Instructions for Use

Sim.LED 250 Dimmable
Examination light

SIMEON MEDICAL
PUSHING TECHNOLOGY TO EXCELLENCE

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CO 003-01700

Before starting any work please read these Instructions for Use!

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Technical Service

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1 General

Thank you for purchasing this product! This product bears the CE mark and thus fulfills the basic safety and performance requirements of the EU Medical Device Regulation (MDR).

Distributor

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Manufacturer

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Auf der Huhfuhr 8
D-42929 Wermelskirchen
Telephone: +49 (0) 2193-5105 - 0
Website: www.provita.de

1.1 Information on these Instructions for Use

These Instructions for Use enable the safe and efficient handling of the Sim.LED 250 Dimmable Examination light. The Instructions for Use are an integral part of the lighting and must be stored near the unit, in a manner accessible to personnel, at all times.

Persons who handle the light must have carefully read the Instructions for Use and understood the contents before starting any work. The basic requirement for a safe work process is the adherence to all safety and handling instructions in this manual.

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

The illustrations in 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.

 **WARNING!**	**Risk of death or severe bodily injury!** Non-observance could **possibly** result in death or severe bodily injury!
 **CAUTION!**	**Risk of minor bodily injury or material damages!** Non-observance carries a **minor risk** of bodily injury or material damages!
 **Important!**	Risk of material damages: Possible damage to or destruction of the product or other objects, but also loss of data or loss of working hours due to non-observance of the instructions.

Symbols

☞ Indicates handling instructions.

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

↳ *"Reference title", page 24* is a cross-reference to a chapter in this document.

Copyright protection

These Instructions for Use are copyright-protected.

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

Infringements will be liable to compensation for damages. We reserve the right to assert further claims.

Limitation of liability

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

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

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

1.2 Spare parts

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

 **WARNING!**	**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 damages, malfunctions, or a total breakdown of the unit. – Only use original manufacturer spare parts or manufacturer-approved spare parts. – In case of doubt, always contact the distributor.

1.3 Warranty provisions

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

1.4 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.

1.5 Intended use

The light provides local illumination to parts of the body during medical examinations and procedures. It is exclusively intended for offering support during diagnostics and treatments which can be interrupted without endangering the patient should the light source fail. The light is not suitable for use in operating theatres or for operation in explosion-prone or oxygen-rich environments. The light is only intended for use in dry, interior areas.

The concept of intended use also includes adherence to all specifications in these Instructions for Use.

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

WARNING!

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 or oxygen-rich 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 body.

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

Any changes to this medical unit are fundamentally not allowed. Exceptions are only given to authorised technical specialists appointed by the distributor.

1.6 Incoming inspections

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

1.7 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 distributor are used together with the unit.

Technical safety controls

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

Technical safety controls may only be conducted by the distributor's personnel, or by authorised specialists who have received written approval from the distributor.

The protocol prepared by the authorised 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 distributor 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

Malfunctions or unit defects that lead to bodily injury must be

immediately notified to the authorities in charge and to the distributor.

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 authorised 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.

1.8 Dismantling and disposal

The unit must be dismantled and undergo environmentally-sensible disposal.

Dismantling should only be conducted by trained, skilled personnel.

 **WARNING!**	**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 distributor must also be involved when conducting unit relocations at a later time. – Dismantling and relocations may not be conducted by independent parties.

2 Operation

2.1 Installation and initial start-up

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

 **WARNING!**	**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 distributor's personnel or by persons authorised by the distributor. – The distributor must also be involved when conducting unit relocations at a later time. – Installation and relocations by independent parties are not allowed.

 **WARNING!**	**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!

2.2 Variants and accessories

The Sim.LED 250 examination light is available in different variants.

In addition, SIMEON offers a standard as well as a dimmable variant for all product versions.

2.2.1 Ceiling mounting

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

2.2.2 Wall mounting

Wall mounting over extension arm: Five joints allow positioning.

2.2.3 Mobile variants

Variant 1 with mobile stand: Two joints and one flex arm (1) allow positioning. Secure stand thanks to five casters with brakes.

Variant 2 with mobile stand: Four joints allow positioning. Secure stand thanks to five casters with brakes.

Operation

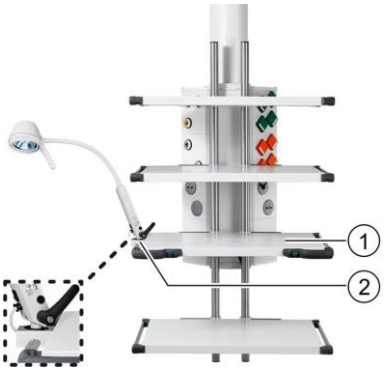
Variant 3 with mobile stand: Five joints allow positioning. Secure stand thanks to five casters with brakes.

Variants 1 and 2 are also available with a height-adjustable mobile stand (1). Here we see variant 2.

2.2.4 Variants with wall bracket or clamp bracket

Variants 1 to 3 are also available with a bracket (1) for wall mounting and a bracket for standard rails (2).
Here we see variant 1 with the wall bracket.

Here we see variant 2 with the wall bracket.



Here we see variant 1 with the bracket for standard rails (2), installed on the standard rail of a tray (1) on Sim.CARRY.

2.3 Visual inspection of the light

Before switching on the light, ensure that they are undamaged and correctly plugged in. There is no danger when an intact light is used as intended *“Intended use”, page 8*.

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

WARNING!

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 light must immediately be disconnected from the mains by turning off the main switch in the OR (wall- and ceiling-mounted versions; for mobile lamps, pull the power plug). Perform repairs! Never continue to supply voltage to defective lights!
- Repairs may only be conducted by skilled electricians!
- Keep moisture away from live parts. Moisture could lead to a short-circuit.
- Before conducting any maintenance, cleaning or repairs, switch off the power supply and safeguard against reconnection.
- Before starting any work, ensure that:
  - a visual inspection for 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!

