conformity |
|  | 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. |
| MD | Indicates that the object in question is a medical device (DIN EN ISO 15223) |
| UDI | Unique Product Identifier, displays a carrier that contains information about a Unique Product Identifier (UDI). |
| EC REP | Local Agent, EC = Agent in the European Union |
| CH REP | 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.

| | |
|---|---|
| **⚠WARNING** | **Risk of injury due to the use of incorrect spare parts!**<br>The use of incorrect or defective spare parts may place personnel and patients at risk as well as cause damages, malfunctions, or a total breakdown of the unit.<br>– Only use original manufacturer spare parts or manufacturer-approved spare parts.<br>– In case of doubt, 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 is voided if unauthorized spare parts are used.

## 1.5 Technical Service

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

In addition, our personnel is always interested in hearing about new information and experiences that may arise from use of the product and that may be valuable for the improvement of our products.

## 1.6 Intended purpose / Intended use

**Intended purpose**

The Sim.LED 3500+ is used for local illumination of the patient's body to assist in diagnosis or treatment, which could be interrupted without endangering the patient in the event of a lighting failure.

**Usage restrictions**

The light is not suitable for use in operating theatres or for operation in explosion-prone or oxygen-rich environments. The examination light is only intended for use in examination rooms.

**Intended use**

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

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.

**Indications**

Lighting during examinations.

**Contraindications**

None known.

| | |
|---|---|
| ⚠ DANGER | **Danger due to incorrect use!**<br>Incorrect use of the unit may lead to dangerous situations. The following are especially considered to be incorrect uses:<br>– Use of the unit in facilities that have not been built in compliance with applicable standards and guidelines regulating the construction of medical facilities.<br>– Use of the unit in explosion-prone or oxygen-rich areas. |

| | |
|---|---|
| | – Use of a damaged unit.<br>– Opening of the unit.<br>– Use of the unit by unqualified personnel.<br>– Use of the unit when objects are hanging from its extension arm, spring arm, or light body. |

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 observed in order to make sure they are functioning reliably in this environment.

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

## 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. If necessary, they must be revised.

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 together 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-observance of time limits!**

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

**Notification of accidents and damages**

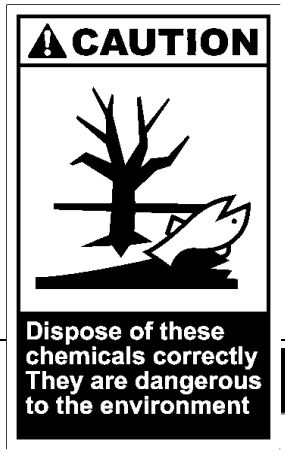
All serious incidents which occur in connection with the product must be reported to SIMEON Medical and the competent authority of the country in which the incident took place.

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-sensible disposal.

Dismantling should only be conducted by trained, skilled 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, skilled personnel.
- The manufacturer must also be involved when conducting unit relocations at a later time.
- Dismantling and relocations may not be conducted by independent parties.

## 1.10 Authorized representatives and importers


**MedEnvoy Switzerland**
Gotthardstraße 28
6302 Zug
Switzerland

# 2 Operation

| | |
|---|---|
|  | **Read all instructions first before operating!** |
|  | **Operating is to be performed by properly trained and authorized personnel only!** |
|  | **Do not drink any alcohol or take any drugs before or during the operating and follow the safety instructions carefully.** |
|  | **Prevent direct glare! Users, patients and third parties should avoid looking into the surgical light for long periods of time.** |
| ⚠WARNING | This product emits potentially hazardous optical radiation. Do not look into the light emitted by the operating light. Eye injury can occur. |

## 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.


**Risk of death due to faulty installation or faulty initial start-up!**

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

- The installation and initial start-up may only be conducted by the manufacturer's personnel or by persons authorized by the manufacturer.
- The manufacturer must also be involved when conducting unit relocations at a later time.
- Installation and relocations by independent parties are not allowed.


**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 electric shock!**

Unreliably grounded lights could cause an electric shock!

Ensure that the light has been correctly grounded: For mobile variants: Only use power outlets with a grounded socket! Never touch the patient and the light system at the same time!


**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!

## 2.2 Variants and accessories

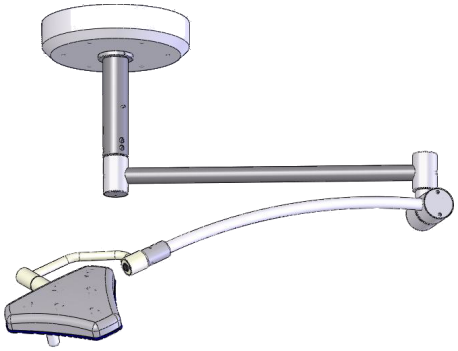
The Examination Lighting Sim.LED 3500+ is available in different variants.

Power rating for the extension arm for all variants:

- 3-pole extension arm: Supply voltage: max. 30 V DC, current: max. 16 A

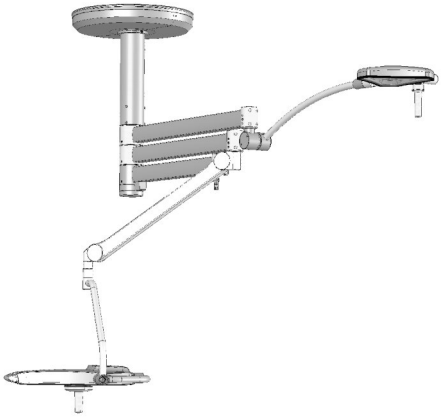
The sterile handle (SteC Sim.LED ExL - Art. No. 141-0000011) is available as an accessory.