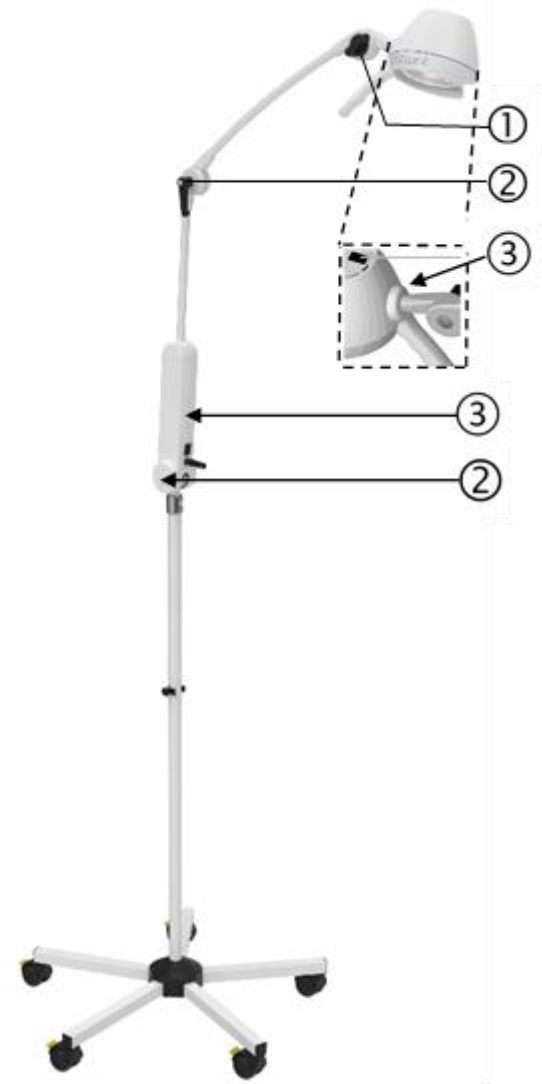
Risk of infection due to improper hygiene, disinfection, or sterilisation!

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

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

WARNING!	**Risk of injury due to contamination of wounds!** Damage to the light body or to the handle can cause loose or porous parts to fall into wounds and contaminate them. – Conduct a visual and functional inspection every time before using the unit. – Do not operate the unit if exterior damages are present. – Inspect the handles for firm positioning every time, before using the unit.

2.4 Applying the brakes



☞ The braking power at the joints should be set using the braking elements available there – T grip (1), clamp lever (2) or brake screw (3) – in such a way that the light body and the joint arms are held in all positions.

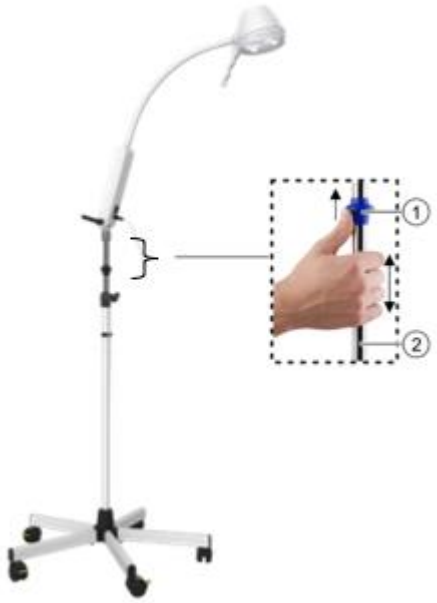
Here we see a variant with a stand and the maximum number of joints. The brake elements are in the same places on lights with wall brackets and clamp brackets.

The T grips (1) and clamp levers (2) at the joints are only used to set the braking screws and are not locking screws!

It is not necessary to set the braking power on the light body on versions with a flex arm.

The clamp levers (2) can be released by pulling the grip and then clicked into another position again.

2.5 Setting the stand height



The height-adjustable stand is equipped with a quick adjustment function.

- ☞ Hold the inner tube (2) firmly enough to secure the weight of the light.
- ☞ Push the lock (1) upward and move the inner tube to the desired height.
- ☞ Release the lock (1)

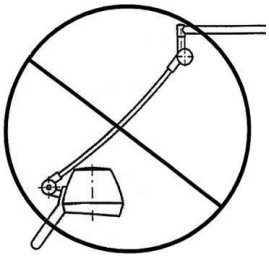
The inner tube (2) is now locked in position again.

2.6 Positioning the light

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

Positioning the extension arm variant on the wall/ceiling

☞ Move the light bodies into the desired position using the handle (1). Avoid overstretching the cable in the joints!



Positioning the light with the wall bracket or clamp bracket

Move the light bodies into the desired position using the handle (1).

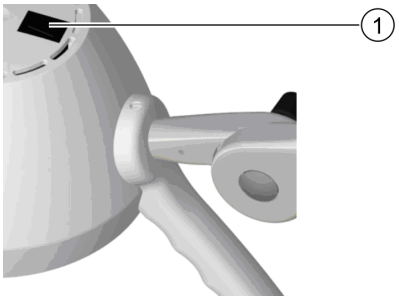
Positioning the mobile variants

- ☞ If the power cable is too short for the new position of the light, pull out the power plug (2) and secure the cable on the mobile stand in such a way that it is not kinked.
- ☞ Release the brake lever (3) on the braked casters.
- ☞ Secure the mobile stand (1) 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) on the braked casters.
- ☞ If the power plug (2) was pulled out before the mobile stand was repositioned, plug the power plug (2) into a suitable power outlet with a grounded socket.

2.7 Switching the light on/off

CAUTION!	**Possible tissue damage due to drying of the wound!** The superimposed illuminated fields from multiple light bodies produce a combination of high illumination intensities and generate an elevated temperature in the illuminated area. This can cause tissue damage. – Separate the superimposed illuminated fields from multiple light bodies. – In the event of incipient drying of the wound, reduce the illumination intensity of the light bodies immediately, e.g. increase the distance from the light to the wound.

CAUTION!	**Possible eye damage due to glare** Looking directly into the light can be damaging to the eyes. – Protect patients' eyes from the direct light of the lamps. – Reduce the illumination intensity.



Switching on the unit

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

☞ Set the power switch (1) to **I**.

⇨ The light shines at full brightness.

Switching off the unit

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

☞ Set the power switch (1) to **0**.

⇨ The light is turned off.

Disconnecting the unit from the mains power supply

In the case of wall- and ceiling-mounted variants, always use the main switch (part of the building installation) to disconnect the unit from the mains power supply. Pull out the power plug on mobile lights and on lights with a wall bracket or clamp bracket.

Requirement for switching on the light The main switch in the examination room is switched on or the power plug for the mobile version is plugged into the power outlet.

2.8 Control of the dimming function

CAUTION!	– Never leave the light unattended. – This will help to avoid accidents! – Carefully swivel the light into the desired position using the handle.

CAUTION!	– Avoid shocks and impacts to increase the service life of the illuminants. – The clamping lever can be disengaged by pulling the handle and re-engaged in another position. This allows you to avoid any interfering edges and walls.

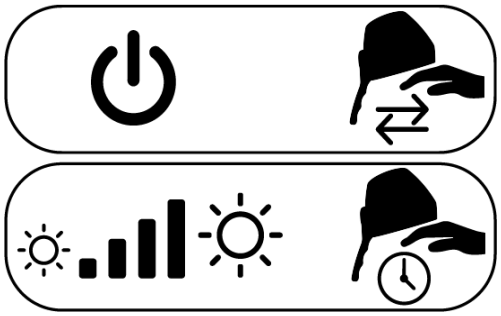


Figure 1

☞ For switching on and off, give a short impulse by moving the hand under the sensor **(Figure 1).**

☞ In the first dimming process, the light becomes brighter. When dimming again, the brightness decreases. Prerequisite for switching on the light: The main switch in the examination room is switched on or the power plug of the mobile version is inserted in the socket.

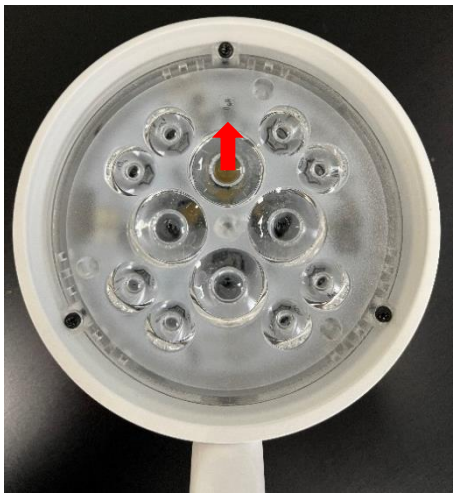


Figure 2

NOTE

The sensor is located in the front part of the light **(Figure 2).**

3 Maintenance

WARNING!

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 distributor or by persons authorised by the distributor.

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 distributor if you have questions regarding maintenance work and intervals, contact information is found on page 2.

Interval	Maintenance work	Personnel
Annually	Conduct technical safety controls of the unit in accordance with the Service manual.	Distributor
As required	Clean and disinfect the unit ↳ *"Cleaning the* unit*", page 24.* ↳ *"Disinfecting the unit:* Wiping disinfection*", page 25*.	Medical qualified personnel

3.2 Maintenance work

3.2.1 Cleaning the unit

Important!	**Material damages due to the use of improper cleaning agents!** Abrasive, corrosive, or paint-thinning cleaning agents may damage the surface of the unit. – Do not use any abrasive, corrosive or paint-thinning cleaning agents, or agents containing benzene or alcohol. – Always apply the cleaning agent in such a manner that no liquid is able to penetrate the unit. – Only clean accessible parts using neutral, tenside-based cleaning agents (manual dishwashing liquid, neutral cleansers).

WARNING!	**Risk of death due to electric shock!** There is an immediate risk of death due to electric shock when coming into contact with live parts. – Switch off the power supply to the unit from the main switch in the examination room before cleaning, disinfecting or sterilising. With mobile variants, also pull the power plug from the power outlet. – Safeguard the main switch or power plug from unintended switching-on/plugging-in. – Always protect the unit from splash water and never wet-clean or wet-disinfect the unit. – 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 (clamp and mobile variants).

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

3.2.2 Disinfecting the unit: Wiping disinfection

 **WARNING!**	**Health risk due to disinfectant!** Disinfectants may contain agents hazardous to health. – Always select and use disinfectants that comply with local hygienic and operating regulations. – You can find recommendations and information on the selection and use of disinfecting agents, in the most current standards and guidelines on disinfection and explosion protection.

 **Important!**	**Risk of material damages due to spray disinfectants!** Spray mist may cause short-circuits in the electrical installations and corrosion of the mechanical components. – Do not use spray disinfectants. – All components, including accessories and connecting cables, may only be disinfected by wiping with a surface disinfectant. – You can find recommendations and information on the selection and use of disinfecting agents, in the most current standards and guidelines on disinfection and explosion protection.

 **Important!**	**Risk of material damages when using unsuitable disinfectants!** Chloride- and halide-containing disinfectants and excessively alcoholic disinfectants may corrode the unit's surfaces or plastic parts. – Do not use any chloride- or halide-containing disinfectants. – Only use disinfectants with a low alcohol content. – Apply the disinfectant in such a manner that no moisture or liquid is able to penetrate the unit. – You can find recommendations and information on the selection and use of disinfecting agents, in the most current standards and guidelines on disinfection and explosion protection.

☞ 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 Troubleshooting

4.1 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 distributor. The Technical Service address can be found on page 2.