### 2.2.1 Ceiling mounting, single



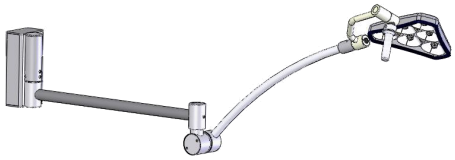
Mounting on a ceiling tube with a diameter of 70 mm:
Four joints allow for optimal positioning.

### 2.2.2 Ceiling mounting as part of a light combination



Sim.LED 3500+ as part of a light combination
(ceiling tube diameter 125 mm):
Four joints allow for optimal positioning.

### 2.2.3 Wall mounting



Wall mounting over extension arm: Four joints allow for positioning.

### 2.2.4 Mobile variants

Variants with mobile stand (cable length: 4.3 m.):

Four joints allow positioning. Secure stand thanks to casters with brakes.


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

Do not hang any objects on the mobile stand 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 risk when intact lights are used as intended *"Intended purpose* / Intended use*", page 10*.

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). Conduct repairs! Never supply voltage to defective lights!
- ☞ Repairs may only be conducted by skilled electricians!
- ☞ Keep moisture away from live parts. 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 adhered to,
  - there are no unauthorized persons in the vicinity of the unit.

**WARNING**

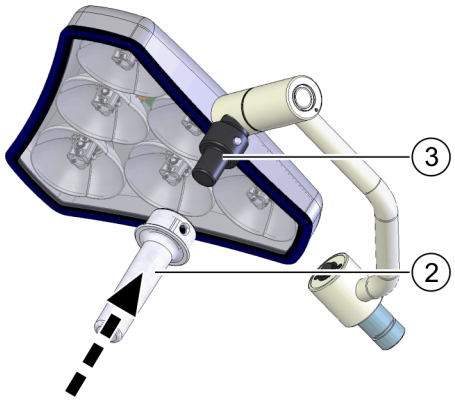
**Risk of infection due to improper hygiene, disinfection, or sterilization!**

There is a risk of infection upon contacts 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!**<br>Damage to the light head or to the sterilizable handle can cause loose or porous parts to fall into wounds and contaminate them.<br>☞ Conduct a visual and functional inspection before each use of the lighting unit.<br>☞ Do not operate a damaged unit.<br>☞ Inspect the sterilizable handles for safe positioning before each use of the lighting equipment. |

## 2.4 Replacing the sterile handle



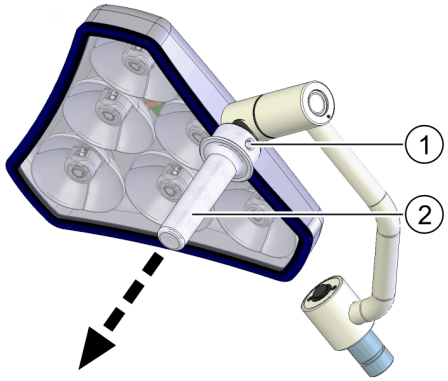

**Intended use**

The sterilizable handle 142-0000011 is used for sterile positioning of the light head.

**Inserting the sterile handle**

☞ Ensure that the sterile handle (2) has been properly disinfected and sterilized.

☞ Press / turn the sterile handle (2) until the safety snaps audibly into the handle unit (3). If necessary, turn slightly until the release button (1) is visible through the hole in the sterilisable handle.




**Removing the sterile handle**

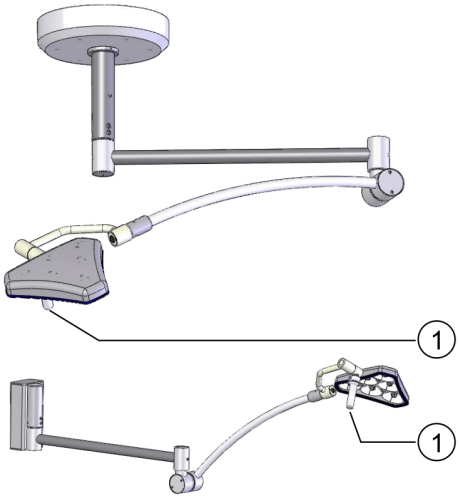
☞ Press the release button (1) on the sterile handle (2).

☞ Pull the sterile handle out of the handle unit.

☞ Inspect the sterile handle (2) for wear and damages, and dispose of or replace if necessary.

☞ If the sterilisable handle is undamaged, it can now be cleaned, disinfected and then sterilized.

## 2.5 Positioning the lights




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

**Positioning the wall/ceiling variants**

- ☞ Move the lamp bodies into the desired position using the handle (1).


**Positioning the mobile variants**

- ☞ If the power cable is too short for the new position of the light, pull out the power plug and secure the cable in such a way that it is not kinked.
- ☞ Using the handle (1), ensure that the spring arm is in the lowest possible position when the mobile stand is transported, in order to optimize the light's balance.
- ☞ Release the brake lever (3, 4) on the braked casters.
- ☞ Secure the mobile stand (2) 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.
- ☞ Apply the brake lever (3, 4) on the braked casters.
- ☞ If the power plug was pulled out before the mobile stand was repositioned, plug the power plug into a suitable power outlet with a grounded socket.
- ☞ Move the light bodies into the desired position using the handle (1).