Description of fault	Cause	Remedial action	Personnel
The light body is too tight / too loose	The braking power has been set too high/low.	Setting the braking power ↳ *"Applying the* brakes*", page 17*	Trained specialist personnel with appropriate tools
Unit does not light up	Power supply to the room is turned off	Turn on power supply to the room	Medical qualified personnel
	Mobile or clamp light: Power plug pulled out	Insert power plug into a suitable power outlet with a grounded socket.	Medical qualified personnel
	Device was turned off using power switch	Switch device on ↳ *"Switching the light* on/off*", page 21*	Medical qualified personnel
	Power supply is interrupted	Inspect voltage and fuses	Electrical experts qualified for the medical field
	Lamp is defective	Replace lamp	Distributor
	Fuse is defective	Replace fuse	Distributor

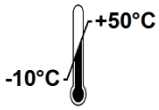
5 Technical data

	Description/designation	Sim.LED 250 Dimmable Examination light
General information		
	Weight of the light body [kg]	2
	Light source lifespan [h]	> 25,000
Connection values		
	Power supply primary voltage [VAC]	~ 100 – 240
	Voltage range DC [V]	12-24
	Current consumption, maximum [A]	0.75
	Current consumption, average [A]	0.70
	Power consumption [VA]	16
	Protection class acc. to IEC 601	II
	Light body safety class pursuant to IEC 60529-1	IP 20
Technical light values		
	Illumination intensity EC at distance of 0.5 metres [klx]	12-70
	Colour rendering index R_a	92
	Red rendering index R9	61
	Illumination field diameter d_{10} [mm]	130
	Illumination field diameter d_{50} [mm]	70
	Total illumination strength [W/m²]	154
	Colour temperature [K]	4,000
Operating conditions		
	Temperature range [°C]	10 – 30
	Relative air humidity [%]	30 – 75
	Air pressure [hPa]	700 – 1,060

We reserve the right to make technical changes; tolerance ±10%

5.1 Explanation of symbols

Adhere to the Instructions for Use



Ambient temperature for storage and shipment

Pressure

min: 500HPa

max: 1060HPa

Specifications on minimum (min.) and maximum (max.) air pressure (pressure) for storage and transportation.

Humidity (rel.)

min: 0%

max: 90%

Specifications on minimum (min.) and maximum (max.) air humidity (humidity (rel.)) for storage and transportation.

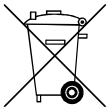
Date of manufacture

Protection class II according to DIN EN 60601-1

CE mark of conformity

IP20

Protection category

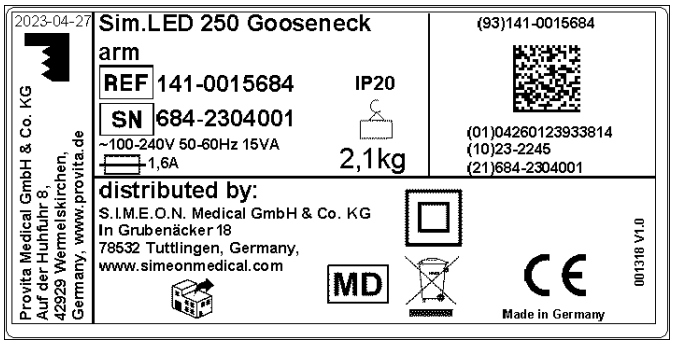


Must not be disposed of as household waste.

5.2 Type plate

The system's type plate is located (see positions indicated by arrows in the images below):

- at the top on the extension arm on the ceiling variant.
- left on the wall bracket on the wall variant.
- on the power supply unit housing on the clamping and mobile variants.



It includes the following information:

Distributor address, product type, article number (REF), serial number (SN), protection category, electrical power data

5.3 Guidelines and manufacturer's declaration concerning electromagnetic compatibility (EMC)

Guidelines and manufacturer's declaration pursuant to DIN EN 60601-1-2 Section 6.8.3.201 a) 3) table 201: Electromagnetic emissions		
The unit is designed for operation in an electromagnetic environment like the one described below. The user must ensure that the unit is being used in such an environment.		
Electromagnetic interference checks	**Compliance level**	**Electromagnetic environment - Guidelines**
HF emissions according to DIN EN 55011	Group 1	The device uses HF energy only for its internal function. Therefore, its HF emission is very low and interference with adjacent electronic equipment is unlikely.
HF emissions according to DIN EN 55011	Class B	The unit is suited for use in all facilities and in residential areas, including those that are directly connected to the public mains supply system for residential buildings.
Emission of harmonics according to DIN EN 61000-3-2	Class A	
Emission of voltage fluctuations / Flickers according to DIN EN 61000-3-3	Complies	

Guidelines and manufacturer's declaration pursuant to DIN EN 60601-1-2 Section 6.8.3.201 a) 3) table 201: Electromagnetic emissions			
The unit is designed for operation in an electromagnetic environment like the one described below. The user must ensure that the unit is being used in such an environment.			
Electromagnetic interference checks	**Test level pursuant to DIN EN 60601**	**Compliance level**	**Electromagnetic environment - Guidelines**
Discharge of static electricity (ESD) according to DIN EN 61000 4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be made of wood or cement or be covered with ceramic tiles. When the floor consists of a synthetic material, the relative air humidity must be at least 30 %.
Rapid transient electrical interference / bursts according to DIN EN 61000-4-4	±2kV for mains supply lines ±1kV for input/output lines	±2kV for mains supply lines ±1kV for input/output lines	The quality of the supply voltage must conform to that in a normal commercial or hospital environment.
Surges according to DIN EN 61000-4-5	±1kV normal mode voltage ±2 kV common mode voltage	±1kV normal mode voltage ±2 kV common mode voltage	The quality of the supply voltage must conform to that in a normal commercial or hospital environment.
Voltage drops, short interruptions and fluctuations in the supply voltage according to DIN EN 61000-4-11	<5% U_T (95% drop in U_T) for ½ period 40% U_T(60% drop in U_T) for 5 periods 70% U_T(30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 seconds	<0% U_T (100% drop in U_T) for ½ period 40% U_T(60% drop in U_T) for 5 periods 70% U_T(30% drop in U_T) for 25 periods < 0% U_T (> 100% drop in U_T) for 5 seconds	The quality of the supply voltage must conform to that in a normal commercial or hospital environment. If the user requires continued operation, even during an interruption to the power supply, it is advisable that the unit be powered from an uninterrupted power supply.
Magnetic field at the supply frequency (50/60 Hz) according to DIN EN 61000-4-8	3 A/m	3 A/m	Magnetic fields at the mains frequency must be similar to the typical values found in commercial or hospital settings.
Note: U_T is the mains alternating voltage before applying the test levels.			