## 2.6 Switching lights on/off and dimming the lights

| | |
|---|---|
| ⚠CAUTION | **Possible tissue damage due to drying of the wound!**<br>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.<br>– Separate the superimposed illuminated fields from multiple lamp bodies.<br>– 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. |

| | |
|---|---|
| ⚠CAUTION | **Possible eye damage due to glare**<br>Looking directly into the light can be damaging to the eyes.<br>– Protect patients' eyes from the direct light of the lamps.<br>– Do not look directly into the light |

**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 version is plugged into the power outlet.


**Switching on the unit**

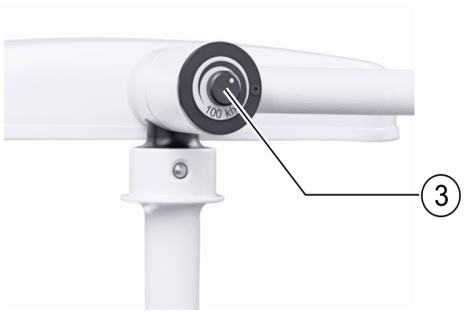
☞ Make sure that no one is looking directly into the light reflectors (2).

☞ Set the power switch (1) to **1**.

⇨ The light will be lit.


### Dimming the unit

- ☞ Make sure that no one is looking directly into the light reflectors (2).
- ☞ Turn the rotary knob (3) toward the right.
  - ⇨ The light will become lighter.
- ☞ Turn the rotary knob (3) toward the left.
  - ⇨ The light will become darker.




### Switching off the unit

- ☞ Ensure that the room is sufficiently illuminated, even without the lights on, to be able to move around safely.
- ☞ Set the power switch (1) to **0**.
  - ⇨ The lights are turned off.

# 3 Maintenance

**Read all instructions first before maintenance!**

**Maintenance is to be performed by properly trained and authorized personnel only!**

**Do not drink any alcohol or take any drugs before or during the maintenance and follow the safety instructions carefully.**

**DANGER**

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

Errors during maintenance may result in life-threatening situations and cause significant material damages. Thus, please note:

☞ Maintenance may only be conducted by employees of the manufacturer or by persons authorized by the manufacturer.

***NOTICE***

The unit is primarily secured with T3.15A/250V fuses. The fuses may not be replaced by maintenance personnel.

## 3.1 Maintenance plan

The following sections describe the work that is required for the optimal and fault-free operation of the unit.

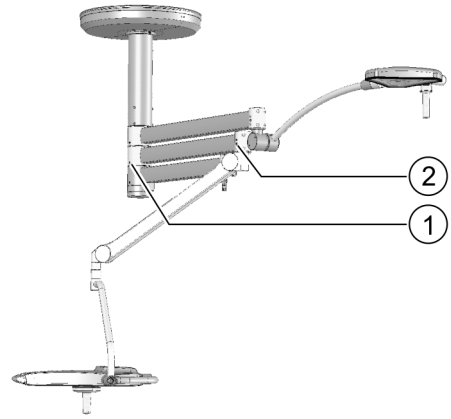
If increased wear is observed during regular inspections, shorten the required maintenance intervals in accordance with the actual signs of wear and tear. Contact the manufacturer if you have questions regarding maintenance work and intervals, contact information is found on page 2.

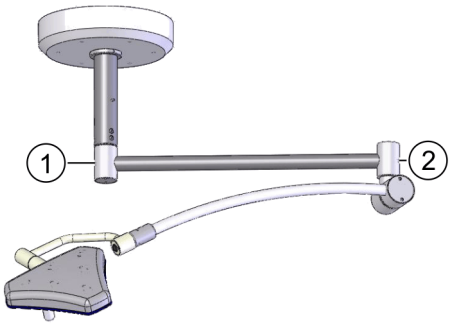
| Interval | Maintenance work | Personnel |
|---|---|---|
| Biennial | Conduct technical safety controls of the unit in accordance with the Service manual. | Manufacturer |
| As required | Check the braking power for the extension arm and adjust if required ↬ "*Setting the extension arm's braking power*", *page 26.* | Operator's medical technicians |
| Before every sterile use | Replace the sterilisable handle with a cleaned and steam-sterilized sterilisable handle ↬ *"Replacing the sterile handle", page 20.* | Medical qualified personnel |
| Before every use | Clean and disinfect the unit<br>↬ *"Cleaning the unit*", *page 27.*<br>↬ *"Disinfecting the unit: Wiping disinfection*", *page 28*. | Medical qualified personnel |

## 3.2 Maintenance work

| | |
|---|---|
| DANGER | **Risk of death due to incorrect maintenance!**<br>Errors during maintenance may result in life-threatening situations and cause significant material damages.<br>Only allow trained, qualified personnel to conduct maintenance.<br>Dismantling and relocations may not be conducted by independent parties. |

### 3.2.1 Setting the extension arm's braking power




In the case of ceiling mounting: if positioning of the lights is too tight or too loose, the braking power must be adjusted on the extension arm.

Extension arms that are mounted on a ceiling tube with a diameter of 125 mm possess two brake screws (1) on opposite sides of the ceiling tube, and one brake screw (2) on the side of the extension arm.

☞ Adjust the braking power using a size 5 hexagon socket wrench. Turn the brake screw in a clockwise direction to increase the braking power. Turn the brake screw counterclockwise to decrease it.

Extension arms that are mounted on a ceiling tube with a diameter of 70 mm possess one brake screw (1) on the ceiling tube, and one brake screw (2) on the side of the extension arm.

☞ Adjust the braking power using a size 5 hexagon socket wrench: Turn the brake screw in a clockwise direction to increase the braking power. Turn the brake screw counterclockwise to decrease it.