Guidelines and manufacturer's declaration pursuant to DIN EN 60601-1-2 Section 6.8.3.201 b) table 204: Resistance to electromagnetic interference			
The unit is designed for operation in an electromagnetic environment like the one described below. The user must ensure that the unit is being used in such an environment.			
Electromagnetic interference checks	**Test level pursuant to DIN EN 60601**	**Compliance level**	**Electromagnetic environment - Guidelines**
Conducted HF interference according to DIN EN 61000-4-6 Radiated HF interference according to DIN EN 61000-4-3	3 V_{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Portable and mobile remote devices may not be used at a distance to the unit (including the cables) that is smaller than the recommended safety distance that has been calculated pursuant to the equation specific to the transmission frequency. Recommended safety distance: $d = 1{,}17\sqrt{P}$ $d = 1{,}17\sqrt{P}$ For 80 MHz to 800 MHz $d = 2{,}33\sqrt{P}$ For 800 MHz to 2.5 GHz With *P* as the nominal output of the transmitter in watts (W) according to information from the transmitter manufacturer, and *d* as the recommended safety distance in metres (m). The field strength of stationary radio transmitters, calculated as part of a local inspection[a], must fall below the compliance level for all frequencies[b]. Interference is possible in the area surrounding units that bear the following symbol. 
Note 1:	The higher frequency range applies at 80 MHz and at 800 MHz.		
Note 2:	These guidelines may not be applicable in every case. The spread of electromagnetic waves is influenced by absorption and reflection from buildings, objects, and humans.		

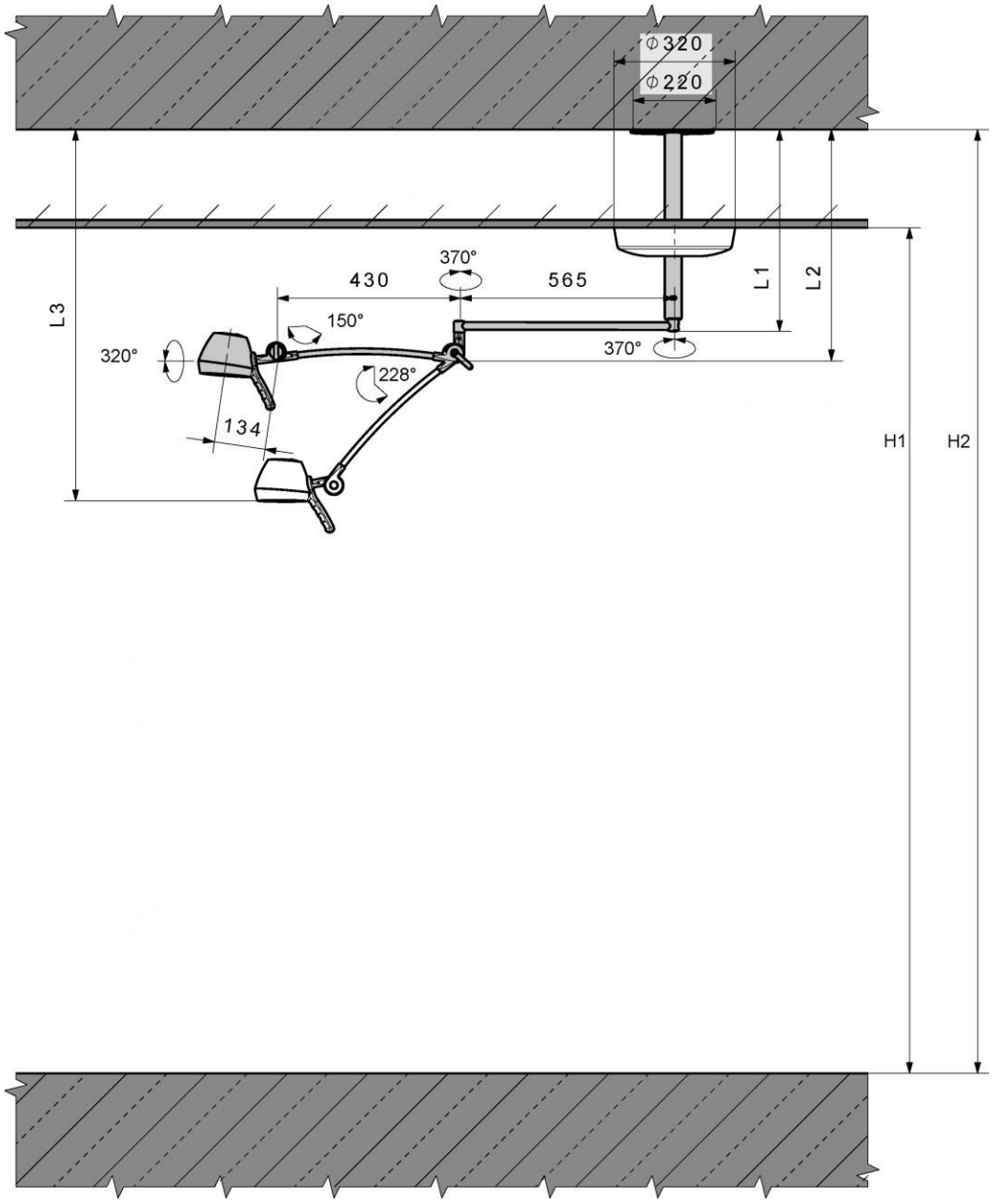
[a] The field strength of stationary transmitters, e.g., base stations of cordless telephones and land mobile services, amateur radio stations, AM and FM radio and television broadcasting stations may not, in theory, be accurately predetermined. In order to determine the electromagnetic environment in relation to stationary transmitters, a study of the location should be considered. If the field strength measured at the location in which the unit is used exceeds the above-mentioned compliance level, the unit will need to be monitored in terms of proper function. If unusual performance characteristics are observed, additional measures may be necessary such as changing the position or moving the unit to another location.