# 4 Preparation

## 4.1 Cleaning the unit

| | |
|---|---|
| NOTICE | **Material damages due to the use of improper cleaning agents!**<br>Abrasive, corrosive, or paint-thinning cleaning agents may damage the surface of the unit.<br>– Do not use any abrasive, corrosive or paint-thinning cleaning agents containing benzine or aldehyde.<br>– Always apply the cleaning agent in such a manner that no liquid is able to penetrate the unit.<br>– Only clean accessible parts using neutral, tenside-based cleaning agents (manual dishwashing liquid, neutral cleansers). |
|  | **Risk of death due to electric shock!**<br>There is an immediate risk of death due to electric shock when coming into contact with live parts.<br>– 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.<br>– Safeguard the main switch or power plug from unintended switching-on/plugging-in.<br>– Always protect the unit from splash water and never wet-clean or wet-disinfect the unit.<br>– Always ensure that no liquid / no moisture is able to penetrate into the unit through openings. |

☞ Disconnect the power supply (wall/ceiling mounting) or pull the power plug (mobile variants).

☞ Wipe the unit using a moist - not wet - cloth.

## 4.2 Disinfecting the unit: Wiping disinfection

| | |
|---|---|
| **⚠WARNING** | **Health risk due to disinfectant!**<br>Disinfectants may contain agents hazardous to health.<br>– Always select and use disinfectants that comply with local hygienic and operating regulations.<br>– 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. |
| ***NOTICE*** | **Risk of material damages due to spray disinfectants!**<br>Spray mist may cause short-circuits in the electrical installations and corrosion of the mechanical components.<br>– Do not use spray disinfectants.<br>– All components, including accessories and connecting cables, may only be disinfected by wiping with a surface disinfectant.<br>– 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. |
| ***NOTICE*** | **Risk of material damages when using unsuitable disinfectants!**<br>Chloride- and halide-containing disinfectants and excessively alcoholic disinfectants may corrode the unit's surfaces or plastic parts.<br>– Do not use any chloride- or halide-containing disinfectants.<br>– Apply the disinfectant in such a manner that no moisture or liquid is able to penetrate the unit.<br>– 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. |

☞ Disconnect the power supply (wall/ceiling mounting) or pull the power plug (mobile variants).

☞ All of the unit's components, including connecting cables, must undergo wiping disinfection.

## 4.3 Preparing the sterilizable handle

**Products:** 141-0000011 SteC Sim.LED ExL (GTIN: 04250613810824)

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

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| **Pretreatment at the site of Use:** | Remove heavy dirt with a disposable cloth/paper towel with low particulate release. |
| **Storage and transport:** | No special requirements.<br>It is recommended to prepare the handles as soon as possible after use. |
| **Preparation prior to cleaning** | No special requirements.<br>No disassembly necessary. |
| **Automated cleaning** | **Furnishings**<br>Cleaner/disinfector: Miele PG8535 with standard furnishings with floor grilles, mesh basket and bottle rack<br>*(It is recommended to use a cleaner/disinfector in accordance with ISO 15883.)*<br><br>**Cleaning products**<br>neodisher® MediClean Dr. Weigert # 510643/1114<br><br>**Cleaning instructions**<br>For automatic cleaning, place the product into the cleaner/disinfector upright with the opening facing downwards.<br>The sterile handle 141-0000011 SteC Sim.LED ExL is placed into a bottle rack.<br>The automatic cleaning process is conducted with the following steps (based on the DES-VAR-TD program from Miele):<br>• Rinsing 1 min (cold water)<br>• Cleaning at 55°C (± 2 °C) for 5 min with neodisher® MediClean (0.3 % v/v) cleaning product<br>• Neutralization with 1/3 cold water and 2/3 warm water for 1 min<br>• Rinsing with 1/3 cold water and 2/3 warm water for 1 min<br>• Thermal disinfection with A0-value > 3.000<br>• Drying: Do not exceed a temperature of 120°C |
| **Manual cleaning:**<br>*(if automated cleaning is not possible)* | **Furnishings**<br>Ultrasound bath: Bandelin RK510H<br><br>**Cleaning products and material**<br>Toothbrush (medium) Dr. Best<br>neodisher® MediClean Dr. Weigert; # 534621/1115 |

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| | **Cleaning instructions**<br>Completely submerge the products in the ultrasound bath (filled with 0.5 % (v/v) neodisher® MediClean in demineralized water).<br>Ultrasound treatment at 35 kHz for 10 min.<br>Do not exceed the maximum temperature of 40 °C in the process!<br><br>After the ultrasound treatment, remove any visible residue with the cleaning product and the toothbrush.<br><br>Then rinse the product for 1 min in demineralized water (temperature 20°C - 25°C) |
| **Manual disinfection:** | The disinfectant solution should be used in accordance with the instructions on the label!<br><br>**Manual disinfection**<br>Sekusept® active Ecolab; # 4254FM6908, 4305FM5509<br><br>**Disinfection instructions**<br>Completely submerge the product in the disinfectant solution Sekusept® active 3 % (w/v) (prepare the solution according to the manufacturer's instructions).<br>Temperature: 20 °C ± 2 °C<br>Time: 15 min<br>Avoid air bubbles on the surface during the immersion bath!<br><br>Then rinse the product completely for at least 3 min. in cold demineralized water. |
| **Maintenance, inspection and testing:** | Visually inspect all handles for damage, discoloration and wear. |
| **Packaging:** | A standardized, sterilizable system can be used. The bag must be large enough for the handle, so that the seal is not under tension. |
| **Sterilization:** | It is recommended to use damp heat (steam) for sterilization!<br><br>**Furnishings**<br>Steam autoclave: Systec HX-320<br>*(It is recommended to use a sterilizer in accordance with EN 285.)*<br>Sterilization packaging: Brömeda, REF 68170912<br><br>**Sterilization instructions**<br>Individually package the products<br>Temperature of saturated steam: 134°C<br>3x fractionated pre-vacuum<br>Sterilization time: 4 min<br>Resulting half-cycle exposure time: 2 min<br>Drying time: 10 min<br><br>Improper steam sterilization may damage the sterilizable handles and make their surfaces porous and prone to cracks.<br>Do not exceed the maximum temperature of 134 °C. |
| **Storage:** | No special requirements. |

| | |
|---|---|
| **Additional information:** | When sterilizing reusable handles in an autoclave cycle, it must be ensured that the maximum load for the sterilizer is not exceeded. |
| **Contact to manufacturer:** | **S.I.M.E.O.N. Medical GmbH & Co. KG**<br>In Grubenäcker 18<br>78532 Tuttlingen<br>GERMANY<br>Telephone: +49 (0) 7461 90068-888<br>E-mail: service@simeonmedical.com |

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.

# 5 Troubleshooting

## 5.1 Malfunctions

The following table describes possible causes for 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.

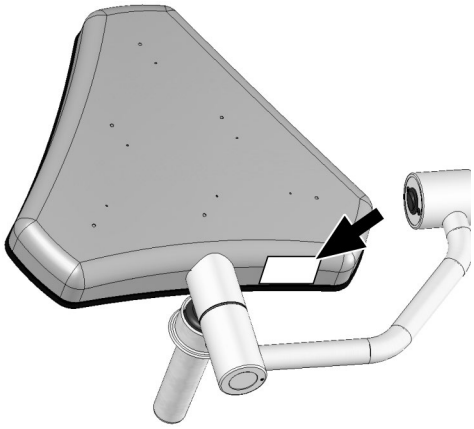
| Description of fault | Cause | Remedial action | Personnel |
|---|---|---|---|
| Light head rises or sinks uncontrollably | Spring arm defective | Replace spring arm | Manufacturer |
| The light head is too tight / too loose | The braking power has been set too low / high. | Set the braking power ↳ *"Setting the extension arm's braking power", page 26* | Trained specialist personnel with appropriate tools |
| The sterile handles show cracks and are porous | Sterilization/disinfection were conducted improperly | Dispose of and replace the cracked and porous sterile handles. In the future, conduct sterilizing/disinfecting procedures only in accordance with the Instructions for Use manual ↳ *"Preparing the sterilizable handle", page 29* | Medical qualified personnel |
| | End of lifespan reached | Dispose of and replace sterile handle | Medical qualified personnel |
| Unit does not light up | Power supply to the room is turned off | Turn on power supply to the room | Medical qualified personnel |
| | Unit turned off at the power switch | Switch on unit ↳ *"Switching lights on/off and dimming the lights", page 22* | Medical qualified personnel |
| | Power supply is interrupted | Inspect voltage and fuses | Manufacturer |
| | Electronics are defective | Replace electronics | Manufacturer |
| | Lamp is defective | Replace lamp | Manufacturer |

# 6 Technical data

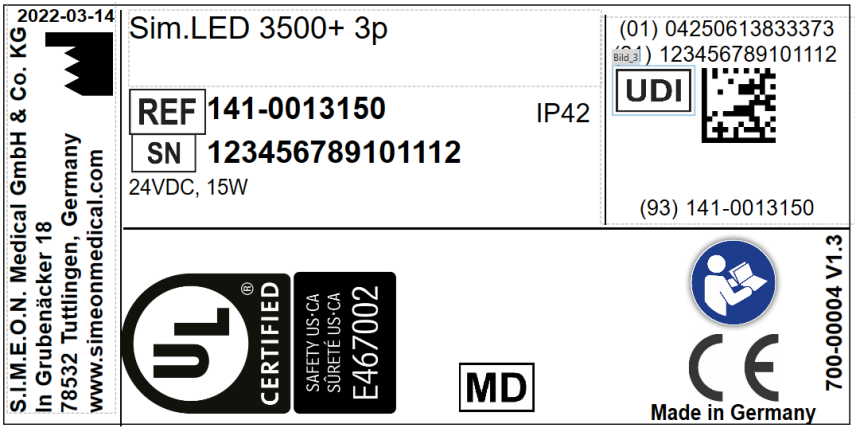
| | Description/designation | Sim.LED 3500+ | |
|---|---|---|---|
| **General information** | | | |
| | Weight of the light head | 3 kg | 6.6 lbs. |
| | Light source lifespan | 60,000 h | |
| **Connection values** | | | |
| | System: | | |
| | Supply voltage AC | 100 – 240 V | |
| | Mains frequency | 50-60Hz | |
| | Power consumption | 31VA – 44VA | |
| | Light head: | | |
| | Voltage DC | 24 V | |
| | Rated power | 15 W | |
| | Protection class acc. to IEC 60601-1 | I | |
| | Light head safety class pursuant to IEC 60529-1 | IP 42 | |
| **Technical light values** | | | |
| | Illumination intensity EC at distance of 1m/39.4inches | 90 klx | |
| | Brightness regulation | 40 – 90 klx | |
| | Color rendering index $R_a$ | 96 | |
| | Red rendering index R9 | 96 | |
| | Illumination field diameter $d_{10}$ | 150 mm | 5.9 inches |
| | Illumination field diameter $d_{50}$ | 87 mm | 3.4 inches |
| | Total illumination strength | 222 W/m² | |
| | Color temperature | 4,500 K | |
| **Operating conditions** | Temperature range | 5 – 40 °C | 41 – 104 °F |
| | Relative air humidity, maximum | 95 % | |
| | Air pressure | 700–1,060 hPa | |
| | Operating mode | Continuous operation | |
| | Usage | Indoor Use | |
| | Pollution Degree | 2 | |
| | Overvoltage Category | II | |

Technical specifications are subject to change; tolerance ±10%

## 6.1 Type plate



The light head's type plate is located directly on the light head (see position indicated with the arrow in the adjacent image).