[b] Above the frequency range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

Recommended safety distances between portable and mobile RF telecommunication devices and the unit, pursuant to DIN EN 60601-1-2 section 6.8.3.201 b), table 206			
The device is suitable for operation in an electromagnetic environment in which HF interference is controlled. The user can help avoid electromagnetic interference by ensuring a minimum distance between portable and mobile RF telecommunications devices (transmitters) and the unit – depending on the power output of the communications device as indicated below.			
	Safety distance depending upon the transmission frequency (in m)		
Rated power *P* of the transmitter in watts	150 kHz to 80 MHz $d = 1{,}17\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2{,}33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.4
100	11.7	11.7	23.3
For transmitters for which the maximum rated power is not listed in the table above, the recommended safety distance *d* can be estimated in metres (m) using the equation in the corresponding column, whereby *P* is the maximum rated power of the transmitter in watts (W) according to information from the transmitter manufacturer.			
Note 1:	The higher frequency range applies at 80 MHz and at 800 MHz.		
Note 2:	These guidelines may not be applicable in every case. The spread of electromagnetic waves is influenced by absorption and reflection from buildings, objects, and humans.		

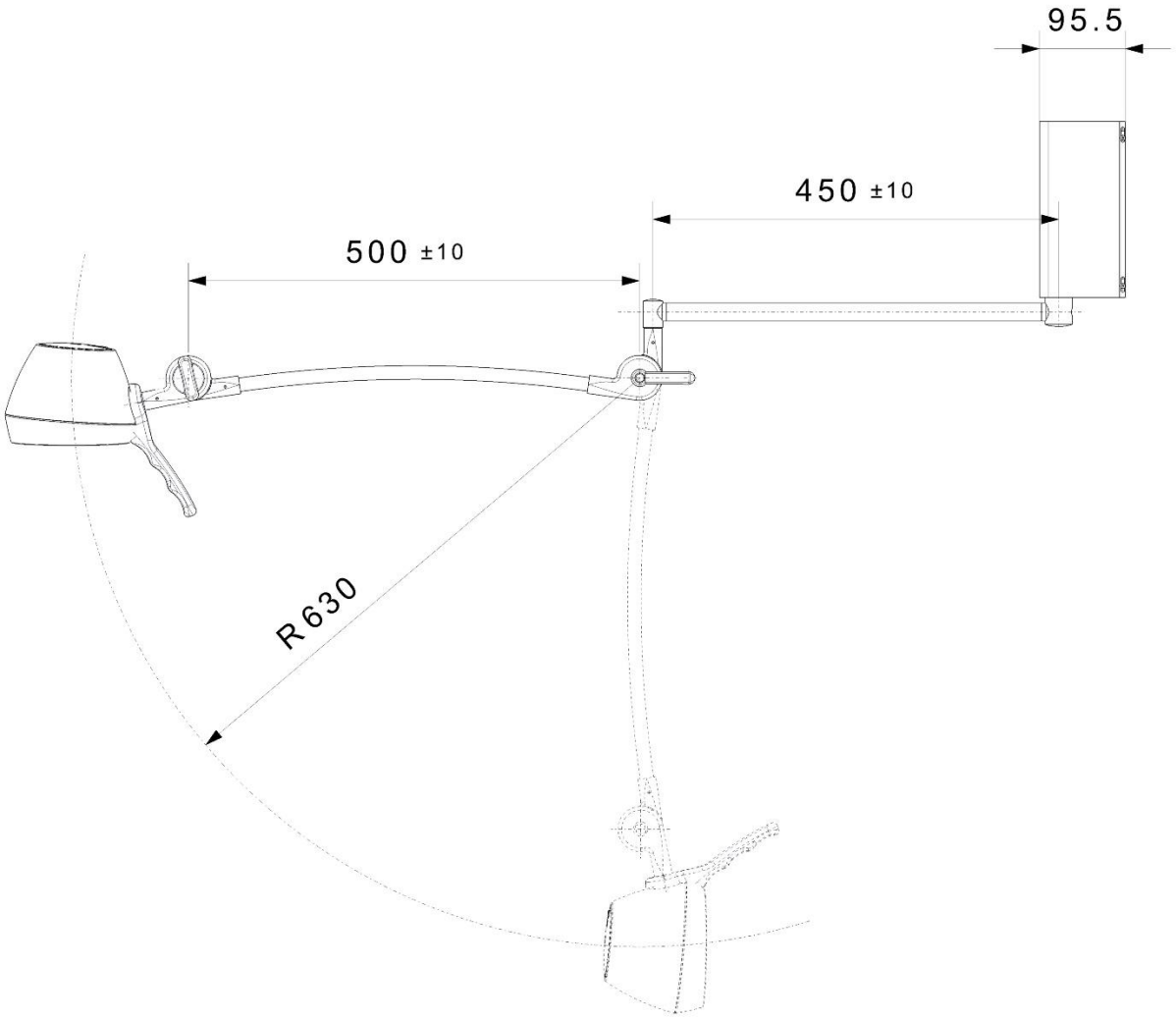
5.4 Dimension sheets

5.4.1 Ceiling variants

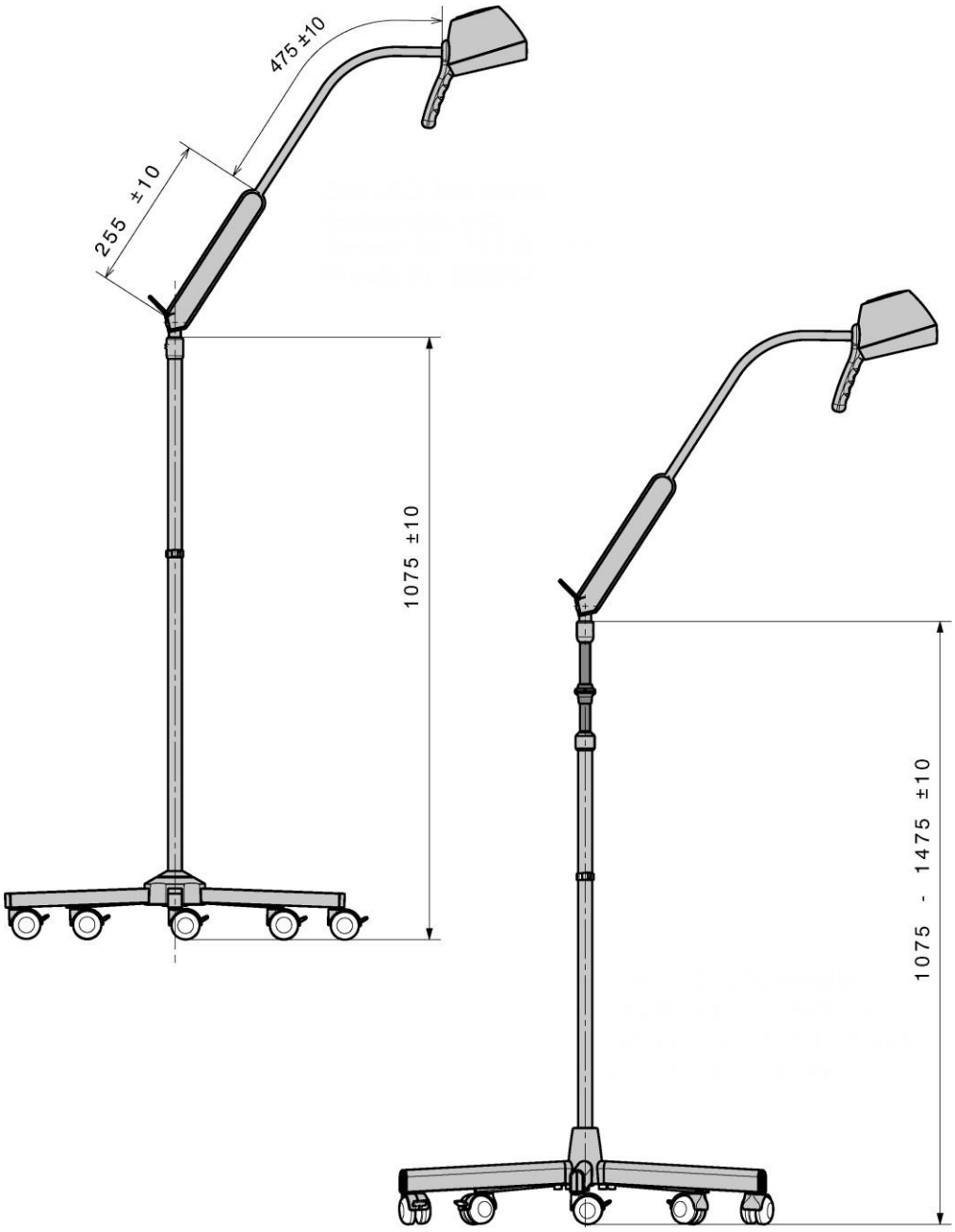


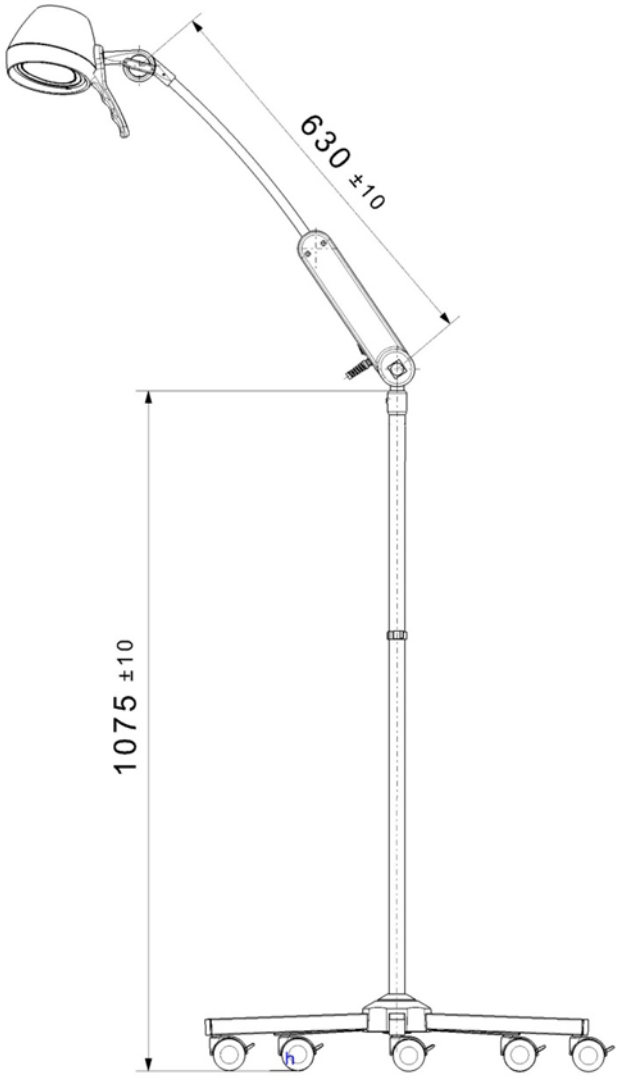
Variants with intermediate ceilings

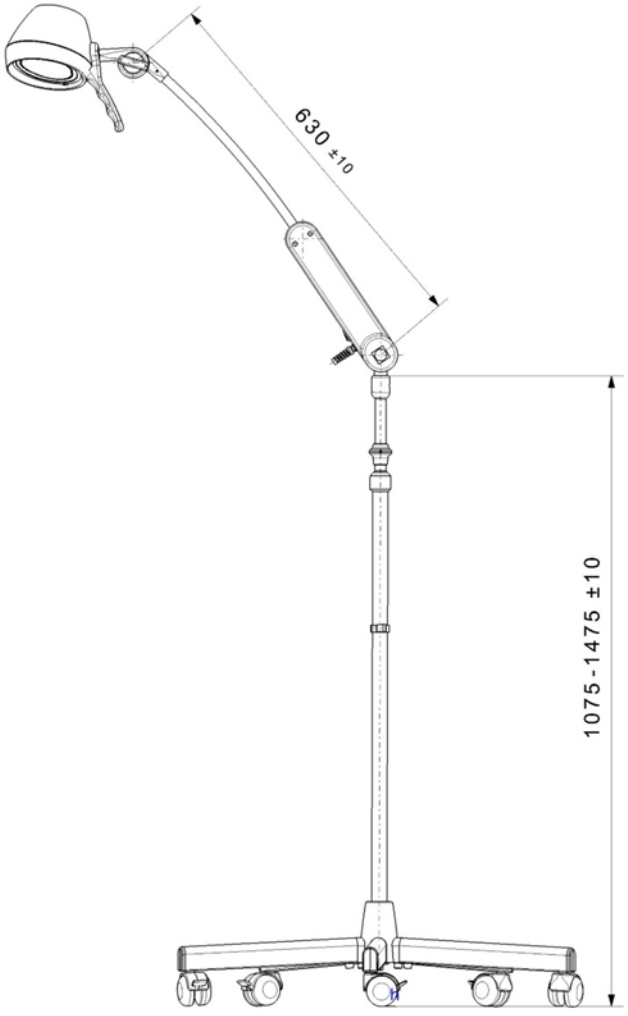
5.4.2 Wall variants

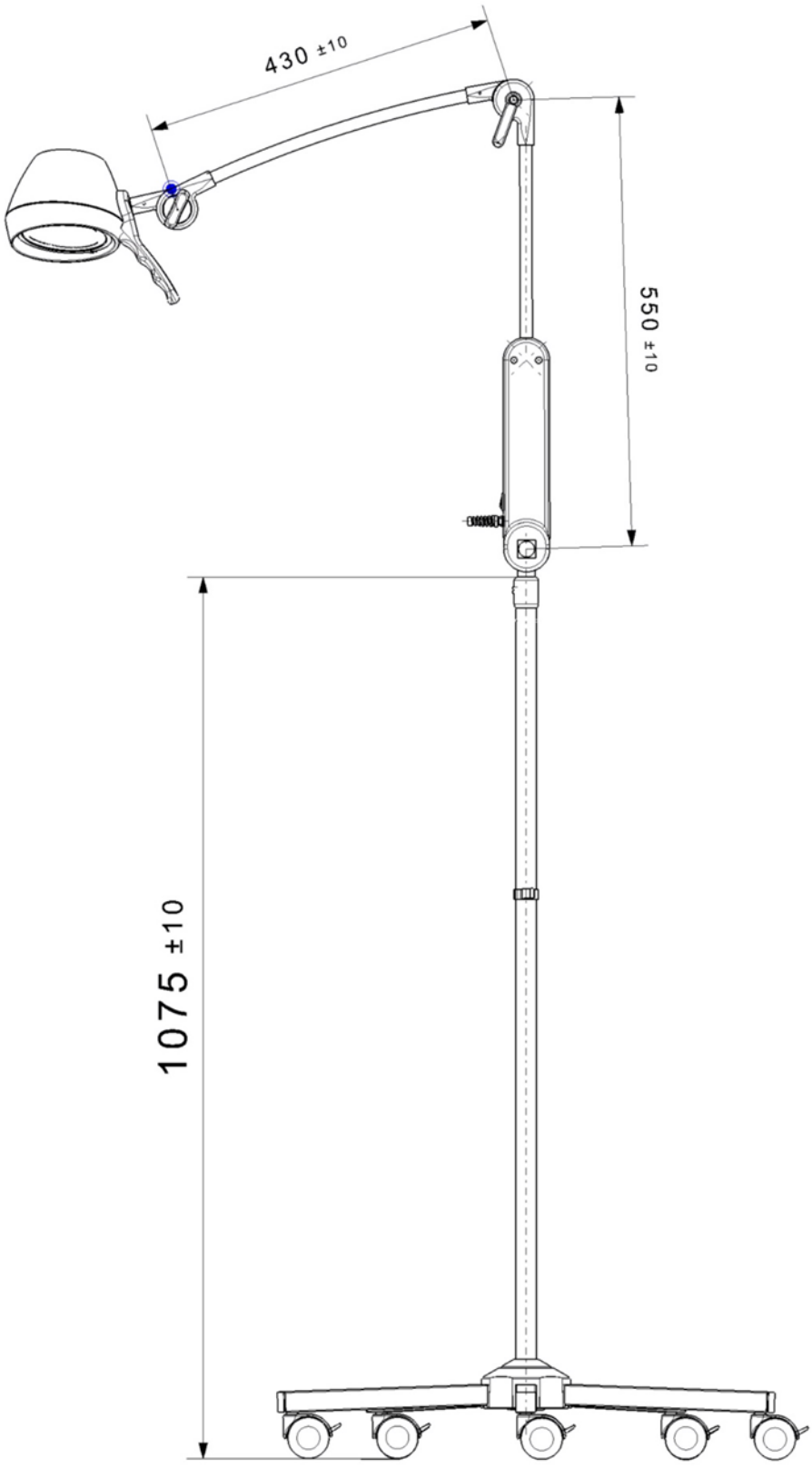


5.4.3 Mobile variants




630 ±10
1075 ±10


630 ±10
1075-1475 ±10


430 ±10
550 ±10
1075 ±10

5.4.4 Clamp variants