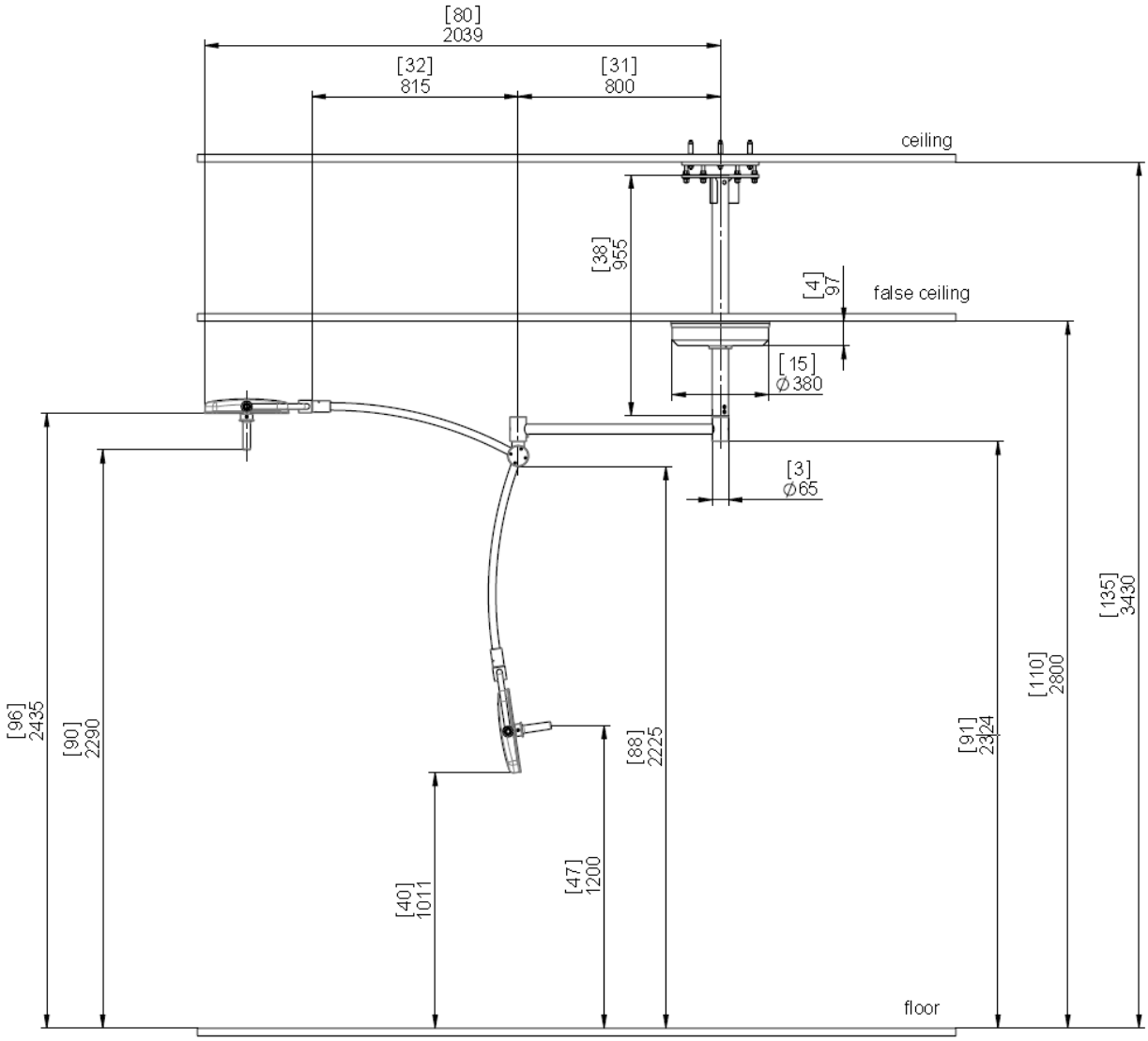



It includes the following information:

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

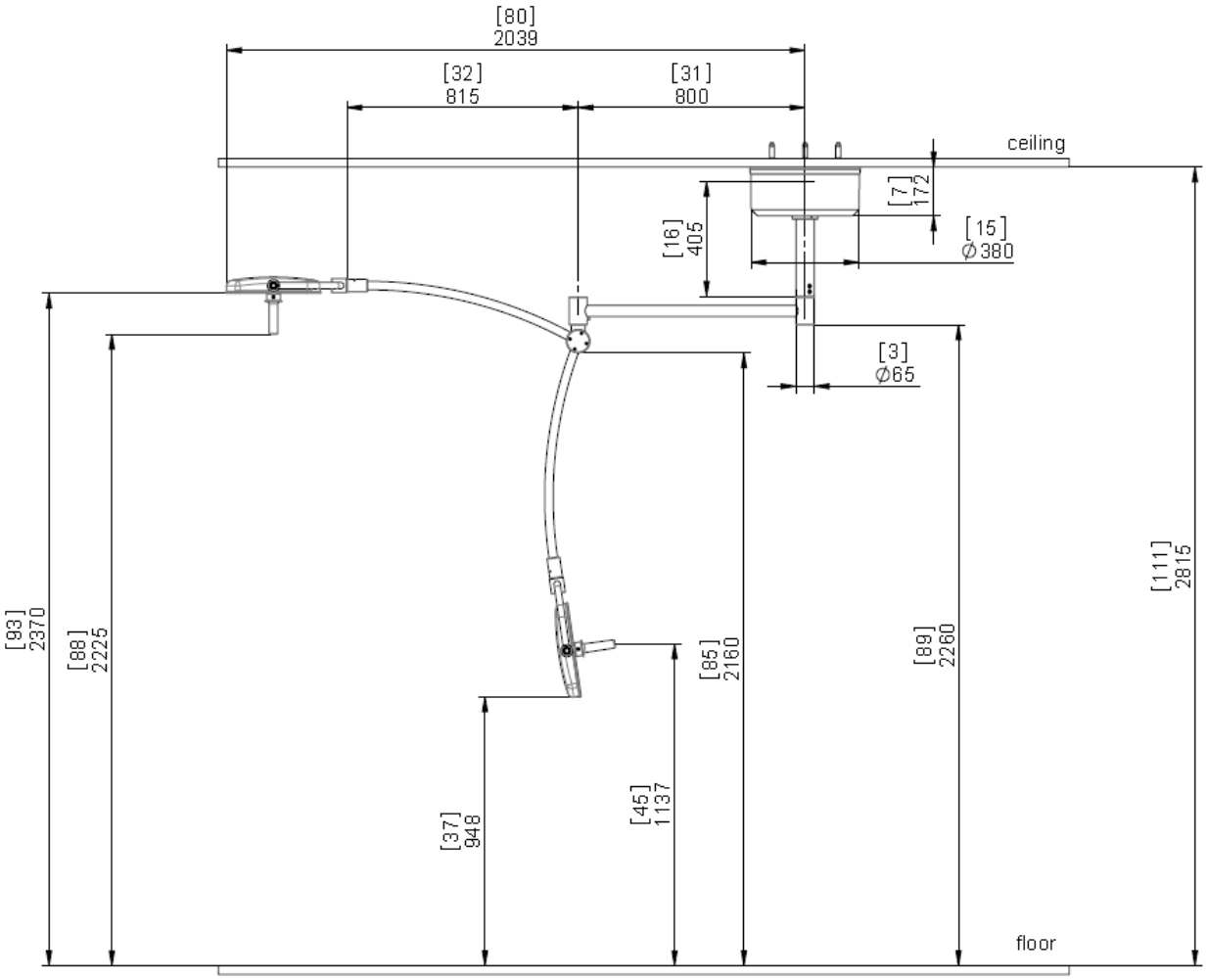
## 6.2 Dimension sheets

### 6.2.1 Ceiling variants




Variants with intermediate ceilings

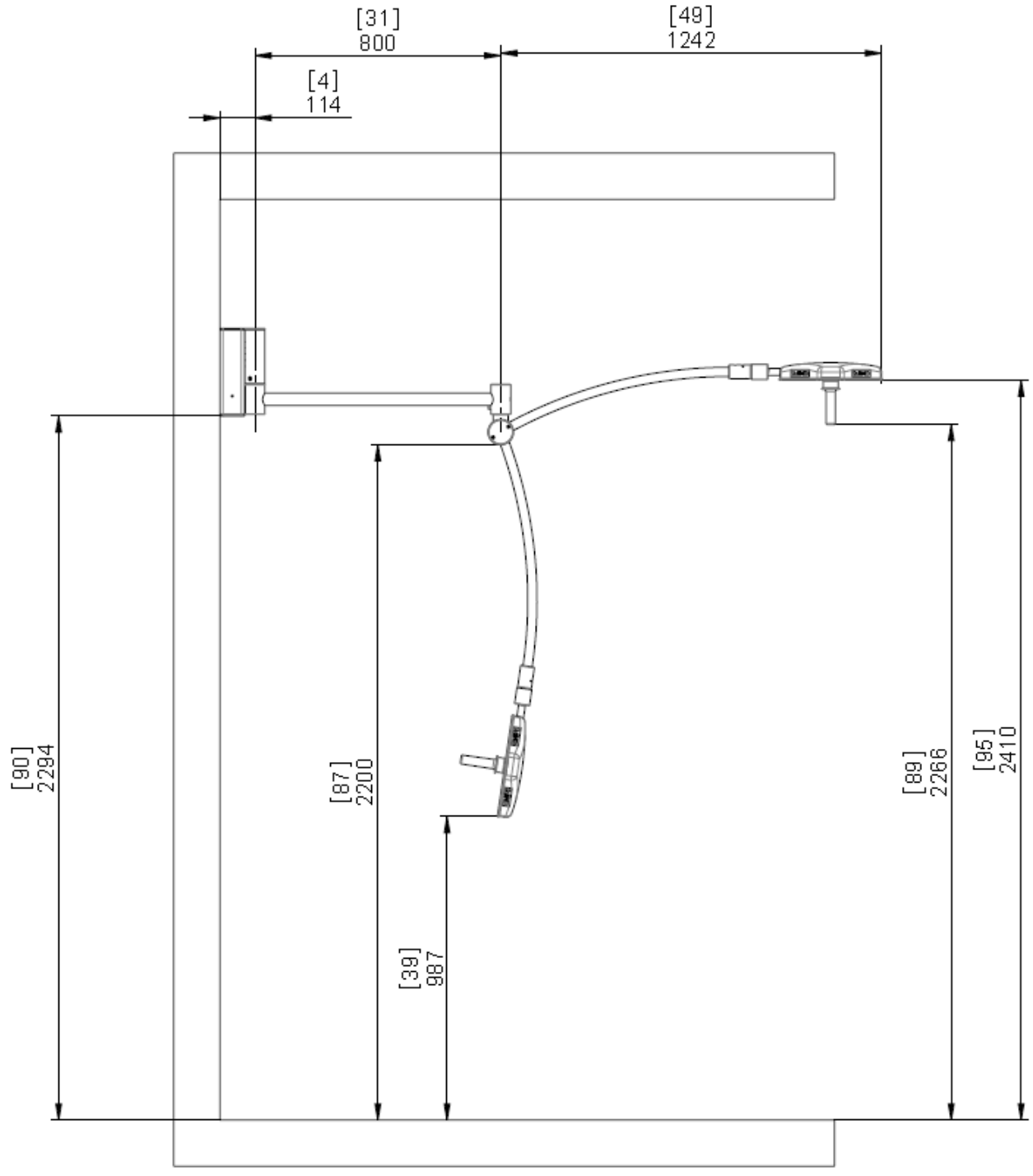
mm [inch]




Variants for raw ceilings

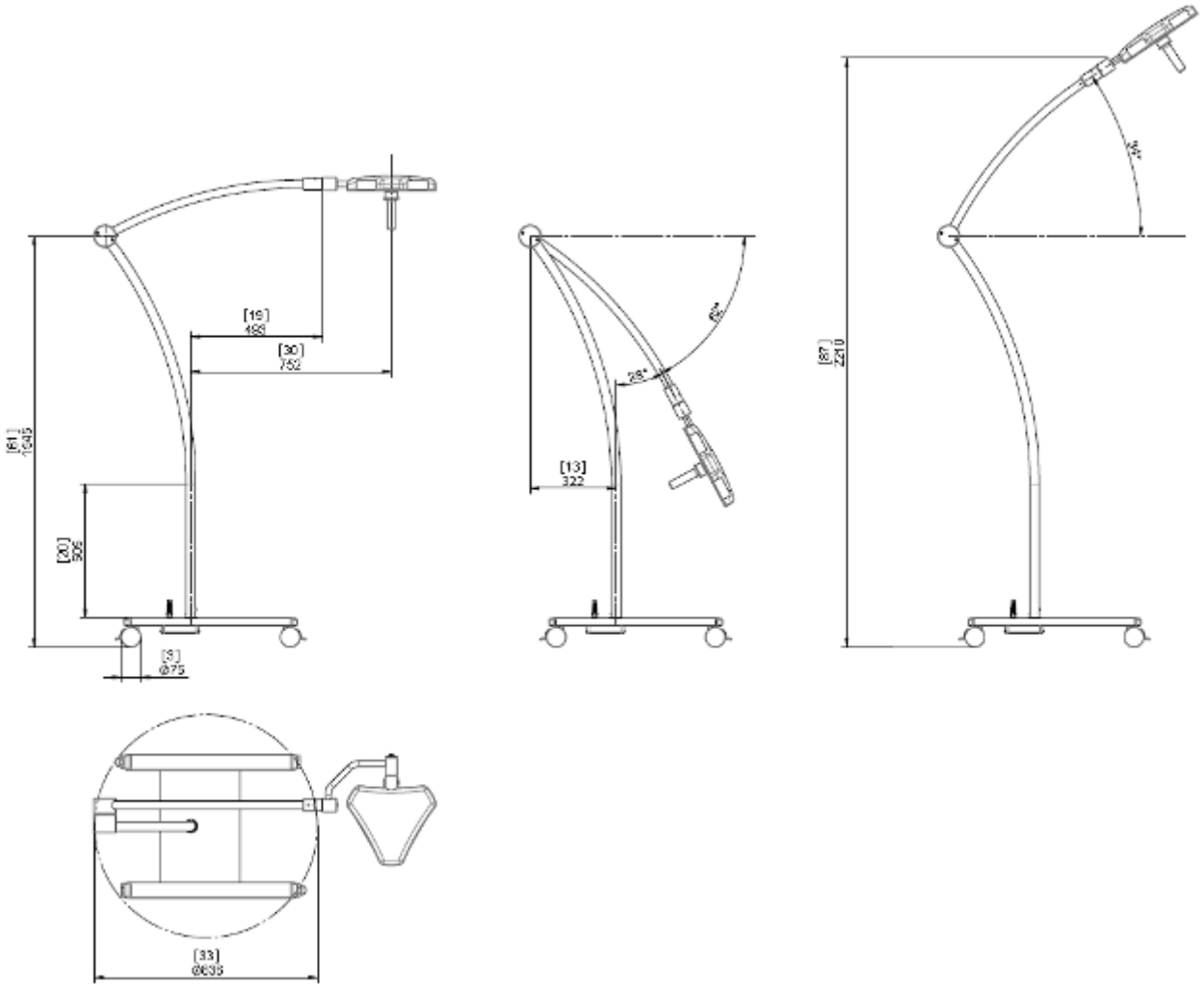
mm [inch]

### 6.2.2 Wall variants




mm [inch]

### 6.2.3 Mobile variants




mm [inch]